



Assessment of changes to functional systems by service providers and the oversight of these changes by competent authorities

CRD TO NPA 2014-13 — **ISSUE 2** — RMT.0469 & RMT.0470 — 10.07.2015

Related Opinion No 03/2014

EXECUTIVE SUMMARY

The overall objective of RMT.0469 & RMT.0470 is to provide a harmonised set of rules (by clarifying and enhancing the existing ones) for certified service providers of ATM/ANS and other ATM Network functions to perform the assessment of changes to functional systems and for competent authorities regarding the oversight of these changes. These proposed rules will amend the ones in CRD 2013-08 'Requirements for service providers and the oversight thereof' published on 6 June 2014 (and initially proposed through Notice of Proposed Amendment (NPA) 2013-08 — published on 10 May 2013).

During the NPA 2014-13 public consultation, the Agency received 1 277 comments. The Agency expresses its appreciation to the stakeholders who have not only provided their individual comments to the draft proposals, but also expressed their coordinated views through the relevant European stakeholder groups. The Agency considers that the comments received contributed essentially to the improvements of the proposed rule.

The Agency has reviewed all the comments received, but regarding the issue of the related Opinion No 03/2014, priority has been given to the comments related to the Implementing Rule, leaving for a later stage the analysis and completion of the responses to the comments related to the AMC/GM. However, the Agency has concluded that the NPA 2014-13 public consultation has brought real benefits to the development of the above-mentioned Opinion.

Note: This document is **Issue 2 of the CRD published on 12 December 2014**. This amended version of the CRD contains the analysis of and responses to **all comments**, including those related to the AMC/GM.

The most contentious issues during the consultation were the definition of functional system; the content of oversight audits in this respect; the competent authority's risk-based decision to review notified changes; the handling of multi-actor changes to functional changes; the identification of change drivers; and the criteria for the safety and safety support assessments.

The Agency trusts that the related to the Implementing Rule responses in this CRD to NPA 2014-13 satisfy the commentators insofar as they provide further clarification on the subject addressed.

Based on the comments and responses thereto provided with this CRD, Opinion No 03/2014 was developed.

Applicability		Process map	
Affected regulations and decisions:	Commission Implementing Regulations (EU) Nos 1034/2011 and 1035/2011; Commission Regulation (EC) No 482/2008.	Concept Paper:	No
Affected stakeholders:	Member States; competent authorities/National Supervisory Authorities; service providers; Network Manager; and the Agency	Terms of Reference:	19.6.2012
Driver/origin:	Legal obligation (Regulation (EC) No 216/2008) and feedback from the implementation of the existing requirements	Rulemaking group:	Yes
Reference:	N/A	RIA type:	Full
		Technical consultation during NPA drafting:	No
		Publication date of the NPA:	24.6.2014
		Duration of NPA consultation:	3 months
		Review group:	Yes
		Focussed consultation:	No
		Publication date of the Decision:	2015/Q4
		RMT.0470	



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1. Procedural information

1.1. The rule development procedure

The European Aviation Safety Agency (hereinafter referred to as the 'Agency') developed this Comment-Response Document (CRD) in line with Regulation (EC) No 216/2008¹ (hereinafter referred to as the 'Basic Regulation') and the Rulemaking Procedure².

This rulemaking activity is included in the [Agency's Rulemaking Programme](#), under RMT.0469 & RMT.0470. The scope and timescale of the tasks were defined in the related Terms of Reference (see process map on the title page).

The draft Regulation and AMC/GM have been developed by the Agency based on the input of the Rulemaking Task RMT.0469 & RMT.0470. All interested parties were consulted through NPA 2014-13, which was published on 24 June 2014. A total of 1 277 comments were received from 42 stakeholders, including industry, national aviation authorities, and associations.

The resulting text of the proposed Implementing Rule (IR) has been developed by the Agency based on the analysis of the comments.

An initial version of the CRD, containing all the responses to comments on the IR provisions and the RIA of NPA 2014-13, was published by the Agency on 12 December 2014. This CRD has been completed with the missing responses to the comments on the AMC and GM proposed in NPA 2014-13. The text included in the initial version remains intact in this current document, and any new text added to the original published document to complete the responses to the AMC/GM has been added using text in blue font, as this paragraph.

The process map on the title page contains the major milestones of this rulemaking activity.

1.2. The structure of this CRD and related documents

This CRD provides:

- a summary of the comments on the IR provisions and the Regulatory Impact Assessment (RIA) of NPA 2014-13 and the responses thereto; ~~and~~
- responses to the individual comments on the IR provisions and the RIA of NPA 2014-13; ~~and~~
- [responses to the individual comments on the AMC/GM of NPA 2014-13.](#)

The resulting rule text is provided in:

- Annex I: Definitions;

¹ Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79, 19.3.2008, p. 1).

² The Agency is bound to follow a structured rulemaking process as required by Article 52(1) of the Basic Regulation. Such process has been adopted by the Agency's Management Board and is referred to as the 'Rulemaking Procedure'. See Management Board Decision concerning the procedure to be applied by the Agency for the issuing of Opinions, Certification Specifications and Guidance Material (Rulemaking Procedure), EASA MB Decision No 01-2012 of 13 March 2012.



- Annex II (Part-ATM/ANS.AR) as follows: ATM/ANS.AR.C.30, ATM/ANS.AR.C.35 and ATM/ANS.AR.C40;
 - Annex III (Part-ATM/ANS.OR) as follows: ATM/ANS.OR.A045, ATM/ANS.OR.B.005, ATM/ANS.OR.B.040 and Subpart C; and
 - Annex IV (Part-ATS) as follows: ATS.OR.205 and ATS.210
- to Opinion No 03/2014.

1.3. The next steps in the procedure

The Opinion, which contains the proposed changes to EU regulations and is addressed to the European Commission, will be published together with this CRD.

The CRD containing the comments related to the draft AMC/GM and the responses thereto and the Decision containing the final associated AMC and GM will be published by the Agency when the related IR is adopted by the Commission. In the meantime, from the publication of the Opinion and until the adoption by the Commission, the Agency will continue amending the AMC/GM according to the comments received. It will additionally publish a 2nd NPA to complete those parts of AMC/GM that were missing in NPA 2014-13 and were, therefore, not consulted.



2. Summary of comments and responses

The NPA 2014-13 public consultation was launched on 24 June 2014 and the commenting period closed on 24 September 2014. In total, 1 277 comments were received from 42 stakeholders — 15 national aviation authorities (including one military one), 17 air navigation services providers, 3 organisations linked to air navigation services providers, 4 professional associations of ATCOs, 1 aircraft manufacturer, and 2 individuals.

In order to timely issue Opinion No 03/2014, which contains the proposed changes to EU regulations and is addressed to the European Commission, the Agency decided to focus with higher priority on the analysis of the comments related to the IR text and the RIA, leaving for a later stage the completion of the analysis, including the comments, related to the AMC/GM. Nevertheless, the Agency has concluded that the public consultation of NPA 2014-13 on the requirements for the assessment of changes to functional systems has brought real benefits to this rulemaking activity and contributed to the improvement of the final Opinion. Stakeholders and interested parties provided valuable comments and, in many circumstances, alternative proposals to the IR. These were accompanied by justifications, which facilitated the review and amendment of the initial proposal made in the NPA and the development of the final one.

The most contentious commented issues during the consultation were as follows:

- the definition of functional system;
- the content of oversight audits with regard to the oversight of functional changes by service providers;
- the special way the management procedures for changes to functional systems are managed;
- the competent authority's risk-based decision to review notified changes as well as the risk-based review itself of functional changes;
- the handling of multi-actor changes to functional systems, including coordination and interactions between service providers, and between aviation undertakings and competent authorities;
- the processes within the management system to identify change drivers for changes to functional systems, including those emanating from internal and external circumstances that could affect the service providers and the monitoring of the performance of the functional system;
- the processes within the management system to improve safety, whenever feasible;
- the criteria for the safety and safety support assessments of changes to the functional system;
- the necessity for an objective for safety for changes to the functional system; and
- the safety criteria expressed in terms of other measures that relate to safety.

659 out of 1 277 comments were directly or indirectly linked to the IR text, including comments related to the RIA, and were responded as follows: 116 were accepted, 157 partially accepted, 298 were noted and 88 were not accepted.



The distribution of comments received on NPA 2014-13 according to stakeholders’ sectors, as well as the distribution of how the comments were responded, are shown in Table 1 and Figure 1 and Figure 2, respectively.

Section of NPA 2014-13	Pages	Comments
General	-	53
Explanatory Note	1–31	274
Implementing Rule	32–39	252
AMC/GM	40–196	600
RIA	197–217	80
Appendices	217–229	18
Total		1 277

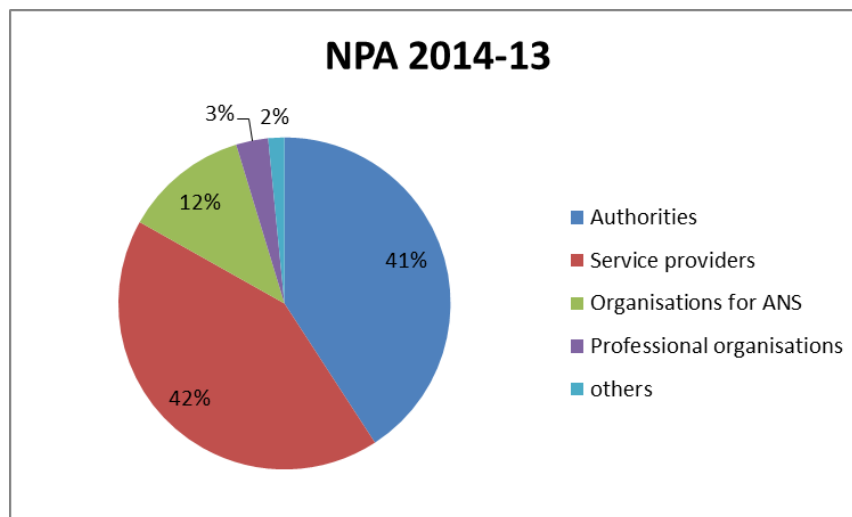


Figure 1: Distribution of the comments received according to stakeholders’ sectors

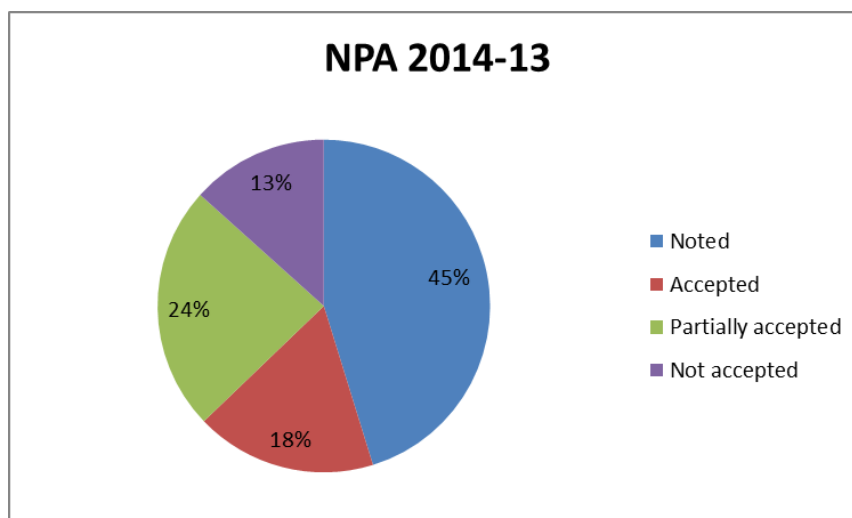


Figure 2: Distribution of the responses in CRD to NPA 2014-13



The following paragraphs provide a summary of the major changes introduced in the resulting IR text following the public consultation on the NPA 2014-13 proposal along with the explanation of said changes.

1. **Definitions.** The following definition has been added as requested by commentators:

‘Argument’ means a claim that is supported via inferences by a body of evidence.’

In addition, the definitions introduced (i.e. ‘aviation undertaking’ and ‘functional system’) have been amended following suggestions made during the consultation. In particular, the definition of functional system has been complemented with the appropriate scope, extending ‘ATM/ANS’ to ‘ATM/ANS and other network functions’ to be in line with the scope of the regulated service providers as defined in Article 2 of Opinion No 03/2014. Moreover, in the definition of ‘aviation undertaking’, the word ‘organisation’ has been replaced by ‘service providers’ to align it with the definitions presented in CRD to NPA2013-08.

2. **ATM/ANS.AR.A.005 Oversight functions.** A new paragraph is introduced to include a generic need for the competent authorities to be ready to establish coordination arrangements to ensure the effective selection and review of multi-actor changes, involving service providers under the oversight of other competent authorities. The Agency has decided to introduce this modification based on the responses to question Q4 in NPA 2014-13. Said responses suggested not regulating at all or regulating at a generic level and wait for further experience to be gained in areas such as FABs.
3. **ATM/ANS.AR.C.010 Oversight.** Provisions (b)(5) and (b)(6) proposed in NPA 2014-13 have been moved to AMC/GM. Many comments highlighted that there was an overlap between the general requirement to audit compliance, already included in CRD to NPA 2013-08 (ATM/ANS.AR.C.010(b)(1)), which covers the verification of compliance with all the requirements for the service providers including those related to the changes to functional systems, and, thus, the provisions proposed.
4. **ATM/ANS.AR.C.030 Approval of change management procedures for functional systems.** The provision has been simplified. This was suggested by several commenters and the provided justification was that with the explicit adoption of service providers’ Management System and SMS, as proposed in CRD to NPA 2013-08, these change management procedures are considered to be a part of the MS/SMS and, therefore, are already covered by the provisions in CRD to NPA 2013-08. Although this aspect could be considered in this way, the actual intent of the proposed provisions for management of the change management procedures for functional systems is to allow them to be managed independently of the MS/SMS. There are two reasons for this: (a) to ensure their review and approval by the competent authority every time they are changed, and (b) to also provide flexibility for service providers to develop them and receive approval for them at any time prior to their use, which could be after certification. In any case, if the service provider wishes to have them reviewed and approved at the time of certification and as part of the MS/SMS, that is also possible and the provision does not prevent this from happening. There were many suggestions to move the provision in (a)(3) of NPA 2014-13 related to deviations from procedures for a particular change, when requested by the service provider, to AMC, but it was finally left at IR level after consideration that this provision only introduces flexibility for the service providers.



5. **Elements of the risk-based decision to review changes to functional system.** The **ATM/ANS.AR.C.035** requirement has been renamed. In addition, the Agency has considered appropriate to delete the word ‘unsound’ from the provision as many comments suggested that this word was subjective and had negative connotations, in the sense that it may imply that the service provider will perform its activities inadequately. Despite the fact that there was no intent either to imply mistrust in the service provider or to question its competency, the Agency has redrafted the provision to more clearly describe the elements of the risk that is intended, following a proposal supported by several commentators, i.e. the likelihood of the argument being complex and unfamiliar to the service provider and the severity of possible consequences of the change. In addition, provision (b)(1) in NPA 2014-13, related to other review criteria, has been redrafted to improve clarity. Several commentators have requested that this provision is moved to AMC, but after analysing the responses to question Q3 in NPA 2014-13 and recognising that what this provision contains is the criteria based on which the decision should be taken, the Agency deemed it appropriate to retain the provision at the IR level.
6. **Review of notified changes by competent authorities.** The provisions in **ATM/ANS.AR.C.040** have been amended following the suggestions by various commentators. Provision (a)(1) in NPA 2014-13 has been removed as it seems neither necessary nor practical to verify, during the review of the safety (support) case, that the procedures applied by the service provider for the change were those approved. This aspect can be checked during audits. Provision (a)(2) in NPA 2014-13 is a duplicate of the management system provisions for the competent authority, which are contained in CRD to NPA 2013-08, and, thus, has been removed. Finally, the requirement in (b), that requested the competent authority to conduct the review in a manner proportionate to the risk associated with the change, has been removed. The main reason for this, as indicated by several commentators, is that there is no GM associated with this provision that identifies what this risk is and how it may be used to modulate the review. The Agency has monitored the research conducted on this subject and can see no final result at this moment. Until there has been further development that identifies this risk and provides a model to modulate the review based on the risk, the Agency considers it appropriate to remove this requirement from the proposal.
7. **Multi-actor changes.** Several amendments have been introduced to the requirements related to the multi-actor changes in **ATM/ANS.OR.A.045(e) & (f)** in NPA 2014-13. The requirement for conducting a coordinated assessment has been simplified to clearly limit the objective of that coordination to the determination of dependencies, and common assumptions and risk mitigations, and later to their alignment. The provision about the completion of the list of affected service providers and aviation undertakings included in (e)(2) in NPA 2014-13 has been removed, as this is already covered in the notification of change. Moreover, the requirement for the service providers and aviation undertakings to agree on common assumptions and risks mitigations of provisions in (f) has been streamlined to avoid requiring parties to agree, which may not be possible. The requirement has been changed and now the parties are required to use ‘agreed and aligned assumptions and risks mitigations’. In order to avoid overloading the term ‘notify’, the word ‘inform’ is now used when communicating with other service providers and aviation undertakings.



8. The provisions for the **management system** in **ATM/ANS.OR.B.005** have been significantly altered. Multiple commentators argued that the proposed provision, **ATM/ANS.OR.B.005(5)** about **change drivers**, was already covered in CRD to NPA 2013-08 and that, nevertheless, service providers could hardly be capable of fulfilling the requirement with any degree of confidence, and the cost would be likely to outweigh the benefit of the new provision. The overlap was acknowledged and the Agency has amended the current requirement ATM/ANS.OR.B.005(4) in CRD to NPA 2013-08 to cover the intent of this provision, i.e. to cover drivers for change within the organisation and the context as well. Moreover, the requirement **ATM/ANS.OR.B.005(6)** to **improve performance of the functional system whenever feasible** has also been removed considering the comments received. The supporting arguments provided by commentators can be summarised as follows: on the one hand, there is a risk of prosecution if they do not consider a change that would have been technically and economically feasible to implement, and on the other hand, service providers other than ATS may be forced to break contractual agreements with customers. In addition, for ATS providers, many commentators considered this requirement already covered by the SMS as proposed in CRD to NPA 2013-08. The Agency has decided to remove this provision until a more thorough analysis is carried out, and at least AMC/GM are developed and available to be evaluated together with the requirement in the IR.
9. **Monitor the functional system.** The requirement for service providers to monitor the functional system has been simplified and redrafted. In particular, it has been reduced to one single provision: to monitor the behaviour of the functional system, and when its performance does not reach a defined level, then this would trigger a change. The monitoring criteria identified in the requirements for safety assessments and safety support assessments, proposed in the new ATM/ANS.OR.C.005(b)(2) and ATS.205(b)(6), establish defined levels of performance for the change. The defined level of performance for the overall service is the combination of these criteria with the already existing performance criteria for the service. Having established the performance criteria, there is a need to have a process that actually monitors them and acts when they are not met. This is the process described in **ATM/ANS.OR.B.005(d)**. The responses to question Q6 have shown a desire to keep the requirements to monitor the functional system, and the Agency concurs with this view. As a consequence, the provision has been maintained but with a simplified wording. The need to develop additional AMC/GM is recognised. Many comments were received arguing that the use of the term 'substandard performance' is subjective and is not always a valid criterion. The Agency believes that the term 'substandard' has been misunderstood. As explained above, the level of performance of a service is declared by the service provider using monitoring criteria and is not necessarily based on a predefined and agreed industry standard. In order to address this misunderstanding, the Agency has replaced 'substandard performance' with 'underperformance'. AMC/GM will be developed to ensure the intent is clear and to provide means to comply with this requirement.
10. **Procedures to manage changes to functional systems.** The provision in ATM/ANS.OR.B.010(a) has been redrafted to explicitly require the use of procedures to manage changes to functional systems, which before was stated implicitly.
11. **Scope of safety assessment and safety support assessment.** The scope of the change has been rearranged in both ATM/ANS.OR.C.005 and ATS.OR.205 to become an intrinsic part of the



change, and not of the safety assessment (or safety support assessment). Monitoring 'requirements' have been renamed monitoring 'criteria'.

12. **Objective for safety of changes to functional systems ('the system as safe as before')**. A high number of commentators argued against the need for an objective for the safety of a change, as they consider the safety criteria enough to judge the acceptability of any change. However, the Agency, supported by several commentators (mainly competent authorities replying to question Q7), believes that it is important to keep some form of it as the objective for safety sets the top-level goal. The safety criteria result from decomposing this goal into the parts of the change. Consequently, without the 'goal', the validity of the set of safety criteria cannot be established. It is recognised that the link between safety criteria and the objective for safety of changes is not well established in the proposal and, therefore, it has been moved from the **ATS.OR.200 Safety management system** to **ATS.OR.210(c)(2)** to make this link more clear. The objective for the safety of the change is now set as a collective condition on the safety criteria that needs to be satisfied. The final goal has been redrafted so that the safety criteria collectively ensure that the change does not introduce an unacceptable risk to the safety of the service after the change is in operation. The proposal made in the NPA 2014-13 is then considered only one of the means to achieve the change and does not introduce unacceptable risks, but there may be other strategies or means to achieve the same goal. It is recognised that this goal may not be achieved in all circumstances and, thus, the requirement to agree with competent authorities on subsequent actions is kept. Additional AMC/GM will be developed in due time to clarify these situations and to propose alternatives.
13. **Safety criteria**. Following comments received regarding the provisions in **ATS.OR.210(b)** about the different forms the safety criteria can take, the Agency has moved the list of different forms to AMC. The commentators considered that these forms provided the means by which point (a) should be implemented and so were more suitable at AMC material. The IR is now less prescriptive, thus allowing more flexibility. A number of commentators remarked that they could not see the possibility of using 'proxies' in the proposal in NPA 2014-13, but these had been identified in AMC/GM. In fact, proxies were present within the former provision (b). A proxy is one of the 'other measures related to safety risks'. With the new wording, the 'other measures related to safety risks' are kept at IR level, and the explicit use of the word 'proxies' is introduced in AMC, together with the other alternatives, previously in provision (b), that are also related to safety risks.
14. **'Approve' vs 'accept'**. Many commentators have objected to the use of the term 'approve' on the basis that the current Regulation (EU) No 1034/2011 uses the term 'accept' and that the use of 'approve' would mean that the competent authority would take responsibility for the change from the service provider. It should be noted that 'approve' is defined in legal terms as 'to give formal sanction to; to confirm authoritatively'. 'Accept', on the other hand, is a term generally used in contractual law. The term 'acceptance' means 'an offeree's assent, either by express act or by implication from conduct, to the terms of an offer in a manner authorized or requested by the offeror, so that a binding contract is formed.' Other dictionary definitions point in slightly different directions, stating that 'to accept' means 'consent to receive or undertake (something offered); give an affirmative answer to (an offer or proposal); say yes to; receive as adequate, valid, or suitable; regard favourably or with approval; believe or come to recognise (a



proposition) as valid or correct; take upon oneself (a responsibility or liability); acknowledge; tolerate or submit to (something unpleasant or undesired).’ The term ‘approval’ is very clearly linked to some form of formal authorisation. However, in legal terms, as detailed above, the term ‘accept’ is not so clear. Nevertheless, the term ‘accept’ has been used in the context of administrative law, and not of contractual law. As can be seen from the above definitions, when used in this context, the term ‘accept’ may also be interpreted as simply meaning an acknowledgement of receipt, or as the recognition of something as adequate, valid or suitable. In this latter sense, the meaning of acceptance may easily be confused with approval, since both require a review of the content of a certain document or proposal and signify that the document or proposal is in compliance with the applicable requirements. In other words, any use of the term ‘accept’ in such context should be interpreted as meaning the same as ‘approval’: the level of responsibility incumbent on the authority is the same. Since legislative acts must be clear, easy to understand and unambiguous, leaving no uncertainty in the mind of the reader, the use of ‘acceptance’ in this latter context should be avoided. Therefore, in determining which term should be used in a specific situation, the intention of the legislator must be analysed. If the legislator’s intention is to impose an action on the authority, so that a given application is assessed and evaluated by the authority and is only valid after a positive appraisal or assessment, then the term ‘accept’ should be read in a specific, restricted context, as meaning the same as ‘approve’. For this reason, whenever the legislator’s intention is that the authority is required to assess, review and give a binding appraisal on a given document or procedure of an applicant, as it is the case in this proposal, then the correct legal term is ‘approve’ and not ‘accept’.

2.1. Summary of comments and responses to AMC and GM

After completing responses to [all](#) comments on NPA 2014-13, i.e. including individual responses to comments on AMC and GM, the statistics of the consultation are as follows: 1 277 comments were received, from which 291 were accepted, 328 partially accepted, 371 were noted and 287 were not accepted.

After updating the responses to all comments, the distribution of how the comments were responded is shown in Figure 3 below.



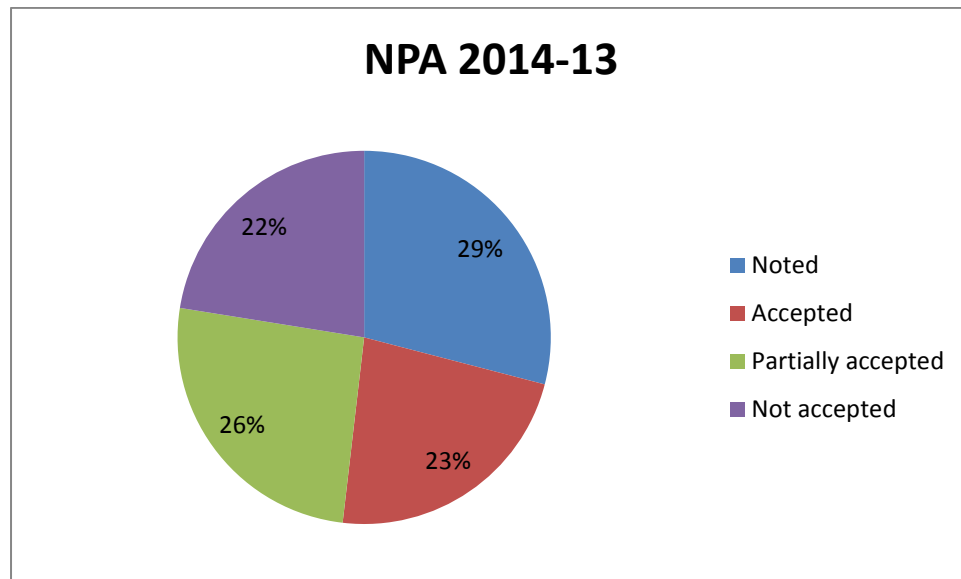


Figure 3: Distribution of all 1277 responses in CRD to NPA 2014-13

The completed analysis of comments on AMC and GM and the responses thereto have mainly led to a major restructure of the resulting guidance material, in addition to specific and small-scale changes to the material as a result of the consultation. During the consultation, one of the main conclusions was that there is a need for a more well-structured material and the location of the elements was not apparent. As a result, introductory guidance material has been created to serve as an overview and index to the various parts of the Implementing Rule, AMC and GM associated with the management, assessment assurance and oversight of changes to functional systems. This introductory GM explains their relationships in order to maintain their coherence. In addition, due to the extensive nature of the GM and also its wide-ranging scope, the GM has been split into two parts. One of them is integrated with the rest of AMC/GM in its normal structure, helping thus in illustrating the meaning of a requirement or specification, and is used to support the interpretation of them. The other part of it, and the most extensive one, is grouped as an Appendix to the above-mentioned overview GM, which has a broader scope and contains more extensively the underlying principles of the provisions that deal with the management, assessment, assurance and oversight of changes to functional systems. Moreover, additional changes have been introduced in line with the changes in the resulting IR text as explained in the section above. The draft AMC/GM is still being updated to reflect the changes of the IR text during the comitology process until the adoption by the European Commission, but it is published together with this CRD for information purposes.

3. Resulting text

3.1. *Draft regulation (Draft EASA Opinion)*

The resulting IR provisions related to this CRD are not presented in this document but are introduced in Annex V to the draft regulation proposed through Opinion No 03/2014.

3.2. *Draft AMC and GM (Draft ED Decision)*

The resulting text of AMC/GM is not ready yet and, therefore, it is not presented in this document. At a later stage, the Agency will complete the review of comments related to AMC/GM, will amend the AMC/GM material and publish the CRD with responses to the comments placed with regard to the AMC/GM during the consultation of NPA 2014-13. In addition, the Agency plans to issue a 2nd NPA during 2015 that will complete the package of AMC/GM. Said NPA will be duly consulted in due time.



4. Individual comments (and responses)

In responding to comments, a standard terminology has been applied to attest the Agency's position. This terminology is as follows:

- (a) **Accepted** — The Agency agrees with the comment and any proposed amendment is wholly transferred to the revised text.
- (b) **Partially accepted** — The Agency either agrees partially with the comment, or agrees with it but the proposed amendment is only partially transferred to the revised text.
- (c) **Noted** — The Agency acknowledges the comment but no change to the existing text is considered necessary.
- (d) **Not accepted** — The comment or proposed amendment is not shared by the Agency.



4.1. IV. CRD table of comments, responses and resulting text

(General Comments)	-
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comment	<p>2</p> <p style="text-align: right;">comment by: <i>EUROCONTROL Safety Team</i></p> <p>Many factors contribute to the safe(r) delivery of a service. Rulemaking is only one of these factors because safety also depends on good leadership from the top management, the right tools, the way the organisation is setup, a good SMS which includes a sound safety risk assessment process supported by proper risk classification. For the greatest impact regulation should address the way the organisation is set up and the SMS.</p> <p>The attempt to provide a harmonised set of rules and to clarify the existing ones through these AMCs and guidance material is greatly welcomed. However, some of the material in the proposed IR would be more appropriate as AMC. Substantial revision of ANSPs’ SMS may be required to comply with the “letter” of the law as currently proposed in this NPA. Furthermore these changes may not lead to the desired improvement in the safety of service delivered.</p> <p>Examples are:</p> <ul style="list-style-type: none"> • Page 33 - ATM/ANS.AR.C.010(6)(b) • Page 34 - ATM/ANS.AR.C.035 • Page 35 - ATM/ANS.OR.A.045(e) • Page 36 - ATM/ANS.OR.B.005(a)(5) • Page 36 - ATM/ANS.OR.B.005(a)(6) • Page 36 - ATM/ANS.OR.B.005(d) • Page 38 - ATS.OR.201 • Page 39 - ATS.OR.210
response	<p>Partially accepted</p> <p>Finding the optimal balance between IR/AMC/GM is not always an easy task. Too many details in the IR may be perceived as too prescriptive, whereas too few details as too lose. The principles followed to set requirements at these two levels of law (hard and soft law) aim at accommodating two objectives: to ensure harmonisation in the implementation when it is required, and to provide flexibility to comply with the law. To achieve this, the Agency has attempted to state the ultimate goal of the regulation along with the criteria to judge that goal at the IR level, and left at the AMC level the means for the addressees to comply with the law and its intent. In most circumstances, we need to have the criteria to judge the IR intent in the IR text, and not in AMC. This will help to implement the law as intended (i.e. ensuring harmonisation), but also to avoid distortion of the law if applied in a different way from what intended. The decision to move text from IR to AMC has to be made on a case-by-case basis. For instance, the removal of AR.C.035(b) would mean that the criteria on which the decision by the competent authority was made were not part of the rule. Consequently, any criteria would be acceptable and there would be little point in having the rule.</p>



It is, however, recognised that some material could be moved to AMC, and the Agency has decided to do so in certain cases. The following provisions have been moved to AMC/GM material:

- ATM/ANS.AR.C.010(b)(5) &(6);
- ATM/ANS.OR.B.005(d)(2); and
- ATS.OR.210(b).

comment

3

comment by: *EUROCONTROL Safety Team*

The guidance material includes some good examples and diagrams.

On the other hand there the use of examples (way too many) is an indication that no clear position can be taken, almost every example could be reused to support the opposite thesis (e. g. table 1 on page 66, as all the ones provided from pages 187 - 192). Some articles or paragraphs contradict other ones in the NPA. The reading line is not clear, at times even confusing; concepts are thrown without clear reference to explanations, facts or reasoning. Examples of this are:

- Page 40 - GM2 Article 2
- Page 40 - GM2 Article 2 (2) (b)
- Page 40 - GM2 Article 2(2) (d)
- Page 40 - GM2 Article 2 Footnote 18
- Page 43/44 - GM2 Article 2 (2) (g), (h) and (i)
- Page 44 - GM2 Article 2 (2) (j)

response

Partially accepted

The Agency acknowledges that the AMC/GM need, though a refocus exercise, a deep reorganisation and check of consistency. At present, the CRD is addressing only comments pertaining to the IR text, due to the time pressure to issue the related EASA Opinion. A considerable amount of time is needed to rework, amend and complete the AMC/GM in an appropriate and effective manner, and this cannot be done at this stage. Future work is planned to review the comments on the AMC/GM and complete the CRD in due time.

comment

4

comment by: *EUROCONTROL Safety Team*

- In general, AMCs should describe how to implement a given requirement (one means of implementing it). A number of proposed AMCs are too vague to achieve this aim.
- There are a number of overly complicated and very long AMCs. Such AMCs should be split in to separate smaller AMC each addressing a specific sub-topic. This will make the text easier to follow but, more important, permit the service providers to propose alternative means of compliance for the individual sub-topics.
- In the description of some proposed AMCs and also guidance material, both “should” and “shall” are used.



	<ul style="list-style-type: none"> • Reference is made multiple times to SWAL, HAL, DAL, HWAL and PAL with no reference to any guidance material. Suggest adding reference standards/specifications for SWAL, HAL, DAL, HWAL and PAL, e.g. ED153, etc. • Minimal reference for the need to assess the implications of both common cause and common mode effects. • There is a danger that the GM will be used by the CA as a test of whether the IR and/or AMC have been satisfied.
response	<p>Partially accepted</p> <p>Please see the response to comment No 2.</p> <p>The comment is clear enough to enable assessment of which AMCs are too vague; however, comments have been addressed individually on each AMC.</p> <p>Regarding the use of assurance levels, please see the response to comment No 1165.</p> <p>With regard to the use of ‘shall’ in AMC and GM, it must be highlighted that AMC or GM cannot use any language that expresses an obligation (neither ‘shall’ nor ‘must’), as they only provide one means to comply with the IR. There is always the possibility to propose an AltMoC or to comply directly with the IR without any reference to the AMC. The AMC and GM have been reviewed to avoid the use of ‘shall’ or ‘must’.</p>
comment	<p>5 comment by: <i>EUROCONTROL Safety Team</i></p> <p>Some sections of this proposed IR and AMC duplicate MS/SMS elements found in CRD 2013-08. This duplication could to possibly lead to internal inconsistencies, duplicate regulation and a lack of legal certainty. It is recommended that this NPA should not specify any requirement or AMCs that have already been addressed in CRD 2013-08. Examples are:</p> <ul style="list-style-type: none"> • Page 33 ATM/ANS.AR.C.010(b)(5) • Page 33 ATM/ANS.AR.C.030 • Page 36 ATM/ANS.OR.B.005(a)(5) • Page 36 ATM/ANS.OR.B.005(a)(6) • Page 36 ATM/ANS.OR.B.005(d)
response	<p>Partially accepted</p> <p>The Agency has also identified some of these issues and has taken care of resolving them, when appropriate. Such cases are listed here, and appropriate responses are given to the individual comments related to them:</p> <ul style="list-style-type: none"> — ATM/ANS.AR.C.010(b)(5); — ATM/ANS.OR.B.005(a)(5); — ATM/ANS.OR.B.005(a)(6); and



— ATM/ANS.OR.B.005(d)(2).

comment

6

comment by: *EUROCONTROL Safety Team*

The rule does not appear to comply with EASA's own principles of performance based regulation because the NPA contains much prescriptive regulation and consequently is not performance based. The only concession to performance based regulation appears to be that an ATS provider may use a multi-valued safety risk classification scheme.

It is quite significant to note that although this NPA was published almost at the same time as A-NPA 2014-12 it seems that NPA 2014-13 does not follow the basic principles expounded in A-NPA 2014-12 because:

- It does not help in “modernising the regulatory system to render it more proportional” (see A-NPA 2014-12 2.2 The need for change);
- It does not recognise there are “inconsistencies and differences in approach between different domains of aviation regulation”. (see A-NPA 2014-12 2.2 The need for change);
- It does not help to “render it (regulation) more proportional; improve its ability to identify and mitigate safety risks, and monitor performance in a systemic, performance-based manner” and “ensure a consistent approach between the different technical and operational domains of aviation regulation” (see A-NPA 2014-12 2.3 the objectives of the change).

The misalignment of this NPA with other regulation is very much in evidence when compared with the requirements for aerodromes. This NPA is very different and more complex than the IR/AMC/GM for aerodromes addressing the same topic. The better alignment of the two sets of implementing measures would have led to better understanding and coordination between the key players (aerodrome operator, ATM/ANSP, and their competent authorities). A clear example of the misalignment is the introduction of the concept of “functional system”. The requirements from ADR.OR.B.040 Changes of EU 139/2014, address “change to the aerodrome, its operation, its organisation or its management system”, without referring to “functional systems”. In fact the term/concept “functional system(s)” is not used in any other field of civil aviation covered by the Basic Regulation, thus adding confusion and complexity, for no added-value.

response

Not accepted

The Agency disagrees that the proposal is too prescriptive (with the new amendments, it provides even more flexibility). It has to be taken into account that the current Regulations that govern these areas, Regulations (EU) Nos 1034/2011 and 1035/2011, are quite prescriptive, and this proposal represents a move away from that prescriptiveness. Nevertheless, there cannot be a radical swift.

Although they are not identified by the commentator, there are many other instances where the IR text is performance-based. Moreover, criteria are provided to be used by service providers and CAs to be able to achieve the intent of the regulation. Maybe, this has been perceived by the commentator as prescriptive, but this was not in any case the Agency's



intention. Of course, there may be a few parts that are prescriptive, but the regulation in the majority — and the spirit of the proposed rule — is not intended to be prescriptive. Some examples (non-exhaustive list) are:

- The decision of a CA to review or not a notified change is based on risk, but the precise model to identify this risk is left to the CAs (GM is given to describe criteria to be used, but the text does not prescribe how the model should be).
- It is left to the CA–provider agreement to decide when certain changes will be implemented without review (but not without assessment/assurance).
- Providers should coordinate assessment/assurance, but it is up to them to decide how to achieve that coordination. The way to be done is not prescribed.
- The proposed rule text requires processes to monitor the management system and the functional system, but it is left to the provider to develop the best processes, indicators, the level of performance below acceptable (now introduced as ‘underperformance’), etc. that suit them best. There is no prescription on how to do this monitoring.
- The proposed rule text allows the provider to use different methods to conduct the safety assessment depending on the type of change. The current regulation (Regulation (EU) No 1035/2011) prescribes a single way to do it. Safety criteria that the change should meet can be assessed in terms of safety risks (preferable), but it is allowed as well in terms of proxies (i.e. other measures related to safety risks), recognised standards or codes of practice, or referring to performance of existing systems.

If the commentator just asks for a high-level goal in the regulation without criteria to judge it and explanation of the intent, the proposal is certainly not the case. But this does not mean that the regulation is prescriptive.

In addition, the objective of harmonisation should also be taken into account.

The Agency concurs with the commentator that the aerodromes rules do not use the term ‘functional system’ and that it may have been useful to align with that approach. However, the long tradition in the regulatory framework in the ATM world in Europe with the term ‘functional system’ should be considered. Moving away from there may have been more detrimental.

comment 175

comment by: *Cris Val*

The safety regulatory approach of EASA NPA 2014-13 “Requirements for safety assessment of changes to ATM/ANS functional systems” is not consistent, neither proportional, with the existing approach EASA has taken for decades in the domain of airworthiness of aircraft and related products, parts and appliances in connection with the changes of equipment (aircraft and their components), the changes of management procedures, the changes of operational and maintenance procedures and the changes related to personnel (Ref. Commission



Regulation (EU) No 748/2012 of 3 August 2012).

The way EASA is “viewing safety” in this NPA 2014-13 is a matter of concern. Reference is made to the following issues:

“GM1 Annex I Definitions(35) & ATM/ANS.OR.C.005 & ATS.OR.205 General SERVICES, INFORMATION AND THE RESPONSIBILITY FOR SAFETY”

(i)..... “the provider of a service may not ‘control’ the use of the service and, therefore, will not be able to judge whether it will be used safely. This has been argued for the case of a navigation service provider. It is equally true for all service providers. However, while an ATS provider cannot be said to have absolute control over the use of any service directly supplied to an a/c, those services are provided within the framework of a navigational plan (a plan controlling separation) for all a/c receiving an ATS. Within that plan, the ATS provider has to be aware and take care of the fact that the initial plan may not be adhered to and so will have to modify the plan in order that all a/c remain safe. Consequently, it is only the ATS provider that can perform a safety assessment and provide a safety case. All other service providers can only perform safety support assessments and provide safety support cases.”

“GM2 Annex I Definitions(35) & ATM/ANS.OR.C.005 & ATS.OR.205 General AIR TRAFFIC SERVICE — VIEW OF SAFETY

(f) Other service providers, i.e. Surveillance, Communications, Navigation, MET, ATFM, AIS, DAT and ASM service providers, enable the air traffic controller’s plans to be formulated and implemented. In the airspace where ATS is provided, the only impact they have on safety is that they perform in a manner anticipated by the ATS provider e.g. they behave as is required by their contract with the ATS provider even though that contract may be abstract, as in the case of satellite navigation services.

(g) Consequently, these service providers are not responsible for the safety of the ATS, but are responsible for the ‘trustworthiness’ of the services they provide to the ATS provider.”

If this is the right approach of viewing safety, then it should be applied also to the other aviation domains. Let’s take for example what should be the outcome of applying this “view” for the airworthiness of aircraft and air operations:

1. Only the air operators can provide a safety case for their services, i.e “air operations services”. The design, production and maintenance organizations of aircraft and related products, parts and appliances can only perform safety support assessments and provide safety support cases.

2. The design, production and maintenance organizations of aircraft and related products, parts and appliances are not responsible for the safety of the air operations of aircraft. They are responsible for the ‘trustworthiness’ of their services. Only the pilots (air operators) are responsible for the safety of air operations.

This is totally unacceptable from a safety point of view.

In this respect, I do not support at all this EASA NPA 2014-13, rejecting it.

I look forward for the time when the same regulation approach will be taken for all aviation domains.

response Not accepted

The Agency believes that the conceptual explanation given in the GM has been



misinterpreted by the commentator. What is meant by the 'view of safety' is the ability to manage and evaluate operational safety risks (probability × severity of accident). There are two main areas of safety: operational safety and technical safety. The 'view of safety' described in GM refers to the operational risks that the providers of services used by the aircraft can assess and manage.

The design, production and maintenance organisations of aircraft and related products do have a view and responsibility of 'technical' safety. They can assess and manage risks that will impact the safety of a flight, but those risks are main technical and not operational.

comment

234

comment by: UK CAA

Page No: general**Paragraph No:** general**Comment:**

The UK CAA welcomes the opportunity provided by the NPA to improve existing legislation and considers this a positive development. Whilst the UK CAA generally supports the proposed IR text, we have significant concerns regarding both the structure and content of the associated AMC and GM material. These concerns centre upon the accessibility – and therefore acceptability - of the proposed text to industry, and subsequent application of the requirements of this particular legislative package.

The UK CAA is of the view that whilst the draft AMC and GM may be technically correct, the content is presented in an overly complex structure and style that renders it difficult for the intended audience to read, assimilate and ultimately apply.

We believe that GM material should have a narrative that assists the reader in understanding what they need to do to satisfy the legal requirements of the proposed rule. However, as presented the material does not offer this narrative and raises the following concerns:

- The extensive cross-referencing does not foster a clear and immediate understanding of the material or ease of application.
- The AMC and GM material appears to have been drafted with a single audience in mind and not necessarily the diversity of those parties that will have to understand, comply with and apply the total system approach required. In short, they appear to be written for safety specialists where as we believe that the target audience includes ATCOs, pilots, airspace and Instrument Flight Procedure designers, etc.
- We do not believe that smaller service providers have the resource to readily understand the NPA as presented. To facilitate understanding and application of the requirements of the rule, we recommend the inclusion of detailed exemplar safety arguments for the types of changes that they would be required to make, as templates for them to apply.
- The GM is presented as a technical paper rather than as material to support practical application of the legislative requirements. It is accepted that this is necessary to have such a basis, however, to be useful it should be extended to provide pragmatic guidance to industry on what they have to do comply with the legislation.

Justification: Clarity and practical application of the proposed text.



response Partially accepted

The Agency appreciates the comments and suggestions to improve the GM part. At present, the CRD is addressing only comments pertaining to the IR text. A considerable amount of time is needed to rework, amend and complete the AMC/GM in an appropriate and effective manner, and this cannot be done at this stage. Future work is planned to review the comments on the AMC/GM and complete the CRD in due time.

The AMC & IR are legal documents and would not be used daily. However, it is difficult to see why they are not at an appropriate level given the nature of the issues they address.

In general, whilst ATCOs, pilots, instrument and flight procedure designers will be an important part of any safety assessment (or safety support assessment), they would neither be expected to have to understand the details of such an assessment, nor are they expected to carry out the assessments themselves, although they may participate and be involved in the activities necessary to comply with these provisions. It is for the professional safety personnel within the organisation to provide local interpretation of the technicalities in a manner that is easily assimilated by those stakeholders who need to be involved. This will vary from organisation to organisation and from change to change and so could not be the subject of EASA level AMC/GM.

comment 235 comment by: UK CAA

Page No: general
Paragraph No: general
Comment: All GM

It is intended that this document will form part of what is currently NPA 2013-08. Combining these documents, Requirements, AMC and GM gives a page count in excess of 600 pages.

This is somewhat excessive and unwieldy for a single item of legislation whose format does not lend itself to ease of use, with the AMCs and GMs being mixed together and separated from the requirements.

The GM is fragmented into parts relating to specific sections of the IR/AMC. As a result it is difficult for those who most need the guidance to understand it. The guidance material needs to be more naturally structured for readability as a standalone document, and then cross-referenced from the AMC appropriately

The GM contains multiple levels of material, but there does seem to be a considerable amount of guidance that is present to explain the background circumstances surrounding a change and surrounding regulation of changes that is distinct from guidance on how to implement the IR and AMC. It would be very useful to separate these background circumstances such that they create a background introduction or 'story'.

The UK CAA would recommend that the GM is published as a separate document to better enable easier cross referencing and practical use of these documents for both CAs and ANSPs.



	<p>Justification: Clarity and practical application of the proposed text.</p>
response	<p>Accepted</p> <p>The Agency acknowledges that the GM has room for improvement (certain parts are incomplete and others can be more focussed). Therefore, it needs a deep reorganisation and check of consistency. At present, the CRD is addressing only comments pertaining to the IR text. A considerable amount of time is needed to rework, amend and complete the AMC/GM in an appropriate and effective manner, and this cannot be done at this stage. Future work is planned to review the comments on the AMC/GM and complete the CRD in due time. The generic GM needs to be reconsidered and restructured. The proposal made by the commentator will be duly considered during the phase of the AMC/GM finalisation.</p>
comment	<p>236 comment by: UK CAA</p> <p>Page No: general Paragraph No: general Comment: The UK CAA is of the belief that unless AMC and GM is rendered more accessible to all intended audiences, they will struggle to accept and comply with the regulatory requirements. Without reworked AMC and GM, successful implementation of the resultant regulatory package will require a detailed deconstruction of its contents by CAs at local level into more readily understandable formats and languages. This undermines the principle of harmonised application of the proposed regulation and is both inappropriate and unnecessary. Extension of the GM is required to satisfy the need for harmonised application of the proposed regulation.</p> <p>If the above is not addressed we believe that industry will be impacted as follows:</p> <ul style="list-style-type: none"> · Industry will not readily appreciate that the proposed regulatory package allows for a scalable approach to presenting adequate and appropriate safety arguments for changes. · Any flexibility provisions contained within the rule making package are unlikely to be immediately apparent to industry. <p>Consequently, both will lead to a perception that the package places disproportionate demands on resources which will in turn result in deterring industry from implementing safety improvements.</p> <p>Justification: Clarity, practicality</p>
response	<p>Partially accepted</p> <p>Please refer to the response to comments No 3 and No 235</p>
comment	<p>237 comment by: UK CAA</p> <p>Page No: general Paragraph No: general</p>



Comment:

The approach taken to consulting on NPA 2013-08, NPA 2014-13 and second AMC/GM NPA raises concerns about the final content of the complete legislative package:

- The NPA will lead to finalisation of IR text. However, CAs and industry alike will not have sight of the complete supporting AMC and GM until conclusion of the subsequent AMC/GM - only NPA. Until AMC and GM in their entirety are available, it is impossible for stakeholders to assess conclusively whether the proposed regulatory package is acceptable or not. The UK CAA seeks clarification on how EASA will seek to address this.

- We cannot be certain that the scope of the safety assessment undertaken by ATS providers identifies and addresses effects on the safety of aircraft, as currently required by Regulation 1035 of 2013 Annex II paragraph 3.2.2 (b)(ii). Clarification is requested.

- It is not clear how the objectives of the NPA relate to ICAO Annex 19 principles or how consistency with, for example, SESAR Safety Reference Material (as referred to in the PCP Regulation) and/or state level means of implementing SES, can be achieved. It is vital that appropriate mechanisms are in place to support the safety assurance challenges of deploying the PCP ATM functionalities. EASA is invited to provide clarity on how the current draft will contribute to meeting these challenges

The UK CAA would value the opportunity for stakeholders to review and comment on the finally combined ATM/ANS IR and associated AMC/GM. This would assist in providing the clarity required for its eventual implementation.

Justification: Clarity, practicality

response

Partially accepted

If the intent of the rule is clear, the elaboration of the AMC/GM should not pose an excessive problem to accept the IR text. The consultation of AMC/GM will take place at a later stage and should ensure appropriate and adequate means of compliance and guidance. The scrutiny of the IR text will trigger additional needs to develop guidance material as well, and will help to better complete the package.

The scope of the safety assessment should address effects on the safety of aircraft, as required by ATS.OR.205 (b)(4). This requirement addresses the analysis of risks of the effects related to the change, which implies an analysis of the likelihood of accident and the severity of that accident due to the presence of the change. It is not clear what the source of the commentator's concern is.

The provisions included in the proposal are in line with the content of CRD to NPA 2013-08, which has been aligned with Annex 19. This proposal only details change management, which is outlined in the SMS principles. In addition, it clarifies the activity for those service providers that are not included in Annex 19. It is acknowledged that no thorough analysis has been carried out against SESAR SRM, but the Agency has participated in the review of the SRM and no incompatibilities have been identified so far. The level of confidence that the evidence provided by the SRM achieves is not an intrinsic property of the method itself, but it highly depends on the application of it. In other words, the application of SRM does not guarantee obtaining sufficient evidence to use in an argument required by this proposal, but it can help to build confidence in the evidence generated. This proposal does not depend on



the method used, it only outlines the criteria to judge the results obtained by the application of the SESAR SRM.

The Agency acknowledges the value of the comment on the finally combined ATM/ANS IR and the AMC/GM thereto. This will only be possible once the full package of AMC/GM is completed, which has not been possible at this moment. Nevertheless, the commentator is assured that the opportunity will be given to stakeholders to comment on the AMC/GM once the full package is ready, offering the chance for the AMC/GM to be reviewed together with the IR.

comment

238

comment by: UK CAA

Page No: general**Paragraph No:** general

Comment: In the UK CAA's view , given that the amended rule will establish a valid mode of operation of risk-based oversight of risk-based safety assessment, it is questionable whether this mode of operation is appropriate for the complete scope of the regulation. The costs of such an approach are significant, even when all aspects are addressed in a manner commensurate with risk. Such an approach also requires high levels of assurance expertise, which are in scarce supply.

The NPA appears to suggest that there are parts of ATM/ANS that are low risk in terms of their services and systems used, and effectively are of 'too low' risk in a manner analogous to low severities in Figure 2 on p100 of the NPA. If it is agreed that such a segment of the industry exists, UK CAA recommends that it should be subject to different regulatory methodology, rather than be forced to bear the burden of the costs of a risk-based approach to safety assurance and oversight. We suggest that this could be implemented by a derogation arrangement.

Justification: Proportionate regulation.

response

Partially accepted

The whole idea of the risk-based approach (assurance and oversight) is certainly based on the existence of segments of the services that pose different risks, as the commentator rightly points out. It seems, however, difficult, if not impossible, to identify those segments of the services a priori. This is the reason why the approach taken has been the introduction of a generic requirement, which will apply differently to different types of services and changes. It seems more appropriate to build the flexibility and proportionality through AMC which will be introduced once they are finalised.

comment

239

comment by: UK CAA

Page No: general**Paragraph No:** general

	<p>Comment: The material is extensive, encompassing the whole scope of risk and systems safety engineering, and assurance, and UK CAA recommend that EASA consider defining a staged method of adoption, so that SPs and CAs can concentrate on developing existing SMS, change management and regulatory procedures and practices in a coordinated and controlled manner.</p> <p>Justification: Practicality</p>
response	<p>Not accepted</p> <p>It is acknowledged that a period of time to introduce all these changes will be required. The transition phase should serve this purpose, but, at this stage, it is not considered appropriate to delay implementation, as the commentator seems to suggest.</p>
comment	<p>240 comment by: UK CAA</p> <p>Page No: general Paragraph No: general Comment: The UK CAA recommends the creation of tutorial material, examples and training courses. Justification: To assist in the practical application of the requirements</p>
response	<p>Noted</p> <p>This is certainly something that will be needed once the rule is adopted, but not at this stage where the requirements are being defined.</p>
comment	<p>241 comment by: UK CAA</p> <p>Page No: general Paragraph No: general Comment: Being generic, in that the NPA must cover all changes, the majority of the GM material is valid for changes of reasonable size, to the detriment of its applicability to small changes. There are many more small changes than larger ones, and UK CAA recommends that guidance material on how to correctly justify smaller changes should be provided. This could perhaps address changes whose scope is entirely on the causal side of the hazards, and introduce no new hazards. Particular issues with smaller changes are the setting of safety criteria and the definition of monitoring arrangements for performance validation purposes (e.g. p195 GM1 ATS.OR.205(b)(7)) Justification: Utility</p>
response	<p>Partially accepted</p> <p>If by ,‘smaller changes’ the commentator means changes with small impact or low severity (low risk), then the justification should be easier. There is no apparent reason why the</p>



justification or the monitoring criteria should be a problem for those changes. On the contrary, the activities should be easier to be carried out and the monitoring criteria much more loose. The IR provides enough flexibility for the service provides and the CAs to decide on the best way to apply the criteria defined in the proposal. It is acknowledged that AMC/GM are likely to be improved to reflect that and provide more practical ways of implementation and guidance. However, this has not been possible at this stage.

comment

242

comment by: UK CAA

Page No: general**Paragraph No:** general**Comment:** General comment relating to AMC

It is the UK CAA's understanding that AMC is a more detailed explanation of the IR t0065t and is soft law and audit findings can be issued for non-compliance with the requirements of the AMC, AMC should therefore be unambiguous. The AMCs currently contain words such as 'should' and 'may'. Auditing against such terminology is difficult as this provides the Service Provider and the CA with options on the status of compliance.

Justification: Clarity of Acceptable Means of Compliance**Proposed Text:** Within the AMCs suggest replace 'should' and 'may' with 'shall' and 'must'

response

Not accepted

An AMC or GM cannot use any language that expresses an obligation (neither 'shall' nor 'must'), as they only provide one means to comply with the IR. There is always the possibility to propose an AltMoC [or to comply directly with the IR without any reference to the AMC.](#) [When auditing organisations against proposed AMC \(or AltMoC\), the words 'should' and 'may' included in the AMC/AltMoC should be considered 'shall' and 'must', and if they are complied, then the compliance with the associated IR must be assumed.](#)

comment

243

comment by: UK CAA

Page No: general**Paragraph No:** general**Comment:**

NPA 2013-08 and the aerodrome legislation 139/2014 both require a common management system where the ANSP and Aerodrome Certificate holder are the same entity.

NPA 2014-13 and NPA 2013-08 refer to the 'notifications' of changes. The associated aerodrome legislation 139/2014 requires 'notification' for changes that do not require prior approval and 'applications' for changes that require approval.

Given the increasing amount of aviation-related EU regulatory material that is both created by EASA and/or derived from ICAO, an EASA-owned lexicon of common terms – essentially a compendium of all definitions, terminology and abbreviations that appear in regulatory



material 'parented' by the EASA Basic Regulation (as amended) is in the UK CAA's view considered necessary. We recommend that incorporation of terms used in material 'parented' by the Single European Sky is also incorporated. Such a lexicon could be hosted on the EASA and Eurocontrol websites and amended as terms are introduced, amended or withdrawn. As such it would be the EASA equivalent of ICAO Doc 9713 — International Civil Aviation Vocabulary.

Justification: An EASA lexicon would ensure consistency of understanding and application of the terms and abbreviations used within aviation-related EU regulatory material by the EU, its agencies, Member States and industry alike.

The UK CAA recommends that the same terminology is used in both legislation i.e. notifications and applications. We would invite EASA to consider the development of a common lexicon of words and phrases used in EASA documents and EU aviation legislation.

response

Noted

The Agency sees very positively this UK CAA initiative concerning a common lexicon on the terms and abbreviations/acronyms used within the aviation-related EU regulatory material. UK CAA is encouraged to raise this issue also in the relevant EASA rulemaking Advisory Bodies.

comment

273

comment by: EUROCONTROL

General Comments

The EUROCONTROL comments are a compilation of comments received from the various centres of expertise that exist within the Agency, including from the Maastricht Upper Area Control Centre, i.e. a provider of air navigation services.

This NPA has the specific objective to provide a harmonised set of rules (by clarifying and enhancing the existing ones) for certified service providers to perform the assessment of changes to functional systems, and enhance the rules for competent authorities for the oversight of these changes. The objective is, therefore, to improve harmonisation and to facilitate the maintenance of a high level of safety by providing a clear set of implementing provisions, Acceptable Means of Compliance (AMC) and Guidance. The proposed changes are expected to improve understanding of the concepts associated with the assessment of changes to the functional systems by certified service providers and the relationship between the service providers and the competent authorities during the oversight activities of the latter. By improving the understanding of these concepts, it is expected that harmonisation across Europe will also improve. The overall impression on the document is that this NPA has failed to meet its stated objective.

This being said, EUROCONTROL shares the view that, by and large, the proposed set of implementing provisions (IR), Acceptable Means of Compliance (AMC) and Guidance Material (GM) significantly improve the deficiencies of the current regulation in force, when it comes to safety assessment of changes. The attempt to provide a harmonised set of rules and to clarify the existing ones through these AMCs and guidance material is greatly welcomed. The guidance material includes some good examples and diagrams. On the other



hand there are a number of shortcomings which prevent this NPA from achieving its stated objective.

In general, concerning AMCs only, it believed that they should describe how to implement a given requirement (one means of implementing it). A number of proposed AMCs are too vague to achieve this aim. In the description of some proposed AMCs and also guidance material, both “should” and “shall” are used.

The NPA seems immature owing to these shortcomings. The use of examples, way too many, is a probable indication that no clear position can be taken. Moreover, almost every example given could be reused to support an opposite thesis to the one presented (cf. Table 1 on p.66; as all the ones provided from p.187 till p.192). There are also apparent contradictions between some articles or paragraphs. Finally, the reading line is not enough clear since new concepts are presented without sufficient explanations or the support by factual evidence.

More specifically the proposed IR/AMC/GM material is very different from the equivalent material for aerodromes addressing the topic of safety assessment of changes. It is also much more complex. Given the high number of interactions between ATM/ANS and aerodromes, a better alignment of the two sets of implementing measures (respectively for ATM/ANS and for aerodromes) could have significantly eased coordination between the key players (aerodrome operator, ATM/ANSP, and their competent authorities).

One example amongst many of area requiring clarification is the concept of “functional system”, as introduced in the proposed IR/AMC/GM. The definition of ‘functional system’ has been revised and introduces the notion of ‘aviation undertaking’. Owing to the fact that such a concept is not used in any other fields of civil aviation covered by the Basic Regulation, its introduction adds some confusion and complexity, for no or little added-value.

The NPA introduces also the notion of a ‘safety support assessment/case’. The distinction between the type of safety assessment performed by ATS providers from other service providers is welcomed. However, the use of varying terms to describe the same process does not add any clarity. It is essential to stress the scope of the safety assessment but there is no need to invent new terms to describe the activity according to where the boundary is.

Some form of safety assessment should be carried out whenever a change to the operations of ATM/ANS services, or a change to the organisation / management system of ATM/ANSPs is to be implemented. This proposal would better reflect the requirements from ADR.OR.B.040 Changes of Reg. 139/2014, which merely talk about “change to the aerodrome, its operation, its organisation or its management system”, without having to talk about “functional systems”.

EUROCONTROL thinks also that the proposed NPA seems to be based on working methods of ANSPs involved in drafting the regulation. However, there are other methods that are equally relevant as a means of compliance. We wonder how these could be taken into account without forcing ANSPs to revise their methods, with additional cost impact but no safety benefit.

It is not clear why the current NPA is limited to new / modified ATM/ANS Functional Systems and does not address the safety of an ATM service. In doing so, not only there is might be an impact when considering e.g. SESAR, but as well the NPA seems to perpetuate a current problem with existing Regulations that is that there is no requirement for ATM service



providers to demonstrate the safety of their on-going operations. It is therefore recommended:

1. to broaden the scope of the NPA to include the safety of ATM services
2. that the NPA mentions in section 2.1 of the Explanatory Note that if the safety of the on-going service is not also established – then there is a danger that:

- changes would be built on weak foundations;
- after several changes had been made (especially when changes were made to earlier changes) the task of providing coherent safety assurance information could become increasingly difficult; and
- there could be a lot of unnecessary overlap / duplication between successive safety assessments leading to wastage of valuable safety-assessment resources.

In addition, the NPA speaks of approval by competent authority and no longer of acceptance e.g.

EU 1034/2011

Article 9 1. - *Organisations shall only use procedures accepted by the relevant competent authority...*

Article 10 2.(i) - *provide notification of acceptance...*

NPA 2014-13

ATM/ANS.AR.C.030 *Approval of change management procedures...*

ATM/ANS.AR.C.040 (c) (1) – *approve the argument*

Are there any legal implications in the change from acceptance to approval?

Finally, concerning the Regulatory Impact Assessment (from p. 197 onward), it seems that the data are used sometimes to support a pre-established position but without being complemented by a strong factual evidence.

response

Partially accepted

The general comments on AMC/GM will be responded to in the CRD associated with them. It is acknowledged that this material requires rework. While the commentator suggests that the examples are excessive, the Agency has received other comments to complete with additional examples (especially related to small service providers). A balance should be found. Please see the responses to comments Nos 3 and 235.

Whilst it is accepted that certain consistency between aerodromes and ATM rules could be ensured; however, the difference lies in the details of the requirements whereas the principle of both is the same.

The notion of an aviation undertaking is used in the rule to differentiate those stakeholders regulated by the proposed IR from those not regulated. It is explained in GM and makes the rule simpler and more concise. It should not make understanding difficult once the concept is understood.

The definition of a functional system is present in Regulation (EU) No 1035/2011 and its continued use is necessary in order to differentiate it from the definition of a system in the SES regulations. It is also useful as it allows the differences inherent in changing a operational



system to be clearly distinguished from those related to changing management systems or organisations.

It should be stressed that a safety support assessment is not a safety assessment. It provides the evidence for the assurance that the service will meet its specification and so can be used, with confidence, by an air traffic service provider in his safety assessment. Since the activities and objectives for the assessment are necessarily different from those of a safety assessment, the language difference is a by-product of this difference and not something intended to confuse.

The proposed IR provides requirements on the objectives of the management, assessment and assurance of changes. Unlike Regulation (EU) No 1035/2011, it does not describe methods. Providing the methods that EUROCONTROL suggests to satisfy these objectives would be acceptable. This flexibility was one of the main reasons for proposing changes to Regulation (EU) No 1035/2011, and it is one of the elements highly requested by ANSPs. The safety benefit foreseen lies in providing a clear coherent set of objectives for the safety assurance of changes.

Seeking a safety assessment of all the service providers was a goal of ESARR 4 and Regulation (EC) No 2096/2005. However, this was never achieved and the rationale behind the proposed rule is that since the ATM system as a whole is viewed as being safe enough, then the safety of the system can be assured by making sure that each change leaves the system at least as safe as it was before (or alternatively it does not introduce unacceptable risks). This does not rely on an assessment of the actual safety of all the provided services, but it does maintain the current level of safety and does not pose any restrictions on SESAR.

Since the safety case assures the safety of the change in relation to the current system, there is no need for degradation of safety just because many changes have been performed. Furthermore the reuse of evidence and the use of evidence from other implementations is allowed by this proposed regulation which should ensure no duplication or waste of effort when creating safety cases.

Please see comment No 840 for a response to the concerns over the use of 'approve'.

Please see the responses to comments on the RIA and the reassessed RIA, as regards the final point.

The development of the Aerodrome Regulation with regard to assessment of changes of the operation used an earlier version of material developed for ATM/ANS. The aerodrome provisions were published, but the provisions related to ATM continued evolving, while the aerodrome parts were frozen for publication. The Agency acknowledges that some wording is different, but it seems only that the ATM counterpart is more detailed. It should be acknowledged that in the aerodromes rules the concept of functional system is not present.

comment

274

comment by: *Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)*



	<p>The proposed regulation is not yet mature. There are several indications one being the extensive use of examples, and another one being that there are a number of direct statements indicating the lack of maturity in the proposal, f.i.</p> <p><i>“In the meantime, nothing prevents the CAs from starting to apply the provision based on the guidance material available. If they do, the Agency would appreciate their feedback on its implementation. This information would help the Agency to further develop the necessary AMC.” [ref 2.3.4, page 21]</i></p> <p>The proposed IR will also result in a Wide range of severity classification schemes [ref page 16]</p> <p>Furthermore it is not acceptable that a single requirement in the IR requires extensive number of GM and AMCs to be understood.</p>
response	<p>Partially accepted</p> <p>There are certainly different levels of maturity with regard to different provisions, but that does not mean that the whole proposal is immature. The example given only shows certain level of immaturity of the actual model to apply, but the criteria to be used and even the elements that capture the criteria are clearly defined. This does not prevent the proposal for the risk-based selection to review changes. Some other concepts proposed have been withdrawn, e.g. the risk-based review.</p> <p>The general comments on AMC/GM will be responded to in the CRD associated with them.</p> <p>Initially, within the Rulemaking Group, the provision of a universal severity scheme was favoured. However, after analysing a considerable number of schemes, which are recorded in the GM on ‘Risk analysis in terms of safety risk’, the Group came to the conclusion that a universally acceptable severity scheme was not feasible at the moment. The Group was not able to agree on a set of schemes to be used in different circumstances.</p> <p>This choice may have a negative impact on harmonisation as each ATS provider could develop their own severity scheme to be used in risk evaluation. However, this could be mitigated in the long term by reviewing the severity schemes used by ATS providers and seeking to minimise their variation, consequently, providing either a single severity scheme or a small set of them. Moreover, since the proposal in this NPA contains the criteria for a severity scheme in the AMC, the variation in the number of different schemes should be limited to a manageable number.</p> <p><i>The fact that a single requirement requires extensive GM or AMC is the result of the complexity of the concept/requirement that the Regulation is dealing with. There is nothing that limits the AMC/GM if it is considered useful for the applicability or understanding of the requirement. This is perfectly acceptable.</i></p>
comment	<p>275</p> <p>comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i></p> <p>The proposed regulation significantly increases complexity for the both for CA and Service</p>



	<p>Providers. When implementing current regulation, Sweden has adopted one procedure within the national legislation to deal with changes to functional systems for ATS and CNS providers. As we interpret the new proposal Sweden will have to accommodate individual procedures from each Service provider. Sweden has currently 25 Service providers and we expect the number to increase when the IR becomes effective, many of these service providers are very small (ATS up to 10 000 movements a year).</p>
response	<p>Noted</p> <p>It may be feasible to have a single procedure for both ATS and CNS providers provided it respects the differences identified in ATM/ANS.OR.C.005 and ATS.OR.205. CNS providers cannot assess the safety of the changes they make and so should focus on the trustworthiness of the service they provide. Whilst this does not involve safety risk, in most other aspects, there could be a considerable amount of commonality.</p> <p>While each service provider is expected to have its own change management procedures, there is no reason why a common set of management procedures could not be envisaged, providing each service provider uses them and, in each environment, the rules about the management, assessment and assurance of change are followed.</p>
comment	<p>276 comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i></p> <p>Increased scope of the IR compares to current regulation, increased number of approvals, increased complexity etc. will significantly drive the cost for both CA and ANSPs meanwhile the improvement in safety could be questioned.</p> <p>This is not in line with the performance regulation EU No 390/2013</p>
response	<p>Partially accepted</p> <p>The intention of the proposed IR is not to lead to an increased number of approvals. The approval of assurance arguments is based on their review. The selection of assurance arguments for review is risk-based. This should ensure an appropriate number of approvals to be given.</p> <p>The draft regulation proposes the amalgamation of the two Commission Implementing Regulations (EU) Nos 1034/2011 and 1035/2011 into one single rule. This would provide for the alignment of the scope and applicability of the requirements for the service providers. However, as indicated in the RIA, already today Regulation (EU) No 1034/2011 requires all service providers to conduct an assessment of changes to their functional systems. Therefore, for providers of ANS, ATFM and ASM, this is not considered a new element. In reference to DAT providers, it could be assessed as a new requirement; however, DAT providers are already regulated (although via voluntary measures based on EASA Opinion No 01/2005) and the change management requirements are applicable to this type of providers.</p>



Having in mind the above-mentioned, potential short-term cost which is legitimate for every regulatory change should be compensated with the long-term benefits expected for all stakeholders.

comment

315

comment by: *BAF-M.Jancokova*

EASA AMC + GM must be comprehensive but considered just as a possible means of compliance. It must still be feasible to introduce Alternative means of compliance. Therefore it is recommended to split complex AMCs into separate subsets in order to be able to use individual parts as AMCs.

response

Partially accepted

The fact that an AMC is large does not imply that one service provider or CA cannot propose an AltMoC to only one element of the AMC. The need for splitting the AMC will be analysed at a later stage. General comments on AMC/GM will be responded to in the CRD associated with them.

An AMC or AltMOC relates to a specific part of an IR. The fact that an AMC exists does not preclude the creation of AltMOC covering all or part of the same scope as an existing AMC. Consequently, the implied relationship drawn here is incorrect and does not, on itself, force the production of small AMCs. The fact that an AMC is long does not preclude the use of AltMOC to specific subparts of the AMC. However, splitting AMCs may be considered appropriate to ease readability or applicability.

In fact the only AMC that has a significant number of comments about its length is AMC1 ATS.OR.205(b). Following acceptance of said comments, the AMC has been split.

comment

316

comment by: *BAF-M.Jancokova*

Though the intention of this regulation is not to stick to certain methods but rather follow a goal based approach, it might be helpful if additional AMCs were introduced which could be used especially by small ANSPs as a kind of recipe, e.g. for safety assessments, safety (support) cases etc. In that context work already done could be built on or carried on (e.g. Eurocontrol SAM).

response

Noted

General comments on AMC/GM material and their analysis will be tackled in the CRD associated with them.

The distinction seems more appropriate for GM, even though the creation of additional AMCs to address proportionality could be tackled in future amendments of the material.



comment	<p>317 comment by: <i>BAF-M.Jancokova</i></p> <p>Consistently throughout the NPA the term "approve" is used in the context of "approve/approval of a change (by the CA)". In regulation 1034/2011, the formulation is, however, different, namely (see article 10 (3)): "The introduction into service of the changes under consideration in the review shall be subject to acceptance by competent authorities." What is intended by replacing "acceptance" by "approval". Shall CAs take more responsibility than it is the case now?</p>
response	<p>Noted</p> <p>No additional responsibilities are envisaged. Please see comment No 840 for a detailed response to the concerns over the use of 'approve'.</p>
comment	<p>357 comment by: <i>Air Navigation Services of the Czech Republic</i></p> <p>Generally, the new IR would require re-writing Safety Management Manuals of ANSPs and change the procedures already agreed between ANSPs and their respective NSAs (CAs). It should be analysed whether such changes improve safety (not just regulation itself) to an extent justified by the cost mentioned.</p>
response	<p>Noted</p> <p>In most cases, since this proposed regulation clarifies and simplifies the previous regulations and improves flexibility by focussing on the goals for the management, assessment and assurance of change, the effect on the current SMS manuals should be minimised. The RIA examines the cost and safety implications of the change and in all cases argues that there is an overall improvement.</p>
comment	<p>369 comment by: <i>skyguide Corporate Regulation Management</i></p> <p>SUMMARY ISSUES:</p> <p>a. Offer of Support. we believes that it is very important that this regulation is implemented correctly and in a way that will deliver safety benefit for the industry. We have an extensive experience in the practicalities of performing risk assessments and the background in the creation of the rule. We would like to offer our continuing support to EASA in improving the quality of the rule. We believe that creating safety is not just achieved by rulemaking but also (primarily by) good leadership from the top management (level 1), having the right tools and organisational setup (level 2), a good SMS (level 3), a good safety risk assessment process (level 4) and proper risk classification (level 5). We believe that the regulation should attempt to stay at the highest level (2 or 3) to have the greatest impact.</p> <p>b. Level of detail and split between IR and AMC. We believes that some of the material in the proposed IR would be more appropriate AMC. We support the specific suggestions</p>



provided by CANSO (in Appendix A), which it is believed build on the proposals in the NPA and make the rule easier to implement (and therefore more effective) by both CAs and service providers.

c. **Overlap between the Management System and Safety Management System requirements (MS / SMS Split).** We believe that some of the IR and AMC in this NPA duplicates MS/SMS elements already addressed in CRD 2013-08. The placing of overlapping requirements with CRD 2013-08 introduces the potential for internal inconsistencies, duplicate regulation and a lack of legal certainty. We believe that NPA 2014-13 should not specify IR / AMC that is already addressed in NPA 2013-08. We support some specific suggestions provided by CANSO (in Appendix A), which we believe builds on the proposals in the NPA and make the rule easier to implement (and therefore more effective) by both CAs and service providers.

d. **Performance Based Regulation.** We believe that the IR (and AMC) is not performance based as the NPA contains much prescriptive regulation. Both EASA and the European Commission are consulting on the industry views on a Performance Based Approach to Regulation and Oversight. The EN makes the statement that “existing provisions do not always support the concept of better regulation or performance-based regulation.” We do not believe that the proposed provisions support these principles either. The EN notes one specific objective is to have a more performance-based regulation by allowing the ATS provider to use a multi-valued safety risk classification scheme (which is actually a severity classification scheme). This appears to be the only concession to Performance Based regulation, and is not helpful to large service providers as it is not possible to apply the criteria selectively within a complex operation.

i. **The IR does not achieve the perceived intention of the rule.** We believe there are a number of areas where the text of the IR does not achieve the intent of the rule, in some cases making the application of the IR difficult if not impossible. We have provided specific examples in the detailed review comments.

ii. **Some of the IR is infeasible**, i.e., it is not possible to do easily or conveniently and is impractical. We are concerned that EASA may place requirements on service providers and CAs that are not possible to demonstrate compliance with. We have provided specific examples in the detailed review comments.

iii. **Some of the IR is unbounded and uses subjective language**, for instance the requirement for service providers to consider changing their functional system if it is technically and economically feasible to improve performance by doing so. We consider this to be poor regulatory practice.

iv. **Overly complicated and Missing AMC.** We believe that very long AMC should be subdivided in to separate AMC , i.e., AMC1, AMC2, AMC3, etc. each dealing with a specific sub-topic This will allow service providers to propose alternative means of compliance for individual means of compliance for individual parts rather than the whole of the material. In some cases additional AMC would also be helpful.

v. **Missing, Incorrect and more focused Guidance Material.** We believe there is a need for more efficient guidance (less, but more focused and efficient) material, both for service providers and for CAs which will be particularly important for the safe and efficient deployment of SESAR. We are also surprised to see definitions in GM which it feels is



inappropriate.

e. **Transitional Arrangements.** We are concerned about the transitional arrangements for this proposed rule. We note that CRD 2013-08 has no specific text in Art 8 and 9 regarding Transitional provisions and Repeal other than referring to the Opinion. It is therefore not clear to us which provisions are being referred to in this NPA. Is it the whole of CRD 2013-08 or just the provisions in this NPA? If it is the latter then what are the transitional arrangements for the provisions in the CRD? It is noted that the proposed transitional arrangements of 2 years only applies to existing “service providers” regulated under 1034/2011 and 1035/2011. Does this mean that those service providers (using the CRD 2013-08 definition) who are not regulated by 1034/2011 and 1035/2011 have no transition period?

f. **Explanatory Note (EN) and Regulatory Impact Assessment (RIA).** We question whether the RIA is accurate, in particular whether EASA appears to be interpreting 1034/2011 and 1035/2011 to support its own RIA (retrospectively) rather than as originally intended. We do not believe that the EN and RIA provide adequate analysis on how this proposed rule will support the safe and efficient deployment of SESAR.

response

Partially accepted

a. **Offer of support:** The Agency takes due consideration of the comments and proposals provided and does share the same opinion. The ultimate aim is of common interest and working together side by side will facilitate the achievement of it.

b. **Level of detail and split between IR and AMC:** Finding the optimal balance between IR/AMC/GM is not always an easy task. Too many details in the IR may be perceived as too prescriptive, whereas too few details as too loose. The principles followed to set requirements at these two levels of law (hard and soft law) aim at accommodating two objectives: to ensure harmonisation in the implementation when it is required, and to provide flexibility to comply with the law. To achieve this, the Agency has attempted to state the ultimate goal of the regulation along with the criteria to judge that goal at the IR level, and left at the AMC level the means for the addressees to comply with the law and its intent. In most circumstances, we need to have the criteria to judge the IR intent in the IR text, and not in AMC. This will help to implement the law as intended (i.e. ensuring harmonisation), but also to avoid distortion of the law if applied in a different way from what intended. The decision to move text from IR to AMC has to be made on a case-by-case basis. For instance, the removal of AR.C.035(b) would mean that the criteria on which the decision by the competent authority was made were not part of the rule. Consequently, any criteria would be acceptable and there would be little point in having the rule. It is, however, recognised that some material could be moved to AMC, and the Agency has decided to do so in certain cases.

c. **Overlap:** The Agency has also identified some of these issues and taken care of resolving them, when appropriate such (e.g. ATM/ANS.OR.B.005(a)(5), (a)(6) or (d)(2)).

d. **Performance-Based Regulation** Taking due consideration of the comment, the subject provision is amended to provide more flexibility compared to the current Regulations that govern these areas, Regulations (EU) Nos 1034/2011 and 1035/2011. Moreover, criteria are



provided to be used by service providers and competent authorities to be able to achieve the intent of the regulation. The Agency believes that the objectives of performance-based rulemaking are better met with this 'revised' proposal. Some examples (non-exhaustive list) are:

- The decision of a CA to review or not a notified change is based on risk, but the precise model to identify this risk is left to the CAs (GM is given to describe criteria to be used, but the text does not prescribe how the model should be).
- It is left to the CA-provider agreement to decide when certain changes will be implemented without review (but not without assessment/assurance).
- Providers should coordinate assessment/assurance, but it is up to them to decide how to achieve that coordination. The way this is regulated is not prescribed.
- The proposed rule text requires processes to monitor the management system and the functional system, but it is left to the provider to develop the best processes, indicators, the level of performance below acceptable (now introduced as 'underperformance'), etc. that suit them best. There is no prescription on how to do this monitoring.
- The proposed rule text allows the provider to use different methods to conduct the safety assessment depending on the type of change. The current regulation (Regulation (EU) No 1035/2011) prescribes a single way to do it. Safety criteria that the change should meet can be assessed in terms of safety risks (preferable), but it is allowed as well in terms of proxies (i.e. other measures related to safety risks), recognised standards or codes of practice, or referring to performance of existing systems.

In addition, the objective of harmonisation have been taken into account.

d.i. IR does not achieve perceived intention: In general, the Agency believes that the IR does meet its intention and it has been drafted having in mind this objective. If there are instances where this has not been achieved, it has been unintentional and corrected as appropriate. Furthermore, for a detailed response, please see the responses to the other comments you have submitted.

d.ii. Infeasible IR: In general, the Agency believes that the IR is feasible. If there are instances where this has not been achieved, it has been unintentional and corrected as appropriate. Furthermore, for a detailed response please see the responses to the other comments you have submitted.

d.iii. Unbounded IR: The Agency has reviewed these unbounded terms, where detailed comments have identified them, and in some instances they have been modified or removed altogether. In the example given, the commentator is invited to refer to the response to comment No 53 for a detailed answer.

d.iv. Overly complicated & missing AMC: General comments on AMC/GM will be responded to in the CRD associated with them. However, the Agency acknowledges that the AMC/GM has room for improvement (certain parts are incomplete and others can be more focussed).



Therefore, it needs a deep reorganisation and check of consistency. At present, the CRD is addressing only comments pertaining to the IR text. A considerable amount of time is needed to rework, amend and complete the AMC/GM in an appropriate and effective manner, and this cannot be done at this stage. Future work is planned to review the comments on the AMC/GM and complete the CRD in due time. The generic GM needs to be reconsidered and restructured. The proposal made by the commentator will be duly considered during the phase of the AMC/GM finalisation. The fact that an AMC is large does not imply that one service provider or CA cannot propose an AltMoC to only one element of the AMC. The need for splitting the AMC will be analysed at a later stage, but the length of it should not be intrinsically considered a defect.

d.v. Missing, incorrect and more focussed GM: General comments on AMC/GM will be responded to in the CRD associated with them.

e. Transitional arrangements: There is no proposed transition period in this NPA. What is proposed for certain requirements is the delay of applicability in addition to the transitional period decided by the European Commission in relation to CRD 2013-08. In the final Opinion, a common transition period is proposed all service providers. There is nothing that implies that the new providers included in the definition included in CRD 2013-08 will not have the transition period. Said period will be discussed in the Single Sky Committee and will be finally adopted by the European Commission.

Regarding the repeal of Regulations (EU) Nos 1034/2011 and 1035/2011, it is clearly stated in section 1.3 of CRD 2013-08 that the proposal aims at repealing those regulations, even though the precise text has not been introduced. The same applies to this NPA.

The intention is not to have two periods running in parallel, possibly resulting in the applicability for those requirements to be 4 years (depending on the transition period decided later), but a single transition period of 2 years.

f. EN & RIA: There was no intention to interpret Regulations (EU) Nos 1034/2011 and 1035/2011 retrospectively. In fact, at the very beginning of the process, the principles embodied in these regulations were identified, documented and broadcast via workshops. The proposed IR respects these principles and the RIA argues that they have been implemented in an appropriate way. The scope of application was in some cases misrepresented in the original RIA. The RIA has been reassessed using the correct scope. The results can be found in the Opinion. For a more detailed response to the issue raised here, the commentator is invited to refer to the responses provided to comments on the RIA section of the CRD. It is acknowledged that no thorough analysis has been carried out against SESAR safety reference material, but the Agency has participated in the review of the SRM and no incompatibilities have been identified so far. This proposal requires an acceptable level of confidence in the assessments. The level of confidence that the evidence provided by the SRM achieves is not an intrinsic property of the method itself, but it highly depends on the application of it. In other words, the application of SRM does not guarantee obtaining sufficient evidence to use in an argument required by this proposal, but it can help to build confidence in the evidence generated by SESAR projects. This proposal does not depend on the method used, it only outlines the criteria against which to judge the results obtained by



the application of the SESAR SRM. In that sense, it does not pose any restriction on the assessments performed by SESAR.

comment

374

comment by: *Air Navigation Services of the Czech Republic*

We propose to review the split between IR and AMC. We believe that some parts of the proposed IR would be more appropriate as an AMC. We think such changes would make the rule easier to implement by both CAs and service providers, thus increasing its effectiveness. We propose to move the following parts of the IR to AMC (and change "shall" to "should"):

- ATM/ANS.AR.C.010(b)(6)
- ATM/ANS.OR.A.045(e)
- ATM/ANS.OR.B.005(a)(6)
- ATM/ANS.OR.B.005(d)

response

Partially accepted

ATM/ANS.AR.C.010(b)(6): Please see the response to comment No 2.
 ATM/ANS.OR.A.045(e): Please see the response to comment No 47.
 ATM/ANS.OR.B.005(a)(6): This clause has been deleted.
 ATM/ANS.OR.B.005(d): Please see the response to comment No 54.

comment

455

comment by: *NAV Portugal E.P.E*

General Comments:

NAV Portugal supports CANSO and EUROCONTROL comments (positions) since they were coordinated and they reflect NAV Portugal's views.

From NAV Portugal point of view, this NPA does not fully address and solve the issues identified with the current regulation. The areas where difficulties were encountered, for which the existing AMC and guidance material was insufficient or difficult to follow, are still not adequately addressed.

The NPA introduces the notion of a 'safety support assessment/case'. The distinction between the type of safety assessment performed by ATS providers from other service providers is welcome, but there is almost no difference between both processes. It is essential to clarify the scope of the safety assessment but, at the same time, there's no need to invent new terms to describe the activity according to where the boundary is.

Regarding the NPA structure, NAV Portugal would like to highlight these topics:

Level of detail in the IR –Some parts should be moved to AMC to make the rule easier to implement and more effective to CAs and service providers as well. CANSO has a proposal that was coordinated and is in line with NAV's views.

There are overlapping areas with CRD 2013-08 addressing the Management System and Safety Management System requirements. This overlap may lead to duplication and inconsistencies.



	<p>The IR and associated AMC contains much prescriptive regulation, which is not in line with European Commission goal to improve regulation and it is not performance-based regulation. There are also other problems with the IR:</p> <ul style="list-style-type: none"> • It is NAV Portugal's opinion that the IR does not achieve its stated intentions. • Some of the IR is impractical and very difficult (and costly) to demonstrate and verify compliance with. • Some requirements are not stated in a demonstrable way, using language that is inappropriate for regulatory requirements. • The AMC is very complicated, extensive and not covering all the IR. <p>The guidance material should be reviewed as it is unfocused, incomplete, confusing and even contradictory.</p>
response	<p>Partially accepted</p> <p>It should be stressed that a safety support assessment is not a safety assessment. It provides the evidence for the assurance that the service will meet its specification and so can be used, with confidence, by an air traffic service provider in his safety assessment. Since the activities and objectives for the assessment are necessarily different from those of a safety assessment, the language difference is a by-product of this difference and not something intended to confuse. For a detailed response to the comment on the difference between safety and safety support, please see comment No 273.</p> <p>For a detailed response to the comment on the level of detail in the IR, please see comment No 2.</p> <p>For a detailed response to the comment on the overlapping area with CRD 2013-08, please see comment No 5.</p> <p>For a detailed response to the other comments that are coincident to CANSO's comments, please see the response to comment No 369.</p>
comment	<p>459 comment by: APROCTA</p> <p>As noted by the NPA at its Explanatory Note, a broader approach to the safety assessment is needed. From our Professional Association point of view (APROCTA), some of the key issues identified for risk assessment limitations, as “when used for certain types of change, e.g. the available data and/or models may be inappropriate for a specific quantitative risk assessment”, might be tackled if key stakeholders, like professional associations of operational staff (air traffic controllers associations) are involved in the process. We proposed that a total system approach could be reached more straight forward if the experience gained by operational staff not necessary linked to the ANSP, is taken into account.</p> <p><i>Commission Implementing Regulation (EU) N° 1035/2011</i>, states at its ANNEX II, Specific requirements for the provision of air traffic services, Part 4, Working methods and operating procedures, that Providers of air traffic services shall be able to demonstrate that their working methods and operating procedures are compliant with the standards set by the</p>



Convention on International Civil Aviation Annex 11 on air traffic services in its 13th edition of July 2001, including all amendments up to No 47-B, as far as they are relevant for the provision of air traffic services in the airspace concerned.

ICAO Annex 11 (13th edition of July 2001, amendments up to No 47-B), regarding Safety Management (2.27) states at 2.27.5 that *any Significant safety - related change to the ATS system, including the implementation of a reduced separation minimum or a new procedure, shall only be effected after a safety assessment has demonstrated that an acceptable level of safety will be met **and users have been consulted**.*

It also states at 2.30, Contingency Arrangements, that *air traffic services authorities shall develop and promulgate contingency plans for implementation in the event of disruption, or potential disruption, of air traffic services and related supporting services in the airspace for which they are responsible for the provision of such services. Such contingency plans shall be developed with the assistance of ICAO as necessary, in close coordination with the air traffic services authorities responsible for the provision of services in adjacent portions of airspace **and with airspace users concerned**.*

So, the industry has been commonly accepting professional pilots associations besides aircraft operators as users or airspace users (ICAO Global Air Traffic Management Operational Concept, First Edition - 2005). Probably because it is clearly understood that pilots, in general, “use” the airspace. However, in many air navigation procedures and documents as well as in many safety teams, it is increasingly being specified and accepted that professional associations of pilots **and air traffic controllers** (with or without specific distinction) should be consulted on safety issues as fully operational stakeholders:

1. ICAO Safety Management Manual, Third Edition - 2013 (Doc 9859-AN/474).

ICAO sets out that it is **essential to involve all internal and external aviation system stakeholders** having a potential impact on the organization’s safety performance. Furthermore, any potential inputs should be taken into consideration at an early stage of SMS implementation and throughout future internal evaluations of the SMS (Chapter 5, Safety Management Systems; 5.2, Scope), and specifically naming **professional associations**.

2. ICAO Threat and Error Management (TEM) in Air Traffic Control (Cir 314-AN/178).

ICAO recognizes that in the constant drive to improve the margins of safety in aviation operations, all the experience by the aviation industry is needed and welcome. Under this headline, the collection of every piece of safety data during normal operations brings possible threats and errors. Normal Operations Safety Surveys or NOSS, a proposed tool for the ATC environment, *requires the joint sponsorship from management **and the association representing air traffic controllers**.*

3. ICAO Manual on the Prevention of Runway Incursions, First Edition - 2007 (Doc 9870-AN/463).

*A runway incursion prevention programme should start with the establishment of runway safety teams at individual aerodromes [...]. The team should comprise representatives from aerodrome operations, air traffic service providers, airlines or aircraft operators, pilot and **air traffic controller associations** and any other groups with a direct involvement in runway operations.* (Chapter 3, Establishing a Runway Incursion Prevention Programme).

4. EUROCONTROL European Action Plan for the Prevention of Runway Incursions, Edition



2.0.

*Local Runway Safety Teams should be established to lead actions on local runway safety issues. [...] Experience has demonstrated that these teams have been effective at helping to minimise the risk of runway incursions at individual aerodromes, where local issues such as taxiway layout, runway configuration and aircraft operators' needs can be taken into account. [...] **The team should consist of**, as a minimum, representatives from at least the three main groups associated with manoeuvring area operations, namely the Aerodrome Operator (which would include a vehicle driver), Ground Handling Associations when appropriate, representatives from the Air Navigation Service Provider / and local **Air Traffic Controller associations** and pilots from Aircraft Operators / and local pilot associations that operate at the aerodrome and other organisations that operate on the manoeuvring area.*

5. 5. EUROCONTROL European Action Plan for the Prevention of Runway Excursions, Edition 1.0.

*A Local Runway Safety Team should form a key element in the aerodrome runway safety programme and should ensure that a strong focus is maintained on runway safety across all parties creating, de facto, an aerodrome level safety management function. [...] **The team should consist of**, as a minimum, representatives from the main groups associated with takeoff and landing operations, namely the Aerodrome Operator (which could include navigation aids engineers, infrastructure maintenance etc.) Meteorological Offices and Aeronautical Information Service Providers, representatives from the Air Navigation Service Provider, local **Air Traffic Controller associations** and pilots from Aircraft Operators, local pilot associations that operate at the aerodrome and other relevant organisations that operate on the manoeuvring area.*

6. 6. Comisión de Estudio y Análisis de Notificaciones de Incidentes de Tránsito Aéreo (Spain).

The Spanish Air Traffic Incident Report's Study and Analysis Commission (CEANITA), is a Ministerial Board which objectives are to provide advice and assistance on aviation safety issues to the Spanish Aviation Safety Agency (AESA) and to the Spanish Air Force General Department. This Commission is currently governed by the *ORDEN PRE/697/2012 de 2 April, por la que se establecen las normas de funcionamiento de la Comisión de Estudio y Análisis de Notificaciones de Incidentes de Tránsito Aéreo*. **The Board has representatives from AESA, the Spanish Air Force, ANSPs, Airlines, Professional Pilot and Air Traffic Controllers Association** (Article 6). CEANITA is integrated into the State Safety Programme for Civil Aviation (SSP).

At GM1 ATM/ANS.OR.A.045 (e) Changes to the functional system, CHANGES AFFECTING MULTIPLE SERVICE PROVIDERS AND AVIATION UNDERTAKINGS—GENERAL, an example of changes affecting multiple service providers and/or undertakings is about a runway usage, a clear one where a local runway safety team has a relevant role.

Even more, at GM2 ATM/ANS.OR.A.045 (e) Changes to the functional system, AFFECTED STAKEHOLDERS—SERVICE PROVIDERS AND AVIATION UNDERTAKINGS, stakeholders with dependencies with the changed service include staff associations.

So at this point, Aprocta considers that Regulation Nº 1035/2011 is not fully complete regarding pointing out **who are the operational stakeholders that should be involved in the**



risk assessment to give it a broader approach (and maybe so making it more understandable for operational staff), and therefore has the same amount of indetermination as ICAO Annex 11 regarding who are the air space users that should be involved in functional changes assessments.

This NPA does have the chance to, as recital 16 of Regulation (EU) N° 1035/2011 foresees, to adapt it “towards a total system approach, taking into account the integration of these provisions into a future common regulatory structure for civil aviation safety **and the experience gained by stakeholders** [...]”.

As a conclusion, maybe the best one is by the International Federation of Air Traffic Controllers Association, IFATCA, on the paper A STATEMENT ON THE FUTURE OF GLOBAL AIR TRAFFIC MANAGEMENT BY IFATCA (version 1.0, 27 February 2007):

IFATCA considers that the best way to address the problems being experienced in ATM is by all members of the ATM community cooperating. The cooperation required is a serious working together that requires pragmatism and compromise by all involved. This involves collaborative decision making that requires involvement in the process and in the consequences. It requires commitment to change and a will to act at all levels including at state level.

[...].

response

Partially accepted

The majority of this comment relates to GM and will be fully answered in the CRD associated with the AMC/GM.

The argument about the involvement of representative bodies is accepted. The involvement of all stakeholders who are affected by a change is promoted in the IR. The term ‘aviation undertakings’ covers all entities that may be affected by a change but do not fall within the scope of the regulation. GM explains that in some instances these include representative bodies of interested stakeholders such as ATCO and Pilot groups. Nevertheless, the IR cannot list particular representative organisations and require them to be consulted because the range of changes is extremely large and not all may need the involvement of all such representative bodies.

The commentator makes some useful comments. However, the IR/AMC/GM places no limits on those who should perform or support the safety and safety support assessments. The aim of the opinion is to be ‘goal based’, i.e. it does not regulate process but regulates for the successful application of process. Clearly, the successful application of process is conditional on the use of the right people. In other words, it should not be possible to produce a valid safety or safety support case without the use of the right people and the right procedures.

The GM pointing to the involvement of all parties to assess hazards, assumptions and risks is highlighted, but the stress is on the involvement of the operators (air traffic controllers and pilots) whenever is required. The responsibility is on the service providers to involve the most appropriate personnel to satisfactorily assess the changes, but the option to involve representative bodies is well recognised in the AMC/GM.



comment	466	comment by: CAA CZ
	<p>The CAA of the Czech Republic (CAA CZ) welcomes the NPA and perceives it as a direct response to the EU NSAs demand on clear guidance to difficult process related to the safety of ATM changes assessment. CAA CZ is pleased that the provisions included within the NPA justify the approach the CAA CZ has taken especially in regards of last paragraph of article 10 EU Reg. 1034/2011. However the CAA CZ at same time identifies some parts of the NPA to be somehow too academic (severity classification schemes) or too generic and abstract (substitution of the EU IR 482/2008). Provisions not commented have received generic support from the CAA CZ.</p>	
response	<p>Noted</p> <p>The Agency takes due consideration of the comment. The comments related to the AMC/GM will be fully answered in the CRD associated with them.</p>	
comment	569	comment by: skyguide Corporate Regulation Management
	<p>Attachment #1</p> <p>We agree with the proposed changes in the attached file - Appendix A - made by CANSO.</p>	
response	<p>Partially accepted</p> <p>Please see the responses to the specific comments that justify the proposal in this Annex addressing each individual modification.</p>	
comment	656	comment by: CANSO
	<p>Attachment #2</p> <p>In the attachment (Appendix A), please find the CANSO's detailed proposals on the format of the proposed IR/AMC within NPA 2014-13.</p>	
response	<p>Partially accepted</p> <p>Please see the responses to the specific comments that justify the proposal in this Annex addressing each individual modification.</p>	
comment	668	comment by: Swedavia



	Swdavia agree CNS providers shall perform safety support assessment. We also want to prepose that the authority should get a limited time to respond to avoid unnessesary time delay.
response	<p>Partially accepted</p> <p>The Agency takes due consideration of the comment and proposal provided by the commentator; however, it proved impractical to include it in the IR text due to the vast range of changes. What is acceptable to a type of changes is not to others.</p>

comment	675 comment by: ROMATSA
	<p>1. SUMMARY ISSUES:</p> <p>a.</p> <p>Offer of Support. ROMATSA supports CANSO opinion that it is very important this regulation be implemented correctly and in a way that will deliver safety benefit for the industry. Given CANSO extensive experience in the practicalities of performing risk assessments and the background in the creation of the rule, ROMATSA do support CANSO offer for continuing support to EASA in improving the quality of the rule.</p> <p>b. Level of detail and split between IR and AMC. ROMATSA supports CANSO opinion that some of the material in the proposed IR would be more appropriate AMC. Specific suggestions have been made (in Appendix A), to make the rule easier to implement (and therefore more effective) by both Competent Authorities (CAs) and service providers.</p> <p>c. Overlap between the Management System and Safety Management System requirements (MS / SMS Split). ROMATSA supports CANSO opinion that some of the IR and AMC in this NPA duplicate MS/SMS elements already addressed in CRD 2013-08 - Requirements for service providers and the oversight thereof. The placing of overlapping requirements with CRD 2013-08 introduces the potential for internal inconsistencies, duplicate regulation and a lack of legal certainty. NPA 2014-13 should not specify IR / AMC that is already addressed in NPA 2013-08. Specific suggestions have been made (in Appendix A), to make the rule easier to implement (and therefore more effective) by both CAs and service providers.</p> <p>d. Performance Based Regulation. ROMATSA supports CANSO opinion that the IR (and AMC) is <u>not</u> performance based as the NPA contains much prescriptive regulation.</p> <p>i. The IR does not achieve the perceived intention of the rule. ROMATSA supports CANSO opinion that there are a number of areas where the text of the IR does not achieve the intent of the rule, in some cases making the application of the IR difficult if not impossible (see specific examples in the detailed review comments).</p> <p>Some of the IR is not feasible, i.e., it is not possible to do easily or conveniently and is impractical. ROMATSA supports CANSO concern that EASA may place requirements on service</p> <p>i. providers and CAs that are not possible to demonstrate compliance with (see specific</p>



examples in the detailed review comments).

ii. **Some of the IR is unbounded and uses subjective language**, for instance the requirement for service providers to consider changing their functional system if it is technically and economically feasible to improve performance by doing so. ROMATSA supports CANSO opinion that this to be poor regulatory practice.

iii. **Overly complicated and Missing AMC**. ROMATSA supports CANSO opinion that very long AMC should be subdivided in to separate AMC , i.e., AMC1, AMC2, AMC3, etc. each dealing with a specific sub-topic This will allow service providers to propose alternative means of compliance for individual means of compliance for individual parts rather than the whole of the material. In some cases additional AMC would also be helpful.

iv. **Missing, Incorrect and more focused Guidance Material**. ROMATSA supports CANSO opinion that there is a need for more efficient guidance (less, but more focused and efficient) material, both for service providers and for CAs which will be particularly important for the safe and efficient deployment of SESAR.

b. **Transitional Arrangements**. ROMATSA supports CANSO concern regarding the transitional arrangements for this proposed rule. CRD 2013-08 has no specific text in Art 8 and 9 regarding Transitional provisions and Repeal other than referring to the Opinion. It is therefore not clear which provisions are being referred to in this NPA. Is it the whole of CRD 2013-08 or just the provisions in this NPA? If it is the latter then what are the transitional arrangements for the provisions in the CRD? It is noted that the proposed transitional arrangements of 2 years only applies to existing “service providers” regulated under 1034/2011 and 1035/2011. Does this mean that those service providers (using the CRD 2013-08 definition) who are not regulated by 1034/2011 and 1035/2011 have no transition period?

c. **Explanatory Note (EN) and Regulatory Impact Assessment (RIA)**. ROMATSA supports CANSO concern whether the RIA is accurate, in particular whether EASA appears to be interpreting 1034/2011 and 1035/2011 to support its own RIA (retrospectively) rather than as originally intended. EN and RIA do not provide adequate analysis on how this proposed rule will support the safe and efficient deployment of SESAR. SESAR is not referenced meaningfully in the document, which is believed to be a major omission for the industry.

response

Partially accepted

Please see full response to comment No 369.

comment

814 comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
General Comment	The quality of the document makes it sometimes difficult to follow it (e.g. references to <i>Annex I Definitions (35)</i>)	This NPA is quite important for the functioning of the whole system and it should be as clear as possible in order



	'Functional system', GM1 Article 2(2) Definitions which is nowhere to be found within the NPA).	to avoid present and future misunderstandings.
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response

Accepted

The Agency has checked and, where necessary, corrected all the references within the IR. It will check and correct the references within the AMC/GM before publishing the CRD related to them along with the ED Decision.

comment

816

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
General Comment	We are quite interested in knowing what effect the second NPA will have on the first NPA and, further to this, on the overall Opinion stemming from NPA 2013-08, NPA 2014-13,...	The way that the integration of the second NPA in the Opinion and derived Regulation is carried out will have an effect on the implementation of the new EASA ATM/ANS Regulation. Whether this effect is positive (streamlining) or negative (burdensome) is dependent on this overall process.

response

Noted

The Agency concurs with this concern and acknowledges the value of the comment on the finally combined ATM/ANS IR and the AMC/GM thereto. This will only be possible once the full package of AMC/GM is completed, which has not been possible at this moment. Nevertheless, the commentator is assured that the opportunity will be given to stakeholders to comment on the AMC/GM once the full package is ready, offering the chance for the AMC/GM to be reviewed together with the IR.

comment

817

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION



<p>General Comment</p>	<p>The way in which the GM are written is confusing as it implies that, in many cases, EASA deems that the material is '<i>mandatory</i>' and that it is taken for granted that the ANSPs will proceed as established by EASA in the GM.</p> <p>There is even cross-references between the GM and the provisions in the IR and/or the AMC, when in fact <u>GM does neither imply nor ensure that its application is mandatory.</u></p>	<p>For the sake of standardisation, the material included as GM should be thoroughly reviewed and it should be made perfectly clear that it will not be generally applicable (as it is neither hard law nor soft law) and those GM that are expected from the ANSPs should be moved either to the IR or to the AMC.</p>
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response

Accepted

Responses to the general comments on AMC/GM as well as their analysis will be presented in the CRD associated with them. Please see the responses to comments Nos 3 and 235 for clarification.

comment

818

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>General Comment</p>	<p>We wonder where are the concepts of '<i>Declaration of Verification of Systems</i>' and '<i>Declaration of Conformity/Suitability for Use</i>' addressed, both within this NPA and, further to this, within the ATM/ANS new structure set by EASA in the overall NPA 2013-08.</p>	<p>The concepts associated to interoperability should be handled together with the ones on safety change management in order to maintain the coherence with the current processes ("<i>backward compatibility</i>") as established in article 6.1(d) and article 10.2 of regulation (EU) No 1034/2011.</p>

response

Noted

These concepts are not directly addressed by the IR. However, ATM/ANS.OR.C.005 does



expect changes to systems to comply with all the applicable regulations. Furthermore, the evidence used in the assurance argument for a change does not have to be produced from scratch and it may use the concepts DoV or DoC.

comment 819

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
General Comment	<p>This NPA is difficult to follow as it is fully cross-referenced and intimately intertwined with NPA 2013-08.</p> <p>The use of terminology that is quite similar or event identical but takes different meanings (e.g. the use of the term 'risk') is not helpful, either.</p>	<p>We would recommend a clear use of terms and concepts in order to avoid current and future misunderstandings in the application of the regulation.</p>

response Noted

The publication of two separate NPAs has not helped in increasing clarity, but the publication of one single Opinion is expected to ameliorate this aspect. As for the same terminology used with different meanings, the comment is not shared, as the term 'risk' is used in the same sense as in NPA 2013-08. When referring to 'safety risk', the term has exactly the same meaning in both NPAs; whereas, when the term is just 'risk', then it has to be explained what type of risk is meant by the regulation. The need to specify the nature of 'risk' is widespread in common English language, and other regulations.

comment 841

comment by: Naviair

Naviair general comments to NPA 2014-13

1. Naviair do not believe that NPA 2013-08 and 2014-13 will enhance Safety of Air Traffic. We believe that the result would be better with EU 1034/2011, EU 1035/2011 and ED 125 (made to a EU regulation).
2. Naviair does not support complicated regulations like NPA 2013-08 and NPA 2014-13. We believe that a simple and understandable regulation is the best way to secure Safety. With



such kind of regulation we do not need AMC, EN and GM.

Naviair specific comments to NPA 2014-13:

3. Naviair support the High Level Comments from CANSO and Eurocontrol Safety Team.

4. Overlap between the Management System and Safety Management System requirements (MS/SMS Split):

Naviair believe that some of the IR and AMC in this NPA duplicate MS/SMS elements already addressed in CRD 2013-08. The placing of overlapping requirements with CRD 2013-08 introduces the potential for internal inconsistencies, duplicate regulation and a lack of legal certainty. We believe that NPA 2014-13 should not specify IR/AMC that is already addressed in NPA 2013-08.

5. Performance Based Regulation:

Naviair believes that the IR (and AMC) is not performance based as the NPA contains much prescriptive regulation. Both EASA and the European Commission are consulting on the industry views on a Performance Based Approach to Regulation and Oversight. The EN makes the statement that “existing provisions do not always support the concept of better regulation or performance-based regulation.” We do not believe that the proposed provisions support these principles either. The EN notes one specific objective is to have a more performance-based regulation by allowing the ATS provider to use a multi-valued safety risk classification scheme (which is actually a severity classification scheme). This appears to be the only concession to Performance Based regulation.

6. Explanatory Note (EN) and Regulatory Impact Assessment (RIA):

Naviair do not believe that the EN and RIA provide adequate analysis on how this proposed rule will support the safe and efficient deployment of SESAR.

response

Partially accepted

1. The Agency does not share the commentator’s opinion for the reasons explained in the Explanatory Note to the NPA. On the one hand, the positive aspects of those regulations have been kept, and on the other hand, the shortcomings have been addressed (at least this was the aim).

2. The Agency acknowledges that the objective is to have simple and understandable regulations. Besides that though, the regulations should, in addition, be unambiguous, complete and correct. That is the aim with this proposal.

The rest of the comments are covered in the response given under comment No 369, where the commentator is invited to refer for a full and comprehensive response.

comment

953

comment by: CAA Norway

The general impression is that NPA 2014-13 will improve and harmonise the change management processes in Europe. The introduction of a safety support assessment is one of the new principles introduced that will benefit the process. The introduction of multi-actor changes will hopefully lead to increased focus on dependencies and how a change will affect



other service providers or aviation undertakings, which of our opinion also will improve the process. Having said that, we do think the requirement on a coordinated assessment on multi-actor changes is a bit strict, and can in some situations be infeasible. This is covered in a separate comment.

Another worry is that some of the NPA paragraphs have a considerable amount of extensive GM. GM is in general a good thing, but when there are a lot of pages to read on topics which in general are well understood, the danger is that the GM is not read at all. This might be the case for GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045 as well as for GM1 Annex I Definitions (35). In general it should be considered to shorten these GM's or to split them in several parts. The software assurance principle is "hidden" in these GMs and it would of our opinion be beneficial to have that covered in a separate GM.

It is also seen as important to keep up the pressure on the Risk based review process. AMC and GM in this area are awaited and will further improve and harmonise our change management process.

response Accepted

The Agency takes due consideration of the comments and proposals provided. The comment on multi-actor changes is acknowledged and the provisions have been modified to relax the coordination requirement.

General comments on AMC/GM material and their analysis will be tackled in the CRD associated with the AMC/GM material. Please see the responses to comments Nos 3 and 235 for clarification.

comment 1067

comment by: *bmvit/CAA/NSA*

The NSA of Austria welcomes this NPA on guidance to the implementation of the difficult process related to safety assessment of changes to ATM/ANS functional systems. However the NSA identified some parts of the NPA too academic (new severity classification), too generic and abstract (substitution of EU IR 482/2008) and sometimes not practicable.

response Noted

The Agency takes due consideration of the comments and proposals provided. General comments on AMC/GM and their analysis will be tackled in the CRD associated with them. Please see the responses to comments Nos 3 and 235 for clarification.

comment 1076

comment by: *Belgocontrol*

The attempt to provide a harmonised set of rules and to clarify them through AMCs and GM is greatly welcomed. However, some of the material in the IR would be more appropriate as AMC. If not substantial revision of ANSPs' SMS may be required to comply with the proposed



	NPA.
response	<p>Partially accepted</p> <p>Please see the response to comment No 2.</p>
comment	<p>1080 comment by: <i>Belgocontrol</i></p> <ul style="list-style-type: none"> · AMCs should describe how to implement a given requirement (one means to implement it). Some of the proposed AMCs are too vague to achieve this aim. · There are some very complicated and long AMCs. Such AMCs should be split into separate smaller AMCs, each addressing a specific sub-topic. This will make the text easier to follow and it will permit the service providers to propose more easily alternative means of compliance for the sub-topics. · In some of the AMCs and also GM, both “should” and “shall” are used. <p>Reference is made multiple times to SWAL, HAL, DAL, HWAL and PAL with no reference to any guidance material. Maybe reference standards/specifications for SWAL, HAL, DAL, HWAL and PAL, e.g. ED153, etc. should be added</p>
response	<p>Partially accepted</p> <p>The fact that an AMC is large it does not imply that one service provider or CA cannot propose an AltMoC to only one element of the AMC. The need for splitting the AMC will be analysed at a later stage, but the length of it should not be intrinsically considered a defect. General comments on AMC/GM will be responded to in the CRD associated with them. However, the Agency acknowledges that the GM material has room for improvement (certain parts are incomplete and others can be more focussed). Therefore, it needs a deep reorganisation and check of consistency. At present, the CRD is addressing only comments pertaining to the IR text. A considerable amount of time is needed to rework, amend and complete the AMC/GM in an appropriate and effective manner, and this cannot be done at this stage. Future work is planned to review the comments on the AMC/GM and complete the CRD in due time. The generic GM needs to be reconsidered and restructured. The proposal made by the commentator will be duly considered during the phase of the AMC/GM finalisation.</p> <p>Please see the response to comment No 4.</p>
comment	<p>1081 comment by: <i>Belgocontrol</i></p> <p>Some sections of the IR and AMC duplicate MS/SMS elements from CRD 2013-08. This duplication could possibly lead to internal inconsistencies, and a lack of legal certainty. It is recommended that this NPA does not specify any requirement or AMCs that has already</p>



response	<p>been addressed in CRD 2013-08</p> <p>Partially accepted</p> <p>Please see the response to comment No 5.</p>
comment	<p>1082 comment by: <i>LFV</i></p> <p>LFV support the high level comments from CANSO and Eurocontrol Safety Team</p>
response	<p>Noted</p> <p>Please see the response to comment No 369 that addresses CANSO's high level comments.</p>
comment	<p>1086 comment by: <i>Belgocontrol</i></p> <p>The IR does not appear to comply with EASA's objective to have a performance based regulation as it contains much prescriptive regulation and thus not performance based. The only concession to performance based regulation appears to be the possibility to use a multi-valued safety risk classification scheme.</p>
response	<p>Not accepted</p> <p>Please see the response to comment No 6.</p>
comment	<p>1087 comment by: <i>Belgocontrol</i></p> <p>This NPA is different and more complex than the IR/AMC/GM for aerodromes addressing the same topic. A better alignment of the different regulations would lead to a better understanding and coordination between the key players (aerodrome operator, ATM/ANSP, and their competent authorities).</p>
response	<p>Partially accepted</p> <p>Whilst it is accepted that certain consistency between aerodromes and ATM rules could be ensured; however, the difference lies in the details of the requirements whereas the principle of both is the same.</p>
comment	<p>1113 comment by: <i>Isavia ltd.</i></p> <p>In general Isavia agrees with what is proposed in the NPA. We would like to make one comment/question:</p>



	<p>Refer to item (f) in AMC1 ATS.OR.205(b) "Severity classification of accident leading to harmful effects" where it says that <i>When performing a risk analysis in terms of risk, the ATS provider should ensure that the harmful effects of all hazards are allocated a safety severity category.</i></p> <p>Definition of [safety] risk is „the combination of the overall probability, or frequency of occurrence of a harmful effect induced by a hazard and the severity of that effect.”</p> <p>Guidance is provided on severity schemes GM1 ATS.OR.205.(b)4(d). No guidance however is provided in terms of probability (or frequency) scheme to use in conjunction with the severity classification. Are service providers expected to create a probability scheme or will it be sufficient to refer to the service provider’s history data?</p>
response	<p>Noted</p> <p>The general comments on AMC/GM will be responded to in the CRD associated with them. It is, however, anticipated that the probability should be estimated using the most appropriate data at hand. In certain situations, this may be based on the service provider’s history data, but in other cases the data can be more generic and based on others service providers data or studies. There is no one single approach that fits all cases.</p>
comment	<p>1153 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>NATS propose that some of the AMC do not conform to the EASA definition of AMC – essentially that, compliance with the AMC allows a presumption of compliance with the Implementing Rule. NATS suggests that AMC falling into this category should be re-titled Guidance Material. By way of examples:</p> <p>AMC1 ATM/ANS.AR.030 (sic), if complied with, does not appear to fully address the related IR (ATM/ANS.AR.C.030) e.g. the IR requires CA approval whereas the AMC does not mention approval.</p> <p>AMC1, AMC2 and AMC3 ATM/ANS.OR.A.045(a) appears to fall short of satisfying its related IR (e.g. no mention of undertakings).</p> <p>AMC1 ATM/ANS.OR.A.045(d) effectively repeats the related IR.</p> <p>AMC1 ATM/ANS.OR.A.045(e)(3) places an additional burden on service providers (overarching safety argument) that is not in the related IR.</p> <p>AMC1 ATM/ANS.OR.B.010(a) and AMC2 ATM/ANS.OR.B.010(a);(b) appear to fall short of satisfying its related IR (e.g. no deviation from the approved procedures; we do not believe that AMC2 is about getting the modification or deviation approved).</p> <p>AMC1 ATM/ANS.OR.C.005 is only three lines long; we would wish clarification as to how this implements over twenty lines of IR?</p> <p>AMC1 ATM/ANS.OR.C.005(a)(2) requires a safety support case and similar wording to that of the related IR.</p> <p>AMC1 ATM/ANS.OR.C.005(b)(1) relates to completeness of the scope of the safety support</p>



assessment whereas the relates IR relates to the definition of the scope of the change. The AMC does not appear to be a way of implementing the related IR.

AMC3 and AMC4 ATM/ANS.OR.C.005(a)(2) relate to determination of the specification of the changed service and of the operational context for the change respectively. This does not appear to relate to the IR that this AMC is implementing. This is an example where a minimum amount of IR is implemented by four specific AMC, albeit the traceability between IR and AMC is difficult to justify. (Note that this AMC does not sit in numerical order as it relates to OR.C.005(a) and comes after AMC/GM that relates to OR.C.005(b))

AMC1 ATS.OR.205(a)(2) requires a safety case and similar wording to that of the related IR.

It is noted that ATM/ANS.AR.C.035, ATM/ANS.AR.C.040, ATM/ANS.OR.A.045(c), ATM/ANS.OR.A.045(e)(1),(2),(4), ATM/ANS.OR.B.005(a)(5), (a)(6), (d), ATM/ANS.OR.C.005(a)(1), ATS.OR.201(b), (c), ATS.OR.205(a)(1), ATS.OR.210 have no AMC. Of greatest concern is the lack of any AMC for ATS.OR.210 Safety Criteria (there is one GM of six lines of text) given the importance of this aspect of the rule. It is noted that EASA has no plans to produce additional AMC/GM for Safety Criteria which we believe needs to be reviewed and addressed.

Given that EASA has identified that further AMC and GM is to be developed it is difficult to judge the suitability of the IR without the complete AMC (and GM) especially if no AMC is deemed necessary for some of the IR.

Quote from EASA website in support of NATS' concerns:

"AMCs are non-binding standards adopted by EASA to illustrate means to establish compliance with the Basic Regulation and its Implementing Rules.

The AMCs issued by EASA are not of a legislative nature. They cannot create additional obligations on the regulated persons, who may decide to show compliance with the applicable requirements using other means. However, as the legislator wanted such material to provide for legal certainty and to contribute to uniform implementation, it provided the AMC adopted by EASA with a presumption of compliance with the rules, so that it commits competent authorities to recognise regulated persons complying with an EASA AMC as complying with the law."

response

Partially accepted

The Agency appreciates very much NATS' thorough analysis and it is sure that this comment will help improve the final AMC/GM. However, comments on AMC/GM and their analysis will be tackled in the CRD associated with them. Please see the responses to comments Nos 3 and 235 for additional clarification.

In particular, the Agency concurs with the comment that safety criteria need additional AMC/GM. Some text has been redrafted in this area, and additional AMC/GM will be discussed and completed in due time.

[AMC1 ATM/ANS.AR.030: Agreed. The AMC should be titled AMC1 ATM/ANS.AR.C.030\(a\) and some lead-in text has been added.](#)

[AMC1 ATM/ANS.OR.A.045\(a\): Agreed — old terminology used. However, this part of the AMC has become GM. Not agreed for AMC2 and AMC3 ATM/ANS.OR.A.045\(a\).](#)



AMC1 ATM/ANS.OR.A.045(d): Not accepted — please see the responses to comments Nos 716 and 1234.

AMC1 ATM/ANS.OR.A.045(e)(3): Not accepted. There is no additional burden. This AMC simply links the assurance required in ATM/ANS.OR.C.005(a)(2) and ATS.OR.205(a)(2) with the notion of a multi-actor change. It might be useful to include this linkage with GM. The overarching safety argument should be always provided.

AMC1 ATM/ANS.OR.B.010(a): Not accepted — (a) is not about deviations.

AMC2 ATM/ANS.OR.B.010(a);(b): Partially accepted. The AMC is about both modifications and deviations. However, it does not add anything to the IR text and so it has been moved to GM.

AMC1 ATM/ANS.OR.C.005: Accepted. The AMC has been deleted as this is already covered by requirements in the provider's management system.

AMC1 ATM/ANS.OR.C.005(a)(2): Not accepted — The AMC defines only the form of the argument to be provided. It allows subsequent AMC/GM to use the term 'safety support case' instead of 'argument', which may be ambiguous. AMC2 is about completeness of the argument and by inference also its validity.

AMC1 ATM/ANS.OR.C.005(b)(1): Partially accepted — However, the scope of the change has been moved to C.005(a)(1) and subtly altered. On reflection, the AMC adds nothing to the IR and has been removed.

AMC3 and AMC4 ATM/ANS.OR.C.005(a)(2): Accepted — out of sequence. AMC1 ATM/ANS.OR.C.005(b)(1) has been removed.

AMC1 ATS.OR.205(a)(2): Not accepted — The AMC defines only the form of the argument to be provided. It allows subsequent AMC/GM to use the term 'safety support case' instead of 'argument', which may be ambiguous.

No AMC for ATS.210: Partially accepted — There is AMC related to safety criteria included in AMC1 ATS.OR.205(b). This is because ATS.OR.210 is actually part of 205(b) and was separated for clarity. Now, we have introduced some AMC to ATS.OR.210 related to the validity of safety criteria. Additional AMC may be developed in the 2nd NPA.

comment 1154

comment by: *NATS National Air Traffic Services Limited*

The level of guidance material does not seem appropriate and proportionate to the level of the IR. NATS also believes that the GM should help organisations to understand and implement the rule. NATS finds that some of the GM is used to justify the decisions made (rather than to provide clarity and Guidance) and much of the Guidance is hard to understand and does not help organisations to implement the rule. The language used is complex and sometimes colloquial - NATS do not feel this is appropriate. The GM contains significant levels of internal cross-referencing; we believe that it could be better presented as it is confusing in its current form. Some IR has up to five GM to the same IR (e.g. GM1



response	<p>ATS.OR.205(a)(2) to GM5 ATS.OR.205(a)(2))</p> <p>Partially accepted</p> <p>The Agency appreciates very much NATS' thorough analysis and it is sure that this comment will help improve the final AMC/GM. However, comments on AMC/GM and their analysis will be tackled in the CRD associated with them. Please see the responses to comments Nos 3 and 235 for additional clarification.</p> <p>The level of referencing is high and, even though it hinders readability, it improves precision.</p> <p>Please refer to the responses to comments Nos 3 and 235 for additional clarifications.</p>
comment	<p>1156 comment by: NATS National Air Traffic Services Limited</p> <p>Attachment #3</p> <p>Please find attached some additional comments for consideration in relation to, but not directly aligned with the text of NPA 2014-13</p>
response	<p>Partially accepted</p> <p>For a detailed response to each item in the file please see the response to comment No 369.</p>
comment	<p>1168 comment by: Avinor ANS</p> <p>a. Offer of Support. Avinor ANS believe it is important that this regulation is implemented correctly and think that we should see a real benefit for the industry. With the practical experience of performing risk assessments and knowledge of the history of creating the rule, we would like to offer our comments and support to EASA in improving the quality of the rule. Avinor ANS believe that the regulation should attempt to stay at the highest level, management and organisation, to provide impact.</p> <p>b. Level of detail and split between IR and AMC. Avinor ANS is of the opinion that some of the material in the proposed IR should be AMC. Some proposals will follow, build on the proposal in the NPA, that we believe will facilitate implementation of the rule and therefore make it more effective, for both CAs and service providers.</p> <p>c. Overlap between the Management System and Safety Management System requirements (MS / SMS Split). Avinor ANS believe that some of the IR and AMC in this NPA duplicate MS/SMS elements that is already in CRD 2013-08. This introduces the potential for internal inconsistencies, duplicate regulation and a lack of legal certainty that should be avoided. In our opinion NPA 2014-13 should not have IR / AMC already addressed in NPA 2013-08. We have made some suggestions, build on the proposals in the NPA that we believe will facilitate implementation of the rule and therefore make it more effective, for both CAs</p>



and service providers.

d. **Performance Based Regulation.** Avinor ANS believe that the IR (and AMC) is not performance based, since the NPA contains considerable prescriptive regulation. EASA and the European Commission are consulting the industry on a Performance Based Approach to Regulation and Oversight. We do not believe that the proposed provisions fully support the principle of better and more performance based regulation. The EN notes a specific objective of having a more performance-based regulation by allowing the ATS provider to use a multi-valued safety risk classification scheme (this is in reality a severity classification scheme). This appears to be the only concession to Performance Based regulation, and is not helpful for us in practical use, since it is not possible to apply the criteria selectively within a complex operation.

i. **The IR does not achieve the perceived intention of the rule.** Avinor ANS think there are a number of areas where the text of the IR does not achieve the intention of the rule. Sometimes making the application difficult or even impossible. We have provided specific examples on this in the review comments, for instance in the requirement that the service shall be at least as safe after the change as it was before the change.

ii. **Some of the IR is such that it is not possible or impractical to do.** Avinor ANS is concerned that EASA may place requirements on service providers and CAs that are not possible to demonstrate compliance with. An example is for instance requiring a list of the service providers and other aviation undertakings that are affected by a change.

iii. **Some of the IRs uses subjective language,** for instance the requirement for service providers to consider changing their functional system if it is technically and economically feasible to improve performance by doing so. Avinor ANS consider this to be inappropriate and impossible to demonstrate satisfactorily.

iv. **Complicated and missing AMC.** Avinor ANS believe that very long AMCs should be subdivided in to separate AMCs, dealing with a specific sub-topic, allowing service providers to propose alternative means of compliance for the separate means of compliance rather than the whole of the material. In some cases additional AMC would also be helpful.

v. **Missing, Incorrect and more focused Guidance Material.** Avinor ANS believe there is a need for more efficient (and less) guidance material, both for service providers and for CAs. this will be particularly important for the safe and efficient deployment of SESAR. There is also definitions in the GM that in our opinion is not appropriate.

e. **Transitional Arrangements.** Avinor ANS are concerned about the transitional arrangements for the proposed rule. We note that CRD 2013-08 has no specific text in Art 8 and 9 regarding Transitional provisions and Repeal, only referring to the Opinion. Therefore it is not clear to us which provisions are being referred to in this NPA (the whole CRD 2013-08 or only the provisions in this NPA?). If it is the latter, what are then the transitional arrangements for the provisions in the CRD? We register that the proposed transitional arrangements of 2 years applies to existing “service providers” regulated under 1034/2011 and 1035/2011. Does this mean that those service providers (using the CRD 2013-08 definition) who are not regulated by 1034/2011 and 1035/2011 have no transition period?

f. **Explanatory Note (EN) and Regulatory Impact Assessment (RIA).** Avinor ANS question if the interpretation of the 1034/2011 and 1035/2011 is such that it provides support to its own RIA (retrospectively). We would like to see a better analysis on how this proposed rule



	will support the safe and efficient deployment of SESAR. SESAR is not referenced meaningfully in the document, which we believe is a major potential issue for the industry.
response	Partially accepted For a detailed response, please see comment No 369.
comment	1203 comment by: CAA-NL General Comment: The Netherlands proposes to amend regulations in other domains and possible the BR in order to align these with the consultation requirements outside the ATM domain at an appropriate moment (Part OPS, Part Aerodrome, etc).
response	Noted Until specific proposals are made, we can only make a generic statement that the IRs should be amended if justified by the presence of misalignments.

Notice of Proposed Amendment 2014-13

p. 1

comment	25 comment by: NATS National Air Traffic Services Limited Attachment #4 Document: NATS Appendix A This will be referred to throughout the NATS comments
response	Noted Please refer to the appropriate section where the specific comment/proposal is made by the commentator and the response provided.

EXECUTIVE SUMMARY

p. 1

comment	131 comment by: ENAIRE The use of new terms, concepts (safety support assessment, unsound), in our opinion, introduces even more complexity instead of clarify.
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response	<p>Partially accepted</p> <p>The term ‘unsound’ is used in its normal English meaning, and the Agency believes that it leaves no room for ambiguity or misinterpretation; therefore, the Agency is of the opinion that it no way introduces any kind of complexity. Nevertheless, it has been removed and now ‘unfamiliar and complex argument’ is used.</p> <p>The term ‘safety support assessment’ is extensively explained in AMC/GM. For additional explanation, see the response to comment No 273.</p>
comment	<p>132 comment by: ENAIRE</p> <p>The use of subjective and ambiguous terms (as “unsound”) is not appropriate for an NPA.</p>
response	<p>Accepted</p> <p>The term ‘unsound’ is used in its normal English meaning, and the Agency believes that it leaves no room for ambiguity or misinterpretation; therefore, the Agency is of the opinion that it no way introduces any kind of complexity. Nevertheless, it has been removed and now ‘unfamiliar and complex argument’ is used.</p>
comment	<p>176 comment by: DSNA</p> <p>general remarks :</p> <ol style="list-style-type: none"> 1. Changes proposed by the draft new regulation are supposed to harmonize or uniform the implementation at European level. This regulation is not the silver bullet, <u>the key concept of change is still missing</u> in the regulation and the related GM is too noncommittal (not efficient) and does not provide a clear understanding of what is or what is not a change in the scope of the regulation. Therefore, the intended purpose will be missed and there remains a risk of an unequal and unbalanced implementation of this regulation at the discretion of each AR. The objective of having a level playing field between ANSPs in Europe would be missed and some ANSP would bear additional compliance costs which so far cannot be accounted for in the Performance Regulation. 2. There is no assessment of the cost benefit for this new regulation. The costs of implementing what appears to be new administrative arrangements and changes in accepted practices will be borne by the ANSP essentially and that cost will be significant in an economic context already tense. 3. Regardless of cost, expected safety gains do not seem obvious. 4. This regulation provides interesting developments such as the possible use of proxies, the removal of the level 1 & 2 for deciding to review a change by the CA. However, the AMC and GM are often complicated (over complicated) and portray <u>a very academic approach and an unrealistic approach to safety</u>. <p>All the essential elements used in this document should be defined in order to foster a common understanding. For example, words like safety criteria, safety assurance,</p>



safety acceptability, assurance case, argument, evidence are used but they are not clearly defined.

Undoubtedly, the implementation will be difficult and will be seen more as an administrative burden. This new regulation brings much more complexity and redundancy and is far removed from its original purpose.

Also, it is necessary to simplify the regulatory framework and let CA's enough flexibility in the implementation of regulations depending on the maturity of the ANSP. EASA's task in standardization audits will be much more complicated to ensure correct and uniform application of regulations.

5. According to EASA (e.g. in the explanatory notes), **some concepts or requirements are unachieved and need to be reworked. Therefore, having these unfinished concepts in a rule will lead to many difficulties and misunderstanding.**
6. It should be clarified that **the changes addressed in the part of the rule related to ATS are actually safety related changes.**
7. Numbers of figures (in AMC/GM) are not always correctly incremented.

response

Partially accepted

1. The Agency disagrees with the commentator that the concept of change is not addressed. There is an extensive GM that explains the concept of change to functional systems. It is infeasible to give a different definition for a change without making an assessment (safety or safety support). The limits seem clear and there is flexibility for CAs to define changes that need no approval or that require a very simple assessment. The Agency believes that the level playing field is captured because it has always been the intent to capture at the IR level the criteria against which any means of compliance should be judged, leaving enough flexibility but never left at the discretion of the CAs. If any ANSP considers that the regulation is applied inconsistently, then the goal of the regulation would not be achieved. Therefore, the criteria must be kept at the level of the IR.

2. The economic analysis has been qualitatively carried out. The RIA has not been challenged with costs figures.

3. The RIA has tried to identify the benefits in terms of harmonisation and clarity on means for service providers to reach the same standards of quality in their service delivery. As with any change in regulation, there will be costs increase incurred during the learning and bedding in phase of the transition from one set of rules to another. In this case, the transient impact may be quite large as it involves regulating the assurance of some disciplines more precisely. However, the longer-term effects on cost savings, should, in the end compensate this short-term increase.

4. The Agency does not completely share the view of the commentator. Whilst the language may appear too 'academic', it is in fact technical and precise because of the nature of the subject. It will be reviewed and simplified, when possible. The opinion on unrealistic approach is not shared and many of the terms mentioned are actually defined in GM and have extensive explanatory material. [GM has been restructured to ease reading, hopefully](#)



making the text simpler.

5. This is partially accepted. Some of these concepts, e.g. risk-based review, have been removed. Others, e.g. risk-based selection, have criteria in the rule but details are not completely described yet; still, they do not cause any problem in the regulation.

6. There is no need to mention 'safety-related' changes as what the regulation addresses are changes to the functional system. Some of the changes will have an impact on safety (i.e. safety risk) and others will not (i.e. no safety risk associated), but it seems infeasible to define a priori what 'safety-related' is. The current approach seems more appropriate.

7. The numbering will be reviewed when the AMC/GM are completed. [This AMC has been restructured and the numbering and indentation have been now reviewed and amended accordingly.](#)

comment 459 ❖

comment by: APROCTA

As noted by the NPA at its Explanatory Note, a broader approach to the safety assessment is needed. From our Professional Association point of view (APROCTA), some of the key issues identified for risk assessment limitations, as "when used for certain types of change, e.g. the available data and/or models may be inappropriate for a specific quantitative risk assessment", might be tackled if key stakeholders, like professional associations of operational staff (air traffic controllers associations) are involved in the process. We proposed that a total system approach could be reached more straightforward if the experience gained by operational staff not necessary linked to the ANSP, is taken into account.

*Commission Implementing Regulation (EU) N° 1035/2011, states at its ANNEX II, Specific requirements for the provision of air traffic services, Part 4, Working methods and operating procedures, that **Providers of air traffic services shall be able to demonstrate that their working methods and operating procedures are compliant with the standards set by the Convention on International Civil Aviation Annex 11 on air traffic services in its 13th edition of July 2001, including all amendments up to No 47-B, as far as they are relevant for the provision of air traffic services in the airspace concerned.***

ICAO Annex 11 (13th edition of July 2001, amendments up to No 47-B), regarding Safety Management (2.27) states at 2.27.5 that *any Significant safety - related change to the ATS system, including the implementation of a reduced separation minimum or a new procedure, shall only be effected after a safety assessment has demonstrated that an acceptable level of safety will be met **and users have been consulted.***

It also states at 2.30, Contingency Arrangements, that *air traffic services authorities shall develop and promulgate contingency plans for implementation in the event of disruption, or potential disruption, of air traffic services and related supporting services in the airspace for which they are responsible for the provision of such services. Such contingency plans shall be developed with the assistance of ICAO as necessary, in close coordination with the air traffic services authorities responsible for the provision of services in adjacent portions of airspace*



and with airspace users concerned.

So, the industry has been commonly accepting professional pilots associations besides aircraft operators as users or airspace users (ICAO Global Air Traffic Management Operational Concept, First Edition - 2005). Probably because it is clearly understood that pilots, in general, “use” the airspace. However, in many air navigation procedures and documents as well as in many safety teams, it is increasingly being specified and accepted that professional associations of pilots **and air traffic controllers** (with or without specific distinction) should be consulted on safety issues as fully operational stakeholders:

1. ICAO Safety Management Manual, Third Edition - 2013 (Doc 9859-AN/474).

ICAO sets out that it is *essential to involve all internal and external aviation system stakeholders having a potential impact on the organization’s safety performance. Furthermore, any potential inputs should be taken into consideration at an early stage of SMS implementation and throughout future internal evaluations of the SMS* (Chapter 5, Safety Management Systems; 5.2, Scope), and specifically naming **professional associations**.

2. 2. ICAO Threat and Error Management (TEM) in Air Traffic Control (Cir 314-AN/178).

ICAO recognizes that in the constant drive to improve the margins of safety in aviation operations, all the experience by the aviation industry is needed and welcome. Under this headline, the collection of every piece of safety data during normal operations brings possible threats and errors. Normal Operations Safety Surveys or NOSS, a proposed tool for the ATC environment, *requires the joint sponsorship from management and the association representing air traffic controllers*.

3. 3. ICAO Manual on the Prevention of Runway Incursions, First Edition - 2007 (Doc 9870-AN/463).

*A runway incursion prevention programme should start with the establishment of runway safety teams at individual aerodromes [...]. The team should comprise representatives from aerodrome operations, air traffic service providers, airlines or aircraft operators, pilot and **air traffic controller associations** and any other groups with a direct involvement in runway operations.* (Chapter 3, Establishing a Runway Incursion Prevention Programme).

4. 4. EUROCONTROL European Action Plan for the Prevention of Runway Incursions, Edition 2.0.

*Local Runway Safety Teams should be established to lead actions on local runway safety issues. [...] Experience has demonstrated that these teams have been effective at helping to minimise the risk of runway incursions at individual aerodromes, where local issues such as taxiway layout, runway configuration and aircraft operators’ needs can be taken into account. [...] **The team should consist of**, as a minimum, representatives from at least the three main groups associated with manoeuvring area operations, namely the Aerodrome Operator (which would include a vehicle driver), Ground Handling Associations when appropriate, representatives from the Air Navigation Service Provider / and local **Air Traffic Controller associations** and pilots from Aircraft Operators / and local pilot associations that operate at the aerodrome and other organisations that operate on the manoeuvring area.*

5. 5. EUROCONTROL European Action Plan for the Prevention of Runway Excursions, Edition 1.0.

A Local Runway Safety Team should form a key element in the aerodrome runway safety



programme and should ensure that a strong focus is maintained on runway safety across all parties creating, de facto, an aerodrome level safety management function. [...] **The team should consist of**, as a minimum, representatives from the main groups associated with takeoff and landing operations, namely the Aerodrome Operator (which could include navigation aids engineers, infrastructure maintenance etc.) Meteorological Offices and Aeronautical Information Service Providers, representatives from the Air Navigation Service Provider, local **Air Traffic Controller associations** and pilots from Aircraft Operators, local pilot associations that operate at the aerodrome and other relevant organisations that operate on the manoeuvring area.

6. 6. Comisión de Estudio y Análisis de Notificaciones de Incidentes de Tránsito Aéreo (Spain).

The Spanish Air Traffic Incident Report's Study and Analysis Commission (CEANITA), is a Ministerial Board which objectives are to provide advice and assistance on aviation safety issues to the Spanish Aviation Safety Agency (AESA) and to the Spanish Air Force General Department. This Commission is currently governed by the *ORDEN PRE/697/2012 de 2 April, por la que se establecen las normas de funcionamiento de la Comisión de Estudio y Análisis de Notificaciones de Incidentes de Tránsito Aéreo*. **The Board has representatives from AESA, the Spanish Air Force, ANSPs, Airlines, Professional Pilot and Air Traffic Controllers Association** (Article 6). CEANITA is integrated into the State Safety Programme for Civil Aviation (SSP).

At GM1 ATM/ANS.OR.A.045 (e) Changes to the functional system, CHANGES AFFECTING MULTIPLE SERVICE PROVIDERS AND AVIATION UNDERTAKINGS—GENERAL, an example of changes affecting multiple service providers and/or undertakings is about a runway usage, a clear one where a local runway safety team has a relevant role.

Even more, at GM2 ATM/ANS.OR.A.045 (e) Changes to the functional system, AFFECTED STAKEHOLDERS—SERVICE PROVIDERS AND AVIATION UNDERTAKINGS, stakeholders with dependencies with the changed service include staff associations.

So at this point, Aprocta considers that Regulation Nº 1035/2011 is not fully complete regarding pointing out **who are the operational stakeholders that should be involved in the risk assessment to give it a broader approach** (and maybe so making it more understandable for operational staff), and therefore has the same amount of indetermination as ICAO Annex 11 regarding who are the air space users that should be involved in functional changes assessments.

This NPA does have the chance to, as recital 16 of Regulation (EU) Nº 1035/2011 foresees, to adapt it “towards a total system approach, taking into account the integration of these provisions into a future common regulatory structure for civil aviation safety **and the experience gained by stakeholders** [...]”.

As a conclusion, maybe the best one is by the International Federation of Air Traffic Controllers Association, IFATCA, on the paper A STATEMENT ON THE FUTURE OF GLOBAL AIR TRAFFIC MANAGEMENT BY IFATCA (version 1.0, 27 February 2007):

IFATCA considers that the best way to address the problems being experienced in ATM is by all members of the ATM community cooperating. The cooperation required is a serious



working together that requires pragmatism and compromise by all involved. This involves collaborative decision making that requires involvement in the process and in the consequences. It requires commitment to change and a will to act at all levels including at state level.

[...].

response

Partially accepted

The majority of this comment relates to GM and will be fully answered in the CRD associated with the AMC/GM.

The argument about the involvement of representative bodies is accepted. The involvement of all stakeholders who are affected by a change is promoted in the IR. The term ‘aviation undertakings’ covers all entities that may be affected by a change but do not fall within the scope of the regulation. GM explains that in some instances these include representative bodies of interested stakeholders such a ATCO and pilot groups. However, the IR cannot list particular representative organisations and require them to be consulted because the range of changes is extremely large and not all may need the involvement of all such representative bodies.

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comment

974

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Table of Contents (page 2)	The header of the section in page 37 (<i>ATM/ANS.OR Subpart D</i>) appears as <i>ATM/ANS.OR.C</i> instead of <i>ATM/ANS.OR.D</i> .	Typographical error

response

Accepted

This has been corrected.

comment

975

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION



<p>Table of Contents (page 3)</p>	<p>GM1 ATM/ANS.OR.A.045(e)(3) appears twice (pages 114 and 116). Wouldn't the second instance be in fact GM₂ ATM/ANS.OR.A.045(e)(3)?</p>	<p>Typographical error</p>
<p>response</p>	<p>Accepted</p> <p>This will be corrected.</p>	

comment 977 comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Table of Contents (page 4)</p>	<p>GM3 ATM/ANS.OR.B.010(a) follows GM3 ATM/ANS.OR.B.010(a). Shouldn't this ought to be GM₂ ATM/ANS.OR.B.010(a)? If this would be so, the rest of the GM for ATM/ANS.OR.B.010(a) should be renumbered accordingly.</p>	<p>Typographical error</p>

response Accepted

This will be corrected.

comment 978 comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Table of Contents (page 4)</p>	<p>GM1 ATM/ANS.OR.B.005(a)(5) is written as GM1 ATM/ANS.OR.B005(a)(5).</p>	<p>Typographical error</p>

response Accepted

This will be corrected.



comment 981 comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Table of Contents (page 4)	The numbering convention used for the AMC and GM for <i>ATM/ANS.OR.C.005</i> is not consistent with the one used through the rest of the document.	Normally, the AMC and GM for each level (requirement, subrequirement, sub-subrequirement...) starts with number one. However, this is not the case for <i>ATM/ANS.OR.C.005</i> , where the numbering starts with one at the upper level and is not reset at lower levels.

response Accepted
This will be corrected.

comment 982 comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Table of Contents (page 6)	<i>GM1 AT.S.OR.205(b)(4)</i> is written as <i>GM1 AT.S.OR.205(b)4</i> .	Typographical error

response Accepted
This will be corrected.

1. Procedural information p. 8-9

comment 7 comment by: EUROCONTROL Safety Team

The EN lacks adequate analysis on how the proposed regulation supports the safe and efficient deployment of SESAR.



response

Noted

The implementation of SESAR will be realised through a combination of changes. This proposed regulation is not addressed specifically to SESAR, but it includes all changes stemming from SESAR. The important aspect is that the changes (from SESAR or others) are assessed and assured with enough level of confidence, which SESAR SRM application may bring. It is acknowledged that no thorough analysis has been carried out against SESAR safety reference material, but the Agency has participated in the review of the SRM and no incompatibilities have been identified so far. This proposal requires an acceptable level of confidence in the assessments. The level of confidence that the evidence provided by the SRM achieves is not an intrinsic property of the method itself, but it highly depends on the application of it. In other words, the application of SRM does not guarantee obtaining sufficient evidence to use in an argument required by this proposal, but it can help to build confidence in the evidence generated by SESAR projects. This proposal does not depend on the method used, it only outlines the criteria against which to judge the results obtained by the application of the SESAR SRM. In that sense, it does not pose any restriction on the assessments performed by SESAR.

comment

16

comment by: *NATS National Air Traffic Services Limited*

Section 1.4 - Page 9

In para 1.4 the NPA makes clear that further AMC and GM remains to be developed. NATS reserve the right to change or add to its existing comments depending on the content of the additional material to be produced in an NPA later this year.

response

Noted

comment

318

comment by: *BAF-M.Jancokova*

Art. 1.4 It is difficult to comment on the NPA at hand since important AMC and GM is still missing at this point in time and, instead, postponed in another NPA published later.

response

Noted

comment

757

comment by: *DFS Deutsche Flugsicherung GmbH*Attachment [#5](#)

DFS as a CANSO member wants to offer support to improve the quality of NPA 2014-13 to achieve a good regulation with the most positive impact on safety, which is at the same time feasible to fulfill for all affected parties.



	<p>DFS wishes to make some general comments. In many cases our detailed comments support one of these.</p> <p>These comments are numbered a,b,c.... . Where our comment supports such a comment, it will be stated in the last line with "reference to high level comment [a]".</p> <p>Furthermore we would like to provide in the attachment a summary of all our comments which change the text of an IR/AMC/GM or changes the level of IR to become AMC, AMC become GM or vice versa.</p>
response	<p>Partially accepted</p> <p>The Agency takes due consideration of the comments and proposals provided by the commentator. Please refer to your specific comment where the rationale of the proposal is explained and where the related response is provided. Some proposals have been accepted, while others have not.</p>

2. Explanatory Note — 2.1. Overview of the issues to be addressed

p. 10-13

comment	<p>8</p> <p>comment by: EUROCONTROL Safety Team</p> <p>The Regulatory Impact Assessment is a tool to support decision-making. The aim of the RIA is to determine the best option to achieve the objective of a rulemaking activity while minimising potential negative impacts. An inaccurate RIA undermines confidence in the outcome. Consequently it seems that the arguments presented in the RIA are not wholly accurate.</p> <p>The assertions made are not supported by any evidence particularly in view that ANSPs have been in compliance with EU 1035/2011 (and its predecessors) for some considerable time and without issue.</p> <p>The way that EU 1034/2011 and EU 1035/2011 have been interpreted in the EN seems to suit the selected Options (as opposed to the RIA informing the IR). Several examples can be mentioned:</p> <ol style="list-style-type: none"> 1. Interpreting retrospectively current applicable regulation rather than as originally intended. 2. It is stated <i>...1034/2011 implies that all the certified services...</i> but EU 1034/2011 Art 9 1 makes it quite clear that it applies to ATS and CNS providers. 3. EU 1034/2011 Art 3 (5) clearly defines what is meant by <i>organisation</i> and it is NOT service providers. However, the RIA asserts that <i>organisations</i> means all service providers. 4. It is stated that the existing provisions are not always complete and the lack of safety objectives associated with the severity classification scheme is used as an example. Regrettably safety objectives are also missing from this NPA. 5. Finally some of the cross references to EU 1034/2011 and EU 1035/2011 appear incorrect (e.g. EU 1034/2011 Art 9(2) should be Art 10(2)).
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response

Partially accepted

The Agency concurs with the commentator's analysis of the importance of the RIA. Parts of the RIA have been revisited and updated in light of this and other comments and the results are presented in the Explanatory Note to the Opinion. This revisiting is an ongoing process in qualitative terms.

The assertions in the Explanatory Note are supported with rational statements. The Agency has provided examples of certain deficiencies in the current Regulations (EU) Nos 1034/2011 and 1035/2011. They are not justified by quantitative data, but with the rational statements of the deficiencies supported by examples, which have not been challenged and do not undermine their validity.

1. There was no intention to interpret Regulations (EU) Nos 1034/2011 and 1035/2011 retrospectively. In fact, at the very beginning of the process the principles embodied in these regulations were identified, documented and broadcast via workshops. The proposed IR respects these principles and the RIA argues that they have been implemented in an appropriate way. The scope of application was in some cases misrepresented in the original RIA. The RIA has been reassessed using the correct scope.

2 & 3. The example mentioned by the commentator seems flawed. Article 9.1 of Regulation (EU) No 1034/2011 applies to 'organisations', which according to its definition in (it should be noted that the commentator is referring to the wrong article) Article 2(5) 'means either an air navigation service provider or an entity providing ATFM or ASM or other network functions'. In addition, Regulation (EU) No 1035/2011 defines 'organisation' differently in its Article 2(7) as 'an entity providing air navigation services'. The inconsistency seems clear.

4. The Agency disagrees with the statement that there is no safety objective in this NPA. The NPA is proposing the requirement ATS.OR.210(b) to capture the safety of the change (not having the system as safe as before the change), which is a high-level safety objective that the safety criteria should meet. In the current Opinion, this has been changed to 'ensure the change does not create an unacceptable safety risk'.

5. The Agency would like to apologise for the incorrect references, which have been reviewed and corrected.

comment

17

comment by: *NATS National Air Traffic Services Limited*

Section 2.1 - Overview of issues to be addressed (Page 10)

The assertions made by EASA are not supported by any evidence especially given that ANSPs have been in compliance with 1035 (and its predecessors) for some considerable time and without known issues.

EASA appears to be interpreting 1034/2011 and 1035/2011 to suit its own RIA



(retrospectively) rather than as originally intended. For example EASA states “...1034/2011 implies that **all** the certified services...” whereas 1034/2011 Art 9 1. makes it quite clear that it applies to ATS and CNS providers. Similarly EASA asserts that “organisations” means all service providers whereas 1034/2011 clearly defines what is meant by organisation in Art 3 (5) and it is NOT service providers.

A number of the cross references to 1034/2011 and 1035/2011 appear incorrect (e.g. 1034/2011 Art 9(2) should be Art 10(2)).

EASA claim that existing provisions do not include sufficient AMC/GM. In fact there is no AMC/GM and this is not surprising given the pedigree of the existing rules. (SES)

EASA assert that the existing provisions are not always complete and cite the lack of safety objectives associated with the severity classification scheme as an example. It is noted that the safety objectives are also missing from this NPA.

response

Partially accepted

The assertions in the Explanatory Note were supported with rational statements. The Agency has provided examples of certain deficiencies in the current Regulations (EU) Nos 1034/2011 and 1035/2011. They are not justified by quantitative data, but with the rational statements of the deficiencies supported by examples, which have not been challenged and do not undermine their validity.

There was no intention to interpret Regulations (EU) Nos 1034/2011 and 1035/2011 retrospectively. In fact, at the very beginning of the process the principles embodied in these regulations were identified, documented and broadcast via workshops. The proposed IR respects these principles and the RIA argues that they have been implemented in an appropriate way. The scope of application was in some cases misrepresented in the original RIA. The RIA has been reassessed using the correct scope and published again in the Opinion.

The example mentioned by the commentator seems flawed. Article 9.1 of Regulation (EU) No 1034/2011 applies to ‘organisations’, which according to its definition in (it should be noted that the commentator is referring to the wrong article) Article 2(5) ‘means either an air navigation service provider or an entity providing ATFM or ASM or other network functions’. In addition, Regulation (EU) No 1035/2011 defines ‘organisation’ differently in its Article 2(7) as ‘an entity providing air navigation services’. The inconsistency seems clear.

The Agency would like to apologise for the incorrect references, which have been reviewed and corrected.

The commentator seems to agree with the fact that there are no AMC/GM, which is the only reason why they are proposed in the NPA. The Agency does not see any flaw in this argumentation to justify the introduction and proposal of AMC/GM.

Finally, the Agency disagrees with the statement that there is no safety objective in this NPA. This objective was proposed in ATS.OR.201 in the NPA, and now the requirement ATS.OR.210(b)(2) is proposed to capture the safety of the change (which has been modified



as follows: 'ensure the change does not create an unacceptable safety risk').

comment 358 comment by: *Air Navigation Services of the Czech Republic*

The statements made here by EASA are not supported by any evidence, e.g. ANSPs have been in compliance with 1035/2011 for some considerable time and without issue.

EASA seems to interpret 1034/2011 and 1035/2011 to suit its own RIA and the selected options (retrospectively):

- EASA states here that "...1034/2011 implies that all the certified services..." whereas 1034/2011 Art 9 1. makes it quite clear that it applies to ATS and CNS providers.
- EASA states that "organisations" means all service providers whereas 1034/2011 clearly defines what is meant by organisation in Art 2(5), and it is NOT service providers.
- EASA states that the existing provisions are not always complete and the lack of safety objectives associated with the severity classification scheme is shown as an example. But safety objectives are also missing from this NPA.
- EASA states that the existing provisions do not include sufficient AMC/GM - in fact there is no AMC/GM

Some cross references to 1034/2011 and 1035/2011 appear incorrect (e.g. 1034/2011 Art 9(2) should be Art 10(2)).

response Partially accepted

Please refer to the response to comment No 17.

comment 371 comment by: *skyguide Corporate Regulation Management*

The assertions made by EASA are not supported by any evidence especially given that ANSPs have been in compliance with 1035 (and its predecessors) for some considerable time and without issue.

EASA appears to be interpreting 1034/2011 and 1035/2011 to suit its own RIA (retrospectively) rather than as originally intended. For example EASA states "...1034/2011 implies that all the certified services..." whereas 1034/2011 Art 9 1. makes it quite clear that it applies to ATS and CNS providers. Similarly EASA asserts that "organisations" means all service providers whereas 1034/2011 clearly defines what is meant by organisation in Art 3 (5) and it is NOT service providers.

A number of the cross references to 1034/2011 and 1035/2011 appear incorrect (e.g. 1034/2011 Art 9(2) should be Art 10(2)).

EASA claim that existing provisions do not include sufficient AMC/GM. In fact there is no AMC/GM and this is not surprising given the pedigree of the rules.

EASA assert that the existing provisions are not always complete and cite the lack of safety objectives associated with the severity classification scheme as an example. It is noted that



response	<p>the safety objectives are also missing from this NPA.</p> <p>Partially accepted</p> <p>Please refer to the response to comment No 17.</p>
comment	<p>594 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>The statements made in chapter 2.1 are not supported by evidence. The references to 1034/2011 are 1035/2011 are not always correct (e. g. EASA states "...1034/2011 implies that all the certified services..." whereas 1034/2011 Art 9 1. applies to ATS and CNS providers. Similarly EASA asserts that "organizations" means all service providers whereas 1034/2011 defines what is meant by organization in Art 3 (5) and it is not service providers.) Reference to high level comment "e"</p>
response	<p>Partially accepted</p> <p>Please refer to the response to comment No 17.</p>
comment	<p>625 comment by: <i>CANSO</i></p> <p>The assertions made by EASA are not supported by any evidence especially given that ANSPs have been in compliance with 1035 (and its predecessors) for some considerable time and without issue. EASA appears to be interpreting 1034/2011 and 1035/2011 to suit its own RIA (retrospectively) rather than as originally intended. For example EASA states "...1034/2011 implies that all the certified services..." whereas 1034/2011 Art 9 1. makes it quite clear that it applies to ATS and CNS providers. Similarly EASA asserts that "organisations" means all service providers whereas 1034/2011 clearly defines what is meant by organisation in Art 3 (5) and it is NOT service providers. A number of the cross references to 1034/2011 and 1035/2011 appear incorrect (e.g. 1034/2011 Art 9(2) should be Art 10(2)). EASA claim that existing provisions do not include sufficient AMC/GM. In fact there is no AMC/GM and this is not surprising given the pedigree of the rules. EASA assert that the existing provisions are not always complete and cite the lack of safety objectives associated with the severity classification scheme as an example. It is noted that the safety objectives are also missing from this NPA.</p>
response	<p>Partially accepted</p> <p>Please refer to the response to comment No 17.</p>
comment	<p>676 comment by: <i>ROMATSA</i></p>



OVERVIEW OF THE ISSUES TO BE ADDRESSED

The assertions made by EASA are not supported by any evidence especially given that ANSPs have been in compliance with 1035 (and its predecessors) for some considerable time and without issue.

EASA appears to be interpreting 1034/2011 and 1035/2011 to suit its own RIA (retrospectively) rather than as originally intended. For example EASA states "...1034/2011 implies that all the certified services..." whereas 1034/2011 Art 9 1. makes it quite clear that it applies to ATS and CNS providers. Similarly EASA asserts that "organisations" means all service providers whereas 1034/2011 clearly defines what is meant by organisation in Art 3 (5) and it is NOT service providers.

A number of the cross references to 1034/2011 and 1035/2011 appear incorrect (e.g. 1034/2011 Art 9(2) should be Art 10(2)).

EASA claim that existing provisions do not include sufficient AMC/GM. In fact there is no AMC/GM and this is not surprising given the pedigree of the rules.

EASA assert that the existing provisions are not always complete and cite the lack of safety objectives associated with the severity classification scheme as an example. It is noted that the safety objectives are also missing from this NPA.

Supporting comment to Summary Issue: Regulatory Impact Assessment

response

Partially accepted

Please refer to the response to comment No 17

comment

756

comment by: *DFS Deutsche Flugsicherung GmbH*

High level comment "a"

Level of detail and split between IR and AMC

To achieve the above mentioned, we suggest to reduce the level of detail in the IR and move some parts to AMC.

A suggestion can be found in the attachment.

Examples for this can be found in the detailed comments, where reference to this high level comment is made.

response

Partially accepted

Finding the optimal balance between IR/AMC/GM is not always an easy task. Too many details in the IR may be perceived as too prescriptive, whereas too few details as too lose. The principles followed to set requirements at these two levels of law (hard and soft law) aim at accommodating two objectives: to ensure harmonisation in the implementation when it is required, and to provide flexibility to comply with the law. To achieve this, the Agency has attempted to state the ultimate goal of the regulation along with the criteria to judge that goal at the IR level, and left at the AMC level the means for the addressees to comply with the law and its intent. In most circumstances, we need to have the criteria to judge the IR



intent in the IR text, and not in AMC. This will help to implement the law as intended (i.e. ensuring harmonisation), but also to avoid distortion of the law if applied in a different way from what intended. The decision to move text from IR to AMC has to be made on a case-by-case basis. For instance, the removal of AR.C.035(b) would mean that the criteria on which the decision by the competent authority was made were not part of the rule. Consequently, any criteria would be acceptable and there would be little point in having the rule.

It is, however, recognised that some material could be moved to AMC, and the Agency has decided to do so in certain cases. Please refer to your specific comments to find the responses to each of your proposals.

comment

820

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Explanatory Note Section 2.1 <i>Overview of the issues to be addressed</i>	In relation to the sentence " <i>Moreover, there is some evidence that safety assessments that are based only upon an explicit risk assessment are not always well understood by key stakeholders like operational staff</i> " we would be quite keen to look into that evidence.	We would like to understand the context of this assertion in order to better assess the NPA.

response

Noted

This has been communicated to the Agency by ANSPs. It is, however, not surprising that figures, such as 10^{-7} , are more cryptic and difficult to grasp for people who lack a mathematical background than figures of workload, error rates, etc. (i.e. proxies), which are more intuitive.

comment

843

comment by: Naviair

The assertions made by EASA are not supported by any evidence especially given that ANSPs have been in compliance with 1035 (and its predecessors) for some considerable time and without issue.

response

Noted

The assertions in the Explanatory Note were supported with rational statements. The Agency has provided examples of certain deficiencies in the current Regulations (EU) Nos 1034/2011 and 1035/2011. They are not justified by qualitative data, but with the rational statements of



the deficiencies supported by examples, which have not been challenged and do not undermine their validity.

comment

1000

comment by: LVNL

A causal factor in the difficulty of setting up regulation for safety assessments in ATM is the fact that the rulemaking traditionally has focused on too low levels of significance. This is present since the era of ESARR 4, which was straightforwardly carried over into rule 2096/2005. Later on, this was fast-tracked into 1034/2011 and 1035/2011 without change. Delivering sufficient safety (absence of risk) in the provision of Air Traffic Services is mainly influenced by

- (1) good leadership from the top management,*
- (2) the right tools and organisational setup,*
- (3) a good SMS,*
- (4) a good safety risk assessment process,*
- (5) proper risk classification.*

The regulation should therefore attempt to stay on the higher levels (levers 2 and 3) for the greatest impact. Providing detailed rulemaking on levels 4 and 5 creates the significant risk of rules being impractical, difficult to inspect or audit and not leaving enough freedom for alternative means, whilst not providing tangible safety benefits.

As this NPA is entirely aimed at level 4 (safety risk assessment), it should attempt to focus on practical implementations, leaving enough flexibility for alternative means of compliance. As a general principle, this means that the IR should stay at the 'goal' level, the AMC should specify one or means of compliance of 'how' this could be achieved. The GM would then give some practical examples.

response

Partially accepted

The Agency concurs with the commentator's analysis of what levels have more impact. However, this proposal is not restricted to level 4, but it deals also with 2 and, to some extent, 3. When there was an attempt to tackle level 2 and 3 with provisions, the latter were criticised of overlapping with CRD to NPA2013-08.

See the response to comment No 2 for discussion on IR/AMC balance.

comment

1001

comment by: DFS Deutsche Flugsicherung GmbH

High level comment "b"

Overlap between requirements on Management System and Safety Management System

DFS believes that the duplication of requirements on MS that are already addressed in CRD for NPA 2013-08 also for SMS in NPA 2014-13 carries the potential for internal inconsistencies



and lack of legal certainty.

Suggestions to remove this are also contained in the attachment to comment no 757

Examples for this can be found in the detailed comments.

response

Partially accepted

Please see the response to comment No 5 as well as the responses to specific proposals made by the commentator to change the IR.

comment

1002

comment by: *DFS Deutsche Flugsicherung GmbH*

High level comment "c"

Performance

Based

Regulation

DFS believes that NPA 2014-13 can be improved to be more performance based and therefore more helpful on our way to a more safe future.

response

Partially accepted

Please see the response to comment No 6.

comment

1003

comment by: *DFS Deutsche Flugsicherung GmbH*

High level comment "c.i"

The IR does not achieve the perceived intention of the rule

DFS believes that the wording in the NPA 2014-13 leaves too much room for interpretation and is convinced that it was not meant that way, because some possible interpretations are not feasible.

The comment most critical for DFS regarding the "as safe as" in ATS.OR.201 (b) is falling in this category.

Examples for this can be found in the detailed comments.

response

Partially accepted

In general, the Agency believes that the IR does meet its intention and it has been drafted having in mind this objective. If there are instances where this has not been achieved, it has been unintentional and corrected as appropriate. However, for a detailed response please see the responses to the other comments you have submitted. In particular, ATS.OR.201(b) has been moved to ATS.OR.210(b)(2) and reworded as 'ensure that the change does not



create an unacceptable risk'

comment 1004 comment by: DFS Deutsche Flugsicherung GmbH

high level comment "c.ii."

Some of the IR is infeasible

DFS believes there are requirements in the NPA 2014-13 that are infeasible or can be interpreted in a way that is infeasible.

Examples for this can be found in the detailed comments.

response Partially accepted

In general, the Agency believes that the IR is feasible. If there are instances where this has not been achieved, it has been unintentional and corrected as appropriate. However, for a detailed response, please see the responses to the other comments you have submitted..

comment 1005 comment by: DFS Deutsche Flugsicherung GmbH

High level comment "c.iii."

Some of the IR is unbounded and used subjective language

Again, there are requirements that seem not feasible to fulfil, in case specifically because of the used wording (e.g. "consider").

Examples for this can be found in the detailed comments.

response Partially accepted

The Agency has reviewed these unbounded terms, where detailed comments have identified them, and in some instances they have been modified or removed altogether. In the example given, the commentator is invited to refer to the response to comment No 53 for a detailed answer.

comment 1006 comment by: DFS Deutsche Flugsicherung GmbH

High level comment "c.iv."

Missing AMC

Examples for this can be found in the detailed comments.



response

Partially accepted

Please refer to the responses to comments Nos 3 and 235.

comment

1007

comment by: *DFS Deutsche Flugsicherung GmbH*

High level comment "c.v."

Missing, Incorrect and confusing Guidance Material

DFS as a member of CANSO believes there is a need for more efficient guidance (less, but more efficient and less confusing).

Examples for this can be found in the detailed comments.

response

Partially accepted

Please refer to the responses to comments Nos 3 and 235.

comment

1009

comment by: *DFS Deutsche Flugsicherung GmbH*

High level comment "d"

Transitional Arrangements

The requirements for transition did only become clear when talking to a EASA representative and are not clear in the NPA 2014-13.

The example for this can be found in the detailed comments.

response

Noted

Please refer to the response to comment No 20.

comment

1010

comment by: *DFS Deutsche Flugsicherung GmbH*

High level comment "e"

Explanatory Note (EN) and Regulatory Impact Assessment (RIA)

The EN and RIA seem to not always be correct or supported by arguments.

Examples for this can be found in the detailed comments.

response

Partially accepted



The RIA has been reviewed and the updated one has been published in the Opinion. For specific responses, please refer to your specific comments.

comment

1088

comment by: *Belgocontrol*

The RIA is a decision-making tool to determine the best option to achieve the objective of a rulemaking activity while minimizing potential negative impacts. It seems that the arguments presented in the RIA are not completely accurate which undermines confidence in the outcome.

The assertions made are not supported by any evidence particularly in view that ANSPs have been in compliance with EU 1035/2011 for some considerable time without real issues.

The way that EU 1034/2011 and EU 1035/2011 have been interpreted seems to suit the selected Options (as opposed to the RIA informing the IR). Several examples can be mentioned:

1. Interpreting retrospectively current applicable regulation rather than as originally intended.
2. It is stated ‘...1034/2011 implies that all the certified services...’ but EU 1034/2011 Art 9 1 makes it quite clear that it applies to ATS and CNS providers.
3. EU 1034/2011 Art 3 (5) clearly defines what is meant by organisation and it is NOT service providers. However, the RIA asserts that ‘organisations’ means ‘all service providers’.
4. It is stated that the existing provisions are not always complete and the lack of safety objectives associated with the severity classification scheme is used as an example. However safety objectives are also missing from this NPA.
5. Some of the cross references to EU 1034/2011 and EU 1035/2011 seem to be incorrect (e.g. EU 1034/2011 Art 9(2) should be Art 10(2)).

response

Partially accepted

Please refer to the response to comment No 17.

comment

1260

comment by: *EUROCONTROL*

Explanatory Note - Page 10

Section 2.1

Need for a broad-based approach to safety assessment

Last but one §

It seems that the intent of this section is to reveal some shortcomings in the current safety assessment approach. A broad-based approach to safety assessment is mentioned as a way to address current deficiencies but no explanation is really given about what ‘broad-based’ actually mean/infer. Reading between the lines it seems that the issue is about the current general preference for an over-procedural, process-based, tick-in-the-box approach to safety assessment by both safety regulators and ATM service providers. However this is not



explicitly mentioned.

In the case the above understanding is correct, it is suggested to explicitly mention in the text the current shortcomings related to an over-procedural, process-based, tick-in-the-box approach to safety assessment.

Need for a broad-based approach to safety assessment

Last §

What is 'valid' should come from setting out logically sound safety arguments for these changes that will also define the rigour related to the evidence to be gathered (product-based and process-based evidence). Usage of the term 'valid' does not read 100% right in this case since it is not explained what a 'valid' safety assessment means.

It is therefore suggested to introduce the concept of safety argument that has to be sub-divided until a level is reached at which a piece of documented evidence, of a manageable size, could be produced to show that the corresponding strand of the argument is valid. And, even then, it is proposed to add that it is not sufficient merely to offer the evidence – rather it is necessary to provide the rationale as to why and how the evidence validates the argument for which it is offered.

Issues identified with the implementation of the Existing Regulations

Last §

Firstly, what is a safety case with respect to a safety assessment is not explained. Secondly, either for a Project Safety Case or a Unit Safety Case, there is no explicit regulatory requirement to do so. The result is that there is currently little or no take-up of the idea by ANSPs.

It is therefore suggested to make the issue with existing Regulations clearer.

Issues identified with the implementation of the Existing Regulations

Last but one dash

First, while performance-based safety regulation sounds like a promising concept, it is still at this time a fundamentally unknown territory (i.e. how much different it is from risk management and current SMS practices remains to be assessed).

What is certain is that PBR should be highly demanding in terms of data requirements – whereas the need for data is presented as an issue on page 10, last §.

Finally it is not clear how PBR would be a solution to the issue highlighted in the following paragraph related to the usage of specific methods.

It is suggested to rather use here the concept of safety argument and associated evidence. The latter (i) must be presented only to the degree and extent necessary to support the related argument; (ii) must be clear, unequivocal, conclusive and, wherever possible, objective; and (iii) must be appropriate (e.g. from safety analyses, simulations, tests, previous usage, compliance with standards); and finally, the rigour of the evidence must be appropriate to the associated risk.

Section 2.3

CNS providers performing safety support assessment instead of safety assessment

First it is not clear why this part is limited to CNS providers and does not include e.g. AIS providers as well.

Secondly, the need for this new expression "safety support assessment" is not really explained. First this part should explain that the first, and sometimes difficult, step in a safety



assessment, is deciding what to argue and from what viewpoint. Within that framework the following should be answered:

1. Who is making the claim – service provider or service user?
2. What is the service that is being provided (across which interface)?
3. Who are the users of the service?
4. What is the application domain?
5. What is the system that provides the service?

If the answer to 1 and 4 is “ATM” or one of its component services, then this is quite straightforward and the wording ‘safety assessment’ is not called into question.

If answers lead to conclude that we’re not *stricto sensu* within the scope of ATM, then the claim could be made from either an AIS/CNS or ATM viewpoint.

It is therefore suggested to better explain the issue as identified in the comment and then explain that the fundamental problem for an AIS or CNS provider in making a safety claim equivalent to that already developed for ATM service providers is that:

- the notion of safety applies only to the domain and sub-domain for which safety criteria have been identified;
- an AIS or CNS provider does not necessarily know for what purposes an ATM system might use AIS/CNS ‘data’ or in what specific environment;
- in any case, an AIS/CNS provider could not reasonably be expected to know what quality and integrity properties are required of data for a particular ATM application; these are rightly the responsibility of the data user – i.e. the ATM service provider.

Without this or similar explanation, it is unlikely that the need for a new term will be properly understood.

response

Partially accepted

Despite the fact that the Agency agrees with many of the statements made by the commentator, not all of them have been fully addressed.

Broad-based approach to safety assessment: The commentator has rightly pointed out the reason for a new approach to safety assessment that is not process-focussed and moves away from a ticking-box exercise. This is explicitly mentioned in the Explanatory Note when it is stated that this is not method-oriented. When moving away from a method and being focussed on the assurance required, the proposed regulation is actually achieving its intended objective of improving the quality of the service it regulates.

The discussion about the term ‘valid’ is correct. The Agency concurs with the statements provided. The rationale behind why and how provided evidence in a safety assessment validates the argument is certainly part of the validity of the assessment. This explanation is considered to fit better in the AMC than in the Explanatory Note. When the AMC are developed, the rationale stated will be taken into account.

Safety case with respect to a safety assessment is not explained in the Explanatory Note, but this is covered in the GM material (i.e. GM1 ATM/ANS.OR.C.005(a)(2) & ATS.OR.205(a)(2)).

The sentence about data issues on page 10 is meant to be related to the risk assessment based on quantitative risks, and not with the application of PRB, which is anyway demanding



in terms of data requirements as rightly pointed by the commentator.

The Agency concurs with the description of characteristics of evidence that the commentator suggests. Once more, this material seems more appropriate to incorporate into the AMC/GM than in the Explanatory Note itself. It will be taken into account later during the development of AMC/GM.

Section 2.3: Accepted. The RIA has been updated to consider the rest of service providers, in addition to CNS. This has been incorporated into the Explanatory Note to the Opinion. Nevertheless, the overall evaluation remains the same.

The same arguments have been captured later in the document (pages 26-27). It may be true that at this stage in the paper the need of safety support assessment is not clear, but it should be after the reading of the whole Explanatory Note. In any case, as the Explanatory Note will be published in a different format, this issue is not relevant (although the elements suggested may be used later when the GM is redrafted).

comment

1268

comment by: *European Transport Workers Federation - ETF*

General Comment.

Taking into account the definition of “Functional system” (*means a combination of procedures, human resources and equipment, including hardware and software, organised to perform a function within the context of ATM/ANS*), ETF stresses the importance of involving the staff affected by any change to the functional system. This must be achieved by appropriate consultation during the audits, in the monitoring requirements, and ensuring staff contribute to the process of risk analysis. There must also be efficient and effective training to adapt staff skills to the change. Furthermore ETF proposes to include within the definition “Aviation undertaking” (*means an entity, person or organisation, other than the organisation regulated by this Regulation that is affected by or affects a service delivered by a service provider*) Trade Unions, representing the human resources component of “functional systems”.

response

Partially accepted

The argument about the involvement of representative bodies is accepted. The involvement of all stakeholders who are affected by a change is promoted in the IR. The term ‘aviation undertakings’ covers all entities that may be affected by a change but do not fall within the scope of the proposed regulation. GM explains that in some instances these include representative bodies of interested stakeholders such a ATCO and pilot groups. Nevertheless, the IR cannot list particular representative organisations and require them to be consulted because the range of changes is extremely large and not all may need the involvement of all such representative bodies.



2. Explanatory Note — 2.2. Objectives

p. 13

comment

277

comment by: *Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)*

It is not clear what benefits the proposed IR will provide compared to the current regulation with regarding the level of safety.

The overall impression is that this NPA has failed to meet it's stated objective.

response

Noted

The Agency disagrees with the commentator as this proposal is believed to resolve the issues listed in section 2.1, and to support the achievement of objectives 2.2. The achievement of all those objectives is difficult to argue at this stage, but the given rationale supports the idea that the regulation is contributing towards them.

In general, the Agency believes that the IR does meet its intention and it has been drafted having in mind this objective. If there are instances where this has not been achieved, it has been unintentional and corrected as appropriate.

2. Explanatory Note — 2.3. Summary of the Regulatory Impact Assessment (RIA)

p. 14-17

comment

9

comment by: *EUROCONTROL Safety Team*

This section is rather a poor summary of the more detailed RIA due to not all options being included in a consistent way :

1. *Risk-based Review Decision by the Competent Authority* does not initially include Option 3 in the list despite this being the chosen Option
2. *Risk-based review by the Competent Authority*
 - Option 3 cannot possibly be the favoured option given the implication of Option 2 because if currently there is insufficient experience existing to write it how can it be then foreseen that there will be sufficient experience to use it in the suggested timescales.
 - Option 1 is dismissed but it is not even mentioned.

response

Accepted

The Agency would like to apologise for these mistakes, which were made due to the fact that the RIA section was reviewed several times before publication, but the summary was not updated accordingly. Efforts will be made to avoid similar situations in the future. In this case, the RIA has been updated and a summary of changes compared to the NPA has been



included in the Opinion.

As regards Option 3, it has been withdrawn (the requirement has been removed from the IR).

comment 18

comment by: *NATS National Air Traffic Services Limited*

2.3 Summary of the Regulatory Impact Assessment (Page 14)

Whilst this is a summary of the more detailed RIA, NATS considers it to be a poor summary as it does not appear to be a fair reflection of the full RIA, e.g. not all options are included in a consistent way that makes reading and understanding the summary very difficult. For example the Risk-based Review Decision by the Competent Authority does not initially include Option 3 in the list and yet it is the chosen Option.

With regard to the risk-based review by the competent authority it appears that, given the implication of Option 2, then Option 3 cannot possibly be the favored option. That is, if there is insufficient experience existing to write it how can it be foreseen that sufficient experience to use it will be forthcoming in the suggested timescales. It is noted that Option 1 is dismissed and yet it is not even mentioned.

Given the history regarding timescales for the development of IR/AMC/GM CANSO NATS strongly supports Option 2 of Risk-based Review Decision by the Competent Authority and Risk-based review by the Competent Authority. Given the timeframe taken to reach this NPA NATS has a concern that two years is insufficient.

response Accepted

Please refer to the response to comment No 9.

comment 319

comment by: *BAF-M.Jancokova*

Part 'Risk-based review decision by the competent authority' is not consistent with Section 4.3.6 of this NPA.

response Accepted

Please refer to the response to comment No 9.

comment 359

comment by: *Air Navigation Services of the Czech Republic*

Not all options are always described making the justification not clear enough, e.g. the Risk-based Review Decision by the Competent Authority does not initially include Option 3 in the list and yet it is the chosen Option. For the Risk-based Review Decision by the Competent



response	<p>Authority we support Option 2.</p> <p>Accepted</p> <p>Please refer to the response to comment No 9.</p>
comment	<p>373 comment by: <i>skyguide Corporate Regulation Management</i></p> <p>Whilst this is a summary of the more detailed RIA we consider it to be a poor summary as it does not appear to be a fair reflection of the full RIA, e.g. not all options are included in a consistent way that makes reading and understanding the summary very difficult. For example the Risk-based Review Decision by the Competent Authority does not initially include Option 3 in the list and yet it is the chosen Option.</p> <p>With regard to the risk-based review by the competent authority it appears that, given the implication of Option 2, then Option 3 cannot possibly be the favored option. That is, if there is insufficient experience existing to write it how can it be foreseen that sufficient experience to use it will be forthcoming in the suggested timescales. It is noted that Option 1 is dismissed and yet it is not even mentioned.</p> <p>Given the history regarding timescales for the development of IR/AMC/GM we strongly supports Option 2 of Risk-based Review Decision by the Competent Authority and Risk-based review by the Competent Authority. Given the timeframe taken to reach this NPA we have concerns that two years is insufficient.</p>
response	<p>Accepted</p> <p>Please refer to the response to comment No 9.</p>
comment	<p>595 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>The summary seems to not reflect the RIA correctly. Reference to high level comment "e"</p>
response	<p>Accepted</p> <p>Please refer to the response to comment No 9.</p>
comment	<p>626 comment by: <i>CANSO</i></p> <p>Whilst this is a summary of the more detailed RIA CANSO considers it to be a poor summary as it does not appear to be a fair reflection of the full RIA, e.g. not all options are included in a consistent way that makes reading and understanding the summary very difficult. For example the Risk-based Review Decision by the Competent Authority does not initially include Option 3 in the list and yet it is the chosen Option.</p> <p>With regard to the risk-based review by the competent authority it appears that, given the implication of Option 2, then Option 3 cannot possibly be the favored option. That is, if there</p>



is insufficient experience existing to write it how can it be foreseen that sufficient experience to use it will be forthcoming in the suggested timescales. It is noted that Option 1 is dismissed and yet it is not even mentioned.
 Given the history regarding timescales for the development of IR/AMC/GM CANSO strongly supports Option 2 of Risk-based Review Decision by the Competent Authority and Risk-based review by the Competent Authority. Given the timeframe taken to reach this NPA CANSO has concerns that two years is insufficient.

response

Accepted
 Please refer to the response to comment No 9.

comment

677

comment by: ROMATSA

Whilst this is a summary of the more detailed RIA ROMATSA supports CANSO opinion to be a poor summary as it does not appear to be a fair reflection of the full RIA, e.g. not all options are included in a consistent way that makes reading and understanding the summary very difficult. For example the Risk-based Review Decision by the Competent Authority does not initially include Option 3 in the list and yet it is the preferred Option.
 With regard to the risk-based review by the competent authority it appears that, given the implication of Option 2 (“propose a coherent risk based rule but delay implementation until sufficient experience exists to use it”), then Option 3 (“propose a risk based review rule but delay implementation until sufficient experience exists to use it”) cannot possibly be the favored option. That is, if there is insufficient experience existing to write it how can it be foreseen that sufficient experience to use it will be forthcoming in the suggested timescales?
 Given the history regarding timescales for the development of IR/AMC/GM ROMATSA supports CANSO opinion in favor of Option 2 of Risk-based Review Decision by the Competent Authority and Risk-based review by the Competent Authority. Given the timeframe taken to reach this NPA ROMATSA supports CANSO concern that two years is insufficient.

response

Accepted
 Please refer to the response to comment No 9.

comment

821

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Explanatory Note Section 2.3 <i>Summary of the Regulatory Impact Assessment (RIA)</i>	This section is not properly numbered and structured so that it does not properly summarize section 4.3 .	This NPA is quite important for the functioning of the whole system and it should be as clear as possible in order to avoid present and future misunderstandings.



Risk-based review decision by the competent authority	<p>For example, neither Option 0 nor Option 3 are listed at the beginning of this section and one has to refer to section 4.3.6 for details on both Options.</p> <p>However, Option 3 is then designed as the preferred one.</p>	
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response

Accepted

The Agency would like to apologise for these mistakes, which were made due to the fact that the RIA section was reviewed several times before publication, but the summary was not updated accordingly. Efforts will be made to avoid similar situations in the future. In this case, the RIA has been updated and a summary of changes compared to the NPA has been included in the Opinion.

comment

823

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Explanatory Note Section 2.3 <i>Summary of the Regulatory Impact Assessment (RIA)</i> Risk-based review decision by the competent authority</p>	<p>Option 3 does not feel right, somehow. Therefore, we cannot support Option 3 as the preferred one unless it be modified in a joint manner based on broad consensus and experience gathered to include a higher degree of robustness and certainty in it.</p> <p>In fact, the requirement for a risk-based review decision is already present in the extant regulations and should, therefore, be implemented by the CAs who have been able to gather sufficient experience in its implementation.</p>	<p>CAs are not "R&D organisations" for them to validate the model proposed in the way indicated ("<i>the model should be implemented by several CAs, and shown to be effective and lead to harmonisation</i>").</p> <p>Further to this, the fact that "<i>the validity of the model needs to be confirmed in practice and, consequently, implementation will be delayed until the work foreseen in the feasibility study has been completed and adequate AMC material has been written</i>" introduces a high degree of uncertainty (and, potentially, risk) on the date of implementation of the model (in fact, delayed <i>sine die</i>) that renders Option 3</p>



		<p>invalid in its present form.</p> <p>We would propose to develop this Option 3 in a joint manner based on broad consensus and experience gathered and not solely on the outcome of the UK CAA study.</p>
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response Not accepted

The alternative given seems to be worse: either reviewing all changes or eliminating a priori many of them without knowing their risk. The proposal, therefore, applies the criteria in the GM and later, when confirmed that the risk is correctly estimated, then the criteria may be moved to AMC. The CA can always decide to use a different set of risk-based criteria.

comment 825

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Explanatory Note Section 2.3 <i>Summary of the Regulatory Impact Assessment (RIA)</i> Removal of Severity classification scheme from IR</p>	<p>Option 1 (universal severity scheme for safety risk) seems to us more pragmatic and prone to harmonization than Option 2 (rules for creating severity schemes for safety).</p>	<p>Although we appreciate the performance-based element of Option 2, we feel that this may result in a big collection of schemes that render the model unworkable in practice, as EASA actually acknowledges.</p> <p>Further to this, the mitigation hinted to in the sentence "<i>However, with appropriate management and oversight, these ought to be reduced to an acceptable number of schemes, which could then be harmonised</i>" introduces a high degree of uncertainty (and, potentially, risk) on the final state of implementation of this Option by relying on an undetermined "<i>appropriate management and oversight</i>" of 28+ CAs.</p>

response Partially accepted



Many service providers have appreciated this flexibility. It is acknowledged that harmonisation is achieved with Option 2 better than with Option 3; however, because of the reasons given in section 4.6.1, the current severity classification scheme is not appropriate.

In any case, it was not possible for the Rulemaking Group to reach a consensus over the definition of a single universal scheme for safety risk.

comment 845

comment by: Naviair

Even if this is a summary of the more detailed RIA it is considered to be a poor summary as it does not appear to be a fair reflection of the full RIA, e.g. not all options are included in a consistent way that makes reading and understanding the summary very difficult. For example the Risk-based Review Decision by the Competent Authority does not initially include Option 3 in the list and yet it is the chosen Option.

response

Accepted

Please refer to the response to comment No 9.

comment 999

comment by: LVNL

In paragraph 2.3. there is no summary of the regulatory impact of the NPA on the service providers to implement this NPA. As it is anticipated that substantial changes to the safety management systems of the service providers would need to be made, this is an omission.

response

Partially accepted

No explanations are given with regard to what changes to the SMS need to be introduced by ATS providers. In any case, the RIA has been updated to cover all services providers affected (e.g. DTA, AIS, ATFM)

comment 1089

comment by: Belgocontrol

This section provides a poor summary of the more detailed RIA as not all options are included in a consistent way :

1. *Risk-based Review Decision by the Competent Authority* does not include Option 3 in the list however it is the chosen Option

2. *Risk-based review by the Competent Authority*

o How can Option 3 be the favoured option taking into account the implication of Option 2: if currently there is insufficient experience to write it, how can it be then foreseen that there will be sufficient experience to use it in the suggested timescales.



	Option 1 is dismissed but not even mentioned.
response	Accepted Please refer to the response to comment No 9.
comment	1169 comment by: <i>Avinor ANS</i> Avinor ANS has concerns that two years is insufficient given the timeframe taken to reach this NPA.
response	Noted Most of stakeholders have answered positively this question. Please see answers to question Q1.

2. Explanatory Note — 2.4. Overview of the proposed amendments — 2.4.1. Proposed amendments to Annex I ‘Definitions for terms used in Annex II to XIII’ p. 17-18

comment	19 comment by: <i>NATS National Air Traffic Services Limited</i> 2.4.1 Proposed amendments to Annex I ‘Definitions for terms used in Annex II to XIII (Page 17) EASA propose to define a functional system as “combination of procedures, human resources and equipment, including hardware and software, organised to perform a function within the context of ATM/ANS”. Given that this NPA integrates into CRD 2013-08 then the definition of “ATM/ANS” will be that contained in the Basic Regulation and as such will not apply to all service providers. It is noted that the definition of hazard was not changed in CRD to NPA 2013-08 as stated. The revised definition was in the original NPA 2013-08 and changed from the definition in 1035/2011. The three definitions that are referred to were removed in NPA 2013-08 and not this NPA as is implied by the text.
response	Accepted The definition of functional system has been complemented with the appropriate scope, extending ‘ATM/ANS’ to ‘ATM/ANS and other network functions’ to be in line with the scope of the regulated service providers as defined in Article 2 of the proposed rule in CRD to NPA 2013-08. The reference to NPA 2013-08 is less appropriate than that to CRD to NPA2013-08, as this is



the most updated resulting text.

The latter remark is unnecessary, as the NPA only states that these terms were not transposed.

comment 244

comment by: UK CAA

Page No: 18

Paragraph No: 2.4.1. Proposed amendments to Annex I 'Definitions for terms used in Annex II to XIII'

Comment: The UK CAA recommends that the definition of 'equipment' is included in the list of definitions in Annex 1 of NPA2013-08. All other definitions contained in GM should also be moved to Annex 1 of the IR.

Justification: Definitions are binding meanings and are applicable to IR, AMC and GM alike and provide legal certainty to the meaning of words, phrases and abbreviations. Such legal certainty can only be achieved by hosting definitions in IR.

response Not accepted

The only reason behind including a definition of equipment in GM was to make clear that when we refer to 'equipment' both its hardware and its software are included. There is no intention to introduce additional terminology at the IR level and it does not seem necessary to include this term in the definition section, as this would create greater disagreements. This term has been well received by a number of commentators in the way it is introduced.

comment 320

comment by: BAF-M.Jancokova

It is supported that the definition of functional systems as found in the current regulation is updated to better reflect what is within the scope of the regulation and what not. The term "ATM/ANS", however, seems not appropriate. It is understood that the intention is to clearly state that providers of ATS, CNS, MET, AIS, ASM and ATFM have functional systems. ATM and ANS as defined in 549/2004 are, however, no disjunct sets. So, in order to avoid double entries, it is recommended to either find another term for "ATM/ANS" (or use the ICAO definition for ANS) or just list the services that are meant.

Remark: The term "equipment" should be clearly defined in the definition section (Annex I), not just in GM.

response Not accepted

The term 'ATM/ANS' has been defined by the Regulation (EC) No 216/2008 (the EASA Basic Regulation) and not by this NPA. However, it does not cover all providers it should (i.e. DAT is included in the Basic Regulation, but not in the definitions of ATM and ANS in the SES regulations).



The only reason behind including a definition of equipment in GM was to make clear that when we refer to 'equipment' both its hardware and its software are included. There is no intention to introduce additional terminology at the IR level and it does not seem necessary to include this term in the definition section, as this would create greater disagreements. This term has been well received by a number of commentators in the way it is introduced.

comment

321

comment by: *BAF-M.Jancokova*

A definition of "harmful effect" should be added to Annex I, Definitions. The definition should clearly state what is to be covered by "harmful effect" and what not. Besides fatalities, this includes clarification on e.g. (light) injuries, stress/discomfort to passengers or damage to aircraft without people being killed/injured/stressed, on the other hand.

response

Not accepted

The concept of 'harmful effect' does not appear in the IR so its definition does not need to be added in Annex I, and can remain at GM level. In addition, for the purpose of this proposed regulation the concern is about the harm on people. The fact that the aircraft is damaged or not, is relevant as far as there is a likelihood to harm people.

comment

322

comment by: *BAF-M.Jancokova*

2.4.1 last two paragraphs: This is contradictory to GM1 ATM/ANS.OR.C.005(a)(2) & ATS.OR.205(a)(2) General
where safety assurance is defined.

response

Accepted

The term 'safety assurance' should not be in the list. Since this is not retained in the Opinion, it will not be reflected.

comment

467

comment by: *CAA CZ*

Question 1: The Agency would like to know the stakeholders' views about the proposed 2-year transition period. If it is not considered sufficient, please provide a justification.
The CAA CZ supports the option allowing two years for transition period.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the



final position taken by the Agency.

comment 758 comment by: ENAIRE

It is not clear where the harmful effect is applicable on. Is it referred to aircraft, or occupants, or flight crew, or controller workload for instance?

response Noted

'Harmful effect', as explained in the GM1 ATS.OR.205(b)(4), is related to harm to humans.

comment 759 comment by: ENAIRE

What about the safety objectives and requirements already defined? How will they be conformed to the proposed amendments?

response Noted

There is an objective for the change (i.e. ensure that no unacceptable risk is introduced by the change). Safety requirements will be set for all elements of the functional system and when each element meets its safety requirements, the functional system meets its safety criteria (please see GM3 ATS.OR.205(a)(3)).

comment 826 comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Explanatory Note Section 2.4.1 <i>Overview of the proposed amendments</i> Proposed amendments to Annex I 'Definitions for terms used in Annex II to XIII'</p>	<p>We would propose to change the definition of 'equipment' introduced in GM1 Annex I Definitions (35)(a)(1) as follows: "‘Equipment’ is an assembly of the framework for locating hardware, the hardware itself (including its <u>contained software</u>) and possibly a cover to act as a barrier between the internal and external environments."</p>	<p>The definition of 'equipment' introduced in the GM and the explanation associated to this definition are misleading.</p> <p>If the intention is that "when a requirement concerns equipment, then that requirement applies to all the constituent parts of the equipment i.e. the framework, the hardware (including its contained software), that are within the scope of the requirement" it is then better to make this explicit in order to avoid present and future misunderstandings.</p>



response Noted

The hierarchy of definitions makes clear that software is included in hardware, so this does not seem necessary. Anyway, comments on AMC/GM will be responded to in the CRD associated with them. A considerable amount of time is needed to rework, amend and complete the AMC/GM in an appropriate and effective manner, and this cannot be done at this stage. Future work is planned to review the comments on the AMC/GM and complete the CRD in due time.

comment 1171

comment by: ENAIRE

In NPA 2013-08, it is explained in the overview of the changes resulting from the consultation, regarding the identification of safety-related systems (old ATSEP.OR.10 requirement), that there is no need to require from a Service Provider to identify the safety-related systems through its SMS, because the term “system” is defined in the NPA related to the “Assessment of changes to functional systems by service providers in ATM/ANS and the oversight of these changes by competent authorities” (RMT.0469). In this NPA (2014-13) the word ‘systems’ from the previous definition has been replaced by ‘equipment’ in order to avoid the difficulty that systems are generally thought of as comprising people, procedures, equipment and architecture and so the term ‘system’ is overloaded in the functional system definition. Furthermore, ‘system’ may be confused with the same term used in Regulation (EC) No 549/200414 where it is inappropriate to cover the concept that we are trying to regulate since it does not include people or procedures and whose scope is limited to ANS. ATM has been complemented with ANS so as to cover the entire scope of the services and be consistent with the scope of the Basic Regulation. In order to complement the definition of functional system and to better understand the scope of the requirements, the definition of equipment has been added in GM:

‘Equipment’ means an assembly of the framework for locating hardware, the hardware itself and possibly a cover to act as a barrier between the internal and external environments.

This definition is too wide and not precise, and taking into account that the definition of the ATSEP is linked to the personnel who operate, maintain, release [...] this “equipment”, any person that manipulates a framework with hardware would be an ATSEP.

We believe that the definition of ATSEP, far from improve, has made a blur, making it more difficult to apply. A farther clarification should be made, either in this NPA 2014-13 or in NPA 2013-08.

response Noted

This comment is related to the definition of ATSEP. Taking into account the definition in CRD to NPA 2013-08 (authorised personnel who are competent to operate, maintain, release from, and return into operations equipment of the functional system), the comment is not



well understood. A person manipulating the cover may or may not be ATSEP. Moreover, it is unclear in what sense the definition of equipment is less precise than the current definition of 'system'.

2. Explanatory Note — 2.4. Overview of the proposed amendments — 2.4.2. Proposed amendments to Article 8 'Transitional provision', Article 9 'Repeal' and Article 10 'Entry into force' in the Cover Regulation p. 18-19

comment 10

comment by: EUROCONTROL Safety Team

This is not clear because CRD 2013-08 has no specific text in Articles 8 and 9 regarding Transitional Provisions and Repeal. This raises the following questions/views:

- Which are the provisions applicable?
- Would the transitional provisions of this NPA be different from those of CRD 2013-08?
- The situation is further complicated by the change in scope of the IR i.e. from 'ATM/ANS service providers' to 'service providers'. Several types of service providers (as per definition of CRD 2013-08) are not currently regulated under EU 1034/2011 and EU 1035/2011. The proposal in 2.4.2 is for 2 years but only for existing service providers regulated under EU 1034/2011 and EU 1035/2011. This implies that service providers as per CRD 2013-08 definition have therefore no transition period.

response Noted

Please refer to the response to comment No 20.

comment 20

comment by: NATS National Air Traffic Services Limited

2.4.2. Proposed amendments to Article 8 'Transitional provision', Article 9 'Repeal' and Article 10 'Entry into force' in the Cover Regulation (Page 18)

NATS notes that CRD 2013-08 has no specific text in Art 8 and 9 regarding Transitional provisions and Repeal other than referring to the Opinion. It is therefore not clear to NATS which provisions are being referred to in this NPA. Is it the whole of CRD 2013-08 or just the provisions in this NPA? If it is the latter then what are the transitional arrangements for the provisions in the CRD? It is noted that the proposed transitional arrangements of 2 years only applies to existing "service providers" regulated under 1034/2011 and 1035/2011. Does this mean that those service providers (using the CRD 2013-08 definition) who are not regulated by 1034/2011 and 1035/2011 have no transition period?

What will the requirements for any new service provider that seeks certification during the



	<p>transition period?</p> <p>As previously stated CRD 2013-08 does not propose repealing 1034/2011 and 1035/2011 as claimed.</p> <p>As previously commented and in response to Question 1 NATS does not believe that 2 years is sufficient if Option 3 of Risk-based Review Decision by the Competent Authority and Risk-based review by the Competent Authority is selected and NATS is in support of Option 2. It is not clear to NATS if the 2 year delay proposed in the NPA under Entry into force is an additional 2 years after the 2 year transition (4 years in total) or the timescales are to run in parallel.</p>
response	<p>Noted</p> <p>There is no proposed transition period. The transition period for the application of the proposed in this NPA rule will be the same as for that in CRD to NPA 2013-08, which will be proposed as a common transition period for the final single Opinion. What was proposed for certain requirements (e.g. ATM/ANS.AR.C.035) was the delay of applicability in addition to the transition period decided by the European Commission in relation to the application of the proposed in CRD to NPA 2013-08 rule. This proposal has been finally withdrawn.</p> <p>All providers should have a transition period. There is nothing that implies that the new providers included in the definition in CRD 2013-08 will not have the transition period.</p> <p>The transition period will be discussed in the SSC and will be finally decided by the European Commission.</p> <p>Regarding the repeal of Regulations (EU) Nos 1034/2011 and 1035/2011, it is clearly stated in section 1.3 of CRD 2013-08 that the proposal aims at repealing those Regulations, even though the precise text has not been introduced. The same applies to this NPA.</p> <p>The intention is not to have two transition periods running in parallel, resulting in the applicability for those requirements to be 4 years, but a single transition period of 2 years.</p>
comment	<p>119 comment by: ENAIRE</p> <p>Answer to Question 2: Yes, the actions ANSPs are currently performing to satisfy EU REG 482/2008 will continue to satisfy this NPA.</p>
response	<p>Noted</p>
comment	<p>120 comment by: ENAIRE</p> <p>Answer to Question 1: Two years after EASA finishes the completed combined rule (Including</p>



all the pending issues open in this NPA material).
The proposed 2-year transition period should be synchronized with NPA 2013-08.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency. In addition, please see the response to comment No 20 for additional clarification.

comment

187

comment by: EUROCONTROL Safety Team

Page 18 2.4.2 Question 1

The changes resulting from new regulation impacts several parties. The work to be compliant will not only depend on the SP's internal arrangements, but also be dependent on coordination and approval processes by the NSA, national regulation being adjusted, harmonisation within the FAB, and coordination of procedures with other providers and aviation undertakings.

Additionally it is not clear if the transition period refers only to the requirement proposed in this NPA or the of NPA 2013-08 or both.

Recommend a transition period of at least two after the completed combined rule is published.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency. In addition, please see the response to comment No 20 for additional clarification.

comment

188

comment by: EUROCONTROL Safety Team

Page 19 Question 2

This proposal does not cover the variation of rigour mandated in EC 482/2008 because that regulation is is very detailed although one may consider that the requirements of EC 482/2008 are broadly integrated in this NPA. On the other hand Option 2 increases the scope of the proposed requirements because it covers the whole functional system and it extends these requirements also to the DAT and Airspace design services. Current ANSPs are all compliant with the EC 482/2008 requirements and the repeal of this regulation would lead to a relaxation of requirements which might negatively impact the safety of the service. The extension of the scope of requirements to cover the whole functional system and also the DAT and Airspace design service is welcomed. However, no AMCs or GM is proposed on this subject although one finds reference to various assurance levels in the proposed text without such text referring to appropriate standards, specifications or methodology.



	<p>Recommend</p> <ol style="list-style-type: none"> 1. Retain EC 482/2008. 2. Before proceeding further with the extension of the scope of requirements to refer to appropriate standards, specifications or methodology as otherwise this would be an infeasible requirement.
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency. AMC/GM should be completed for the elements mentioned and those elements necessary from Regulation (EC) No 482/2008 will be also transposed to this proposed regulation, after a proper analysis is carried out.</p>
comment	<p>245 comment by: UK CAA</p> <p>Page No: 18 Paragraph No: 2.4.2 Question 1 Comment: The NPA correctly identifies that risks associated with introducing – and applying – the proposed legislative package, and recognises the need for transitional arrangements. A 2-year period is suggested, however it is not clear when this will start. Is it from the introduction of the proposed IR material, or from the Agency Decision regarding AMC/GM? Given that the AMC/GM will be subject to further NPA activity, the UK CAA suggests that a 3-year transition from the date the agreed IR material enters law is appropriate. Justification: Clarity of regulatory applicability and introduction of appropriate transitional period.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency. The transition period would start as from adoption of the Regulation in the Official Journal. In addition, please see the response to comment No 20 for additional clarification.</p>
comment	<p>246 comment by: UK CAA</p> <p>Page No: 19 Paragraph No: QUESTION 2 Comment: The UK CAA fully supports the withdrawal of 482/2008. However, its withdrawal does not address the divergent practices that have arisen due to 482/2008 and that have been applied in different states by service providers and CAs. Although the NPA does provide a baseline for the harmonisation of software assurance and it also extends this approach to people, procedures and hardware, it leaves a vacuum in terms of guidance on how to</p>



achieve this assurance.

There are also procedural, financial and time costs (yet to be quantified) in withdrawing 482/2008 as it invalidates agreements and AMCs established between service providers and their CAs, leaving a vacuum that needs to be filled. It will be challenging to re-establish such agreements such that they are compliant with the provisions in the NPA, especially in the absence of EASA guidance and the presence of widely different views of how to properly and adequately assure software.

Consequently, the UK CAA recommends that EASA publish guidance on the assurance of software in a compliant manner.

Justification: EASA guidance will be the most cost-effective and efficient way to remove and prevent further divergent practices emerging and so enhance harmonisation regarding software assurance. This justification applies equally to the assurance of people, procedures and hardware.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.

The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).

comment

278

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

The proposal of a 2 year transition period is not relevant as the IR including AMC and GM is immature and has to be updated and published on a second NPA before progressing further.

response

Noted

The Agency takes due consideration of the answer the question. Please the see Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency. The Agency does not consider that the IR is immature, although it is recognised some AMC/GM are missing.

comment

280

comment by: *Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)*

We interpret this to be a significant increase in scope compared to 482, and thus cost driving. i.e. going from a software safety assurance system to a generic assurance system including all aspects of the functional system.



response	<p>Noted</p> <p>The increase in scope compared to Regulation (EC) No 482/2008 is acknowledged. The assurance of the other elements should also be part of the assessments performed currently. The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).</p>
comment	<p>323 comment by: <i>BAF-M.Jancokova</i></p> <p>Question 1: For the time being a commitment to the proposed transition period cannot be made as there is still no complete picture of the subject due to still missing AMC / GM in connection with the need for clarification on issues within this NPA.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency</p>
comment	<p>324 comment by: <i>BAF-M.Jancokova</i></p> <p>Question 2: The added value of the IR 482/2008 seems to be underestimated and a general repeal should be well-thought-out. The very detailed implications of the IR 482/2008 and standards behind are worth to be kept, however, not in the context of change management and oversight of changes which should stay at a higher level, as described in this NPA (which now includes the concept of assurance for all parts of a functional system).</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.</p> <p>The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).</p>
comment	<p>333 comment by: <i>ATCEUC - Air Traffic Controllers European Unions Coordination</i></p> <p>Question 1: ATCEUC considers that a transition period of 2 years is enough. A 2 year transition period gives enough time to the ANSPs to comply with the new proposed</p>



response	<p>requirements and for the CAs to ensure that procedures for the oversight of changes to the FS comply with the new proposed requirements.</p> <p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency.</p>
comment	<p>361 comment by: <i>Finavia</i></p> <p>Two-year transition period should start at the earliest from the time when GM are available. This would ensure proper implementation.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency.</p>
comment	<p>370 comment by: <i>Finavia</i></p> <p>Referring to question 2 - if Regulation 482/2008 will be repealed it would be important then to include detailed information for requirements (e.g. SWAL-levels) in this documentation - as GM and/or AMC.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency.</p> <p>The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).</p>
comment	<p>372 comment by: <i>Air Navigation Services of the Czech Republic</i></p> <p>Question 1: It is not clear whether the transition period refers to the combined rule (2013-08 and 2014-13). We would support two-year transition period for the finished combined rule (incl. AMC).</p>



Question 2:

Yes, the actions ANSPs are currently performing to satisfy EU REG 482/2008 will continue to satisfy this NPA. We propose to move 482/2008 to AMC and GM.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency. In addition, please see the response to comment No 20 for additional clarifications.

comment

375

comment by: *skyguide Corporate Regulation Management*

requirement applies to all the *constituent* parts of the equipment.

NPA should improve the terms definition in order to avoid confusion. The word Constituent is used as an element of the functional system, how does this relate to the definition provided in EC552/2004?

2-year transitional period seems too short if new concepts (HAL, PAL) need to be introduced for technical people and third parties, we would suggest 5 years in such a case.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.

The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).

comment

377

comment by: *skyguide Corporate Regulation Management*

We note that CRD 2013-08 has no specific text in Art 8 and 9 regarding Transitional provisions and Repeal other than referring to the Opinion. It is therefore not clear to us which provisions are being referred to in this NPA. Is it the whole of CRD 2013-08 or just the provisions in this NPA? If it is the latter then what are the transitional arrangements for the provisions in the CRD? It is noted that the proposed transitional arrangements of 2 years only applies to existing "service providers" regulated under 1034/2011 and 1035/2011. Does this mean that those service providers (using the CRD 2013-08 definition) who are not regulated by 1034/2011 and 1035/2011 have no transition period?

What will the requirements for any new service provider that seeks certification during the transition period?

As previously stated CRD 2013-08 does not propose repealing 1034/2011 and 1035/2011 as claimed.



As previously commented and in response to Question 1 we do not believe that 2 years is sufficient if Option 3 of Risk-based Review Decision by the Competent Authority and Risk-based review by the Competent Authority is selected and we are in support of Option 2. It is not clear to us if the 2 year delay proposed in the NPA under Entry into force is an additional 2 years after the 2 year transition (4 years in total) of the timescales are to run in parallel.

response

Noted

Please refer to the response to comment No 20.

comment

458

comment by: NAV Portugal E.P.E

Attachment [#6](#)

NAV Portugal's answers to the questions presented in this NPA are addressed in the attached file.

response

Noted

The Agency takes due consideration of the answer to the questions. Please see the Agency's responses to comments related to each item requested to be answered for additional information on the final position taken by the Agency.

comment

460

comment by: NAV Portugal E.P.E

response

Noted

comment

468

comment by: CAA CZ

Question 2: Based on the cross reference table and on the justifications and options analysed in the RIA, the Agency would like to seek the stakeholders' views as to whether this proposal sufficiently covers the requirements in Regulation (EC) No 482/2008, which, therefore, could be repealed. If the answer is negative, please provide a rationale and identify those aspects that, according to your analysis, are not covered.

The level of abstraction offered by the NPA sufficiently enables to include SW and associated requirements previously covered by the 482/2008 into the proposed regulation. However the abstraction at the end may go against standardization as it may gradually become unclear what was the ultimate goal described by 482/2008. We suggest to put the provisions of current 482/2008 into AMC/GM.

response

Noted



The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.

The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).

comment 498

comment by: *skyguide Corporate Regulation Management***Question 1:**

We seek clarification on the scope of the material falling under the transition period. Is it all of the material in the combined Rule, of just the ones referenced in NPA 2014-13?

We also seek clarity on the regulations applicable to new ATS providers entering the market. Will they be able to apply the new rules immediately given the transition arrangements?

We seek clarification on the definition of terms in order to avoid confusion. The word Constituent is used as an element of the functional system, how does this relate to the definition provided in EC552/2004?

skyguide answer: Two years up to five years after EASA finishes the completed combined rule; 2-year transitional period seems too short if new concepts (HAL, PAL) need to be introduced for technical people and third parties.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency.

The transition period is applicable to the whole proposed regulation (see the response to comment No 20 for additional clarifications). The question about new ATS providers is not well understood. The transition period is applicable to all providers as from the adoption of the Regulation.

The term 'constituent' of Regulation (EC) No 552/2004 refers to equipment in this proposal.

comment 517

comment by: *Federal Office of Civil Aviation FOCA*

FOCA agrees that a transition period will be required. Due to remaining open points related to this NPA it is, at this stage, not possible to evaluate if the 2 year transition period is realistic.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's



responses to comments related to the transition period for additional information on the final position taken by the Agency.

comment 518 comment by: *skyguide Corporate Regulation Management*

Question 2:

EC 482/2008 is very detailed and not in balance with some other requirements on changes (human, procedure), however the requirements of 482/2008 are broadly integrated in this NPA. Some ANSPs who have spent a lot of money demonstrating explicit compliance with 482/2008 may wish to keep it, therefore an alternative could be to move 482 into AMC or GM level.

skyguide answer: Yes, the actions ANSPs are currently performing to satisfy EU REG 482/2008 will continue to satisfy this NPA.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.

The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).

comment 527 comment by: *Federal Office of Civil Aviation FOCA*

Question 2: FOCA understands and supports the intent to not prescribe a specific risk assessment process. But in this case the proposed solution may not be detailed enough. Although it implicitly imposes that the criticality of a piece of software is defined. It does not sufficiently define that the output of the risk assessment and mitigation process clearly defines what is required by the software.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.

The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).



comment	<p>559 comment by: <i>Frasie Loredana</i></p> <p>QUESTION 1 We consider that the proposed 2 years transition period should be sufficient.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency.</p>
comment	<p>596 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>Question 1: A 2-year transition period would be enough, if our main comments were be accepted. Otherwise - if we have to change our method - we will need significantly more time. Info: without further information from EASA it was unclear when the two-years period would have started. For justification and arguments we support the CANSO opinion. Reference to high level comment "d"</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency. In addition, please see the response to comment No 20 for additional clarifications.</p>
comment	<p>597 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>Question 2: For DFS it is ok to repeal Regulation (EC) No 482/2008. But in the proposal some changes should be done. Here we support the CANSO arguments: For software: there is no variation in rigor. For the whole functional System: It gives an increase in regulation since the requirements cover the whole functional system (see DFS comment Comment no 722).</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.</p> <p>The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of</p>



the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).

Please see the response to comment No 722.

comment

627

comment by: *CANSO*

2.4.2. Proposed amendments to Article 8 ‘Transitional provision’, Article 9 ‘Repeal’ and Article 10 ‘Entry into force’ in the Cover Regulation

CANSO notes that CRD 2013-08 has no specific text in Art 8 and 9 regarding Transitional provisions and Repeal other than referring to the Opinion. It is therefore not clear to CANSO which provisions are being referred to in this NPA. Is it the whole of CRD 2013-08 or just the provisions in this NPA? If it is the latter then what are the transitional arrangements for the provisions in the CRD? It is noted that the proposed transitional arrangements of 2 years only applies to existing “service providers” regulated under 1034/2011 and 1035/2011. Does this mean that those service providers (using the CRD 2013-08 definition) who are not regulated by 1034/2011 and 1035/2011 have no transition period?

What will the requirements for any new service provider that seeks certification during the transition period?

As previously stated CRD 2013-08 does not propose repealing 1034/2011 and 1035/2011 as claimed.

As previously commented and in response to Question 1 CANSO does not believe that 2 years is sufficient if Option 3 of Risk-based Review Decision by the Competent Authority and Risk-based review by the Competent Authority is selected and CANSO is in support of Option 2.

It is not clear to CANSO if the 2 year delay proposed in the NPA under Entry into force is an additional 2 years after the 2 year transition (4 years in total) of the timescales are to run in parallel.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to the transition period for additional information on the final position taken by the Agency. In addition, please refer to the response to comment No 20.

comment

664

comment by: *Swedavia*

Swedavia agree with the 2-year transition period

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to the transition period for additional information on the



final position taken by the Agency.

comment

667

comment by: CAA Norway

Question 1:

The proposed 2-year transition period for CAs to assure that procedures for the oversight of changes to the functional systems will comply with the new proposed requirements is acceptable. This is assuming that the 2-year transition period starts after the completed combined rule is published.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency.

comment

669

comment by: CAA Norway

Question 2

In general, CAA Norway agrees that the requirements in 482/2008 are broadly integrated in NPA 2014-13. We still think that it would be advisable to keep 482/2008, in particular since NPA 2014-13 do not cover the variation of rigour mandated in 482/2008. The fact that 482/2008 is more detailed also makes it more easy for the ANSP to properly implement the regulation and for the CA to assure a proper software assurance oversight.

We will suggest that the integration of 482/2008 in NPA 2014-13 is postponed.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.

The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).

comment

678

comment by: ROMATSA

It is noted that CRD 2013-08 has no specific text in Art 8 and 9 regarding Transitional provisions and Repeal other than referring to the Opinion. It is therefore not clear which provisions are being referred to in this NPA. Is it the whole of CRD 2013-08 or just the



provisions in this NPA? If it is the latter then what are the transitional arrangements for the provisions in the CRD? It is noted that the proposed transitional arrangements of 2 years only applies to existing “service providers” regulated under 1034/2011 and 1035/2011. Does this mean that those service providers (using the CRD 2013-08 definition) who are not regulated by 1034/2011 and 1035/2011 have no transition period?

What will be the requirements for any new service provider that seeks certification during the transition period?

As previously stated CRD 2013-08 does not propose repealing 1034/2011 and 1035/2011 as claimed.

As previously commented and in response to Question 1 ROMATSA supports CANSO opinion that 2 years is sufficient if Option 3 of Risk-based Review Decision by the Competent Authority and Risk-based review by the Competent Authority (“propose a risk based review rule but delay implementation until sufficient

experience exists to use it”) is selected but yet ROMATSA supports Option 2 (“propose a coherent risk based rule but delay implementation until sufficient experience exists to use it”).

It is not clear if the 2 year delay proposed in the NPA under Entry into force is an additional 2 years after the 2 year transition (4 years in total) or the timescales are to run in parallel.

Answer to Question 1

ROMATSA supports CANSO comment to seek clarification on the scope of the material falling under the transition period. CRD 2013-08 has no specific text in Art 8 and 9 regarding Transitional provisions and Repeal other than referring to the Opinion. It is therefore not clear which provisions are being referred to in this NPA. Is it the whole of CRD 2013-08 or just the provisions in this NPA? If it is the latter then what are the transitional arrangements for the provisions in the CRD? It is noted that the proposed transitional arrangements of 2 years only applies to existing “service providers” regulated under 1034/2011 and 1035/2011. Does this mean that those service providers (using the CRD 2013-08 definition) who are not regulated by 1034/2011 and 1035/2011 have no transition period?

Also a clarification is needed on the regulations applicable to new ATS providers entering the market. Will they be able to apply the new rules immediately given the transition arrangements?

Given the lack of clarity over the EASA transitional arrangements, ROMATSA ideally considers that a two year transition would be appropriate as long as “Requirements for service providers and the safety oversight thereof” is complete thus allowing service providers a complete rule with which to demonstrate compliance after a two year transition. Recognizing that the timescale implied by this approach may not be deemed suitable by EASA then ROMATSA considers, as a minimum, that CRD 2013-08 and NPA 2014-13 should form a single opinion and a single decision and that if Option 2 is adopted as stated above then a two year transition period would be appropriate. If Option 3 is pursued then there need to be an additional period of two years for Risk-based Review Decision by the Competent Authority and Risk-based review by the Competent Authority.

ROMATSA supports CANSO answer for two years after EASA finishes the completed



combined rule (“Requirements for service providers and the safety oversight thereof” and “Safety Assessment of changes to ATM/ANS Functional Systems”).

Answer to Question 2

EC REG 482/2008 is very detailed and not in balance with some other requirements on changes (human, procedure), however the requirements of 482/2008 are broadly integrated in this NPA. Some ANSPs who have spent a lot of money demonstrating explicit compliance with 482/2008 may wish to keep it, therefore an alternative could be to transpose 482 into AMC or GM level. However, it is not clear if the EASA transposition of 482/2008 allows for alternative approach in cases where, for example, some of the requirements cannot be applied to changes to specific types of software such as COTS (as provided in 482/2008 Article 5.1).

However this question solely relates to the repeal of 482/2008 and does not consider the broader issues that arise from this decision that are not reflected in the RIA. For instance, EASA proposals in this regard effectively extend the scope of the 482/2008 to all elements of the functional system and to all service providers. This has not been considered in the RIA. If this is the case then EASA should complete the RIA as this aspect is thought to have significant implications for all service providers.

response

Noted

The Agency takes due consideration of the answer to the questions.

Please see the Agency’s responses to comments related to the transition period for additional information on the final position taken by the Agency. In addition, please refer to the response to comment No 20 for additional clarifications.

Please see Agency’s responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.

The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).

The RIA has been updated to cover all the issues mentioned and included in the EN to the Opinion.

comment

702

comment by: *bmvit/CAA/NSA*

add question 1:

The changes resulting from the new regulation will impact several parties/stakeholder.

Additionally the transition period will depend on the implementation time frame of CRD 2013-08.

A minimum of 2 years should be taken into account for the transition period.



response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to the transition period for additional information on the final position taken by the Agency.

comment

791 comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Explanatory Note Section 2.4.2 <i>Proposed amendments to Article 8 ‘Transitional provision’, Article 9 ‘Repeal’ and Article 10 ‘Entry into force’ in the Cover Regulation</i>	Question 1: The Agency would like to know the stakeholders’ views about the proposed 2-year transition period. If it is not considered sufficient, please provide a justification.	A 2-year transition period is seen as reasonable, taking into account all the experience already gathered in the years of implementation of regulations (EC) No 2096/2005, (EC) No 1315/2007, (EU) No 1034/2011 and (EU) No 1035/2011.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to the transition period for additional information on the final position taken by the Agency.

comment

793 comment by: AESA / DSANA

Attachment [#7](#)

PART	COMMENT	JUSTIFICATION
Explanatory Note Section 2.4.2 <i>Proposed amendments to Article 8 ‘Transitional provision’, Article 9 ‘Repeal’ and Article 10 ‘Entry into force’ in the Cover Regulation</i>	Question 2: Based on the cross reference table and on the justifications and options analysed in the RIA, the Agency would like to seek the stakeholders’ views as to whether this proposal sufficiently covers the requirements in Regulation (EC) No 482/2008, which, therefore, could be repealed. If the answer is negative, please provide a rationale and identify those	This question is answered in a separate document, which we hereby attach.



	aspects that, according to your analysis, are not covered.	
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.</p> <p>The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).</p>	
comment	847	comment by: <i>Naviair</i>
	<p>It is not clear which provisions are being referred to in this NPA. Is it the whole of CRD 2013-08 or just the provisions in this NPA? If it is the latter then what are the transitional arrangements for the provisions in the CRD? It is noted that the proposed transitional arrangements of 2 years only applies to existing "service providers" regulated under 1034/2011 and 1035/2011.</p> <p>Question 1: We do not believe that 2 years is sufficient if Option 3 of Risk-based Review Decision by the Competent Authority and Risk-based review by the Competent Authority is selected. We need to know from when the 2 years period starts.</p> <p>Question 2: It is not clear to us how this is going to work. But we do not believe that it will enhance safety. Today we have a clear method for Risk Assessment of changes to our system when the change is in software and when the change is not in software.</p>	
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the questions.</p> <p>Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency. In addition, please refer to the response to comment No 20 for additional clarifications. It should be noted that the risk-based decision has been removed from this proposal.</p> <p>Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.</p> <p>The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).</p>	



comment	<p data-bbox="360 277 424 309">1012</p> <p data-bbox="1246 277 1485 309" style="text-align: right;">comment by: <i>DSNA</i></p> <p data-bbox="360 367 507 398"><u>Question 1:</u></p> <p data-bbox="360 409 1485 723">For DSNA this period is not sufficient, as our ANSP has started two major programs for renewal of its ACC systems whose deployment is to begin in 2016 for the first center, and APP and tower systems the deployment of which is programmed late 2018 at best. By the way, due to call for tenders procedures, the safety cases are in advanced stages (FHA and PSSA) using current SES regulations and derived DSNA procedures : for ACC systems, safety requirements are already agreed through contract with the systems supplier (THALES), for APP and TWR systems they will be set beginning of 2015 as call for tender procedures will start.</p> <p data-bbox="360 734 871 766">In addition, given also the time needed to:</p> <ol data-bbox="360 777 1262 891" style="list-style-type: none"> 1) Elaborate the new procedures and methodologies for safety assessment 2) Coordinate with our CA for approval such procedures, 3) train our staff on it, <p data-bbox="360 902 1485 969">DSNA proposes a transition period of three years after that EASA has finish to complete the AMC and GM.</p>
response	<p data-bbox="360 1003 440 1034">Noted</p> <p data-bbox="360 1070 1485 1227">The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency. Kindly note that changes that are in progress should be dealt with taking into account the current Regulations (EU) Nos 1034/2011 and 1035/2011.</p>
comment	<p data-bbox="360 1323 424 1355">1013</p> <p data-bbox="1246 1323 1485 1355" style="text-align: right;">comment by: <i>DSNA</i></p> <p data-bbox="360 1413 507 1444"><u>Question 2:</u></p> <p data-bbox="360 1456 1485 1608">DSNA agrees that the Regulation (EC) No 482/2008 may be repealed because there is no use to over-regulate about software safety. In the other hand, the provisions establishing a Software Safety Assurance System (SSAS) shall be transposed on GM because many ANSPs are already implementing such provisions for dealing with change affecting software.</p>
response	<p data-bbox="360 1646 440 1677">Noted</p> <p data-bbox="360 1713 1485 1825">The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.</p> <p data-bbox="360 1848 1485 2004">The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).</p>



comment	<p data-bbox="363 271 427 309">1051</p> <p data-bbox="1018 271 1498 309" style="text-align: right;">comment by: DGAC/DSAC - french NSA</p> <p data-bbox="363 360 635 398"><u>Answer to question 1 :</u></p> <p data-bbox="363 443 1498 517">If major comments made by french NSA are taken into account, the 2 year transition period should be ok.</p> <p data-bbox="363 562 635 600"><u>Answer to question 2 :</u></p> <p data-bbox="363 645 1498 965">It seems that all elements of Regulation (EC) N°482/2008 are covered by this new NPA. Nevertheless, we have found some formulations not very clear : for instance, GM3 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional - d. It would deserve to be more explicite. We also have some questions about the extension to all parts of the functional system. The proposed approach seems to be very theoretical and trying to apply the elements of Regulation (EC) N°482/2008 to all parts of the functional system could probably not be so easy. We think that some explicite guidance materials should be necessary to explain what is expected for the other parts of the functional system.</p>
response	<p data-bbox="363 987 587 1025">Question 1: Noted</p> <p data-bbox="363 1055 587 1093">Question 2: Noted</p> <p data-bbox="363 1122 1498 1249">The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the provision on coordination arrangements for additional information on the final position taken by the Agency.</p> <p data-bbox="363 1279 1498 1435">The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).</p>
comment	<p data-bbox="363 1480 427 1518">1072</p> <p data-bbox="1257 1480 1498 1518" style="text-align: right;">comment by: LVNL</p> <p data-bbox="363 1615 1498 1861"><i>Response to Question 1: Agreement with the implementation Period. However in the case of changes involving multiple ANSPs (e.g. within FABs) difficulties may arise in case some ANSPs/countries have already implemented the new regulation, where others may have not. Which rules will apply then? For some countries a 2 year implementation period for a subject as difficult and complex as this one, may be too short.</i></p>
response	<p data-bbox="363 1883 443 1921">Noted</p> <p data-bbox="363 1951 1498 2024">The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the</p>



final position taken by the Agency. The implementation period should be the same for all countries.

comment

1073

comment by: LVNL

Response to question 2: Agreement with option 2 and so delete IR 482/2008, where the essence of the requirement is transposed by this NPA. However deletion of IR 482/2008 does not imply requirements for software evaporate all together. We advise to communicate that requirements for software safety assurance are still applicable.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.

The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).

comment

1077

comment by: bmvit/CAA/NSA

ad question 2:

Currently all ANSPs are compliant with EU regulation 482/2008 requirements and the repeal would lead to a relaxation of these requirements. This might have a negative impact to the safety of the service.

Additionally the requirements should be applied to "people, procedures and equipment" which will increase the work for ANSPs and NSAs significantly.

We recommend to retain the EC 482/2008 or to put the provisions of the current EC 482/2008 into AMC/GM.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.

The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).



comment	<p>1084 comment by: <i>Icetra</i></p> <p>Question 1:</p> <p>A 2 year transition period is considered to be sufficient.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency.</p>
comment	<p>1090 comment by: <i>Belgocontrol</i></p> <p>CRD 2013-08 has no specific text in Articles 8 and 9 regarding Transitional Provisions and Repeal. This raises the following questions/views:</p> <ul style="list-style-type: none"> • Which are the provisions applicable? <p>There is a change in scope of the IR i.e. from 'ATM/ANS service providers' to 'service providers'. However several types of service providers (as per definition of CRD 2013-08) are not currently regulated under EU 1034/2011 and EU 1035/2011. The proposal in 2.4.2 is for 2 years, but only for existing service providers regulated under EU 1034/2011 and EU 1035/2011. This implies that service providers as per CRD 2013-08 definition have therefore no transition period.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency. For instance, please see the response to comment No 20.</p>
comment	<p>1092 comment by: <i>Belgocontrol</i></p> <div style="border: 1px solid black; padding: 5px; margin-top: 10px;"> <p>Page 18 2.4.2 Question 1</p> <p>The effort to become compliant to a new regulation does not only depend on the internal arrangements of the service provider, but also on the coordination and approval processes by the NSA, national regulation being adjusted, harmonisation within the FAB, and coordination of procedures with other providers and aviation undertakings.</p> <p>It is also not clear if the transition period refers only to the requirements proposed in this NPA or of NPA 2013-08 or both.</p> </div>



Recommend a transition period of at least two years after the completed combined rule is published.

Page 19 Question 2

This NPA does not cover the variation of rigor of EC 482/2008. Current ANSPs are all compliant with the EC 482/2008 requirements and the repeal of this regulation may lead to a relaxation of requirements which might negatively impact the safety of the service. The extension of the scope of requirements to cover the whole functional system and also the DAT and Airspace design service is welcomed. However, no AMCs or GM is proposed on this subject although one finds reference to various assurance levels in the proposed text without referring to appropriate standards, specifications or methodology.

Recommend

1. Retain EC 482/2008.
2. Before proceeding further with the extension of the scope of requirements: refer to appropriate standards, specifications or methodology as otherwise this would be an infeasible requirement.

response Noted

Question 1: The Agency takes due consideration of the answer to question Q1. Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency. The assumption is correct and the transition period is for both.

Question 2: The Agency takes due consideration of the answer to question Q2 Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.

The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).

It should be noted that the extension to Airspace Design is to be confirmed, as it is currently not included in the definition of service provider.

comment 1137

comment by: DSAE

Question 1 : The Agency would like to know the stakeholders' views about the proposed 2-year transition period. If it is not considered sufficient, please provide a justification.

DSAE/DIRCAM's answer : The French military CA will not necessarily need a 2-year period to ensure that procedures for the oversight of changes to the functional systems comply with the new proposed requirements.



response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency.

comment

1138

comment by: DSAE

Question 2 : Based on the cross reference table and on the justifications and options analysed in the RIA, the Agency would like to seek the stakeholders' views as to whether this proposal sufficiently covers the requirements in Regulation (EC) No 482/2008, which, therefore, could be repealed. If the answer is negative, please provide a rationale and identify those aspects that, according to your analysis, are not covered.

DIRCAM's answer : All objectives and requirements defined in Regulation (EC) 482/2008 have been transposed and/or reworded within this NPA. 3 remarks :

- Assurance levels are no more mandatory to assess the quality of service of software. However, in case of reuse of some assurance levels, will they be provided in any GM or AMC ? Furthermore, there is no common standard approved by European software experts. Will some standard recognized as the one to comply for software objectives and requirements ?
- On page 226, it is said that all severities of the effect of every hazard is class 1, because this is the most probable outcome under worst-case conditions. We don't agree with this statement. ANSPs usually consider the risk with the worst-credible-case approach. Accidents don't occur every day on our platforms and for this reason severity class 1 is not always picked by ANSPs when performing safety assessments.
- Still on page 226, two new terms appear in this NPA : event and fact. "The table is very good for classifying an event after the fact, but it is not suited for risk analysis before the fact". What does it mean ? Do you want to link the event with the effect ? Is it the same ? Does the fact mean hazard ? These terms have to be defined anyway not to get confused.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.

The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).

Guidance on page 226 assumes not the worst-credible-case approach, but only the worst case possible, thus, accident is the only one of interest (i.e. if the only possible consequence of a hazard is an incident, then no interest to study it because it will never end up in accident and harm).



'After' or 'before' the fact means 'knowing the outcome of a hazard' or 'making a prediction'. Please see GM1 ATS.OR.205(b)(3) for a full explanation.

comment

1207

comment by: CAA-NL

Question 1: The Agency would like to know the stakeholders' views about the proposed 2-year transition period. If it is not considered sufficient, please provide a justification.

Agreement with the implementation Period. However in the case of changes involving multiple ANSPs (e.g. within FABs) difficulties may arise in case some ANSPs/countries have already implemented the new regulation, where others may have not. Which rules will apply then?

For some countries a 2 year implementation period for a subject as difficult and complex as this one, may be too short.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency. The implementation period should be the same for all countries.

comment

1208

comment by: CAA-NL

Question 2: Based on the cross reference table and on the justifications and options analysed in the RIA, the Agency would like to seek the stakeholders' views as to whether this proposal sufficiently covers the requirements in Regulation (EC) No 482/2008, which, therefore, could be repealed. If the answer is negative, please provide a rationale and identify those aspects that, according to your analysis, are not covered.

Agreement with option 2 and so delete IR 482/2008, where the essence of the requirement is transposed by this NPA.

However deletion of IR 482/2008 does not imply requirements for software evaporate all together. We advise to communicate that requirements for software safety assurance are still applicable. We suggest to amend AMC 20-115 to include software considerations for ground based equipment.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.



The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).

comment 1250

comment by: *Finnish Transport Safety Agency*

Transition period should be longer than 2 years. The whole regulation should be ready for implementation at same time, also including the risk based review. Before the implementation all guidelines should be ready, some guidelines for software safety assurance and review should be included. Software is the main element in ATM-systems. There should be 2 year period for finishing guidelines and regulation and after the implementation there should be in addition 2-year delay before of entry into force of the regulation. During the time of 2 year time before entry in force the guidelines could be improved.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency.

Please note that the risk-based review provisions have been deleted.

comment 1251

comment by: *Finnish Transport Safety Agency*

This proposal does not sufficiently cover the requirements in Regulation (EC) No 482/2008, there is no requirements for software safety assurance system. Before the implementation there should be guidelines for software safety assurance and review included. Software is the main element in ATM-systems so there should be special concern for keeping the software safety at least at current level.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.

The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).



comment

1252

comment by: ENAV

Question 1: The Agency would like to know the stakeholders' views about the proposed 2-year transition period. If it is not considered sufficient, please provide a justification.

ENAV seeks clarification on the scope of the material falling under the transition period. Is it all of the material in the combined Rule, of just the ones referenced in NPA 2014-13?

ENAV also seeks clarity on the regulations applicable to new ATS providers entering the market. Will they be able to apply the new rules immediately given the transition arrangements?

ENAV Answer: Two years after EASA finishes the completed combined rule, however since many parties are involved in these changes, this will be very challenging. The work will not only be dependent on the ANSP's internal work, but also be dependent on coordination and approval processes by the NSA, national regulation being adjusted, harmonisation work performed within the FAB, and coordination of procedures with other providers and aviation undertakings performed.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency.

Newcomers should apply the provisions being granted with the same transition period given to others.

comment

1253

comment by: ENAV

Question 2: Based on the cross reference table and on the justifications and options analysed in the RIA, the Agency would like to seek the stakeholders' views as to whether this proposal sufficiently covers the requirements in Regulation (EC) No 482/2008, which, therefore, could be repealed. If the answer is negative, please provide a rationale and identify those aspects that, according to your analysis, are not covered.

EC 482/2008 is very detailed and not in balance with some other requirements on changes (human, procedure), however the requirements of 482/2008 are broadly integrated in this NPA. Some ANSPs who have spent a lot of money demonstrating explicit compliance with 482/2008 may wish to keep it, therefore an alternative could be to move 482 into AMC or GM level.

ENAV Answer: This proposal does not cover the variation of rigour proposed in regulation 482/2008. All demonstration of the safety of a change is done in the safety argument, and there is no requirement on a variation of rigour for this demonstration.



	<p>ENAV believes that Option 2 will give an increase in regulation, since the requirements cover the whole functional system, not only software (i.e. HAL, DAL, HEAL and PAL). We also note that the requirements on assurance levels are extended to also include the services DAT and Airspace design, which is not the case in (EU) 482/2008. Requirements regarding AIS may also be in conflict with (EU) 73/2011.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.</p> <p>The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).</p> <p>Please note ASD is not included in the definition of service provider yet, and needs to be confirmed.</p>
comment	<p>1261 comment by: <i>CANSO</i></p> <p>Question 1: The Agency would like to know the stakeholders' views about the proposed 2-year transition period. If it is not considered sufficient, please provide a justification.</p> <p>CANSO seeks clarification on the scope of the material falling under the transition period. Is it all of the material in the combined Rule, of just the ones referenced in NPA 2014-13? CANSO also seeks clarity on the regulations applicable to new ATS providers entering the market. Will they be able to apply the new rules immediately given the transition arrangements?</p> <p>CANSO Answer: Two years after EASA finishes the completed combined rule, however since many parties are involved in these changes, this will be very challenging. The work will not only be dependent on the ANSP's internal work, but also be dependent on coordination and approval processes by the NSA, national regulation being adjusted, harmonisation work performed within the FAB, and coordination of procedures with other providers and aviation undertakings performed.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the transition period for additional information on the final position taken by the Agency.</p>



comment	1262	comment by: <i>CANSO</i>
	<p>Question 2: Based on the cross reference table and on the justifications and options analysed in the RIA, the Agency would like to seek the stakeholders' views as to whether this proposal sufficiently covers the requirements in Regulation (EC) No 482/2008, which, therefore, could be repealed. If the answer is negative, please provide a rationale and identify those aspects that, according to your analysis, are not covered.</p> <p>EC 482/2008 is very detailed and not in balance with some other requirements on changes (human, procedure), however the requirements of 482/2008 are broadly integrated in this NPA. Some ANSPs who have spent a lot of money demonstrating explicit compliance with 482/2008 may wish to keep it, therefore an alternative could be to move 482 into AMC or GM level.</p> <p>CANSO Answer: This proposal does not cover the variation of rigour proposed in regulation 482/2008. All demonstration of the safety of a change is done in the safety argument, and there is no requirement on a variation of rigour for this demonstration.</p> <p>CANSO believe that Option 2 will give an increase in regulation, since the requirements cover the whole functional system, not only software (i.e. HAL, DAL, HEAL and PAL). We also note that the requirements on assurance levels are extended to also include the services DAT and Airspace design, which is not the case in (EU) 482/2008. Requirements regarding AIS may also be in conflict with (EU) 73/2011.</p>	
response	Noted	
	<p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.</p> <p>The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).</p>	
comment	1269	comment by: <i>European Transport Workers Federation - ETF</i>
	ETF agrees on the proposed 2-year transition period	
response	Noted	

2. Explanatory Note — 2.4. Overview of the proposed amendments — 2.4.3. Proposed amendments to Annex II 'REQUIREMENTS FOR COMPETENT AUTHORITIES IN ATM/ANS AND OTHER NETWORK FUNCTIONS (Part-ATM/ANS.AR)' p. 19-23



comment

21

comment by: NATS National Air Traffic Services Limited

2.4.3. Proposed amendments to Annex II 'REQUIREMENTS FOR COMPETENT AUTHORITIES IN ATM/ANS AND OTHER NETWORK FUNCTIONS (Part- ATM/ANS.AR)' (Page 19)

NATS notes that EASA has used the incorrect title for Annex II of CRD 2013-08 and that the use of ATM/ANS is not appropriate.

As previously commented and in response to Question 1 NATS does not believe that 2 years is sufficient if Option 3 of Risk-based Review Decision by the Competent Authority and Risk-based review by the Competent Authority is selected and NATS is in support of Option 2.

It is not clear to NATS if the 2 year delay proposed in the NPA under Entry into force is an additional 2 years after the 2 year transition (4 years in total) or the timescales are to run in parallel.

With regard to ATM/ANS.AR.C.035 the reader's attention is drawn to the proposal that the decision to review is "risk based" and in 2.4.1 the definition of risk is reiterated from CRD 2013-08. Presumably this means that the risk based decision to review is based upon harmful effects and that the severity and overall probability (or frequency or likelihood) of the assurance case being unsound and the severity of the possible consequences of the change is synonymous with the severity and overall probability of harmful effects. If this is the case it is confusing. If this is not the case then there are two definitions (one explicit, one implied) being used for risk which is not helpful?

NATS supports the notion of risk based oversight and as such the proposed move away from the CA having to review changes that have severity class 1 and 2 (severity based and not risk based) is welcomed. However the EASA proposal for "risk based" is not the same risk, (albeit inferred by the use of severity class rather than actual risk), as is currently used in 1034/2011. That is, 1034/2011 considers risk in the same sense as the risk definition (albeit the severity class alone) whereas the "risk based" proposed by EASA is to a different outcome. NATS considers that it would be more appropriate if the decision to review the notified change were in terms of actual risk as defined in CRD 2013-08. The proposed "assurance case being unsound" does not necessarily mean that the change is unsafe rather that it has been not been adequately documented. Similarly "the severity of the possible consequences of the change" would suggest that worst case should be assumed (use of "possible" – anything is possible).

It is difficult to envisage how the notification data prescribed in AMC2 ATM/ANS.A.045(a) and the change description data prescribed in GM1 ATM/ANS.OR.045(a) would be sufficient to facilitate the CA to decide to review the notified change given the proposed "risk-based" criteria for the decision to review. None of the notified data relates to the adequacy of the assurance case per se (could try and infer from the purpose and reason for the change) nor severity of the possible consequences of the change. It would be more realistic if the safety criteria to be used by the service provider were a part of the risk-based decision as it relates



response	<p>to the service providers perception of the actual risk. It is acknowledged that this may not be available sufficiently early to satisfy the notification process but it should be a consideration</p> <p>Partially accepted</p> <p>The use of 'ATM/ANS' seems appropriate to match the definition of service providers as long as it is completed with 'other network functions'.</p> <p>With regard to the options, the Agency has withdrawn the proposal for risk-based review as it is considered immature at this stage, but keeps the risk-based selection. Because there is already GM provided, the provision for the selection seems feasible in the 2 years' time frame.</p> <p>The risk used, as the commentator points out, is different from the actual risk because that risk is unknown at the time of the decision. The risk should consider the elements of the change and the elements of the change in relation to the service provider carrying out the change.</p> <p>The last paragraph is not completely understood. It is true that the information included in the AMC may be not enough, but together with the information included in the GM (and also considering that the CA is able to request additional information) there should be enough information for the CA to make that decision. In particular, please see item (8) of GM1 ATM/ANS.OR.045(a) related to the consequences of the change result of a preliminary safety assessment coming from the service provider (as explained in point (f) of said GM). Therefore, the CA takes the provider's perception of the actual risk into account (although it is recognised that is not the only element).</p>
comment	<p>122 comment by: ENAIRE</p> <p>Answer to Question 3: We believe this is a decision for the CA. However we believe it will be very difficult to answer as the criteria for an unsound argument are very subjective. Complexity, criticality or an unfamiliar form of argument are better criteria to decide whether or not a decision to review the change by the CA should be taken. Moreover, we consider important to mention that decision based on foreseen severities implies later notification.</p> <p>It seems more subjective the criteria to decide the risk-based review than the one used before. What does "the likelihood of the arguments being unsound" really mean? How can it be measured? The weaknesses of the arguments are based on the accuracy of the facts.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.</p>



Kindly note that the information, based on which the decision is made, may not be provided at the time of notification — see ATM/ANS.AR.C.035(a). The CA will pursue additional information until it has enough to make the decision to review or not.

An agreement on cases that will never be reviewed or will always be reviewed is also identified in (b)(2) and is explained in GM2 ATM/ANS.AR.C.035(b)(1). This is to reduce the administrative burden.

comment 123

comment by: ENAIRE

Answer to Question 4: In principle, we believe is not appropriate to regulate at the moment, but in the future, it should be reviewed once all the actors have more experience. There are different safety culture types among stakeholders for multi-actor changes. Thus, some crucial coordination aspects related to safety should be necessary, such as peer review of the changes implementations with actions plan to put into service together.

response Noted

The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.

comment 189

comment by: EUROCONTROL Safety Team

Page 21 Question 3

This is a decision for the CA however, the proposed criteria for considering an argument as *unsound* are very subjective. At the time of notification of a change, especially if it is a very early notification, there will not be enough information to judge whether the argument could be unsound. Consequently there is the possibility that the CA might reach the wrong conclusion from this scant information. Requests for more information, rejection of the arguments, counter-arguments etc. add more (management) risk to the service provider because there could be more likelihood that an update would be missed and could be source of confusion to all parties. Consequently such an approach requires more resources from both SP and CA to ensure its proper management and results into longer lead times.

EU 1034/2011 §10 already permits the NSA/CA the possibility to review a change based on risk. The current practice allows for the CA to make a decision on criteria it defines (in collaboration with the SPs). It provides the CA with an overview of the changes and allows it to look for more detailed information. This is not because the CA expects that the ANSP will not be able to build a sound safety case but because the CA needs to be involved to be able to review adequately the safety case and finally make a decision on the go/no-go of the implementation of the change. Consequently an “unsound” safety case could be a conclusion



	<p>of the review but not as a criterion for deciding to review.</p> <p>Recommend</p> <ol style="list-style-type: none"> 1. Criteria should include scope, size, complexity, novelty of the change, criticality and safety risk. 2. The information exchanged should include some elements of the safety risk or criticality (for supporting the decision made by the CA to review or not). It will also help the SP to build a safety (support) case commensurate with the safety risk associated to the change.
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.</p> <p>Kindly note that the information, based on which the decision is made, may not be provided at the time of notification — see ATM/ANS.AR.C.035(a). The CA will pursue additional information until it has enough to make the decision to review or not.</p> <p>An agreement on cases that will never be reviewed or will always be reviewed is also identified in (b)(2) and is explained in GM2 ATM/ANS.AR.C.035(b)(1). This is to reduce the administrative burden.</p>
comment	<p>190 comment by: EUROCONTROL Safety Team</p> <p>Page 22 Question 4</p> <p>The proper oversight of multi-actor changes is certainly an important safety matter. The current experience on this topic is very limited and there is not enough knowledge on the matter to be able to say how such coordination arrangements should be regulated. In addition this proposal might conflict with the subsidiarity principle because such arrangements can already be made by the involved member states if considered necessary. Recommend postponing this requirement until there is sufficient knowledge and experience on the matter.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.</p>
comment	<p>249 comment by: UK CAA</p>



	<p>Page No: 21</p> <p>Paragraph No: QUESTION 3</p> <p>Comment: UK CAA supports the concept of a risk based review decision as it is consistent with the philosophy of performance based regulation. We are concerned that during the proposed 2 year transition period, in which there will be no AMC available to advise on how to make the decision, CAs (ourselves included) may select too few sample changes for review.</p> <p>Justification: Clarity</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.</p> <p>Kindly note that the information, based on which the decision is made, may not be provided at the time of notification — see ATM/ANS.AR.C.035(a). The CA will pursue additional information until it has enough to make the decision to review or not.</p> <p>An agreement on cases that will never be reviewed or will always be reviewed is also identified in (b)(2) and is explained in GM2 ATM/ANS.AR.C.035(b)(1). This is to reduce the administrative burden.</p> <p>The 2 years' transition period is proposed as there is already GM upon which the model of the CAs can be built.</p>
comment	<p>252 comment by: UK CAA</p> <p>Page No: 22</p> <p>Paragraph No: QUESTION 4</p> <p>Comment: UK CAA agrees that it would be appropriate to regulate the coordination arrangements between the competent authorities in order to guarantee a proper oversight of multi-actor changes. We suggest that it follows the example given by Commission Implementing Regulation (EU) No 390/2013, Article 5 #2.(b).</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.</p>
comment	<p>281 comment by: Swedish Transport Agency, Civil Aviation Department</p>



		<i>(Transportstyrelsen, Luftfartsavdelningen)</i>
		We propose inadequate instead of unsound, otherwise the expression is ok.
response	Not accepted	This term was used in the past and was also rejected by the Rulemaking Group members. After analysing the comments, the final proposal has been to change to 'likelihood of the argument being complex or unfamiliar to the service provider'. Please see the response to comment No 41.
comment	282	comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i>
		No, no regulation between CAs. This potential situation should be mitigated with agreements between CAs.
response	Noted	The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.
comment	326	comment by: <i>BAF-M.Jancokova</i>
		Question 3: A risk-based decision is supported, but any any case, CAs should always have the freedom to decide to do a review of a change, no matter what rules are generally applied. To make it clear: Even if a rule or matrix, used for decision making, concludes that no review has to be performed, the CA may still individually decide to do so. The notion as introduced here for making the decision is, however, not supported. The review decision should be based on the risk associated with a change. Risk itself is the combination of the overall probability, or frequency of occurrence of a harmful effect induced by a hazard and the severity of that effect. Thus probability and severity of consequences should be the basis for a decision. The notion of the likelihood of an argument being unsound is not understood. In a way it assumes, that CAs do some kind of pre-assessment for every change notified in order to get a feeling for the validity of the arguments presented. But even worse, the formulation puts CAs in a position where they have to assume that arguments presented by an ANSP are not correct/valid. This is not acceptable. General remark as AMC / GM is still missing: Any overly-complicated decision rules for CAs to decide whether to do a review or not should be avoided.



response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.</p> <p>The use of criteria other than risk-based ones is allowed for in ATM/ANS.C.035(b)(2).</p> <p>The risk used for selection is 'the risk posed by a change'. The definition given here is that of safety risk. The argument for not using safety risk is given in GM1 ATM/ANS.AR.C.035(b)(1). The decision rule should not be overly complicated. This is the reason for validating any proposed AMC as described in the Explanatory Note and the RIA.</p>
comment	<p>327 comment by: <i>BAF-M.Jancokova</i></p> <p>Question 4: No need is seen to regulate the coordination arrangements between CAs.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.</p>
comment	<p>328 comment by: <i>BAF-M.Jancokova</i></p> <p>ATM/ANS.AR.C.040 - comment on AR.B.001(d): Where does that text passage come from? It is not found under ATM/ANS.AR.B.001(d)).</p>
response	<p>Noted</p> <p>The Agency would like to apologise, as the reference appears in CRD to NPA 2013-08 and not in NPA 2014-13.</p>
comment	<p>334 comment by: <i>ATCEUC - Air Traffic Controllers European Unions Coordination</i></p> <p>Question 3: we have a different proposal: "... of the likelihood of the argument being unsound the probability of the assurance case to be likely to happen..."</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's</p>



responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.

The response to the question is not well understood.

comment 353 comment by: *ATCEUC - Air Traffic Controllers European Unions Coordination*

Question 4: ATCEUC thinks that there should be general requirements for CAs to coordinate in case no agreement is reached between the two (or more).

There are many situations where the lack of action by CAs has led to changes within ANSPs (even different) affecting the whole system. On the other hand, due to the rearranging situation we are facing in Europe, for instance FABs where both ANSPs and CAs have to coordinate, there is a need to at least provide some guidance material to place requirements on CAs to do their job.

Proper oversight of all changes made by service providers or stemming from agreements between 'undertakings' should be closely monitored. The criteria for coordination should be based on impact analysis on the responsibilities interface. It is an inner part of the tasks to be done in these assessments.

response Noted

The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.

comment 470 comment by: *CAA CZ*

Question 3: The Agency would like to seek the stakeholders' opinion about the expression 'risk-based' review decision, i.e. the risk upon which the decision to review is based, which is proposed to be a combination of the likelihood of the argument being unsound and the severity of the possible consequences of the change. Furthermore, the stakeholders are kindly asked to propose an alternative expression, in case of disagreement, that correctly reflects the intent.

The CAA CZ is of the opinion that risk based decision for review might be adopted by establishing a set of criteria for review. Such criteria, their amendment and exceptions request would be subject to the CA's approval. This way it would be possible to define oversight of changes commensurate to the level of risk they pose since they may be than



	<p>tailored to the national or international (FAB, CBO) specifics and goals. The provisions introduced by the NPA go deep, do not leave method orientated context and may not cover all possible aspects of assessment. The CAA CZ <u>is</u> also able to provide an internal procedure excerpt of the criteria used in oversight of changes (version 2 which is to be implemented by 1 NOV 2014).</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.</p> <p>The commentator seems to be in line with the proposal, but seems not to have noticed the arguments in the Explanatory Note, the RIA and the GM. We would be happy to review the criteria used for the oversight of the changes when addressing the comments to AMC/GM.</p>
comment	<p>471 comment by: CAA CZ</p> <p>Question 4: The Agency would appreciate receiving feedback from stakeholders on the following: would it be appropriate to regulate the coordination arrangements between the competent authorities in order to guarantee a proper oversight of multi-actor changes in addition to the general coordination requirements contained in ATM/ANS.AR.B.001(d), which are included in the resulting text of the CRD to NPA 2013-08? If the answer to the above is positive, what should be the criteria for such coordination? Moreover, how should disagreements between CAs be regulated?</p> <p>Disregarding the fact that current chain of regulation contains elements of inter CAs cooperation, the CAA sees some benefits behind regulation of the coordination arrangements between the competent authorities especially in CBO situations where slightly different strategies of neighbouring FABs may slow down development of appropriate arrangements of neighbouring countries of different FABs. In this sense, it may as well help in coordinated implementation of EU Implementing Rules. All issues related with execution respective arrangements should be in line with concluded state level agreements, be it of FAB or CBO type.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.</p>



comment	<p>522 comment by: <i>skyguide Corporate Regulation Management</i></p> <p>Question 3: We believe this is a decision for the CA. However we believe it will be very difficult to answer as the criteria for an unsound argument are very subjective. Complexity, criticality or an unfamiliar form of argument are better criteria to decide whether or not a decision to review the change by the CA should be taken.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.</p> <p>The final proposal is aligned with this answer.</p>
comment	<p>524 comment by: <i>skyguide Corporate Regulation Management</i></p> <p>Question 4: We believe that this proposal conflicts with subsidiarity principle in that this can be arranged by the involved member states themselves if necessary. FABEC experienced timing problems for multi-actor changes when the competent authorities had no arrangements to guarantee a coordinated review of a change in an coordinated way and in an appropriate timescale. There is a NSAC Manual for FABEC Changes "FABEC Implementation Phase NSAC – Manual Procedure 04 Notification and Review of FABEC Safety Related Changes", perhaps it could be helpful to look at existing procedures when formulating the rule. We believe the reference is probably incorrect. skyguide answer: We recommend not to regulate this at present, but to await sufficient experience, then evaluate need again.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.</p>
comment	<p>539 comment by: <i>Federal Office of Civil Aviation FOCA</i></p> <p>Question 3: FOCA supports the idea that the decision to review should be risk-based. However, FOCA does not support the introduction of the new definition including an</p>



	<p>evaluation of the argument itself. FOCA sees the following problem with this approach:</p> <ul style="list-style-type: none"> - the CA will have to perform an assessment for every change submitted thus generating a significant increase in workload. - Although the proposed approach that GM provides a set of values to support the determination of the likelihood variables, the decision for the review may still not be objective. <p>Therefore, FOCA suggests that the decision for the review should be based on the criticality of the potential risk identified by the ANSP in relation with the change in consideration.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.</p> <p>The decision to review or not should be taken way before the risk has been estimated by the ANSP. It is recognised that the risk-based decision model may not be completely objective, but it seeks and increases objectivity. It is likely to be more objective than the model used at present and it stands a chance of becoming more objective over time.</p> <p>As for the term 'the criticality of the potential risk', elaboration on it is missing, rendering a discussion on its appropriateness not possible.</p>
comment	<p>550 comment by: <i>Federal Office of Civil Aviation FOCA</i></p> <p>Question 4: No. FOCA does not consider the proposal as appropriate. The regulation should reflect that the service providers take the necessary safety measures in order to provide their service in a safe manner. The safe implementation of the change shall remain within the sole responsibility of the service provider, this shall also remain the case for multi-actor changes. The service provider shall ensure appropriate coordination with the other involved provider and verify that the measures are taken to reach the safety criteria set.</p> <p>An additional reason not to proceed with this proposition is that it will only remotely contribute to safety.</p> <p>Therefore, changes affecting cross border should be addressed by the ANSP with the respective NSA concerned.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.</p>



Coordination among service providers is regulated in ATM/ANS.OR.A.45 (e) and (f).

comment

557

comment by: *Frasie Loredana*

QUESTION 3

We support the expression *risk - based review* under the condition that the meaning of the *likelihood of the argument being unsound* is defined.

Justification

Our comment relating to Annex II, ATM/ANS.AR.C.035, b) (1) presents our understanding related to the term the *likelihood of the argument being unsound*.

Question 4

For the moment we do not consider that regulating further the CA arrangements, in addition to those contained in ATM/ANS.AR.B.001.d from CRD of the NPA 2013-08, is necessary.

Justification

In our case the necessary arrangements are in place:

- Coordination with EASA through NCP, with the possibility to coordinate other particular activities depending on the scope, i.e. changes.
- Coordination within the DANUBE FAB context, is already regulated;

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.

The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.

comment

598

comment by: *DFS Deutsche Flugsicherung GmbH*

Question 4:

We do not think that multi-actor changes should be regulated the way it was proposed in this NPA.

But we do think regulation of coordination arrangements between the competent authorities would be helpful here, if sufficient experience - e.g. from FABEC - is evaluated and integrated.

We would like to note that it could be a time problem for multi-actor changes when the



competent authorities have no arrangements to guarantee a coordinated review of a change in a coordinated way and in an appropriate timescale.

There is a NSAC Manual for FABEC Changes “FABEC Implementation Phase NSAC – Manual Procedure 04 Notification and Review of FABEC Safety Related Changes”; perhaps it would be helpful to look at the existing procedures in that manual.

response

Noted

The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.

The response seems to support the approach followed.

comment

665

comment by: *Swedavia*

Swedavia agrees with the dual nature of the risk analysis using likelihood and severity

response

Noted

comment

666

comment by: *Swedavia*

Question 4:

Swedavia agrees with the multilateral proposed solution, the criteria for such changes would be variable depending on the scale and severity, i.e should there be a simple unanimous decision amongst SPs/CAs, or a more reasoned majority vote. To some extent this structure could also apply to resolving disagreements.

response

Noted

The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.

comment

670

comment by: *CAA Norway*

Question 3:



CAA Norway appreciates the idea behind the expression "risk-based" review decision, but we do think the expression is difficult to implement. CAA Norway has encouraged the national ANSPs to notify changes as early as possible. At an early stage, the safety argument will be incomplete and it will be difficult to judge whether the argument is unsound. CAA Norway currently use criteria like scope, size, complexity, novelty, criticality and safety risk and that has worked well for us. It is therefore suggested that the proposed expression is repealed and replaced with an expression that relates to the characteristics of the change itself as well as the safety risk and the criticality and not to the safety argument of the change. .

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.

The final approach takes the elements mentioned into account.

comment 671 comment by: CAA Norway

Question 4:
CAA Norway considers it to be difficult to regulate the coordination arrangements between the competent authorities in order guarantee a proper oversight of multi-actor changes. A regulation of this area could be in conflict with the subsidiarity principles; on the other hand, it could possibly solve possible subsidiarity problems, if expressed properly. CAA Norway has very limited experience on this area at this stage, so it is difficult to come up with a proper advice.

It would be nice if disagreements between CAs could be regulated, but we have no current proposal on how this should be accomplished.

response Noted

The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.

comment 795 comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Explanatory Note Section 2.4.3	Question 3: The Agency would like to seek the stakeholders’ opinion about	We deem that using the term 'risk' for something different to



<p><i>Proposed amendments to Annex II 'REQUIREMENTS FOR COMPETENT AUTHORITIES IN ATM/ANS AND OTHER NETWORK FUNCTIONS (Part-ATM/ANS.AR)'</i></p>	<p>the expression 'risk-based' review decision, i.e. the risk upon which the decision to review is based, which is proposed to be a combination of the likelihood of the argument being unsound and the severity of the possible consequences of the change. Furthermore, the stakeholders are kindly asked to propose an alternative expression, in case of disagreement, that correctly reflects the intent.</p>	<p>what the European ATM community is already used to can lead to confusion and, at the end of the day, put in jeopardy the introduction of the new scheme.</p> <p>Moreover taking into account that this term is also used in risk management to signify a combination of severity and probability.</p> <p>Based on the concept of "decision to review or not review based in the particularities (reliability and worst effects) of the particular change", we would suggest: <u>'review decision based on the soundness of the argument'</u> or <u>'soundness-based review decision'</u>.</p>
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response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.

The term 'risk' is used as the risk we are dealing with is 'the risk posed by the change'. There should be no confusion between this risk and the safety risk that is mentioned later in the proposed regulation; many different types of risk are used all over the world and even in the ATM world (safety risk, economic risk, etc.). However, soundness is not a risk.

comment

797 comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Explanatory Note	Question 4: The Agency would	We deem that the general



<p>Section 2.4.3 <i>Proposed amendments to Annex II 'REQUIREMENTS FOR COMPETENT AUTHORITIES IN ATM/ANS AND OTHER NETWORK FUNCTIONS (Part-ATM/ANS.AR)'</i></p>	<p>appreciate receiving feedback from stakeholders on the following: would it be appropriate to regulate the coordination arrangements between the competent authorities in order to guarantee a proper oversight of multi-actor changes in addition to the general coordination requirements contained in ATM/ANS.AR.B.001(d), which are included in the resulting text of the CRD to NPA 2013-08? If the answer to the above is positive, what should be the criteria for such a coordination? Moreover, how should disagreements between CAs be regulated?</p>	<p>coordination requirements contained in ATM/ANS.AR.B.001(d) should be enough. However, we would welcome GM on this particular coordination.</p>
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response

Noted

The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.

comment

828

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Explanatory Note Section 2.4.3 <i>Proposed amendments to Annex II 'REQUIREMENTS FOR COMPETENT AUTHORITIES IN ATM/ANS AND OTHER NETWORK FUNCTIONS (Part-ATM/ANS.AR)'</i></p>	<p>We support the removal of "new aviation standards" in the new provision ATM/ANS.AR.C.035.</p>	<p>We fully share the rationale stated in the text: "<i>The criteria themselves do not clarify what circumstances would lead to the creation of a new aviation standard and, therefore, its implementation is subjective</i>".</p>



response Noted

comment 849

comment by: *Naviair*

Question 3: We are only providing the NSA with sound arguments. Therefore we do not believe that “risk-based” review decision the way it is described has any meaning. The rules in EU 1034 are better and easier to comply with.
Question 4: No comments.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.

comment 1014

comment by: *DSNA*

Question 3:

DSNA thinks the concept of ' risk-based ' review is not yet mature. A term such as ' unsound ' is unacceptable as too subjective. The decision to follow a change cannot be based on a criterion gravity because it is not available at the time of notification of the change. The decision to follow a change from a CA must be based on the description of the change and it is from the nature of change that criteria such as novelty, complexity, size change can be used by the CA to support the decision to accept or reject a change. So definitely, this process should not be over- regulated and should leave room for debate between CA and ANSPs.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.

Kindly note that it is not about a decision to ‘follow’ a change, but about a decision to review a safety case.

The criteria described are already proposed in the GM section of the NPA, which also describes a way of combining them to come up with a probability number.



comment	<p>1015 comment by: DSNA</p> <p>Question 4: No, would be over-regulation and leave CA to decide the relevance of such or such coordination. Depending on the nature of the change, the impact of the change on an ANSP could be completely different so a coordination between CA would bring delay without improving Safety and would request resources that many actors will not have.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.</p>
comment	<p>1027 comment by: Air Navigation Services of the Czech Republic</p> <p>Question 3: The proposed criteria for considering an argument as <i>unsound</i> are very subjective. At the time of notification of a change, especially if it is a very early notification, there is not enough information to judge whether the argument could be unsound. Consequently there is the possibility that the CA might reach the wrong conclusion from this scant information. See Cmt#363</p> <p>Question 4: We recommend not to regulate this at present, but to await sufficient experience, then evaluate need again. The coordination is agreed among FAB CE member States, yet there is not sufficient experience at the moment. We offer sharing the experience.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.</p> <p>Kindly note that the information, based on which the decision is made, may not be provided at the time of notification — see ATM/ANS.AR.C.035(a). The CA will pursue additional information until it has enough to make the decision to review or not.</p>
comment	<p>1053 comment by: DGAC/DSAC - french NSA</p> <p>Answer to question 3 :</p>



We support the approach of risk based decision as it could improve the efficiency of the competent authority oversight. However, we strongly disagree of that risk based on the likelihood of argument being unsound. The approach proposed by this IR is very theoretical and tries to provide a scientific approach to something that could probably not be modelised. Any tool that will be developed in order to measure such likelihood will surely introduce so much uncertainty that it would be better to use sound engineering judgment. In addition, we strongly fear that the efforts to elaborate and feed such tool at the level of the CA will consume too many resources that should be preferably used in the review of SSA / SA.

We suggest the following requirement : “The competent authority shall determine the need for a review based on specific and documented criteria that shall, as a minimum, include a risk based approach. This does not prevent the use by the competent authority of any other criteria if deemed necessary or adequate”.

Like this, each CA could develop its own approach based on the risk, keeping in mind the risk should be based on probability and severity. But the probability could be appreciated in a more qualitative way.

If enough experience is gained, then the requirements could be modified again.

Answer to question 4 :

No regulation required as so many cases are possible but some guidance on this point will be appreciated.

response

Question 3: Noted

The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.

The word ‘unsound’ has been removed. The aim of the promoted approach is to achieve more objectivity, but the CA may always decide to use a different approach, as long as the criteria are risk-based. Moreover, if one cannot ‘model’ it, how can they come to an objective conclusion? And how does one know that this sound engineering judgement is correct?

Question 4: Noted.

The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.



comment	<p data-bbox="360 237 424 271">1074</p> <p data-bbox="1254 237 1498 271" style="text-align: right;">comment by: LVNL</p> <p data-bbox="360 331 647 365"><i>Response to question 3:</i></p> <p data-bbox="360 371 1498 488"><i>Agreement with the proposal in the NPA, as this allows for focusing on the most important changes. It is proposed to amend the requirements in ATM/ANS.AR.C.035 and ATM/ANS.OR.A.045(a), with the FABEC Initial Safety Impact Assessment (ISIA).</i></p> <p data-bbox="360 495 488 528"><i>Rationale:</i></p> <p data-bbox="360 535 1498 819"><i>More specific criteria to decide whether to review or not are proposed at AMC level as they are required to ensure harmonization of these decisions and a level playing field within Europe. As a result, the rule itself can be slightly more generic. For the proposed criteria, "novelty" and "complexity" are seen as more specific measures for "likelihood" and "consequence of the failure" for the "severity". Furthermore, a link with the Effectiveness of Safety Management is made to allow the CA to differentiate between organizations with different experience levels concerning the safety assessment of changes.</i></p>
response	<p data-bbox="360 831 440 864">Noted</p> <p data-bbox="360 909 1498 1066">The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.</p> <p data-bbox="360 1088 1498 1155">Kindly note that, in the final proposal, 'likelihood of the argument being unsound' has been replaced by 'likelihood of the argument being complex or unfamiliar to the service provider'.</p>
comment	<p data-bbox="360 1223 424 1256">1083</p> <p data-bbox="1126 1223 1498 1256" style="text-align: right;">comment by: bmvit/CAA/NSA</p> <p data-bbox="360 1323 536 1357"><i>ad question 3:</i></p> <p data-bbox="360 1364 1498 1442"><i>The proposed criteria for considering an argument as "unsound" is very subjective and there are not enough information to judge if an argument is "unsound".</i></p> <p data-bbox="360 1449 967 1482"><i>This might end in a wrong conclusion from the CA.</i></p> <p data-bbox="360 1489 1498 1568"><i>We recommend that the criteria should include the size, scope, complexity, criticality and safety risk as well.</i></p>
response	<p data-bbox="360 1581 440 1615">Noted</p> <p data-bbox="360 1659 1498 1816">The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.</p> <p data-bbox="360 1839 1498 1917">Kindly note that, in the final proposal, 'likelihood of the argument being unsound' has been replaced by 'likelihood of the argument being complex or unfamiliar to the service provider'.</p>



comment	<p>1094 comment by: <i>bmvit/CAA/NSA</i></p> <p>ad question 4: Coordination arrangements are already existent at least at FAB level. Any additional regulation may jeopardize existing arrangements. We recommend to delete this requirement or include any "linkage" to existing agreements.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.</p>

comment	<p>1095 comment by: <i>Belgocontrol</i></p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>Page 21 Question 3</p> <p>Although this is a decision for the NSA/CA: the proposed criteria for considering an argument as <i>unsound</i> are very subjective. At the time of notification of a change, especially if it concerns a very early notification, there may not be enough information to judge whether the argument could be unsound. This could lead to the NSA/CA reaching the wrong conclusion. Requests for more information, rejection of the arguments, counter-arguments etc. requires more resources from both service provider and CA.</p> <p>EU 1034/2011 §10 already permits the NSA/CA the possibility to review a change based on risk. The current practice allows the NSA/CA to make a decision on criteria it defines (in collaboration with the service provider). It provides the CA with an overview of the changes and allows it to look for more detailed information. This is not because the CA expects that the ANSP will not be able to build a sound safety case but because the CA needs to be involved to be able to review adequately the safety case and finally make a decision on the go/no-go of the implementation of the change. Consequently an "unsound" safety case could be a conclusion of the review but not a criterion for deciding to review.</p> <p><u>Recommend</u></p> <ol style="list-style-type: none"> 1. Criteria should include scope, size, complexity, novelty of the change, criticality and safety risk. 2. The information exchanged should include some elements of the safety risk or criticality (for supporting the decision made by the NSA/CA to review or not). It will also help the service provider to build a safety (support) case commensurate with the safety risk associated to the change. </div> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>Page 22 Question 4</p> <p>The proper oversight of multi-actor changes is an important safety matter. However, the current experience on this topic is very limited and there is not enough knowledge on the</p> </div>
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matter to be able to say how such coordination arrangements should be regulated.
Recommend postponing this requirement until there is sufficient knowledge and experience on the matter.

response The responses to questions 3 and 4 are noted.

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.

Kindly note that the information, based on which the decision is made, may not be provided at the time of notification — see ATM/ANS.AR.C.035(a). The CA will pursue additional information until it has enough to make the decision to review or not. The data required in paragraph (b)(8) of GM1 ATM/ANS.OR.A.045(a) 'Consequence of the change' includes information related to the preliminary safety assessment by the service providers (linked to criticality).

Finally, kindly note that, in the final proposal, 'likelihood of the argument being unsound' has been replaced by 'likelihood of the argument being complex or unfamiliar to the service provider'.

The Agency takes due consideration of the answer to the question 4. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.

comment 1139

comment by: DSAE

Question 3 : The Agency would like to seek the stakeholders' opinion about the expression 'risk-based' review decision, i.e. the risk upon which the decision to review is based, which is proposed to be a combination of the likelihood of the argument being unsound and the severity of the possible consequences of the change. Furthermore, the stakeholders are kindly asked to propose an alternative expression, in case of disagreement, that correctly reflects the intent.

DIRCAM's answer : DIRCAM agrees on principle. Nevertheless, do we, as CAs, have to assume the weaknesses of part of the ANSPs we oversee ? Here are some ideas for CAs to get an idea of the complexity of a change and aiming at making a decision whether to review the change :

- Novelty of the change : whenever an ANSP wants to perform a change, it is necessary to query about its novelty. Even for a "small" change, the novelty could be an aspect which can be taken into account by CAs to decide to review the change.



	<p>- Feedback. Many changes are steered in a repetitive way. Either on the same platform or under environment conditions slightly different, this type of change may help CAs in their decision to review the change.</p> <p>- Quantity of actors, providers and aviation undertakings involved. Depending on how many people will perform the multi-actor change, CAs will need to review it, for changes involving civilians and militaries as well.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.</p> <p>Kindly note that, in the final proposal, 'likelihood of the argument being unsound' has been replaced by 'likelihood of the argument being complex or unfamiliar to the service provider'.</p> <p>No weakness should be assumed — please see GM1 ATM/ANS.AR.C.035(b)(1). However, faced with certain circumstances, e.g. novelty, complexity, size and span, the service providers are more likely to make (unintended) mistakes.</p>
comment	<p>1140 comment by: DSAE</p> <p>Question 4 : The Agency would appreciate receiving feedback from stakeholders on the following : would it be appropriate to regulate the coordinate arrangements between the competent authorities in order to guarantee a proper oversight of multi-actor changes in addition to the general coordination requirements contained in ATM/ANS.AR.B.001(d), which are included in the resulting text of the CRD to NPA 2013-08 ? If the answer to the above is positive, what should be the criteria for such a coordination ? Moreover, how should disagreements between CAs be regulated ?</p> <p>DIRCAM's answer : As a military CA, DIRCAM doesn't have much interaction with other CAs, thus, the answer to the question would be no, there is no need of specifying coordination arrangements between CAs. In the event of a change involving another CA, coordination arrangements will be discussed and developed case by case.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.</p>
comment	<p>1151 comment by: Ictetra</p>



	<p>Question 3:</p> <p>To use the expression “risk-based review decision” for the process as it is described here is perceived to be counterintuitive since it is not risk, in direct connection to the change, that dictates the level of oversight by the CA but rather how well the ANSP argues his case. The decision of to review or not by the CA, would in fact be based on the thoroughness or the competence of the ANSP rather than the risk of the change.</p> <p>Evidence-based might be a better term since the CA’s decision would be based on evidence submitted in support of the change by the ANSP.</p> <p>Using the term “unsound” and not defining the meaning of that term in the IR itself, only in the GM, is not supported. The continued use of terms such as “valid”, “feasible”, “consistent” that are found in the current regulation is supported.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.</p> <p>Kindly note that, in the final proposal, ‘likelihood of the argument being unsound’ has been replaced by ‘likelihood of the argument being complex or unfamiliar to the service provider’.</p>
comment	<p>1152 comment by: <i>Icetra</i></p> <p>Question 4:</p> <p>We consider the proposed provisions to be sufficient.</p> <p>A provision allowing CAs to seek the assistance of EASA when disagreements are experienced might be of use, AMC provisions might be sufficient</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.</p>
comment	<p>1211 comment by: <i>CAA-NL</i></p> <p>Question 3: The Agency would like to seek the stakeholders’ opinion about the expression ‘risk-based’ review decision, i.e. the risk upon which the decision to review is based, which is proposed to be a combination of the likelihood of the argument being unsound and the severity of the possible consequences of the change. Furthermore, the stakeholders are kindly</p>



asked to propose an alternative expression, in case of disagreement, that correctly reflects the intent.

Agreement with the proposal in the NPA, as this allows for focusing on the most important changes. The Netherlands does support the spirit of the EASA proposal for risk based decision to review a notified change. Nevertheless the Netherlands proposes an amended requirement for ATM/ANS.AR.C.035 and ATM/ANS.OR.A.045(a), in which the FABEC Initial Safety Impact Assessment (ISIA) is incorporated.

Further we propose criteria to decide whether to review or not at AMC level as they are required to ensure harmonization of these decisions and a level playing field within Europe. As a result, the rule itself can be slightly more generic. For the proposed criteria, “novelty” and “complexity” are seen as more specific measures for “likelihood” and “consequence of the failure “for the “severity”. Furthermore, a link with the Effectiveness of Safety Management is made to allow the CA to differentiate between organizations with different experience levels concerning the safety assessment of changes.

See our comments at the relevant paragraphs.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.

Kindly note that the information, based on which the decision is made, may not be provided at the time of notification — see ATM/ANS.AR.C.035(a). The CA will pursue additional information until it has enough to make the decision to review or not. The data required in paragraph (b)(8) of GM1 ATM/ANS.OR.A.045(a) ‘Consequence of the change’ includes information related to the preliminary safety assessment by the service providers (linked to criticality).

Finally, kindly note that, in the final proposal, ‘likelihood of the argument being unsound’ has been replaced by ‘likelihood of the argument being complex or unfamiliar to the service provider’.

comment

1212

comment by: CAA-NL

Question 4: The Agency would appreciate receiving feedback from stakeholders on the following: would it be appropriate to regulate the coordination arrangements between the competent authorities in order to guarantee a proper oversight of multi-actor changes in addition to the general coordination requirements contained in ATM/ANS.AR.B.001(d), which are included in the resulting text of the CRD to NPA 2013-08? If the answer to the above is positive, what should be the criteria for such a coordination? Moreover, how should disagreements between CAs be



regulated?

No, it is not considered necessary to create additional regulation to ensure the coordination, as this is sufficiently arranged through:

- Art 2 of EC (No) 550/2004, as amended by EC (No) 1070/2009
- Art 10 of (EC) No 216/2008, as amended by (EC) No 1108/2009
- NPA 2013-08 ATM/ANS.AR.A.005 Oversight function

Furthermore it depends on the details of the change whether coordination of the review is needed and if a coordination is needed to what extent. This implies that flexibility is needed. Resolution of possible disagreement between CAs is arranged through multinational arrangements that are to be concluded based upon the above requirements.

In case the Agency chooses to insert requirements in the upcoming Regulation, then option 1 is considered most appropriate.

response

Noted

The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.

Flexibility is given to the CAs to establish these arrangements.

comment

1254

comment by: ENAV

Question 3: The Agency would like to seek the stakeholders' opinion about the expression 'risk-based' review decision, i.e. the risk upon which the decision to review is based, which is proposed to be a combination of the likelihood of the argument being unsound and the severity of the possible consequences of the change. Furthermore, the stakeholders are kindly asked to propose an alternative expression, in case of disagreement, that correctly reflects the intent.

ENAV believes this is a decision for the CA. However we believe it will be very difficult to answer as the criteria for an unsound argument are very subjective. Complexity, criticality or an unfamiliar form of argument are better criteria to decide whether or not a decision to review the change by the CA should be taken. In our opinion there will not be enough information at the time of notification of a change to judge whether the argument could be unsound. This "risk" could be better expressed as a list of factors to take into account as indicated in the guidance material, e.g. scope, size, complexity and novelty of the change as well as the safety risk, i.e. likelihood times severity of the consequences.

The NSAs have the possibility to review a change based on risk today, based on (EU) 1034/2011 §10 "When competent authorities determine the need for a review in situations other than those referred to in points (a) and (b)." The risk based review decision will require



response

extensive notification/decision/reply processes, thus requiring a lot of administration and longer lead times. A more fixed review decision criteria would lower the administration for both the ANSP and the NSA. The risk based approach could still be used regarding safety overview, while following up the processes of the ANSP and their implementations.

The response to Question 3 is noted.

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.

Kindly note that the information, based on which the decision is made, may not be provided at the time of notification — see ATM/ANS.AR.C.035(a). The CA will pursue additional information until it has enough to make the decision to review or not. The data required in paragraph (b)(8) of GM1 ATM/ANS.OR.A.045(a) 'Consequence of the change' includes information related to the preliminary safety assessment by the service providers (linked to criticality).

Finally, kindly note that, in the final proposal, 'likelihood of the argument being unsound' has been replaced by 'likelihood of the argument being complex or unfamiliar to the service provider'.

comment

1255

comment by: ENAV

Question 4: The Agency would appreciate receiving feedback from stakeholders on the following: would it be appropriate to regulate the coordination arrangements between the competent authorities in order to guarantee a proper oversight of multi-actor changes in addition to the general coordination requirements contained in ATM/ANS.AR.B.001(d), which are included in the resulting text of the CRD to NPA 2013-08? If the answer to the above is positive, what should be the criteria for such a coordination? Moreover, how should disagreements between CAs be regulated?

ENAV believes that this proposal conflicts with subsidiarity principle in that this can be arranged by the involved member states themselves if necessary.

FABEC have experienced timing problems for multi-actor changes when the competent authorities have no arrangements to guarantee a coordinated review of a change in an coordinated way and in an appropriate timescale. There is a NSAC Manual for FABEC Changes "FABEC Implementation Phase NSAC – Manual Procedure 04 Notification and Review of FABEC Safety Related Changes", perhaps it could be helpful to look at existing procedures when formulating the rule.

We believe the reference is probably incorrect.



	<p>ENAV Answer: We recommend not to regulate this at present, but to await sufficient experience, then evaluate need again.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.</p> <p>The response to the question seems to support the approach followed.</p>
comment	<p>1263 comment by: <i>CANSO</i></p> <p>Question 3: The Agency would like to seek the stakeholders’ opinion about the expression ‘risk-based’ review decision, i.e. the risk upon which the decision to review is based, which is proposed to be a combination of the likelihood of the argument being unsound and the severity of the possible consequences of the change. Furthermore, the stakeholders are kindly asked to propose an alternative expression, in case of disagreement, that correctly reflects the intent.</p> <p>CANSO believe this is a decision for the CA. However we believe it will be very difficult to answer as the criteria for an unsound argument are very subjective. Complexity, criticality or an unfamiliar form of argument are better criteria to decide whether or not a decision to review the change by the CA should be taken. In our opinion there will not be enough information at the time of notification of a change to judge whether the argument could be unsound. This "risk" could be better expressed as a list of factors to take into account as indicated in the guidance material, e.g. scope, size, complexity and novelty of the change as well as the safety risk, i.e. likelihood times severity of the consequences.</p> <p>The NSAs have the possibility to review a change based on risk today, based on (EU) 1034/2011 §10 "When competent authorities determine the need for a review in situations other than those referred to in points (a) and (b)." The risk based review decision will require extensive notification/decision/reply processes, thus requiring a lot of administration and longer lead times. A more fixed review decision criteria would lower the administration for both the ANSP and the NSA. The risk based approach could still be used regarding safety overview, while following up the processes of the ANSP and their implementations.</p>
response	<p>The response to Question 3 is noted.</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.</p> <p>Kindly note that the information, based on which the decision is made, may not be provided</p>



at the time of notification — see ATM/ANS.AR.C.035(a). The CA will pursue additional information until it has enough to make the decision to review or not. The data required in paragraph (b)(8) of GM1 ATM/ANS.OR.A.045(a) ‘Consequence of the change’ includes information related to the preliminary safety assessment by the service providers (linked to criticality).

Finally, kindly note that, in the final proposal, ‘likelihood of the argument being unsound’ has been replaced by ‘likelihood of the argument being complex or unfamiliar to the service provider’.

comment 1264

comment by: CANSO

Question 4: The Agency would appreciate receiving feedback from stakeholders on the following: would it be appropriate to regulate the coordination arrangements between the competent authorities in order to guarantee a proper oversight of multi-actor changes in addition to the general coordination requirements contained in ATM/ANS.AR.B.001(d), which are included in the resulting text of the CRD to NPA 2013-08? If the answer to the above is positive, what should be the criteria for such a coordination? Moreover, how should disagreements between CAs be regulated?

CANSO believe that this proposal conflicts with subsidiarity principle in that this can be arranged by the involved member states themselves if necessary.

FABEC have experienced timing problems for multi-actor changes when the competent authorities have no arrangements to guarantee a coordinated review of a change in an coordinated way and in an appropriate timescale. There is a NSAC Manual for FABEC Changes “FABEC Implementation Phase NSAC – Manual Procedure 04 Notification and Review of FABEC Safety Related Changes”, perhaps it could be helpful to look at existing procedures when formulating the rule.

We believe the reference is probably incorrect.

CANSO Answer: We recommend not to regulate this at present, but to await sufficient experience, then evaluate need again.

response Noted

The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.

comment 1270

comment by: European Transport Workers Federation - ETF

ETF believes that there is a very real risk that an assurance case can be unsound. There are any number of reasons, including political, individual subjectivity, errors, or management



policy which could affect the conduct of the assurance process, and detriment the outcome. It is essential that a provision is included in the final regulation for the CA to review.

ETF agrees with the proposed wording as in the current NPA

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to risk-based selection for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 376, 39 and 41 for clarifications that support that position.

Kindly note that, in the final proposal, 'likelihood of the argument being unsound' has been replaced by 'likelihood of the argument being complex or unfamiliar to the service provider'.

comment 1271

comment by: *European Transport Workers Federation - ETF*

ETF propose to mandate the relevant CAs to draft general requirements which govern the coordination agreements between those CAs. This process should be regulated to ensure proper oversight.

response Noted

The Agency takes due consideration of the answer to the question. The Agency has introduced a generic provision in ATM/ANS.AR.A.005(c). This has been decided after consideration that a generic and high-level requirement to have a process to establish these coordination arrangements, when a multi-actor change requires coordination between CAs would suffice. This provision does not conflict with the subsidiarity principle.

2. Explanatory Note — 2.4. Overview of the proposed amendments — 2.4.4. Proposed amendments to Annex III 'COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part- ATM/ANS.OR)' p. 23-28

comment 22

comment by: *NATS National Air Traffic Services Limited*

Section 2.4.4 (page 24)



ATM/ANS.OR.B.005(a)(5): NATS considers that ATM/ANS.OR.B.005(a)(5) is adequately covered by CRD 2013-08 ATM/ANS.OR.B.005(a)(4).

Proposal:

Delete ATM/ANS.OR.B.005(a)(5) or modify suitably as specific AMC.

response

Partially accepted

There is a certain overlap.(a)(5) is removed, but, in order to keep the scope, (a)(4) has been amended.

comment

23

comment by: *NATS National Air Traffic Services Limited*

Section 2.4.4 (Page 24) - ATM/ANS.OR.B.005(a)(6)

There is a discrepancy between this explanation and the IR itself. The explanation refers to the performance of the service, and in particular the safety performance, whereas the related IR considers changes to the functional system to improve performance. Only ATSP are considered to have a view of safety and, as such, safety performance is only meaningful to ATSP. Whilst all other service providers could seek to improve performance why would they given that their current performance is considered adequate (in meeting a specification or as defined in a contract)? Modifying their performance would not only necessitate a safety assessment or a safety support assessment but could also put them in breach of contract. It is difficult to envisage the circumstances where it would ever be economically feasible to change the functional system even if technically feasible.

response

Accepted

(a)(6) has been removed.

comment

24

comment by: *NATS National Air Traffic Services Limited*

Section 2.4.4 - Page 25 ATM/ANS.OR.B.005(d)

There is a discrepancy between this explanation and the IR itself. The explanation refers to monitor the behavior of the service, whereas the related IR considers monitoring the behavior of the functional system. Monitoring at the level of the service (which would encompass the behavior of the function system) is preferable as measuring at the level of a change to a functional system (as implied by (d)(2)) would be resource intensive for little benefit.



response	<p>Not accepted</p> <p>The monitoring criteria defined as per ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7) need to be actively monitored and followed-up. This will be at the appropriately defined level, either at the level of service or at the level of the functional system (see GM1 ATM/ANS.OR.C005(b)(3) and GM1 ATS.OR.205(b)(7)). Monitoring at the level of the service may in some cases require very long period of times in order to get data, thus, it will be more convenient to monitor properties at the level of subsystems of the functional system.</p> <p>With regard the monitoring criteria, it is worth noting that as changes accumulate, then the monitoring criteria of previous changes are reviewed and where necessary adapted to the new system changed. There will not be accumulation of criteria as the number of changes introduced increases. Several changes that occur during a period of time will most probably not add additional monitoring elements, but they will most likely only update them (only in some cases, additional criteria will be introduced). Consequently, the set of monitoring criteria should be appropriate for the current system no matter how many changes have taken place.</p>
comment	<p>26 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>Section 2.4.4 (page 26) ATM/ANS.OR.B.010</p> <p>ATM/ANS.OR.B.010 is considered to be adequately covered by ATM/ANS.OR.A.040. The change management procedures referenced in this section do not require any special treatment beyond that of any other SMS/MS procedures. That said if they are deemed to be necessary then then should be specific AMC to ATM/ANS.OR.A.040.</p> <p>In 2.4.4 (page 26 ATM/ANS.OR.B.010) it is unclear how a certificate can be issued to a service provider without these procedures being approved as the procedures are the means by which the service provider complies, in part, with the general and specific requirements (as appropriate) as required by ATM/ANS.OR.A.005(b).</p> <p>NATS Proposal: Either delete ATM/ANS.OR.B.010 or make as specific AMC to ATM/ANS.OR.A.040 as proposed in Appendix A.</p>
response	<p>Not accepted</p> <p>The philosophy is that change procedures may be independent of the MS/SMS at certification. They can be submitted at any time prior to their use. The actual intent of the proposed provisions for management of change procedures of functional system is to allow those procedures to be managed independently of the MS/SMS at the time of certification. There are two reasons for this: to ensure their review and approval by the competent authority every time they are changed, and to provide flexibility to service providers to</p>



develop them and receive approval at any time after certification, but always prior to their use. In any case, if the service provider wishes to have them reviewed and approved at the time of certification and as part of the MS/SMS, that is also possible and the provision does not prevent this from happening.

ATM/ANS.OR.A.005(b) refers to the service provider complying with all the common requirements and the applicable Annexes. Because the need for the procedures is only triggered at the time of the first change, at the time of certification the provider could be certified without these procedures being in place and approved.

comment 68 comment by: EUROCONTROL Safety Team

Page 25 The requirement is for the service provider to monitor.....

The EN does not support the IR (ATM/ANS.OR.B.005(d)) because there is a discrepancy between them.

The EN refers to *monitor the behaviour of the service*, but the IR considers *monitoring the behaviour of the functional system*.

response Accepted

The discrepancy is acknowledged. The wording in the proposed rule is the correct one, as it would cover both monitoring at the service level and monitoring at the level of the functional system wherever the monitoring criteria are set as per ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7).

comment 124 comment by: ENAIRE

Answer to Question 5: We agree on the general principle of proactive performance management, which should be part of the management system and the life cycle of the systems in order to identify and evaluate all the change drivers. Proactive performance management proposals are not easily found in this NPA.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has been finally removed from the proposed IR.

comment 125 comment by: ENAIRE



	<p>Answer to Question 6: Disagree. We believe that monitoring effectiveness is already part of the overall SMS requirements listed in CRD 2013-08 and that this should not be part of the NPA that is about risk assessment of changes. We agree that monitoring the performance of the functional system is a good thing, but disagree to monitoring the effectiveness of any individual change as this is likely not always achievable and incurs significant cost. Some system mitigations identified in previous safety assessments studies could be applicable for new changes and not all of those mitigations should be checked each time.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the monitoring of the functional system for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.</p>
comment	<p>191 comment by: EUROCONTROL Safety Team</p> <p>Page 25 Question 5</p> <p>The general principle is welcomed but the proposal seems to be inconsistent with the performance based regulation approach. There are many more factors that influence the decision to improve performance. From the safety point of view change should be done not just because we could but because it is needed.</p> <p>Recommend to delete the proposal made in this NPA for proactive performance management but strive for continuous improvement as foreseen by the Basic Regulation and ICAO SARPs.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has been finally removed from the proposed IR.</p>
comment	<p>192 comment by: EUROCONTROL Safety Team</p> <p>Page 26 Question 6</p> <p>Current regulation and that proposed as part of CRD 2013-08 already include monitoring of effectiveness. Consequently adding another requirement for the monitoring of effectiveness in this NPA seems to be double regulation. The monitoring of the effectiveness of any individual change might be infeasible and also hardly possible.</p> <p>Recommend to delete the proposal made to clarify and close the loop (i.e. check the effectiveness) in relation to the monitoring requirements resulting from the assessment of</p>



response	<p>the changes to functional systems.</p> <p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the monitoring of the functional system for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.</p>
comment	<p>254 comment by: UK CAA</p> <p>Page No: 25 Paragraph No: QUESTION 5 Comment: In principle the UK CAA supports this measure as it is consistent with the concept of performance-based regulation and the 'as low as reasonably practicable' principle practised in the UK.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has been finally removed from the proposed IR.</p>
comment	<p>256 comment by: UK CAA</p> <p>Page No: 26 Paragraph No: QUESTION 6 Comment: The UK CAA supports this measure as it is consistent with the concept of performance-based regulation. However, guidance must be given on what is considered to be reasonable monitoring for changes</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the monitoring of the functional system for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.</p>
comment	<p>283 comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</p>



response	<p>It works today without regulation, thus no regulation required.</p> <p>Noted</p> <p>Not clear what this comment is about.</p>
comment	<p>284 comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i></p> <p>Agree, we consider this necessary in order to comply continuous improvements of the service provided.</p> <p>Propose inadequate instead of unsound.</p>
response	<p>Noted</p> <p>The comment is not well understood. It is assumed it is the answer to question Q6.</p>
comment	<p>329 comment by: <i>BAF-M.Jancokova</i></p> <p>1st paragraph: It is not and cannot be the task of CAs to try to resolve issues amongst stakeholders of multi-actor changes.</p>
response	<p>Noted</p> <p>That is not the intention of the sentence. We agree that this is not the CA's task. There is a suggestion on help to resolve issues in GM, but nothing imposes a requirement on the CAs in this regard.</p>
comment	<p>354 comment by: <i>ATCEUC - Air Traffic Controllers European Unions Coordination</i></p> <p>Question 6: ATCEUC agrees on the need to include monitoring requirements. Monitoring requirements are necessary to guarantee the effectiveness and safety of the implementation process. Some flaws only appear after the changes are fully operational, so it is only natural that the monitoring continues on regular basis. The argument that there will be too many requirements to monitor is in our opinion no excuse, since the monitoring can be developed as a sort of "check-list" easy to manage and easy to apply. Some GM might be helpful, though.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the monitoring of the functional system for additional</p>



information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.

comment	<p>355 comment by: <i>ATCEUC - Air Traffic Controllers European Unions Coordination</i></p> <p>Question 5: ATCEUC thinks that as this is a question about the management and improvement of performance and it is out of the scope of the Agency, that must focus on safety issues, so the whole point ATM/ANS.OR.B.005(a)(6) <i>“a formal process to consider changing their functional system if it is technically and economically feasible to improve performance by doing so”</i> should be deleted from the IR.</p> <p>ATCEUC wonders if this wouldn't increase the ANSPs obligations just to increase performance without really understanding all the interdependencies.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has been finally removed from the proposed IR.</p>
comment	<p>378 comment by: <i>skyguide Corporate Regulation Management</i></p> <p>There is a discrepancy between this explanation and the IR itself. The explanation refers to monitor the behavior of the service, whereas the related IR considers monitoring the behavior of the functional system. Monitoring at the level of the service (which would encompass the behavior of the function system) is preferable as measuring at the level of a change to a functional system (as implied by (d)(2)) would be resource intensive for little benefit.</p>
response	<p>Not accepted</p> <p>The discrepancy is acknowledged. The wording in the proposed rule is the correct one, as it would cover both monitoring at the service level and monitoring at the level of the functional system wherever the monitoring criteria are set as per ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7).</p> <p>The monitoring criteria defined as per ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7) need to be actively monitored and followed-up. This will be at the appropriately defined level, either at the level of service or at the level of the functional system (see GM1 ATM/ANS.OR.C005(b)(3) and GM1 ATS.OR.205(b)(7)). Monitoring at the level of the service may in some cases require very long period of times in order to get data, thus, it will be more convenient to monitor properties at the level of subsystems of the functional</p>



system.

With regard the monitoring criteria, it is worth noting that as changes accumulate, then the monitoring criteria of previous changes are reviewed and where necessary adapted to the new system changed. There will not be accumulation of criteria as the number of changes introduced increases. Several changes that occur during a period of time will most probably not add additional monitoring elements, but they will most likely only update them (only in some cases, additional criteria will be introduced). Consequently, the set of monitoring criteria should be appropriate for the current system no matter how many changes have taken place.

comment

385

comment by: *Air Navigation Services of the Czech Republic*

Question 5:

We agree with the general principles and these are part of all the management systems. We propose not to include it in this IR.

Question 6:

We consider the monitoring as a part of the safety management system, in line with the requirements of 2013-08. We fully support monitoring at the level of the service (functional system level), but do not agree with monitoring at level of individual changes, as this:

- Would need a lot of resources and sometimes might not be even feasible;
- The benefit is considered to be little or doubtful, as a next change would modify the functional system and all the indicators again, so it might not be clear what the indicators for the particular change mean.

response

Noted

The Agency takes due consideration of the answer to the question Q5. Please see the Agency's responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has been finally removed from the proposed IR.

The Agency takes due consideration of the answer to the question Q6. Please see the Agency's responses to comments related to the monitoring of the functional system for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.

With regard the monitoring criteria, it is worth noting that as changes accumulate, then the monitoring criteria of previous changes are reviewed and where necessary adapted to the new system changed. There will not be accumulation of criteria as the number of changes introduced increases. Several changes that occur during a period of time will most probably not add additional monitoring elements, but they will most likely only update them (only in some cases, additional criteria will be introduced). Consequently, the set of monitoring



criteria should be appropriate for the current system no matter how many changes have taken place.

comment 472

comment by: CAA CZ

ATM/ANS.OR.B.005(a)(6)

See answer to the Question 5. The requirement is too formal and too generic especially for the small service providers.

response Noted

See the response to comment No 472.

comment 473

comment by: CAA CZ

Question 5: The Agency would like to know whether the stakeholders agree or disagree with the proposal made in this NPA for proactive performance management and for continuous improvement as foreseen by the Basic Regulation and ICAO SARPs. Please provide the supporting rationale with your answer.

Taking into account both the CA's opinion that the current regulation sufficiently describes the requirements connected with quality and recent discussions on ISO 9001 revision, the CAA CZ expresses its disagreement with the proposal. The requirement is too formal and too generic. As it is difficult to regulate quality (E.g. ADQ) and even harder to develop benchmark system for providers any provision different from generic one might become prescriptive rather than goal based.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has been finally removed from the proposed IR.

comment 475

comment by: CAA CZ

Question 6: The Agency would like to know whether the stakeholders agree or disagree with the proposal made to clarify and close the loop (i.e. check the effectiveness) in relation to the monitoring requirements resulting from the assessment of the changes to functional systems.

Please provide the supporting rationale with your answer.

The CAA CZ supports the option of having closed loop of the change oversight. It has been implemented into the ANSP's change management process required by the CZ CAA already.



	<p>This way the CAA CZ receives full picture of the service provider's SMS, QMS and of overall safety of any change. The CAA CZ understands that it may be difficult for the service providers to monitor ongoing validity of the safety arguments associated with the changes of other than technical nature (E. g. Airspace design).</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the monitoring of the functional system for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.</p>
comment	<p>476 comment by: CAA CZ</p>
	<p>ATS providers will be able to provide a safety argument as the result of the safety assessment.</p> <p>Service providers other than ATS providers shall conduct a safety support assessment.</p> <p>The regulation proposal does not make totally clear whether an ANSP that is at the same time CNS shall provide safety assessment, safety support assessment or both.</p>
response	<p>Noted</p> <p>In this case, the ANSP will provide a safety assessment, but it will include the activities of the safety support assessment embedded as evidence within the safety assessment.</p>
comment	<p>477 comment by: CAA CZ</p>
	<p>All the concepts of the said Regulation ((EC) No 482/2008) are included in various parts of the proposed provisions, but are now applicable to all the parts of functional systems (people, procedures and equipment) rather than to software alone</p> <p>See the answer to the Question 2. The proposal makes the requirements on SW safety too abstract.</p>
response	<p>Noted</p>
comment	<p>529 comment by: skyguide Corporate Regulation Management</p>
	<p>Question 5:</p> <p>We agree on the general principle which should be part of the management system. However this NPA needs an update for proactive performance management.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's</p>



responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has been finally removed from the proposed IR.

comment 532 comment by: *skyguide Corporate Regulation Management*

Question 6:

skyguide believe that monitoring effectiveness is already part of the overall SMS requirements listed in CRD 2013-08 and that this should not be part of the NPA that is about risk assessment of changes. We agree that monitoring the performance of the functional system is a good thing, but disagree to monitoring the effectiveness of any individual change as this is likely not always achievable and incurs significant cost.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the monitoring of the functional system for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.

comment 552 comment by: *Federal Office of Civil Aviation FOCA*

Question 5: FOCA agrees with the proposal made for a proactive safety performance management.

Since the safety assessment of a change and its risk mitigation strategy is based on factual data as well as on assumptions, the regulation should lead the service provider to a continuous safety management process in order to verify if the level of safety defined in the safety assessment is effectively met. It might be helpful to further define in the new regulation the important connection between the occurrence reporting and the safety assessment process. e.g for optimum safety performance management the occurrences should feed into the safety assessment (closed loop). The granularity level of the occurrence monitoring should be at the same level as the granularity level of the safety assessment.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has been finally removed from the proposed IR. It seems that the answer of the commentator is more related to question Q6.



comment	<p>553 comment by: <i>Federal Office of Civil Aviation FOCA</i></p> <p>As stated in the answer to question 5, FOCA supports the improvement made to the regulation in order to actively close the loop.</p>
response	<p>Noted</p> <p>See the response to comment No 552.</p>
comment	<p>561 comment by: <i>Frasie Loredana</i></p> <p>QUESTION 5</p> <p>We consider that the question should identify the Basic Regulation and SARPS provisions that it makes reference to.</p> <p>We do not agree with the proposal for proactive performance management in the context of this NPA.</p> <p>Justification</p> <p>To prevent misinterpretation of the question.</p> <p>The document addresses the safety assessment of changes and therefore the proposal for proactive performance management is exceeding the scope of the document.</p> <p>As presented in the document, the safety performance management is already in place, based on the safety management system - SMS requirements.</p> <p>QUESTION 6</p> <p>We partially agree with the proposal made to clarify and close the loop (i.e. check the effectiveness) in relation to the monitoring requirements resulting from the assessment of the changes to functional systems.</p> <p>We do not support ATM/ANS.OR.B.005 d)(2) and we propose to eliminate it.</p> <p>Justification</p> <p>a) We already require the ATM/ ANS provider to determine the causes for substandard performance, when determined, and to take measures (changes) to eliminate/ mitigate those causes. Please note that the term performance is relative and it depends on the agreed performance that is acceptable and achievable.</p> <p>b) d)(2) In practice, the quality of the argument is demonstrated, after the implementation of the change, by monitoring activities. Based on the monitoring data you can appreciate that some of the arguments are not correct.</p> <p>c) d)(2) From the documentation point of view, this will lead to extra workload that can seriously reduce the ATM/ANSP activity to identify and implement the correct measures.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question Q5. Please see the Agency's responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has</p>



been finally removed from the proposed IR.

The Agency takes due consideration of the answer to the question Q6. Please see the Agency's responses to comments related to the monitoring of the functional system for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.

comment 599

comment by: *DFS Deutsche Flugsicherung GmbH*

There are problems with interpreting ATM/ANS.OR.B.005 (d) with regards to monitoring.

We suggest to distinguish clearly between monitoring of changes and monitoring on service level - and reenter the discussion about monitoring of changes, since that would be resource intensive and the benefit is not all clear yet.

Reference to high level comment "e"

response Not accepted

The monitoring criteria defined as per ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7) need to be actively monitored and followed-up. This will be at the appropriately defined level, either at the level of service or at the level of the functional system (see GM1 ATM/ANS.OR.C005(b)(3) and GM1 ATS.OR.205(b)(7)). Monitoring at the level of the service may in some cases require very long period of times in order to get data, thus, it will be more convenient to monitor properties at the level of subsystems of the functional system.

With regard the monitoring criteria, it is worth noting that as changes accumulate, then the monitoring criteria of previous changes are reviewed and where necessary adapted to the new system changed. There will not be accumulation of criteria as the number of changes introduced increases. Several changes that occur during a period of time will most probably not add additional monitoring elements, but they will most likely only update them (only in some cases, additional criteria will be introduced). Consequently, the set of monitoring criteria should be appropriate for the current system no matter how many changes have taken place.

comment 600

comment by: *DFS Deutsche Flugsicherung GmbH*

Question 5:

DFS agrees on the general principle but this should be only part of the management system. For justification and arguments we support the CANSO opinion.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to continuous improvement of performance for additional



information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has been finally removed from the proposed IR.

comment	<p>601 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>Question 6: DFS agrees to monitoring the performance to the functional System, but disagrees with the monitoring of the effectiveness of all individual changes being regulated. This is not always feasible and creates significant cost. Monitoring is already part of the overall SMS requirements listed in CRD 2013-08. For justification and arguments we support the CANSO opinion.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the monitoring of the functional system for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.</p>
comment	<p>657 comment by: <i>CANSO</i></p> <p>2.4.4 and ATM/ANS.OR.B.005(d)</p> <p>There is a discrepancy between this explanation and the IR itself. The explanation refers to monitor the behavior of the service, whereas the related IR considers monitoring the behavior of the functional system. Monitoring at the level of the service (which would encompass the behavior of the function system) is preferable as measuring at the level of a change to a functional system (as implied by (d)(2)) would be resource intensive for little benefit.</p>
response	<p>Not accepted</p> <p>The discrepancy is acknowledged. The wording in the proposed rule is the correct one, as it would cover both monitoring at the service level and monitoring at the level of the functional system wherever the monitoring criteria are set as per ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7).</p> <p>The monitoring criteria defined as per ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7) need to be actively monitored and followed-up. This will be at the appropriately defined level, either at the level of service or at the level of the functional system (see GM1 ATM/ANS.OR.C005(b)(3) and GM1 ATS.OR.205(b)(7)). Monitoring at the level of the service may in some cases require very long period of times in order to get data, thus, it will be more convenient to monitor properties at the level of subsystems of the functional system.</p>



With regard the monitoring criteria, it is worth noting that as changes accumulate, then the monitoring criteria of previous changes are reviewed and where necessary adapted to the new system changed. There will not be accumulation of criteria as the number of changes introduced increases. Several changes that occur during a period of time will most probably not add additional monitoring elements, but they will most likely only update them (only in some cases, additional criteria will be introduced). Consequently, the set of monitoring criteria should be appropriate for the current system no matter how many changes have taken place.

comment

672

comment by: CAA Norway

Question 5:

CAA Norway supports the proposal made in the NPA 2014-13 for proactive performance management and for continuous improvement.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has been finally removed from the proposed IR.

comment

673

comment by: CAA Norway

Question 6:

CAA Norway agrees with the proposal to complete the monitoring requirements resulting from the assessment of the changes to functional systems.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the monitoring of the functional system for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.

comment

679

comment by: ROMATSA

There is a discrepancy between this explanation and the IR itself. The explanation refers to monitor the behavior of the service, whereas the related IR considers monitoring the behavior of the functional system. Monitoring at the level of the service (which would encompass the behavior of the function system) is preferable as measuring at the level of a change to a functional system (as implied by (d)(2)) would be resource intensive for little



response

benefit.

Supporting comment to summary issue: Explanatory Note – does not support the Implementing Rule

Not accepted

The discrepancy is acknowledged. The wording in the proposed rule is the correct one, as it would cover both monitoring at the service level and monitoring at the level of the functional system wherever the monitoring criteria are set as per ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7).

The monitoring criteria defined as per ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7) need to be actively monitored and followed-up. This will be at the appropriately defined level, either at the level of service or at the level of the functional system (see GM1 ATM/ANS.OR.C.005(b)(3) and GM1 ATS.OR.205(b)(7)). Monitoring at the level of the service may in some cases require very long period of times in order to get data, thus, it will be more convenient to monitor properties at the level of subsystems of the functional system.

With regard the monitoring criteria, it is worth noting that as changes accumulate, then the monitoring criteria of previous changes are reviewed and where necessary adapted to the new system changed. There will not be accumulation of criteria as the number of changes introduced increases. Several changes that occur during a period of time will most probably not add additional monitoring elements, but they will most likely only update them (only in some cases, additional criteria will be introduced). Consequently, the set of monitoring criteria should be appropriate for the current system no matter how many changes have taken place.

comment

799

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Explanatory Note Section 2.4.4 <i>Proposed amendments to Annex III ‘COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR)’</i></p>	<p>Question 5: The Agency would like to know whether the stakeholders agree or disagree with the proposal made in this NPA for proactive performance management and for continuous improvement as foreseen by the Basic Regulation and ICAO SARPs. Please provide the supporting rationale with your</p>	<p>We tend to disagree based on the comments already made to the new provision <i>ATM/ANS.OR.B.005(a)(6)</i>.</p> <p>As stated there, the SKPIs that might be envisaged here have to be the ones defined under the Performance Scheme, which has its own regulations and processes (<i>regulation (EU) n° 390/2013 for RP2</i>).</p>



	answer.	What is of importance is that both processes are coherent and integrated.
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response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has been finally removed from the proposed IR.

comment

801

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Explanatory Note Section 2.4.4 <i>Proposed amendments to Annex III ‘COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR)’</i>	Question 6: The Agency would like to know whether the stakeholders agree or disagree with the proposal made to clarify and close the loop (i.e. check the effectiveness) in relation to the monitoring requirements resulting from the assessment of the changes to functional systems. Please provide the supporting rationale with your answer.	We would agree with the proposal made.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to the monitoring of the functional system for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.

comment

830

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Explanatory Note	We wonder whether the	The change is presented as an integral



<p>Section 2.4.4 <i>Proposed amendments to Annex III 'COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR)'</i></p>	<p>partial approval of a change introduced in the new provision <i>ATM/ANS.OR.A.045</i> is a sensible way to proceed.</p>	<p>project composed of several interrelated parts. The partial approval of some of these parts, although presented as an improvement for the sake of flexibility, can finally result in a higher risk to the project if the full review results in parts not being approved or changes required to the still-not-approved parts that have consequential effects on the parts already approved.</p>
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response

Noted

 Please see the response to comment No 905.

comment

831

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Explanatory Note Section 2.4.4 <i>Proposed amendments to Annex III 'COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR)'</i></p>	<p>Although we very much welcome the concept of '<i>multi-actor change</i>' introduced in the new provision <i>ATM/AND.OR.A.045</i> (as well as the definition of '<i>aviation undertakings</i>'), we feel that the scheme set is somehow weak and puts a big risk unto the ANSP.</p>	<p>On the one hand, the CA may not have jurisdiction on some of the aviation undertakings involved (e.g. military ANSPs). On the other hand, the principle of accountability should be taken into consideration, so that the ANSP should only be made responsible for what is under its reasonable control. This scheme increases the risk of the project for the ANSP to unreasonable levels ("<i>even decide to abandon the change</i>").</p>



response

Noted

The comment is not well understood as there is no explanation of what the risk for the ANSP is. The objectives of multi-actor changes are to identify dependencies, to establish common assumptions and risk mitigations, and also to allow other service providers identify when a change is needed due to other service providers changes.

comment

833

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Explanatory Note Section 2.4.4 <i>Proposed amendments to Annex III 'COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR)'</i>	We would suggest to include in the new provision <i>ATM/ANS.OR.B.005(a)(6)</i> a clear and explicit link with the Performance Scheme (<i>regulation (EU) n° 390/2013 for RP2</i>).	The SKPIs that might be envisaged here have to be the ones defined under the Performance Scheme, which has its own regulations and processes. What is of importance is that both processes are coherent and integrated.

response

Noted

This is not applicable as the provision in (a)(6) has been removed.

comment

834

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Explanatory Note Section 2.4.4 <i>Proposed amendments to Annex III 'COMMON REQUIREMENTS FOR</i>	We would recommend that the terms ' <i>assurance argument</i> ', ' <i>safety support assessment</i> ', ' <i>assurance case</i> ', ' <i>safety support case</i> ', ' <i>safety case</i> ' and ' <i>service specification</i> ' be clearly defined	We would recommend a clear use of terms and concepts in order to avoid current and future misunderstandings in the application of the regulation.



<p><i>SERVICE PROVIDERS (Part-ATM/ANS.OR)'</i></p>	<p>and used with the outmost care.</p>	
	<p>In fact, we would welcome a simplification in the terminology used.</p>	

response

Noted

The Agency has used these terms in a consistent manner. Please see definitions in GM1 ATM/ANS.OR.C.005(a)(2) & ATS.OR.205(a)(2). The reorganisation and review of GM may need to make these definitions more prominent to the readers.

comment

850

comment by: *Naviair*

Regarding 2.4.4 and ATM/ANS.OR.B.005(d)

Question 5: We are monitoring today. The existing rules are OK. It is not possible to directly monitoring every change. Some changes can only be monitored through the ATSR's. An example is a change to a local procedure.

Question 6: See question 5.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has been finally removed from the proposed IR.

comment

984

comment by: *AESA / DSANA*

PART	COMMENT	JUSTIFICATION
<p>Explanatory Note Section 2.4.4 <i>(page 26)</i></p>	<p>The reference in the sentence "A new subpart is proposed to be added to Annex I: 'SUBPART C — SPECIFIC ORGANISATIONAL (...)' should be made to Annex II instead of Annex I.</p>	<p>Typographical error</p>



response

Accepted

This has been corrected.

comment

1016

comment by: DSNA

Question 5:

DSNA thinks it is outside the scope of the Regulation and that these aspects are already covered by other regulations.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has been finally removed from the proposed IR.

comment

1017

comment by: DSNA

Question 6:

Disagree. First it is important to state that we are talking about SAFETY assessment and not all performance assessment (safety is a PART of performance but is not all performance –for e.g. safety is not about economic performance). Monitoring here should be about safety monitoring. Some requirements deserve a specific monitoring after the entry into service of the change, not all of them, but after some weeks/months of service, this monitoring will be addressed through the permanent monitoring put in place in the frame of the MS. It is not realistic to keep a specific monitoring on every requirements of each change, with hundreds of changes per year. Resources would not be sufficient and this will not bring safety at all.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the monitoring of the functional system for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.

comment

1055

comment by: DGAC/DSAC - french NSA

Answer to question 6 :

The french NSA disagree with this proposal as it will lead after a lot of changes to too many



	requirements to monitor. The workload used would be too disproportionate compared to the safety gain.
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the monitoring of the functional system for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.</p>
comment	<p>1075 comment by: LVNL</p> <p><i>Response to Question 5:</i> <i>The concept of proactive performance management is supported, however, proactive performance management and continuous improvement is related to Safety Management in general, which is not the subject of this NPA.</i></p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has been finally removed from the proposed IR.</p>
comment	<p>1078 comment by: LVNL</p> <p><i>Response to question 6:</i> <i>Current regulation and that proposed as part of CRD 2013-08 already include monitoring of effectiveness. Consequently adding another requirement for the monitoring of effectiveness in this NPA seems to be double regulation. The monitoring of the effectiveness of any individual change might be infeasible and also hardly possible.</i> <i>Recommend to delete the proposal made to clarify and close the loop (i.e. check the effectiveness) in relation to the monitoring requirements resulting from the assessment of the changes to functional systems.</i></p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the monitoring of the functional system for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.</p>
comment	<p>1096 comment by: Belgocontrol</p>



Page 25 Question 5

The general principle is welcomed but the proposal seems to be inconsistent with the performance based regulation approach. There are a lot more factors that influence the decision to improve performance. From the safety point of view, a change should be done not just because we could but because it is needed.

Recommend to delete the proposal made in this NPA for proactive performance management, but strive for continuous improvement as foreseen by the Basic Regulation and ICAO SARPs.

Page 26 Question 6

Current regulation and CRD 2013-08 already include monitoring of effectiveness. Adding another requirement for the monitoring of effectiveness in this NPA seems to be double regulation. The monitoring of the effectiveness of any individual change might be difficult.

Recommend to delete the proposal made to clarify and close the loop (i.e. check the effectiveness) in relation to the monitoring requirements resulting from the assessment of the changes to functional systems.

response

Noted

The Agency takes due consideration of the answer to the question Q5. Please see the Agency's responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has been finally removed from the proposed IR.

The Agency takes due consideration of the answer to the question Q6. Please see the Agency's responses to comments related to the monitoring of the functional system for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.

comment

1107

comment by: *bmvit/CAA/NSA*

ad question 5:

The requirements are too formal and too generic. Probably an inconsistency with the performance based regulation approach is existent.

We recommend to delete the aspects of a proactive performance management but check the requirements for continuous improvement as already foreseen in the basic regulation.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has been



finally removed from the proposed IR.

comment	<p>1118 comment by: <i>bmvit/CAA/NSA</i></p> <p>ad question 6: the CRD 2013-08 includes already the monitoring of effectiveness and could lead to a double explanation and misinterpretation. The recommendation is to adapt the text (to CRD 2013-8) or delete the proposal made to clarify and close the loop.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the monitoring of the functional system for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.</p>
comment	<p>1126 comment by: <i>bmvit/CAA/NSA</i></p> <p>Should an ATS-provider who is at the same time CNS provider send always a safety assessment or sometimes only safety support assessments depending on the scope of change?</p>
response	<p>Noted</p> <p>The provider should make a safety assessment, but the activities of the safety support assessment will be embedded as part of the evidence provided in the safety assessment.</p>
comment	<p>1141 comment by: <i>DSAE</i></p> <p>Question 5 : The Agency would like to know whether the stakeholders agree or disagree with the proposal made in this NPA for proactive performance management and for continuous improvement as foreseen by the Basic Regulation and ICAO SARPs. Please provide the supporting rationale with your answer. DIRCAM's answer : DIRCAM is not concerned.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has been finally removed from the proposed IR.</p>



comment	<p data-bbox="363 241 427 271">1142</p> <p data-bbox="1251 241 1485 271" style="text-align: right;">comment by: <i>DSAE</i></p> <p data-bbox="363 331 1485 488">Question 6 : The Agency would like to know whether the stakeholders agree or disagree with the proposal made to clarify and close the loop (i.e. check the effectiveness) in relation to the monitoring requirements resulting from the assessment of the changes to functional systems. Please provide the supporting rationale with your answer.</p> <p data-bbox="363 499 1485 813">DIRCAM's answer : DIRCAM already requires ANSPs to set up monitoring equipment, procedures to ensure continuous safety for all changes. Monitoring requirements have to be put in place for every change. Definition of these requirements enables ANSPs to detect any problem about the system in terms of safety. Moreover, monitoring aspect has to be considered in a general way. Change after change, monitoring actions makes feedback even greater for ANSPs (this kind of feedback may enter into consideration while CAs have to decide whether to review a change). Once an ANSP decides to establish some monitoring system, it will not be difficult to continue monitoring for next changes.</p>
response	<p data-bbox="363 846 443 875">Noted</p> <p data-bbox="363 913 1485 1048">The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the monitoring of the functional system for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.</p>
comment	<p data-bbox="363 1115 427 1144">1155</p> <p data-bbox="1251 1115 1485 1144" style="text-align: right;">comment by: <i>Icetra</i></p> <p data-bbox="363 1205 507 1234">Question 5:</p> <p data-bbox="363 1245 1485 1357">We agree with the view that ANSPs are already required to monitor performance and take appropriate action if performance is found wanting and that changes are occurring today in spite of there not being any regulatory requirements to that effect.</p> <p data-bbox="363 1368 1485 1525">We do also agree however with the proposed provision that requires the ANSP to consider other aspects than economical as triggers for change. This would infer that if the decision is made not to make changes in spite of evidence that it is feasible to do so, this would be documented.</p> <p data-bbox="363 1536 1485 1603">A suggestion for a change this provisions is proposed, refer to the appropriate section for the comment.</p>
response	<p data-bbox="363 1641 443 1671">Noted</p> <p data-bbox="363 1709 1485 1865">The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has been finally removed from the proposed IR.</p>
comment	<p data-bbox="363 1944 427 1973">1157</p> <p data-bbox="1251 1944 1485 1973" style="text-align: right;">comment by: <i>Icetra</i></p>



	<p>Question 6: We agree and think it positive to spell out necessary actions in terms of measuring performance following a change. Establishing a process for the follow-up of changes made to the functional system seems to be a difficult issue for ANSPs and better guidance and stricter regulation might be a good way forward.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the monitoring of the functional system for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.</p> <p>The evaluation of the AMC/GM will be addressed at a later stage during the 2nd NPA development.</p>
comment	<p>1172 comment by: <i>Avinor ANS</i></p> <p>There is a discrepancy between this explanation and the IR itself. The explanation refers to monitor the behavior of the service, whereas the related IR considers monitoring the behavior of the functional system. Monitoring at the level of the service (which would encompass the behavior of the function system) is preferable as measuring at the level of a change to a functional system (as implied by (d)(2)) would be resource intensive for little benefit.</p>
response	<p>Not accepted</p> <p>The discrepancy is acknowledged. The wording in the proposed rule is the correct one, as it would cover both monitoring at the service level and monitoring at the level of the functional system where the monitoring criteria are set as per ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7).</p> <p>The monitoring criteria defined as per ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7) need to be actively monitored and followed-up. This will be at the appropriately defined level, either at the level of service or at the level of the functional system (see GM1 ATM/ANS.OR.C005(b)(3) and GM1 ATS.OR.205(b)(7)). Monitoring at the level of the service may in some cases require very long period of times in order to get data, thus, it will be more convenient to monitor properties at the level of subsystems of the functional system.</p>
comment	<p>1186 comment by: <i>ENAIRE</i></p> <p>Disagree with 'CNS provider cannot dynamically intervene in order to control the safe use of the service it provides, when it sees an unsafe situation developing'. One of the</p>



response	<p>requirements of the ATSEP is to be aware of that.</p> <p>Noted</p> <p>The comment is not understood. How do CNS dynamically intervene in the control of the aircraft operations? The commentator does not provide arguments.</p>
comment	<p>1188 comment by: ENAIRE</p> <p>Disagree with ‘ATS providers will need to conduct a safety assessment of the changes to the functional systems because they will be able to manage the safety of the services they provide’ while ‘Service providers other than ATS providers shall conduct what has been called, in this NPA, a safety support assessment’.</p> <p>In our opinion, the Agency should ask whether the stakeholders agree or disagree with the previous paragraph, since it is an important change in philosophy.</p>
response	<p>Not accepted</p> <p>The Agency has received enough feedback on this aspect through comments and support during the consultation. For the final Agency’s position and justifications, please see the responses to comments Nos 273 and 1199. Besides, there exists enough GM that explains this position. The commentator is not providing arguments against this.</p>
comment	<p>1213 comment by: CAA-NL</p> <p>Question 5: The Agency would like to know whether the stakeholders agree or disagree with the proposal made in this NPA for proactive performance management and for continuous improvement as foreseen by the Basic Regulation and ICAO SARPs. Please provide the supporting rationale with your answer.</p> <p>The Netherlands supports the concept of proactive performance management in general, however, proactive performance management and continuous improvement is related to Safety Management in general, which is not the subject of this NPA.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has been finally removed from the proposed IR.</p>
comment	<p>1214 comment by: CAA-NL</p>



Question 6: The Agency would like to know whether the stakeholders agree or disagree with the proposal made to clarify and close the loop (i.e. check the effectiveness) in relation to the monitoring requirements resulting from the assessment of the changes to functional systems. Please provide the supporting rationale with your answer.

The Netherlands believes that monitoring effectiveness is part of the overall SMS requirements listed in CRD 2013-08 and that this should be part of this NPA. We agree that monitoring the performance of the functional system is a good thing, and agree to monitoring the effectiveness of any individual change for a limited period of time. However we will suggest some different wording for ATM/ANS.OR.B.005 Management system (d)(2) which in our opinion better clarifies the intent of this part of the monitoring function related to the outcome of the change rather than the process that leads to it.

ATM/ANS.OR.B.005 Management system

(d) The service provider shall monitor the behaviour of the functional system and where:
(2) the actual behaviour of a change is found different from its predicted behaviour, the service provider will determine the cause and when the outcome of a change is below expectations, initiate corrective actions.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the monitoring of the functional system for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.

(d)(2) has been removed from the final proposal.

comment

1256

comment by: ENAV

Question 5: The Agency would like to know whether the stakeholders agree or disagree with the proposal made in this NPA for proactive performance management and for continuous improvement as foreseen by the Basic Regulation and ICAO SARPs. Please provide the supporting rationale with your answer.

We agree on the general principle which should be part of the management system. However this NPA needs an update for proactive performance management. To regulate a process to consider changes to improve performance seems to be out of the performance based regulation approach. The market should ensure that performance improvements are considered without having to be regulated.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response



to comment No 53 for clarifications that support that position. Note that (a)(6) has been finally removed from the proposed IR.

comment 1258

comment by: ENAV

Question 6: The Agency would like to know whether the stakeholders agree or disagree with the proposal made to clarify and close the loop (i.e. check the effectiveness) in relation to the monitoring requirements resulting from the assessment of the changes to functional systems. Please provide the supporting rationale with your answer.

ENAV believes that monitoring effectiveness is already part of the overall SMS requirements listed in CRD 2013-08 and that this should not be part of the NPA that is about risk assessment of changes. We agree that monitoring the performance of the functional system is a good thing, but strongly disagree to monitoring the effectiveness of any individual change as this is seldom achievable and incurs significant cost.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the monitoring of the functional system for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.

comment 1265

comment by: CANSO

Question 5: The Agency would like to know whether the stakeholders agree or disagree with the proposal made in this NPA for proactive performance management and for continuous improvement as foreseen by the Basic Regulation and ICAO SARPs. Please provide the supporting rationale with your answer.

We agree on the general principle which should be part of the management system. However this NPA needs an update for proactive performance management. To regulate a process to consider changes to improve performance seems to be out of the performance based regulation approach. The market should ensure that performance improvements are considered without having to be regulated.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to continuous improvement of performance for additional information on the final position taken by the Agency. For instance, please see the response to comment No 53 for clarifications that support that position. Note that (a)(6) has been finally removed from the proposed IR.



comment	1266	comment by: <i>CANSO</i>
	<p>Question 6: The Agency would like to know whether the stakeholders agree or disagree with the proposal made to clarify and close the loop (i.e. check the effectiveness) in relation to the monitoring requirements resulting from the assessment of the changes to functional systems. Please provide the supporting rationale with your answer.</p> <p>CANSO believe that monitoring effectiveness is already part of the overall SMS requirements listed in CRD 2013-08 and that this should not be part of the NPA that is about risk assessment of changes. We agree that monitoring the performance of the functional system is a good thing, but strongly disagree to monitoring the effectiveness of any individual change as this is seldom achievable and incurs significant cost.</p>	
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the monitoring of the functional system for additional information on the final position taken by the Agency. For instance, please see the responses to comments Nos 54, 599 and 680 for clarifications that support that position.</p>	
comment	1273	comment by: <i>European Transport Workers Federation - ETF</i>
	<p>ETF agree with the proposal to include the monitoring requirements due to the necessity to check and verify the effectiveness of changes to functional systems. We also suggest that some GM could be beneficial.</p>	
response	<p>Noted</p> <p>The Agency takes note of the support.</p>	

2. Explanatory Note — 2.4. Overview of the proposed amendments — 2.4.5. Proposed amendments to Annex IV 'SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS)' p. 28-30

comment	27	comment by: <i>NATS National Air Traffic Services Limited</i>
	<p>Section 2.4.5 (page 30)</p> <p>ATS.OR.201(b) & (c):</p> <p>The explanation that “the set of safety criteria, as a whole, shall satisfy the “objective for safety”” (middle Page 30) is taken to mean that in ATS.OR.201(b) “objective for the safety” is the safety criteria. The safety criteria are “used to decide the safety acceptability of a change to a functional system” (middle Page 30).</p>	



	<p>NATS therefore understands that the objective for safety cannot be that the service will be at least as safe after the change as it was before and that satisfaction of the safety criteria is sufficient and recommend that ATS.OR.201(b)&(c) are deleted as shown in Appendix A.</p>
response	<p>Partially accepted</p> <p>The objective for safety sets the top-level goal. The safety criteria are used to decompose this goal into the parts of the change. In this sense, the acceptability of the change depends on the satisfaction of the safety criteria, but these criteria must collectively meet that goal. Consequently, without the 'goal', the validity of the set of safety criteria cannot be established. The only validity that can be established is their internal validity, i.e. that they are individually 'well formed'. The objective for safety was included in the SMS, but after assessing all comments, it has been moved to ATS.OR.210 to more clearly show the link between the objective for safety of a change and the safety criteria. The relationship between the objective for safety and the safety criteria has been clarified (ATS.OR.210(b)(2)), but it has also been redefined to account for situations where some changes could result in a slightly increased risk and still be within the risk budget for the overall service. The requirement for the objective for safety of a change has been redrafted to ensure the safety criteria collectively 'ensure that the change does not create an unacceptable risk to the safety of the service'. Then, the former objective 'as safe as before the change' would be one option to comply with this requirement, and other means can be developed.</p>
comment	<p>28 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>Section 2.4.5 (Page 30)</p> <p>ATS.OR.210: It is noted that the proxy approach is missing from point (b) although it is discussed extensively in the GM. Amend ATS.OR.210(b) in to add: “(3) proxies; and” as proposed in Appendix A.</p>
response	<p>Partially accepted</p> <p>The concept of proxies was present at the level of IR, but encapsulated in the term 'others measures related to risks'. Proxies were not explicitly described at the level of the IR, but are defined in AMC1 ATS.OR.205(b) in points (d) and (e): 'A proxy is some measurable property that can be used to represent the value of something else. In the safety assessment of functional systems, the value of a proxy may be used as a substitute for a value of risk,...'</p> <p>The explanation can be found in GM1 ATS.OR.205(b)(3) & GM2 ATS.OR.205(b)(4).</p> <p>Proxies have been added explicitly to the AMC stemming from comment No 65.</p>



comment	<p data-bbox="360 277 395 309">69</p> <p data-bbox="975 277 1485 309" style="text-align: right;">comment by: <i>EUROCONTROL Safety Team</i></p> <p data-bbox="360 367 1485 443">Page 30 The set of safety criteria, as a whole, shall satisfy the “objective for safety” (middle of page)</p> <p data-bbox="360 450 1485 645">The EN is seemingly in conflict with the IR (ATS.OR.201(b)) because <i>the set of safety criteria, as a whole, shall satisfy the objective for safety</i> is understood to refer to <i>objective for the safety in</i> ATS.OR.201(b). In such a case then the <i>objective for the safety</i> would be the safety criteria. Consequently the requirement is to satisfy the safety criteria and the objective for safety cannot be that the service will be at least as safe after the change as it was before.</p>
response	<p data-bbox="360 678 576 710">Partially accepted</p> <p data-bbox="360 745 1485 1066">The objective for safety sets the top-level goal. The safety criteria are used to decompose this goal into the parts of the change. In this sense, the acceptability of the change depends on the satisfaction of the safety criteria, but these criteria must collectively meet that goal. Consequently, without the ‘goal’, the validity of the set of safety criteria cannot be established. The only validity that can be established is their internal validity, i.e. that they are individually ‘well formed’. The objective for safety was included in the SMS, but after assessing all comments, it has been moved to ATS.OR.210 to more clearly show the link between the objective for safety of a change and the safety criteria.</p> <p data-bbox="360 1090 1485 1408">The relationship between the objective for safety and the safety criteria has been clarified (ATS.OR.210(b)(2)), but it has also been redefined to account for situations where some changes could result in a slightly increased risk and still be within the risk budget for the overall service. The requirement for the objective for safety of a change has been redrafted to ensure the safety criteria collectively ‘ensure that the change does not create an unacceptable risk to the safety of the service’. Then, the former objective ‘as safe as before the change’ would be one option to comply with this requirement, and other means can be developed.</p>
comment	<p data-bbox="360 1496 411 1527">126</p> <p data-bbox="1227 1496 1485 1527" style="text-align: right;">comment by: <i>ENAIRE</i></p> <p data-bbox="360 1585 1485 1697">Answer to Question 7: Disagree with the proposal for having an overall safety objective for the change. There are many other rules that will prevent degradation of safety: safety objectives, a safety policy, the application of SMS, occurrence management, etc.</p>
response	<p data-bbox="360 1731 440 1762">Noted</p> <p data-bbox="360 1798 1485 1910">The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to the overall objective for safety for additional information on the final position taken by the Agency.</p> <p data-bbox="360 1946 1485 2022">The objective for safety has been moved to ATS.OR 210(b)(2) and changed to ensure the change does not introduce unacceptable risks. Please see the response to comments Nos 61</p>



and 288 for additional clarifications.

comment

193

comment by: *EUROCONTROL Safety Team*

Page 29 Question 7

The current 'system' already includes many barriers to prevent the degeneration of safety over time, to name a few - safety objectives, a safety policy, the application of SMS, occurrence management, monitoring and surveys. Additionally the safety criteria for each change will provide the needed safety assurance. Consequently it seems that there is little or no purpose in adding another requirement.

Recommend to delete the proposal for having an overall safety objective for the change.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the overall objective for safety for additional information on the final position taken by the Agency.

The objective for safety has been moved to ATS.OR 210(b)(2) and changed to ensure the change does not introduce unacceptable risks. Please see the responses to comments Nos 61 and 288 for additional clarifications.

comment

258

comment by: *UK CAA*

Page No: 29

Paragraph No: QUESTION 7

Comment: The UK CAA supports this approach but should it be adopted, we suggest it would be necessary to develop and apply criteria for the CA to use in order to determine whether the 'overall objective for safety' was acceptable.

Justification: Harmonisation

response

Noted

The Agency concurs that the approach needs development of AMC/GM. Please note that the objective for safety has been moved to ATS.OR 210(b)(2) and changed to ensure the change does not introduce unacceptable risks. Please see the responses to comments Nos 61 and 288 for additional clarifications.

comment

285

comment by: *Swedish Transport Agency, Civil Aviation Department
(Transportstyrelsen, Luftfartsavdelningen)*

It works today with current regulation, thus no extended regulation required.



response	Noted	
	The Agency is not sure what this comment is about. If it is related to the objective for safety, this has been moved to ATS.OR 210(b)(2) and changed to ensure the change does not introduce unacceptable risks. Please see the responses to comments Nos 61 and 288 for additional clarifications.	
comment	330	comment by: <i>BAF-M.Jancokova</i>
	Question 7: An overall objective for safety for a change is supported but rather in terms of the provision of a global Target Level of Safety or Risk classification schemes. An objective for safety for a change as introduced here, namely explicitly requiring that "the service will be at least as safe after the change as it was before the change" is not supported as it is in clear contradiction to both established safety criteria (e.g. using TLS / RCS) and the extended concept of safety criteria proposed in this NPA. Example: If a service is acceptably safe (supported by using a TLS / RCS) before a change and "slightly less safe" but still acceptably safe (according to the TLS / RCS) after a change, this would still not be acceptable under the new regulation.	
response	Noted	
	The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the overall objective for safety for additional information on the final position taken by the Agency. The objective for safety has been moved to ATS.OR 210(b)(2) and changed to ensure the change does not introduce unacceptable risks. Please see the responses to comments Nos 61 and 288 for additional clarifications.	
comment	331	comment by: <i>BAF-M.Jancokova</i>
	The term "proxy" which is used here should be explained in Annex I, Definitions.	
response	Not accepted	
	The term proxy is not used in the IR text, and, therefore, not added in Annex I, Definitions. It is, however, well defined and explained in AMC/GM.	
comment	356	comment by: <i>ATCEUC - Air Traffic Controllers European Unions Coordination</i>
	Question 7: ATCEUC agrees on the need for an overall objective for safety for the change as part of the SMS. Safety can't be reduced after the changes, and it shouldn't be reduced	



	<p>during them, but if due to the change itself this could not be possible, some mitigation measures should be included to reduce the impact of that decrease in safety (see ATS.OR.201).</p> <p>The fact that ‘the “objective for safety” is that the safety of the service provided by the changed FS is AT LEAST the same as the safety of the service provided before the change’ is fair and reasonable enough. Flexibility is already given when this safety level is not complied with temporarily</p> <p>In any case, safety minima should be guaranteed also DURING a change, applying mitigation measures when needed</p> <p>Our proposal would be to lay down requirements on the change management processes that should be monitored internally by the corresponding undertaking (ANSP) AND periodically/continuously by the appropriate CA. An example for this could be the implementation of a FAB procedure.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to the overall objective for safety for additional information on the final position taken by the Agency.</p> <p>The objective for safety has been moved to ATS.OR 210(b)(2) and changed to ensure the change does not introduce unacceptable risks. Please see the responses to comments Nos 61 and 288 for additional clarifications.</p>
comment	<p>379 comment by: <i>skyguide Corporate Regulation Management</i></p> <p>The explanation that “the set of safety criteria, as a whole, shall satisfy the “objective for safety”” (middle Page 30) is taken to mean that in ATS.OR.201(b) “objective for the safety” is the safety criteria. The safety criteria are “used to decide the safety acceptability of a change to a functional system” (middle Page 30).</p> <p>skyguide therefore considers that the objective for safety cannot be that the service will be at least as safe after the change as it was before and that satisfaction of the safety criteria must be sufficient and recommend that ATS.OR.201(b)&(c) are deleted as shown in Appendix A.</p> <p>It is noted that the proxy approach is missing from point (b) although it is discussed extensively in the GM.</p> <p>Amend (b) in to add: “(3) proxies; and” as proposed in Appendix A</p>
response	<p>Partially accepted</p> <p>For the position on the objective for safety, please see the responses to comments Nos 61 and 288.</p> <p>The concept of proxies was present at the level of IR, but encapsulated in the term ‘others</p>



measures related to risks'. Proxies were not explicitly described at the level of the IR, but are defined in AMC1 ATS.OR.205(b) in points (d) and (e): 'A proxy is some measurable property that can be used to represent the value of something else. In the safety assessment of functional systems, the value of a proxy may be used as a substitute for a value of risk,...'

The explanation can be found in GM1 ATS.OR.205(b)(3) & GM2 ATS.OR.205(b)(4).

Proxies have been added explicitly to the AMC stemming from comment No 65.

comment 397 comment by: *Air Navigation Services of the Czech Republic*

Question 7:

We disagree with the proposal for having an overall safety objective for the change. We strive to always reach the acceptable level of risk, which is not always directly attributable to a specific change.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the overall objective for safety for additional information on the final position taken by the Agency.

Please see the responses to comments Nos 61 and 288 for additional clarifications.

comment 478 comment by: *CAA CZ*

Question 7: The Agency would like to know whether the stakeholders agree or disagree with the proposal for an overall objective for safety for the change as part of the SMS. Please provide the supporting rationale with your answer.

The CAA CZ supports the proposal. It enables to see a change in the overall operational context and its contribution to performance targets.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the overall objective for safety for additional information on the final position taken by the Agency.

Please see the responses to comments Nos 61 and 288 for additional clarifications.

comment 536 comment by: *skyguide Corporate Regulation Management*

Question 7:



	<p>skyguide believe that the worry that safety could degrade over time is unjustified. There are many other rules that will prevent this: safety objectives, a safety policy, the application of SMS, occurrence management, etc. We also suggest that the reason that the safety of Aviation has improved is owing to the efforts of the industry itself, where safety is seen as good for business.</p> <p>We disagree with the proposal for having an overall safety objective for the change.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the overall objective for safety for additional information on the final position taken by the Agency.</p> <p>Please see the responses to comments Nos 61 and 288 for additional clarifications.</p>
comment	<p>558 comment by: <i>Federal Office of Civil Aviation FOCA</i></p> <p>The general intent to maintain or even improve the safety level appears to be adequate. However, based on the definition of safety, the regulation should clearly contain that existing risks and risks introduced or mitigated with the change, need to be identified. It shall not be considered sufficient to argue that the change does not introduce new hazards and therefore the overall objective for safety is achieved.</p> <p>If risks are not identified there is no supporting evidence that the existing system is free of unacceptable risks.</p> <p>Futhermore, if the proposed change introduces a new risk, it might be considered that the overall objective for safety will not be achieved which in turn may hinder the proactive hazard identification which is and remains the pillar of a proactive safety management.</p>
response	<p>Partially accepted</p> <p>The proposal does require identifying the risk introduced by the change (see ATS.OR.210), but it also introduces the possibility of using different approaches (e.g. proxies) that relate to safety risks without the explicit calculation of risks. The objective for safety has been moved to ATS.OR 210(b)(2) and changed to ensure the change does not introduce unacceptable risks.</p> <p>Please see the responses to comments Nos 61 and 288 for additional clarifications.</p>
comment	<p>572 comment by: <i>Frasie Loredana</i></p> <p>QUESTION 7</p> <p>Postpone the possible future requirement for an <i>objective for safety</i> until appropriate and acceptable guidance is agreed by all stakeholders.</p>



Justification

In our opinion the information provided in NPA 2014-13 is not clear or sufficient about how the objective for safety could be established by ATSP. This will have an impact also on supervision activities.

Although, in 2.4.5 it is specified that This is fully explained in GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045 General,

this section INTERACTIONS BETWEEN SERVICE PROVIDERS & COMPETENT AUTHORITIES DURING THE CHANGE PROCESS does not contain the appropriate information on setting objective for safety.

The data necessary to enable setting up quantitative objective for changes can not be obtained in an objective manner. For example, the introduction of a new procedure due to new regulation will affect the objective for safety set for a previous change or changes. In this case the service provider has to establish how the new procedure interact with the other elements of the functional system, how does it modify the objective for safety that have been established for previous changes, if any, and assessed in conjunction with the human factors aspects.

In our view, the establishment of an objective for safety for changes is not practical because you can not predict all the conditions in which the change (e.g. the procedure) can fail. This requires the "identification of all the "unforeseen situations" in wich the change could fail. It is obvious that if it is unforeseen, it can not be identified.

The effect of this requirement will be significant delays in the implementation of changes by the service providers.

There is no proposed definition for objective for safety.

Due to the above reasons, for the moment, we do not support the introduction of an objective for safety.

Include a definition for *objective for safety*.

Justification

If this term is going to be used in a technical manner, it needs to be defined.

Some explanation is found in the Explanatory note, para 2.4.5. but this does not substitute a definition.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the overall objective for safety for additional information on the final position taken by the Agency.

The objective for safety has been moved to ATS.OR 210 (b)(2) and changed to ensure the change does not introduce unacceptable risks. Please see the responses to comments Nos 61 and 288 for additional clarifications.

The term 'objective for safety' is not used as a technical term and not used in the IR at all. The definition seems unnecessary.



comment	<p>602 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>Question 7: DFS disagrees with the proposal for having an overall safety objective for every single change. The worry that safety could degrade over time is unjustified. There are many other rules that will prevent this: safety policy, SMS management safety objective (also FABEC safety objective), occurrence management, etc.. For justification and arguments we support the CANSO opinion.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the overall objective for safety for additional information on the final position taken by the Agency.</p> <p>Please see the responses to comments Nos 61 and 288 for additional clarifications.</p>
comment	<p>630 comment by: <i>CANSO</i></p> <p>2.4.5 and ATS.OR.201(b) & (c) The explanation that “the set of safety criteria, as a whole, shall satisfy the “objective for safety”” (middle Page 30) is taken to mean that in ATS.OR.201(b) “objective for the safety” is the safety criteria. The safety criteria are “used to decide the safety acceptability of a change to a functional system” (middle Page 30). CANSO therefore understands that the objective for safety cannot be that the service will be at least as safe after the change as it was before and that satisfaction of the safety criteria is sufficient and recommend that ATS.OR.201(b)&(c) are deleted as shown in Appendix A.</p>
response	<p>Partially accepted</p> <p>The objective for safety has been moved to ATS.OR 210(b)(2) and changed to ensure the change does not introduce unacceptable risks.</p> <p>Please see the responses to comments Nos 61 and 288 for additional clarifications.</p>
comment	<p>631 comment by: <i>CANSO</i></p> <p>2.4.5 and ATS.OR.210 It is noted that the proxy approach is missing from point (b) although it is discussed extensively in the GM. Amend (b) in to add: “(3) proxies; and” as proposed in Appendix A</p>



response	<p>Partially accepted</p> <p>The concept of proxies was present at the level of IR, but encapsulated in the term ‘others measures related to risks’. Proxies were not explicitly described at the level of the IR, but are defined in AMC1 ATS.OR.205(b) in points (d) and (e): ‘A proxy is some measurable property that can be used to represent the value of something else. In the safety assessment of functional systems, the value of a proxy may be used as a substitute for a value of risk,...’</p> <p>The explanation can be found in GM1 ATS.OR.205(b)(3) & GM2 ATS.OR.205(b)(4).</p> <p>Proxies have been added explicitly to the AMC stemming from comment No 65.</p>
comment	<p>674 comment by: CAA Norway</p> <p>CAA Norway thinks that a general requirement on overall objective for safety for the change is not needed. There are several barriers to avoid the degeneration of safety over time and there may be situations where it is not possible to meet this requirement.</p>
response	<p>Not accepted</p> <p>The objective for safety has been moved to ATS.OR 210(b)(2) and changed to ensure the change does not introduce unacceptable risks.</p> <p>Please see the responses to comments Nos 61 and 288 for additional clarifications.</p>
comment	<p>681 comment by: ROMATSA</p> <p>The explanation that “the set of safety criteria, as a whole, shall satisfy the “objective for safety” is taken to mean that in ATS.OR.201(b) “objective for the safety” is the safety criteria. The safety criteria are “used to decide the safety acceptability of a change to a functional system” (page 30)</p> <p>ROMATSA supports CANSO opinion and understands that the objective for safety cannot be that the service will be at least as safe after the change as it was before and that satisfaction of the safety criteria is sufficient and recommend that ATS.OR.201(b)&(c) are deleted as shown in Appendix A.</p> <p>Supporting comment to summary issue: IR does not achieve the perceived intention of the rule. In this case the IR is in conflict with ATS.OR.210.</p> <p>It is noted that the proxy approach is missing from point (b) although it is discussed extensively in the GM.</p> <p>Amend (b) in to add:“(3) proxies; and” as proposed in Appendix A.</p>



Supporting comment to summary issue: IR does not achieve the perceived intention of the rule.

response

Partially accepted

The objective for safety has been moved to ATS.OR 210(b)(2) and changed to ensure the change does not introduce unacceptable risks.

Please see the responses to comments Nos 61 and 288 for additional clarifications.

comment

803

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Explanatory Note Section 2.4.5 <i>Proposed amendments to Annex IV ‘SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS)’</i></p>	<p>Question 7: The Agency would like to know whether the stakeholders agree or disagree with the proposal for an overall objective for safety for the change as part of the SMS. Please provide the supporting rationale with your answer.</p>	<p>We agree to this proposal, though we are quite interested in seeing how this will be actually implemented. In fact, we deem that there will be a need to develop AMC/GM for this requirement.</p> <p>In any case, this is quite a sensitive question that has very much to do with the SSP (PESO) and the overall safety policy of the Member States and, ultimately, of the EU (EASP).</p>

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to the overall objective for safety for additional information on the final position taken by the Agency.

Please see the responses to comments Nos 61 and 288 for additional clarifications.

comment

835

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION



<p>Explanatory Note Section 2.4.5 <i>Proposed amendments to Annex IV ‘SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS)’</i></p>	<p>We do not support the possibility introduced in this section: "<i>Another possibility would be that the service provider makes a case to the CA that the situation may exist for some time, but that there is a plan to bring the safety risk of the service back to an acceptable level (meaning achieve the ‘objective for safety’) at some point in the future, via, for instance, another change</i>".</p>	<p>This possibility introduces in the process something worse than risk: <u>indeterminacy</u>. No CA should approve a case that relies on actions that "<i>may exist for some time</i>" but which are planned to be addressed "<i>at some point in the future</i>". This would amount to approving an unsafe operation.</p>
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response

Partially accepted

The proposal for the objective of safety has been amended to avoid the introduction of unacceptable risks. The comment is not completely shared, but the new provision seems to address the commentator’s concerns. In the example, in comment No 339, the time between removing the radar and installing a new one is covered by the safety case and so the provider would have to take the mitigation measures needed for this short period of time. The CA would agree with them via their approval of the safety case. If the CA agreed to this short period of higher risk, then they would approve the safety case and signify their agreement to the subsequent course of action.

On the other hand, the provider may be arguing that there is a reduction in safety based on an increased benefit for which there is no mitigation foreseen. The CA’s choice is then to either accept the risk because the benefit is seen to outweigh it or to stop the change. In the former case, the subsequent course of action may be to initiate some studies to find ways of reducing the risk in the long term. Instead, in the latter case, the benefit will not be realised. Most CAs would adopt the former approach.

comment

836

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Explanatory Note Section 2.4.5 <i>Proposed amendments to Annex IV ‘SPECIFIC REQUIREMENTS FOR THE</i></p>	<p>The new provision <i>ATS.OR.205</i> introduces, in fact, a performance-based regulation (PBR) approach.</p>	<p>Although we do support the new PBR approach, we wonder whether the establishment of requirements that are not method-oriented will bring in fact more disharmony than harmony into the EU landscape.</p>



PROVISION OF AIR TRAFFIC SERVICES (Part-ATS)		
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response Noted

The Agency believes that this approach promotes an acceptable balance between the needs of the industry, including flexibility to assess changes and the safety, and harmonisation objectives pursued by the proposed regulation. It is not clear why the commentator believes it will bring disharmony.

comment 851

comment by: Naviair

Question 7: We agree that in general the objective for safety shall be that the safety of the service provided by the changed functional systems is at least the same as the safety of the service provided by the functional system before introducing the change. There may be other objectives where it can be established.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the overall objective for safety for additional information on the final position taken by the Agency.

Please see the responses to comments Nos 61 and 288 for additional clarifications.

comment 1018

comment by: DSNA

Question 7:

We disagree : an "overall objective" for ATM might be attractive in theory, BUT due to the complexity of ATM and the important number of interrelated changes , it might not be possible to meet this requirement in all cases and, trying to do so would lead to complex and potentially unsound arguments. Therefore, the role of the safety criteria for the change without a regulation on the overall safety will be practically more efficient. The argument that safety might degrade over time can be considered, but the answer by overall safety objective would not be appropriate, as human and procedures are the most important causes of ATM safety events. Monitoring safety events, practicing proactive safety, promoting real safety culture revealed to be more efficient in the past and must be part of the SMS.



response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the overall objective for safety for additional information on the final position taken by the Agency.</p> <p>Please see the responses to comments Nos 61 and 288 for additional clarifications.</p>
comment	<p>1085 comment by: LVNL</p> <p><i>The Netherlands has been in the process of defining safety criteria including safety levels for changes to the functional system on a national basis for at least 15 years. EASA is invited to take notice of these developments. We consider an overall safety criterion per functional change to be impossible.</i></p> <p><i>Furthermore, the management requirements in CRD 2013-08 and NPA 2014-13 do have overlap. This may lead to inconsistency in the rules and legal uncertainty. We propose to delete the overlap in the final proposal.</i></p> <p><i>The worry that safety could degrade over time is unjustified. There are many other rules that will prevent this: safety objectives, a safety policy, the application of SMS, occurrence management, etc. We also suggest that the reason that the safety of Aviation has improved in the past up to this moment in time, is not due to efforts limited to regulators, but specifically owing to the efforts of the industry itself, where safety is seen as good for business. Furthermore safety culture in aviation focuses on safety improvement, there is no reason to assume this will change.</i></p>
response	<p>Noted</p> <p>Please see the response to comment No 1216.</p>
comment	<p>1097 comment by: Belgocontrol</p> <p>Page 29 Question 7</p> <p>There are already many barriers to prevent the degradation of safety over time, such as: safety objectives for each change, a safety policy, occurrence management, monitoring, surveys, The safety criteria for each change will provide the needed safety assurance. Consequently it seems that there is little or no purpose in adding another requirement. <u>Recommend</u> to delete the proposal for having an overall safety objective for the change</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the overall objective for safety for additional information</p>



on the final position taken by the Agency.

Please see the responses to comments Nos 61 and 288 for additional clarifications.

comment

1120

comment by: *bmvit/CAA/NSA*

ad question 7:

We recommend to delete the proposal for having an overall safety objective for each change due to the fact that already today enough barriers to prevent a degeneration of the safety over time are in place (like safety policy, safety objective, SMS, occurrence management, oversight monitoring, safety assessment ...).

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the overall objective for safety for additional information on the final position taken by the Agency.

Please see the responses to comments Nos 61 and 288 for additional clarifications.

comment

1143

comment by: *DSAE*

Question 7 : The Agency would like to know whether the stakeholders agree or disagree with the proposal for an overall objective for safety for the change as part of the SMS. Please provide the supporting rationale with your answer.

DIRCAM's answer : DIRCAM already requests ANSPs to act on this way. For instance, it is tolerate, for a large change divided into several transitional periods, not to collect all pieces of assurance before every period of transition. Sometimes ANSPs cannot provide all necessary data to ensure the safety of the change. Therefore, CAs may expect final results of the safety case to accept the change.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the overall objective for safety for additional information on the final position taken by the Agency.

Please see the responses to comments Nos 61 and 288 for additional clarifications.

comment

1159

comment by: *Icetra*

Question 7:



The idea of using an overall „objective for safety“ and obliterating the current requirement of a “safety objective” is not supported. Using the “objective for safety” as a general, overall, approach is supported and has in fact been used by this CA in the first years after the introduction of the SMS/safety assessment requirements. It needs however to be taken into account, and we make the assumption that this is counted for elsewhere in the document, that the trigger for some changes is the fact that the system or component is unsafe (risk is higher than “acceptable”) and hence such an overall objective for safety will be unacceptable for such cases.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to the overall objective for safety for additional information on the final position taken by the Agency.

Please see the responses to comments Nos 61 and 288 for additional clarifications.

comment

1173

comment by: Avinor ANS

It is noted that the proxy approach is missing from point (b) although it is discussed extensively in the GM.

Amend (b) in to add:

“(3) proxies; and” as proposed in Appendix A

response

Partially accepted

Please see the response to comment No 66.

comment

1191

comment by: ENAIRE

We recommend that the concept ‘objective for safety’ should be renamed in order not to lead to confusion with the term ‘safety objective’ from (EU) No 1035/2011.

response

Not accepted

The term ‘objective for safety’ is not used as a technical term and not used in the IR at all. The definition seems unnecessary.

comment

1216

comment by: CAA-NL

Question 7: The Agency would like to know whether the stakeholders agree or disagree with the proposal for an overall objective for safety for the change as part of the SMS. Please provide the supporting rationale



with your answer.

The Netherlands agrees with the proposed requirement. However a clear minimum target cannot be set by Regulation yet, so we propose to work towards target setting in due time.

The Netherlands has been in the process of defining safety criteria including safety levels for changes to the functional system on a national basis for at least 15 years. EASA is invited to take notice of these developments.

The worry that safety could degrade over time is unjustified. There are many other rules that will prevent this: safety objectives, a safety policy, the application of SMS, occurrence management, etc. We suggest that the reason that the safety of Aviation has improved in the past up to this moment in time, is not only due to efforts limited to regulators, but also owing to the efforts of the industry itself, where safety is seen as good for business. Furthermore safety culture in aviation focuses on safety improvement, there is no reason to assume this will change.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the overall objective for safety for additional information on the final position taken by the Agency.

These comments are apparently based on a flawed argument.

Neither safety objectives nor safety requirements exist in this IR.

Safety policy and SMS are simply intended to ensure that the system gets safer over time, which can only be achieved by changing the functional system. There is no absolute level of safety defined so it is unknown how to calculate the TLS for a change.

Monitoring and performing surveys will show that the system does not meet its predicted performance. If the system does not meet its predicted performance levels, a change is to be initiated, but it is unclear what sets the TLS for this change.

Consequently, all we can expect currently is that changes do not introduce unacceptable risk into the system (the new objective for safety introduced after the consultation). The overall system remaining 'as safe as before' is, therefore, considered just a means to achieve it.

Please see the responses to comments Nos 61 and 288 for additional clarifications.

comment

1259

comment by: ENAV

Question 7: The Agency would like to know whether the stakeholders agree or disagree with the proposal for an overall objective for safety for the change as part of the SMS. Please provide the supporting rationale with your answer.

ENAV believes that the use of the safety criteria for each change will provide the needed safety assurance over time.



response	<p>ENAV disagrees with the proposal for having an overall safety objective for the change.</p> <p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the overall objective for safety for additional information on the final position taken by the Agency.</p>
comment	<p>1267 comment by: <i>CANSO</i></p> <p>Question 7: The Agency would like to know whether the stakeholders agree or disagree with the proposal for an overall objective for safety for the change as part of the SMS. Please provide the supporting rationale with your answer.</p> <p>CANSO believe that the use of the safety criteria for each change will provide the needed safety assurance over time.</p> <p>CANSO disagree with the proposal for having an overall safety objective for the change.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to the overall objective for safety for additional information on the final position taken by the Agency.</p>
comment	<p>1283 comment by: <i>EUROCONTROL</i></p> <p>Section 2.4.5 1st dash - Page 28</p> <p>More than the standard debate about RCS, the text should acknowledge that a key impediment to the knowledge of actual safety levels being achieved by service providers is the lack of regulatory requirement for ATM service providers to demonstrate the safety of their on-going operations.</p> <p>Restricting ATM <i>a priori</i> safety assessments to changes to operations / systems may have been a sensible expedient when ESARR 4 was introduced formally in 2003, on the assumption that the ATM service could be considered to have been acceptably safe up to that point. However, the rationale for maintaining that situation several years on is difficult to fathom, on two counts: the assurance of safety achievement based on historical data is diminished by subsequent changes; and there is a limit to the number of changes that can be accommodated before it becomes virtually impossible to know what system configuration is being changed. The simple solution is to carry out, and subsequently maintain, an <i>a priori</i> safety assessment of the whole ATM operation / system – unfortunately, so far, this has evaded the attention of European regulatory bodies.</p> <p>Having such an understanding in place would:</p> <ul style="list-style-type: none"> - maintain a current baseline of the Unit operations and systems, thus facilitating the management of change;



- in many instances, greatly reduce the amount of effort required in order to comply with the safety regulations for risk assessment of changes to the ATM system and also reduce the likelihood of individual project safety assessments defining contradictory safety requirements.

It is therefore suggested to highlight in this section the need for a service provider to demonstrate, a priori, the safety of their on-going operations.

Section 2.4.5

1st dash - Page 29

The text makes explicit 2 objectives for safety of a change being:

- at least as safe as (before the change);
- improving safety if the change is safety-related (e.g. new safety net).

However one case is missing that is to limit the safety deterioration (i.e. still safe but less than before). Without this being considered changes like moving from Distance Based operations to Time-Based operations on APP in head-wind conditions could not be brought into application (aircraft closer and WV stronger).

It is therefore suggested to enlarge the type of 'safety criteria' as suggested in the comment.

response

Partially accepted

It is apparent that the evaluation of the safety of ATM service has been proven unsuccessful. This has led the Agency to propose in this draft regulation the use of a relative approach to risk, instead of the evaluation of the level of safety of the ATM services.

The objective for safety has been changed to ensure the safety criteria prevent unacceptable level of safety being introduced. This way the examples given are possible (we think that they were possible with the old provisions, but now it is certainly acceptable to introduce certain 'controlled' risks). Please see the responses to comments Nos 61 and 288 for additional clarifications.

3. Proposed amendments — 3.1. Draft EASA Opinion — ANNEX I

p. 32

comment

29

comment by: *NATS National Air Traffic Services Limited*

3.1 Draft Regulation (Page 32)

NATS believes that there is a discrepancy between the NPA 2014-13 and CRD 2013-08 in that the philosophy by which the two rules have been created are not consistent, for instance the CRD 2013-08 advocates generic requirements for MS and SMS and yet NPA 2014-13 has specific requirements for changes to functional systems that are already covered by generic CRD 2013-08 provisions.

response

Noted



The Agency does not consider this fact as inconsistency. It has to be taken into account that the requirements are derived from Commission Implementing Regulations (EU) Nos 1034/2011 and 1035/2011 that are more prescriptive than those proposed with NPA 2014-13 in relation to the assessment of changes. In addition, the more detailed requirements of NPA 2014-13 address the need for increased clarity and focus on one particular aspect.

comment

30

comment by: *NATS National Air Traffic Services Limited***3.1 Draft Regulation (Page 32)**

NATS believes that some of the material in the proposed IR would be better as AMC. NATS has made some specific suggestions (in Appendix A), which NATS believes build upon the proposals in the NPA and make the rule easier to implement (and therefore more effective) by both CAs and service providers.

Additionally NATS believes that some of the IR and AMC in this NPA duplicates MS/SMS elements already addressed in CRD 2013-08. The placing of overlapping requirements with CRD 2013-08 introduces the potential for internal inconsistencies, duplicate regulation and a lack of legal certainty.

response

Partially accepted

Please see the responses to comments Nos 2 and 5. Some proposals that have been included in your Appendix A have been incorporated in the resulting text. Please check the final resulting text. The responses to individual changes have been provided in individual comments.

comment

31

comment by: *NATS National Air Traffic Services Limited***Annex I (Page 32)**

Definition 20 – Aviation undertaking - “organisations” are not regulated by this Regulation rather it is service providers as per CRD 2013-08. The definition of “organisation” in 1035/2011 is no longer applicable.

How can an aviation undertaking know if it affects a service delivered by a service provider as they are not regulated by this Regulation and legally no obligations can be placed upon them? As an example a GA infringing controlled airspace could affect the service provided yet would be completely unaware of this Regulation or that they are an aviation undertaking.

Whilst the intent is to be all encompassing the reality is different and the use of such a



	definition makes for infeasible rules.
response	<p>Partially accepted</p> <ul style="list-style-type: none"> — The term ‘organisation’ is replaced by the term ‘service provider’, when referring to those organisations regulated by this Regulation. — This regulation does not impose any requirement on ‘aviation undertakings’. The latter is a collective noun used to refer to the variety of stakeholders that use services provided by ‘service providers’ subject to this regulation. Knowing that they are named ‘aviation undertaking’ or not seems irrelevant. What is of relevance here is that service providers are able to identify their group of aviation undertakings.
comment	<p>32 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>Annex I (Page 32)</p> <p>Definition 35 – Functional system - whilst this definition is in Annex I and not Art 2 it is considered that use of the term “ATM/ANS” invokes the definition Art 3 (q) of 216/2008 (amended). If this is not the case then ATM/ANS is undefined. In either circumstance the scope of functional system is not consistent with the scope of service providers.</p>
response	<p>Accepted</p> <p>ATM/ANS is complemented with ‘other ATM network functions’ to be in line with the scope of service providers as defined in the present CRD.</p>
comment	<p>332 comment by: <i>ATCEUC - Air Traffic Controllers European Unions Coordination</i></p> <p>ATCEUC agrees with the new definition of Functional System because systems are usually thought of as comprising people, procedures, equipment and architecture, and therefore the term would be overloaded in the previous FS definition.</p>
response	<p>Noted</p>
comment	<p>388 comment by: <i>skyguide Corporate Regulation Management</i></p> <p>We believe that some of the material in the proposed IR would be more appropriate as AMC. We have made some specific suggestions (in Appendix A), which it is believed builds upon the proposals in the NPA and make the rule easier to implement (and therefore more effective) by both CAs and service providers.</p> <p>Additionally we believe that some of the IR and AMC in this NPA duplicates MS/SMS elements already addressed in CRD 2013-08. The placing of overlapping requirements with</p>



	<p>CRD 2013-08 introduces the potential for internal inconsistencies, duplicate regulation and a lack of legal certainty.</p>
response	<p>Partially accepted</p> <p>Please see the responses to comments Nos 2 and 5. Some proposals that have been included in your Appendix A have been incorporated in the resulting text. Please check the final resulting text. The responses to individual changes have been provided in individual comments.</p>
comment	<p>603 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>Definition (35)</p> <p>ANNEX I Definitions of terms used in Annexes II to XIII 35 ‘Functional system’ and chapter 2.4.1. Proposed amendments to Annex I ‘Definitions for terms used in Annex II to XIII’ The word ‘systems’ from the previous definition has been replaced by ‘equipment’ in order to avoid the difficulty that systems are generally thought of as comprising people, procedures, equipment and architecture and so the term ‘system’ is overloaded in the functional system definition. Furthermore, ‘system’ may be confused with the same term used in Regulation (EC) No 549/2004 where it is inappropriate to cover the concept that we are trying to regulate since it does not include people or procedures and whose scope is limited to ANS. ATM has been complemented with ANS so as to cover the entire scope of the services and be consistent with the scope of the Basic Regulation.</p> <p>DFS strongly disagrees with the introduction of the definition for “equipment”. The current misfit of existing definitions (within EASA B.R. and SES Regulations) should not be enlarged by adding another non-fitting, inconsistent definition which is created for academic purpose only. The term “equipment” is used in EASA B.R. in combination with aerodromes”. However the academic information given under GM1 to Definition (35) is of no use when to decide what equipment is subject to which regulation. The SES term “constituents” is deemed appropriate to cover the intended scope. Any irritation stemming from definitions in EU law should be solved at the level of the EU law instead of creating more confusion in implementing rules or even their AMC/GM. Some examples: “ATM/ANS system shall mean any combination of safety related equipment and systems (=aggregation of airborne and ground-based constituents as well as space based equipment)”. “Constituent shall mean tangible objects such as hardware as well as intangible objects such as software upon which the interoperability of the EATMN depends.” What is an airborne constituent? Airborne technology is regulated as “product, part and appliance” (which could by that definition be equipment, but not constituent). “Aerodrome equipment shall mean any equipment, software...”. “Safety related” equipment is used only in the context of aerodromes. Proposal: do not create new, helpless definitions but think of a broader and horizontal consistency when adapting the B.R. and repealing the SES Regulations, i.e. with the SES2+ package. Reference to high level comment "c.ii"</p>



response Not accepted

There is not a creation of a new term, but a replacement of the term 'system' which is overloaded. The only purpose to include a definition of equipment in GM was to make clear that when we refer to 'equipment' both its hardware and its software are included. There is no intention to introduce additional terminology. This term has been well received by a number of commentators.

comment 633 comment by: CANSO

CANSO believe that some of the material in the proposed IR would be more appropriate as AMC. CANSO has made some specific suggestions (in Appendix A), which it is believed builds upon the proposals in the NPA and make the rule easier to implement (and therefore more effective) by both CAs and service providers.

Additionally CANSO believes that some of the IR and AMC in this NPA duplicates MS/SMS elements already addressed in CRD 2013-08. The placing of overlapping requirements with CRD 2013-08 introduces the potential for internal inconsistencies, duplicate regulation and a lack of legal certainty.

response Partially accepted

Please see the responses to comments Nos 2 and 5. Some proposals that have been included in your Appendix A have been incorporated in the resulting text. Please check the final resulting text. The responses to individual changes have been provided in individual comments.

comment 837 comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.1 <i>Draft Regulation (Draft EASA Opinion) Annex I</i> <i>Definitions of terms used in Annexes II to XIII</i></p>	<p>We wonder whether the definition #35 for 'functional system' is coherent with the definition of 'equipment' as shown in section 2.4.1 (page 18) of this NPA.</p>	<p>There is an inconsistency in the inclusion/non inclusion of the term 'software'. This term appears in this definition in relation with the equipment ("<i>...</i> equipment, including hardware and software (...)") whereas it is not explicitly stated in the definition proposed for 'equipment'.</p> <p>We kindly refer EASA to the comment that we have made on <i>section 2.4.1</i> and our proposal for amendment of the definition of 'equipment'.</p>



response

Not accepted

The definition of equipment is given to provide a hierarchy of elements and its relation with software and hardware. The main purpose is to be clear that both software and hardware are included as part of the functional system definition. The use of the overloaded term 'system' would not help. Both terms seem coherent.

comment

839

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.1 <i>Draft Regulation (Draft EASA Opinion) Annex I</i> <i>Definitions of terms used in Annexes II to XIII</i></p>	<p>We are not clear whether this definition is #35 (as shown within section 3) or #36 (as stated in sections 2.4.4 and 2.4.6).</p>	<p>Although we understand that this definition is, in fact, #35, there are still inconsistencies in the numbering of Annex I after the introduction of the new definitions proposed by this NPA.</p> <p>We kindly refer EASA to our general comment on the quality of this document.</p>

response

Accepted

Said definition is No 35. The Agency acknowledges the presence of typos, mainly due to last-minute changes made in several parts of NPA 2014-13 and even in the text of CRD 2013-08, which inadvertently passed through without the amendment of the corresponding cross-references. This is one of them. There was a typo in sections 2.4.4 and 2.4.6 due to the above-mentioned changes. The numbering is now corrected in the related Opinion.

comment

852

comment by: Naviair

Naviair has proposed amendments to the IR which are placed at the end of these comments. The amendments are the same as proposed by CANSO.

response

Partially accepted

Please see the responses to comments Nos 2 and 5. Some proposals that have been included in your Appendix A have been incorporated in the resulting text. Please check the final



resulting text. The responses to individual changes have been provided in individual comments.

comment 1070 comment by: *Frasie Loredana*

Include a definition for *objective for safety*.

Justification

If this term is going to be used in a technical manner, it needs to be defined.

Some explanation is found in the Explanatory note, para 2.4.5. but this does not substitute a definition.

response Not accepted

The term 'objective for safety' is not used as a technical term and not used in the IR at all. The definition seems unnecessary.

comment 1160 comment by: *Icetra*

The term „aviation undertaking“ is a very generic, wide-ranging and non-descriptive term. A more descriptive term is suggested for this concept; the term „affected body“ is suggested.

The proposed revised definition of "functional system" is supported and considered an improvement.

response Not accepted

The term 'aviation undertaking' is generic due to the different nature of bodies the proposed regulation is dealing with, from aerodrome operators to aircraft operators, but also regulators. The generic term 'aviation undertaking' is deemed to be more appropriate.

comment 1174 comment by: *Avinor ANS*

We believe that some of the material in the proposed IR would be more appropriate as AMC. In Appendix A we have a proposal, which it is believed builds upon the proposals in the NPA and make the rule easier to implement (and therefore more effective) by both CAs and service providers.

Some of the IR and AMC in this NPA duplicates MS/SMS elements already addressed in CRD 2013-08. The placing of overlapping requirements with CRD 2013-08 introduces the potential for internal inconsistencies, duplicate regulation and a lack of legal certainty.

response Partially accepted

Please see the responses to comments Nos 2 and 5. Some proposals that have been included in your Appendix A have been incorporated in the resulting text. Please check the final



resulting text. The responses to individual changes have been provided in individual comments.

comment 1284

comment by: EUROCONTROL

Proposed amendments – Draft EASA opinion

Section 3.1

Annex I - Page 32

Reading the NPA, it seems that the way “hazard” (as it has been in the past) has been interpreted is that it relates only to hazards generated by the change. This might result (as it happened with previous REG) in the widespread belief that the regulation is concerned only with the failure of ATM systems, leading to the possibility of incomplete and irrational conclusions, e.g. (but not limited to) if the safety criterion is about a net safety improvement. It is suggested that:

1. A definition of safety criteria makes it clear that the prescribed acceptable level of risk is a net value, which takes account of ATM’s positive (accident-prevention) and negative (accident-causation) contributions to aviation safety.
2. As a result of the above, a definition proposing a broader interpretation of hazard is made in Annex I covering both relevant pre-existing aviation hazards (which the ATM/ANS functional system relevant to the change has to mitigate) and generated hazards which are created by failure of the change to the ATM/ANS functional system.

response Partially accepted

The Agency actually concurs with the commentator that the level of risk should account for the positive contribution of the changes and the potential failures. The Agency does not see anything in the IR that prevents this. In addition, the hazards that should be considered are not only those introduced by the change, but also those pre-existing, as the behaviour of the system may change when the change is introduced, and, thus, their analysis is important (please refer to GM1 ATS.OR.205(b)(2)).

The Agency does not see the need at this point to amend the IR text. Certain adjustments and broader explanations may be needed in the AMC/GM that will be proposed in the near future.

comment 1289

comment by: European Transport Workers Federation - ETF

35 "Functional System"

ETF welcomes the definition replacing *systems* with **equipment**

response Noted



3. Proposed amendments — 3.1. Draft EASA Opinion — ANNEX II — ATM/ANS.AR.C.010 Oversight

p. 33

comment 33 comment by: NATS National Air Traffic Services Limited

ATM/ANS.AR.C.010 (b)(5) (Page 33)

“... verify changes made to the functional system:”

This is part of the general oversight process, rather than a special case. Given that proposed ATM/ANS.AR.C.010(5)(i)(ii) and (iii) are confirming that applicable requirements are being met is this not covered by existing ATM/ANS.AR.C.010(b)(1)? If this is deemed necessary then why stop here? Why not add all applicable requirements that the service provider has to comply with? If these are somehow more important draw the CAs attention to them in AMC.

Proposal: Specific proposals for how to achieve this in Appendix A whereby the proposed text is recast as specific AMC for changes to the functional system as part of Oversight.

response Accepted

The provisions have been removed from the IR and will be moved to AMC/GM level.

comment 34 comment by: NATS National Air Traffic Services Limited

ATM/ANS.AR.C.010 (b)(5)(ii) (Page 33)

ATM/ANS.OR.B.010 is about submission and approval of applicable procedures and any modifications and not about in accordance with them as required by (b)(5)(ii). The specific rules should be directly identified in (b)(5)(ii) and avoid ambiguous cross-referencing.

In addition (b)(5)(i) refers specifically to ATM/ANS.OR.A.045 and is also specifically included ATM/ANS.OR.B.10. Therefore ATM/ANS.OR.A.045 is to be complied with according to (b)(5)(i) and be managed in accordance with in ATM/ANS.OR.B.010 in (b)(5)(ii). It is assumed that (b)(5)(i) is correct and therefore when including the specific rules into the text of (b)(5)(ii) ATM/ANS.OR.A.045 should be omitted.

Proposal: Specific proposals for how to achieve this in NATS Appendix A (attached document to comment 25) whereby specific reference has been made to the applicable IR.

response Partially accepted

The provision in question (ATM/ANS.OR.B.010) has been redrafted to make clear the



requirement for the service provider to use these procedures (before this aspect was implicit). The cross reference is correct now.

AR.C.10(b)(5) has been moved to AMC. The wording around the reference has been made clearer.

ATM/ANS.OR.B.10 has been amended to make the reference to the procedures clearer.

comment 35 comment by: NATS National Air Traffic Services Limited

ATM/ANS.AR.C.010 (b)(6) (Page 33)

Given that this text refers to what a CA should look for as part of its oversight, then the CA should seek confirmation that the service provider has initiated a change or provided a valid argument and not indirectly place a requirement on the service provider in AR. The monitoring referred to is undertaken by the service provider. The CA should seek evidence that where the monitoring has detected a shortcoming the service provider has already acted. If the CA finds evidence to the contrary then a finding should be raised. It should not be the case that only when oversight detects a shortcoming that the service provider reacts.

Proposal: Specific proposals for how to achieve this in Appendix A (document attached to NATS comment 25) to these comments by specific text changes.

response Accepted

Considering the NPA 2014-13 consultation, the commented provision has been moved to AMC. When finalising the AMC/GM material, the comment will be taken in due consideration.

comment 70 comment by: EUROCONTROL Safety Team

ATM/ANS.AR.C.010 (b)(5)

The requirement ... *verify changes made to the functional system* is actually part of the general oversight process, rather than a special case. This requirement is already covered by ATM/ANS.AR.C.010(b)(1) [see CRD 2013-08 Page 49].

Recommend that this requirement is removed but retained as AMC on the oversight of changes to the functional system.

response Accepted

The provisions have been removed from the IR and will be moved to AMC/GM level.

comment 71 comment by: EUROCONTROL Safety Team



ATM/ANS.AR.C.010 (b)(6)

This requirement is confusing. It refers to oversight by CA as confirmation on what the service provider should be doing because the monitoring referred to is done by the service provider as required by ATM/ANS.AR.C.010 (b)(5) (iii). If monitoring has indicated a shortcoming, the service provider should have had already initiated remedial actions. In such a case the CA needs only to see evidence that this is being done and raises a finding in case the service provider has not taken any action.

The text is more appropriate as AMC.

Recommend that this requirement is removed but retained as AMC on the oversight of changes to the functional system.

response

Accepted

Considering the NPA 2014-13 consultation, the commented provision has been moved to AMC. When finalising the AMC/GM material, the comment will be taken in due consideration.

comment

178

comment by: DSNA

(5) : "... verify changes made to the functional system:" This is part of the general oversight process, rather a special case. Given that proposed ATM/ANS.AR.C.010(5)(i)(ii) and (iii) are confirming that applicable requirements are being met is this not covered by existing ATM/ANS.AR.C.010(b)(1) ? If this is deemed necessary then why stop here? Why not add all applicable requirements that the service provider has to comply with? If these are somehow more important draw the CAs attention to them in AMC.

Proposal to delete (b)(5) & (6) and to move in an AMC or GM.

response

Accepted

The provisions have been removed from the IR and will be moved to AMC/GM level.

comment

179

comment by: DSNA

(6) : This part is already covered by the 5(iii) for AR requirements.

DSNA request deletion of this provision because this requirement applies to an OR and is therefore inappropriate in a AR provision.

Moreover, we suggest the following modification :

"verify that if, as a result of the monitoring referred to in (5)(iii), the argument, referred to in ATS.OR.205(a)(2) or ATM/ANS.OR.C.005(a)(2), is found to be unsound, then the service provider shall initiate a change or, provide a valid argument **or any appropriate measure to make the risk acceptable**"

response

Accepted



Considering the NPA 2014-13 consultation, the commented provision has been moved to AMC. When finalising the AMC/GM material, the comment will be taken in due consideration.

comment

261

comment by: UK CAA

Page No: 33**Paragraph No:** ATM/ANS.AR.C.010 Oversight

Comment: The requirement under ATM/ANS.AR.C.010(b)(5) for the verification of changes to functional systems does not make clear if the requirement is for all changes to be verified or if this can be done on a sampling basis as part of routine oversight audits which are based on the assessment of associated risks as required by **ATM/ANS.AR.C.015 Oversight programme**

Justification: Clarity of text as to the level of verification required for changes to functional systems

Proposed Text:

'(b) The audits referred to in paragraph (a) shall:

(5) Ensure that changes made to functional systems are verified. The need for such verification shall be based on an assessment of associated risks'

response

Not accepted

Considering additional comments received on NPA 2014-13, the commented provisions have been moved to AMC/GM. Your proposal to amend the IR is not accepted, but the text will be assessed when developing the related AMC/GM.

comment

340

comment by: ATCEUC - Air Traffic Controllers European Unions Coordination

ATM/ANS.AR.C.010 Oversight (b)(5) & (6)

In the monitoring requirements, which may help identify the need for a change in case safety criteria is not met, we think that the staff affected by the change should be involved in the oversight of the functional changes that affect their work, such as changes of software/hardware, working positions, etc. Therefore ATCEUC proposes a new paragraph (c) and some GM.

ATM/ANS.AR.C.010 (c)

(c) To guarantee that the provisions in (b) are fulfilled, the designated body experts that conducts the oversight will seek advice of first-line workers that are affected by the change

GM1 ATM/ANS.AR.C.010(c)

"Examples of workers that may be affected by the change are atcos and/or engineers and/or



	<p><u>atseps and/or technicians, etc.”</u></p>
response	<p>Not accepted</p> <p>The Agency does agree that staff need to be involved in the oversight; however, this issue is handled by the application of the management system provisions and the oversight by the competent authority. The proposal for IR text is not considered necessary. In any case, the provision has been moved to AMC/GM as the activities to confirm that applicable requirements are being met is covered by the existing ATM/ANS.AR.C.010(b)(1).</p>
comment	<p>396 comment by: <i>skyguide Corporate Regulation Management</i></p> <p>ATM/ANS.AR.C.010 (b)(5) “... verify changes made to the functional system:” This is part of the general oversight process, rather a special case. Given that proposed ATM/ANS.AR.C.010(5)(i)(ii) and (iii) are confirming that applicable requirements are being met is this not covered by existing ATM/ANS.AR.C.010(b)(1)? If this is deemed necessary then why stop here? Why not add all applicable requirements that the service provider has to comply with? If these are somehow more important draw the CAs attention to them in AMC. Specific proposals for how to achieve this in Appendix A whereby the proposed text is recast as specific AMC for changes to the functional system as part of Oversight.</p> <p>ATM/ANS.AR.C.010 (b)(6) Given that this text refers to what a CA should look for as part of its oversight, then the CA should seek confirmation that the service provider has initiated a change or provided a valid argument and not indirectly place a requirement on the service provider in AR. The monitoring referred to is undertaken by the service provider. The CA should seek evidence that where the monitoring has detected a shortcoming the service provider has already acted. If the CA finds evidence to the contrary then a finding should be raised. It should not be the case that only when oversight detects a shortcoming that the service provider reacts. Specific proposals for how to achieve this in Appendix A whereby the proposed text is recast as specific AMC for changes to the functional system as part of Oversight.</p>
response	<p>Accepted</p> <p>The provisions have been removed from the IR and will be moved to AMC/GM level.</p>
comment	<p>479 comment by: <i>CAA CZ</i></p> <p>ATM/ANS.AR.C.010 Oversight (iii) are being verified against the monitoring requirements that were identified in the assurance argument as a result of complying with ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7), as appropriate</p>



	Supported by CAA CZ.
response	<p>Noted</p> <p>Your support is appreciated. Due to several comments addressing the duplication of this requirement with one already existing in CRD to NPA 2013-08, the proposed provision has been moved to AMC/GM. Please see also response to comment No 33.</p>
comment	<p>604 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>(b) (5)</p> <p>This is part of the general oversight process. It seems to already be covered by existing ATM/ANS.AR.C.010 (b) (1). Reference to high level comment "b"</p>
response	<p>Accepted</p> <p>The provisions have been removed from the IR and will be moved to AMC/GM level.</p>
comment	<p>605 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>(b) (6)</p> <p>Given that this text refers to what a CA should look for as part of its oversight, then the CA should seek confirmation that the service provider has initiated a change or provided a valid argument and not indirectly place a requirement on the service provider in IR. The monitoring referred to is undertaken by the service provider. The CA should seek evidence that where the monitoring has detected a shortcoming the service provider has already acted. If the CA finds evidence to the contrary then a finding should be raised. It should not be the case that only when oversight detects a shortcoming that the service provider reacts Reference to high level comment "c.i"</p> <p>A suggestion can be found in the attachment to our comment no 757</p>
response	<p>Accepted</p> <p>Considering the NPA 2014-13 consultation, the commented provision has been moved to AMC. When finalising the AMC/GM material, the comment will be taken in due consideration.</p> <p>The Agency agrees with the comment but specific changes in the wording will be analysed when finalising the AMC/GM.</p>
comment	<p>634 comment by: <i>CANSO</i></p> <p>ATM/ANS.AR.C.010 (b)(5)</p>



“... verify changes made to the functional system:”

This is part of the general oversight process, rather a special case. Given that proposed ATM/ANS.AR.C.010(5)(i)(ii) and (iii) are confirming that applicable requirements are being met is this not covered by existing ATM/ANS.AR.C.010(b)(1)? If this is deemed necessary then why stop here? Why not add all applicable requirements that the service provider has to comply with? If these are somehow more important draw the CAs attention to them in AMC.

Specific proposals for how to achieve this in Appendix A whereby the proposed text is recast as specific AMC for changes to the functional system as part of Oversight.

response

Accepted

The provisions have been removed from the IR and will be moved to AMC/GM level.

comment

635

comment by: *CANSO*

ATM/ANS.AR.C.010 (b)(6)

Given that this text refers to what a CA should look for as part of its oversight, then the CA should seek confirmation that the service provider has initiated a change or provided a valid argument and not indirectly place a requirement on the service provider in AR. The monitoring referred to is undertaken by the service provider. The CA should seek evidence that where the monitoring has detected a shortcoming the service provider has already acted. If the CA finds evidence to the contrary then a finding should be raised. It should not be the case that only when oversight detects a shortcoming that the service provider reacts. Specific proposals for how to achieve this in Appendix A whereby the proposed text is recast as specific AMC for changes to the functional system as part of Oversight.

response

Accepted

Considering the NPA 2014-13 consultation, the commented provision has been moved to AMC. When finalising the AMC/GM material, the comment will be taken in due consideration.

The Agency agrees with the comment but specific changes in the wording will be analysed when finalising the AMC/GM.

comment

686

comment by: *ROMATSA*

ATM/ANS.AR.C.010 (b)(5)

“... verify changes made to the functional system:”

This is part of the general oversight process, rather a special case. Given that proposed ATM/ANS.AR.C.010(5)(i)(ii) and (iii) are confirming that applicable requirements are being met is this not covered by existing ATM/ANS.AR.C.010(b)(1)? If this is deemed necessary then why stop here? Why not add all applicable requirements that the service provider has to



comply with? If these are somehow more important draw the CAs attention to them in AMC.

Specific proposals for how to achieve this in Appendix A whereby the proposed text is recast as specific AMC for changes to the functional system as part of Oversight.

Supporting comment to summary issues: Specific Example of MS / SMS Split.

ATM/ANS.AR.C.010 (b)(6)

Given that this text refers to what a CA should look for as part of its oversight, then the CA should seek confirmation that the service provider has initiated a change or provided a valid argument and not indirectly place a requirement on the service provider in the proposed regulation. The monitoring referred to is undertaken by the service provider. The CA should seek evidence that where the monitoring has detected a shortcoming the service provider has already acted. If the CA finds evidence to the contrary then a finding should be raised. It should not be the case that only when oversight detects a shortcoming that the service provider reacts.

Specific proposals for how to achieve this in Appendix A whereby the proposed text is recast as specific AMC for changes to the functional system as part of Oversight.

Supporting comment to summary issues: IR does not achieve the perceived intention of the rule

response

Accepted

The provisions have been removed from the IR and will be moved to AMC/GM level.

comment

882

comment by: *Naviair*

Naviair propose the following text for (page 33-39 of NPA 2014-13):

ANNEX II

REQUIREMENTS FOR COMPETENT AUTHORITIES — SERVICE PROVISION AND NETWORK FUNCTIONS (Part-ATM/ANS.AR)

SUBPART A — GENERAL REQUIREMENTS

SUBPART B — MANAGEMENT (ATM/ANS.AR.B)

SUBPART C — OVERSIGHT, CERTIFICATION, AND ENFORCEMENT (ATM/ANS.AR.C)

~~ATM/ANS.AR.C.010~~ AMC1 ATM/ANS.AR.C.010(a). Oversight

CHANGES TO THE FUNCTIONAL SYSTEM

The audits should:

(a) verify that changes made to the functional system:

(1) comply with ATM/ANS.OR.A.045;

(2) have been managed in accordance with ATM/ANS.OR.C.005, ATS.OR.205 and ATS.OR.210 as applicable; and



(3) are being verified against the monitoring requirements that were identified in the assurance argument as a result of complying with AMC1 ATM/ANS.OR.C.005(c) or AMC1 ATS.OR.205(g), as appropriate.

(b) verify that if, as a result of the monitoring referred to in (a)(3), the argument, referred to in ATM/ANS.OR.C.005(b) or ATS.OR.205(b), was found to be unsound, then the service provider has initiated a change or provided a valid argument.

ATM/ANS.AR.C.030 AMC3 ATM/ANS.AR.C.025(b). Changes

APPROVAL OF CHANGE MANAGEMENT PROCEDURES

(a) The competent authority should review:

(1) those change management procedures submitted by the service provider in accordance with AMC1 ATM/ANS.OR.A.040(a)(2);

(2) all significant modifications to the change management procedures referred to in (1); and

(3) any significant deviation to the change management procedures referred to in (1) for a particular change, when requested by the service provider in accordance with AMC2 ATM/ANS.OR.A.40(a)(2).

(b) The competent authority should approve the procedures, modifications and deviations referred to in (a) when it has determined that they are necessary and sufficient for the service provider to demonstrate compliance with ATM/ANS.OR.A.045, ATM/ANS.OR.C.005, ATS.OR.205 or ATS.OR.210, as applicable.

ATM/ANS.AR.C.035. Decision to review the notified change to the functional system

Upon receipt of a notification in accordance with ATM/ANS.OR.A.045(a), the competent authority shall make a decision on whether to review the change or not. The competent authority shall request any additional information needed from the service provider to support this decision.

AMC1 ATM/ANS.AR.C.035. Decision to review the notified change to the functional system

VALID AND DOCUMENTED CRITERIA

(a) The competent authority should determine the need for a review based on specific, valid and documented criteria that:

(1) as a minimum, ensures that the notified change is reviewed if the combination of the likelihood of a complex or unfamiliar argument and the severity of the possible consequences of the change is significant.

(2) can be used in addition to (1), when the competent authority decides the need for a review based on other documented criteria.

(b) The competent authority should:

(1) inform the service provider of its decision to review the notified change to a functional system or not; and

(2) provide the associated rationale to the service provider on request.

ATM/ANS.AR.C.040. Risk-based review of the notified change to the functional system

(a) When the competent authority reviews the argument for a notified change to a functional system, it shall:

(1) verify that the procedures used by the service provider were approved;

(2) use documented procedures and guidance to perform their review;

(3) assess the validity of the argument presented with respect to ATM/ANS.OR.C.005(b) or ATS.OR.205(b); and



0,
 (4) coordinate its activities with other competent authorities whenever necessary.
 (b) The competent authority shall conduct the review in a manner which is proportionate to the risk associated with the change.
 (c) The competent authority shall:
 (1) approve the argument referred to in ATM/ANS.OR.C.005(b) or ATS.OR.205(b), with conditions where applicable, and so inform the service provider of their acceptability, or
 (2) reject the argument referred to in ATM/ANS.OR.C.005(b) or ATS.OR.205(b) and inform the service provider of their unacceptability with supporting rationale.

response

Partially accepted

- ATM/ANS.AR.C.010: Accepted. The provision has been removed from the IR and will be moved to AMC/GM.
- ATM/ANS.AR.C.025: Not accepted (please see the response to comment No 36)
- AMC1 ATM/ANS.AR.C.035: Not accepted (please see the response to comment No 39)
- ATM/ANS.AR.C.040: The changes proposed are not identified. Please see modifications to final text.

comment

986

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.1 <i>Draft Regulation (Draft EASA Opinion)</i> <i>Annex II</i> REQUIREMENTS FOR COMPETENT AUTHORITIES — SERVICE PROVISION AND NETWORK FUNCTIONS (Part-ATM/ANS.AR)	There is one tabulator too many in provision (b)(6) of ATM/ANS.AR.C.010 Oversight.	Formatting error

response

Accepted

Considering, though, the NPA 2014-13 consultation, the commented provision has been moved to AMC.



comment	1008	comment by: LVNL
	<p>ATM/ANS.AR.C.010 (b)(5) “... verify that changes made to the functional system:” <i>What follows is a reference to rules that should have been followed. However, that already should be part of the general oversight process. Propose to move the contents of this IR to AMC level.</i></p>	
response	<p>Accepted</p> <p>The provisions have been removed from the IR and will be moved to AMC/GM level.</p>	
comment	1011	comment by: LVNL
	<p>ATM/ANS.AR.C.010 (b)(6) <i>Given that this text refers to what a CA should look for as part of its oversight, then the CA should seek confirmation that the service provider has initiated a change or provided a valid argument and not indirectly place a requirement on the service provider in AR. The monitoring referred to is undertaken by the service provider. The CA should seek evidence that where the monitoring has detected a shortcoming the service provider has already acted. If the CA finds evidence to the contrary then a finding should be raised. It should not be the case that only when oversight detects a shortcoming that the service provider reacts.</i></p>	
response	<p>Accepted</p> <p>Considering the NPA 2014-13 consultation, the commented provision has been moved to AMC. When finalising the AMC/GM material, the comment will be taken in due consideration.</p> <p>The Agency agrees with the comment but specific changes in the wording will be analysed when finalising the AMC/GM.</p>	
comment	1098	comment by: Belgocontrol
	<p>ATM/ANS.AR.C.010 (b)(5) The requirement ... <i>verify changes made to the functional system</i> is part of the general oversight process and is already covered by ATM/ANS.AR.C.010(b)(1) [see CRD 2013-08 Page 49]. Recommend that this requirement is removed but retained as AMC on the oversight of changes to the functional system.</p>	
response	<p>Accepted</p> <p>The provisions have been removed from the IR and will be moved to AMC/GM level.</p>	



comment	<p data-bbox="363 271 427 309">1100</p> <p data-bbox="1161 271 1498 309" style="text-align: right;">comment by: <i>Belgocontrol</i></p> <p data-bbox="363 360 671 398">ATM/ANS.AR.C.010 (b)(6)</p> <p data-bbox="363 405 1498 645">This requirement is confusing. It refers to the oversight by CA as confirmation on what the service provider should be doing because the monitoring is done by the service provider as required by ATM/ANS.AR.C.010 (b)(5) (iii). If monitoring has indicated a shortcoming, the service provider should have initiated remedial actions. In such a case the CA needs only to see evidence that this is being done and raises a finding in case the service provider has not taken any action.</p> <p data-bbox="363 651 1498 734">Recommend that this requirement is removed but retained as AMC on the oversight of changes to the functional system.</p>
response	<p data-bbox="363 770 480 808">Accepted</p> <p data-bbox="363 831 1498 958">Considering the NPA 2014-13 consultation, the commented provision has been moved to AMC. When finalising the AMC/GM material, the comment will be taken in due consideration.</p> <p data-bbox="363 965 1498 1070">The Agency agrees with the comment but specific changes in the wording will be analysed when finalising the AMC/GM.</p>
comment	<p data-bbox="363 1128 427 1167">1175</p> <p data-bbox="1161 1128 1498 1167" style="text-align: right;">comment by: <i>Avinor ANS</i></p> <p data-bbox="363 1211 970 1249">“... verify changes made to the functional system:”</p> <p data-bbox="363 1256 1498 1406">This is part of the general oversight process, rather a special case. Given that proposed ATM/ANS.AR.C.010(5)(i)(ii) and (iii) are confirming that applicable requirements are being met is this not covered by existing</p>
response	<p data-bbox="363 1406 480 1444">Accepted</p> <p data-bbox="363 1458 746 1496">It has been moved to AMC/GM.</p>
comment	<p data-bbox="363 1583 427 1621">1176</p> <p data-bbox="1161 1583 1498 1621" style="text-align: right;">comment by: <i>Avinor ANS</i></p> <p data-bbox="363 1666 683 1704">ATM/ANS.AR.C.010(b)(1)?</p> <p data-bbox="363 1711 1498 1794">Specific proposals for how to achieve this in Appendix A whereby the proposed text is recast as specific AMC for changes to the functional system as part of Oversight.</p>
response	<p data-bbox="363 1823 480 1861">Accepted</p> <p data-bbox="363 1868 746 1906">It has been moved to AMC/GM.</p>



comment	1177	comment by: Avinor ANS
	<p>Given that this text refers to what a CA should look for as part of its oversight, then the CA should seek confirmation that the service provider has initiated a change or provided a valid argument and not indirectly place a requirement on the service provider in AR. The monitoring referred to is undertaken by the service provider. The CA should seek evidence that where the monitoring has detected a shortcoming the service provider has already acted. If the CA finds evidence to the contrary then a finding should be raised. It should not be the case that only when oversight detects a shortcoming that the service provider reacts. Specific proposals for how to achieve this in Appendix A whereby the proposed text is recast as specific AMC for changes to the functional system as part of Oversight.</p>	
response	<p>Accepted</p> <p>Considering the NPA 2014-13 consultation, the commented provision has been moved to AMC. When finalising the AMC/GM material, the comment will be taken in due consideration.</p> <p>The Agency agrees with the comment but specific changes in the wording will be analysed when finalising the AMC/GM.</p>	
comment	1222	comment by: CAA-NL
	<p>ATM/ANS.AR.C.010 (b) (5)Oversight</p> <p>The Netherlands doesn't really see the need for this article, as it is already covered by ATM/ANS.AR.C.005 under (a) (1) of CRD 2013-08 and the requirements of the management system in CRD 2013-08 ATS/ANS.OR.B.05:</p> <p>"ATM/ANS.AR.C.005 (a)(1) Verify ATM/ANS providers' compliance with applicable requirements set out in Annex II to XI of this Regulation, and any applicable conditions attached to the certificate before the issue or renewal of a certificate. The certificate shall be issued in accordance with Appendix I to this Part;"</p>	
response	<p>Accepted</p> <p>The provisions have been removed from the IR and will be moved to AMC/GM level.</p>	
comment	1275	comment by: European Transport Workers Federation - ETF
	<p>With reference to the definition of "<i>functional system</i>" ETF consider human resources a crucial element to be involved during the oversight process, and propose to add to ATM/ANS.AR.C.010 the paragraph (c) stating that "<i>staff affected by the change shall be consulted during audits and oversight assessments.</i>"</p> <p>ETF propose to include a GM to the ATM/ANS.AR.C.010(c) to describe the procedures of</p>	



	consultation and to identify the staff affected by the change, e.g. trade unions, staff representatives, etc.
response	<p>Not accepted</p> <p>The Agency does agree to include requirements at the IR level to have the operational staff involved during the audit process. The competent authority will have to check that all requirements have been complied with, including coordination with staff or representatives (as aviation stakeholders), if applicable.</p> <p>In any case, the provision has been moved to AMC/GM, as the activities to confirm that applicable requirements are being met is covered by the existing ATM/ANS.AR.C.010(b)(1), and no additional details are necessary.</p>

3. Proposed amendments — 3.1. Draft EASA Opinion — ANNEX II — ATM/ANS.AR.C.030 Approval of change management procedures for ATM/ANS functional systems

p. 33-34

comment	<p>36</p> <p>comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>ATM/ANS.AR.C.030 Page 33</p> <p>With the explicit adoption of MS and SMS in CRD to NPA 2013-08 it is assumed that these change management procedures are a part of the MS/SMS. As such there is already text on changes to the MS/SMS (although not explicitly procedures).</p> <p>It should be noted that the title of this IR limits its scope to ATM/ANS functional systems (see NATS comment on Definition 35).</p> <p>Furthermore, the competent authority is required to review (a)(2) all modifications to procedures referred to in (1). NATS believes this is infeasible and proposes that only significant modifications should be subject to review.</p> <p>Specific proposals for how to achieve this in Appendix A whereby the proposed text is made AMC to ATM/ANS.AR.C.025(b) Changes - specifically for approval of change management procedures.</p> <p>Proposal: Specific proposals for how to achieve this in NATS Appendix A (document attached to NATS comment number 25) whereby the proposed text is made AMC to ATM/ANS.AR.C.025(b) Changes - specifically for approval of change management procedures.</p>
response	<p>Partially accepted</p> <p>The philosophy is that change procedures may be independent of the MS/SMS at certification. They can be submitted at any time prior to their use. The actual intent of the proposed provisions for management of change procedures of functional system is to allow</p>



those procedures to be managed independently of the MS/SMS at the time of certification. There are two reasons for this: to ensure their review and approval by the competent authority every time they are changed, and to provide flexibility to service providers to develop them and receive approval at any time after certification, but always prior to their use. In any case, if the service provider wishes to have them reviewed and approved at the time of certification and as part of the MS/SMS, that is also possible and the provision does not prevent this from happening.

The title has been amended to not restrict the scope.

The comment about review of all modifications to procedures referred to in (a)(2) is accepted, and only material modifications are reviewed.

In addition, moving the provision in (a)(3) related to deviations from procedures for a particular change, when requested by the service provider, to AMC seems to reduce the flexibility for the service provider to use exceptions to the procedures.

comment 72 comment by: EUROCONTROL Safety Team

ATM/ANS.AR.C.030

These change management procedures should be part of the service provider's MS/SMS and CRD 2013-08 already contains requirements regarding changes to the MS/SMS.

The text is more appropriate as specific AMC on changes to the MS/SMS.

Recommend that this requirement is removed but retained as AMC to ATM/ANS.AR.C.025(b) (Page 25 of CRD 2013-08 Annex A) for the approval of change management procedures which currently lacks AMC.

response Partially accepted

Please refer to the response to comment No 36.

comment 177 comment by: DSNA

With the explicit adoption of MS and SMS in CRD to NPA 2013-08 it is assumed that these change management procedures are a part of the MS/SMS. As such there is already text on changes to the MS/SMS (although not explicitly procedures).

It should be noted that the title of this IR limits its scope to ATM/ANS functional systems.

Furthermore, the competent authority is required to review (a)(2) all modifications to procedures referred to in (1). DSNA believes this is infeasible.

If ATM/ANS.AR.C.030 is not deleted then DSNA proposes to amend (a)(2) : **all material modifications** to the procedures referred to in (1); and

response Partially accepted



The principle is that change procedures for functional system are independent of the MS/SMS at certification. They can be submitted at any time prior to their use.

The Agency wants to make sure that they are approved by the competent authority. Considering the comment, the title of the provision is amended.

The proposal for amendment of (a)(2) is accepted.

Please refer to the response to comment No 36 for additional clarifications.

comment 398 comment by: *skyguide Corporate Regulation Management*

With the explicit adoption of MS and SMS in CRD to NPA 2013-08 it is assumed that these change management procedures are a part of the MS/SMS. As such there is already text on changes to the MS/SMS (although not explicitly procedures). It should be noted that the title of this IR limits its scope to ATM/ANS functional systems (see our comment on Definition 35). Furthermore, the competent authority is required to review (a)(2) all modifications to procedures referred to in (1). We believe this is infeasible.

Specific proposals for how to achieve this in Appendix A whereby the proposed text is made AMC to ATM/ANS.AR.C.025(b) Changes - specifically for approval of change management procedures.

response Partially accepted

Please refer to the response to comment No 36.

comment 606 comment by: *DFS Deutsche Flugsicherung GmbH*

The change management process is also regulated in CRD to NPA 2013-08.

Reference to high level comment "b"

response Not accepted

The principle is that change procedures for functional system are independent of the MS/SMS at certification. They can be submitted at any time prior to their use.

Please see reply to comment No 36.

comment 607 comment by: *DFS Deutsche Flugsicherung GmbH*

(a) (2)

DFS believes that it is infeasible for the CA to review all modifications to procedures referred to in (1).

Reference to high level comment "c.ii"



response Accepted
 'All' is removed and only 'material modifications' are reviewed.

comment 636 comment by: CANSO

With the explicit adoption of MS and SMS in CRD to NPA 2013-08 it is assumed that these change management procedures are a part of the MS/SMS. As such there is already text on changes to the MS/SMS (although not explicitly procedures).
 It should be noted that the title of this IR limits its scope to ATM/ANS functional systems (see CANSO comment on Definition 35).
 Furthermore, the competent authority is required to review (a)(2) all modifications to procedures referred to in (1). CANSO believes this is infeasible.
 Specific proposals for how to achieve this in Appendix A whereby the proposed text is made AMC to ATM/ANS.AR.C.025(b) Changes - specifically for approval of change management procedures.

response Partially accepted
 Please refer to the response to comment No 36.

comment 687 comment by: ROMATSA

With the explicit adoption of MS and SMS in CRD to NPA 2013-08 it is assumed that these changemanagement procedures are a part of the MS/SMS. As such there is already text on changes to the MS/SMS (although not explicitly procedures).
 It should be noted that the title of this IR limits its scope to ATM/ANS functional systems (see comment on Definition 35 Functional system).
 Furthermore, the competent authority is required to review (a)(2) all modifications to procedures referred to in (1). ROMATSA supports CANSO opinion that this is not feasible.
 Specific proposals for how to achieve this in Appendix A whereby the proposed text is made AMC to ATM/ANS.AR.C.025(b) Changes - specifically for approval of change management procedures.
 Supporting comment to summary issues: Specific Example of MS / SMS Split

response Partially accepted
 Please refer to the response to comment No 36.

comment 840 comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION



<p>Proposed amendments Section 3.1 <i>Draft Regulation (Draft EASA Opinion)</i> Annex II REQUIREMENTS FOR COMPETENT AUTHORITIES — SERVICE PROVISION AND NETWORK FUNCTIONS (Part-ATM/ANS.AR) ATM/ANS.AR.C.030</p>	<p>An express approval by the CA is now required for the change management procedures (as well as for their modifications a deviations) while the formal process is currently just the certification or the on-going oversight of the procedures.</p> <p>On the other side, we wonder if, within the new scheme (express approval by the CA), it would still be necessary to verify compliance with the provisions on change management during the certification/recertification process.</p>	<p>This change is not considered justified as the responsible for and owner of the documentation should be the ANSP and, thus, the ANSP should be the one that approves the said documentation, which will then of course be accepted by the CA.</p> <p>We would like to stress the point on the difference between 'to approve' and 'to accept'. The approval entails a higher responsibility and the associated accountability on the process.</p> <p>The reason for this modification should be clearly explained.</p>
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response Not accepted

Please refer to the response to comment No 36 with regard to change management procedures.

From a legal perspective, the correct term to use is 'approved' instead of 'accepted'. The reasons are as follows:

Definitions:

'Approve' is defined in legal terms as 'to give formal sanction to; to confirm authoritatively'. Other definitions point in the same direction: 'officially agree to or accept as satisfactory to consider fair, good, or right; commend (a person or thing); to authorize or sanction.'

'Accept', on the other hand, is a term generally used in contractual law. The term acceptance means 'an offeree's assent, either by express act or by implication from conduct, to the terms of an offer in a manner authorized or requested by the offeror, so that a binding contract is formed.'

Other dictionary definitions point in slightly different directions, stating that 'to accept'



means to: 'consent to receive or undertake (something offered); give an affirmative answer to (an offer or proposal); say yes to; receive as adequate, valid, or suitable; regard favourably or with approval; believe or come to recognise (a proposition) as valid or correct; take upon oneself (a responsibility or liability); acknowledge; tolerate or submit to (something unpleasant or undesired).'

Legal analysis

The term 'approval' is very clearly linked to some form of formal authorisation. All definitions consulted point in that direction. However, in legal terms, as detailed above, the term 'accept' is not so clear. This term is generally used for contractual obligations. Nevertheless, the term 'accept' has been used in the context of administrative law, and not of contractual law. As can be seen from the above definitions, when used in this context, the term 'accept' may also be interpreted as simply meaning an acknowledgement of receipt, or as the recognition of something as adequate, valid or suitable. In this latter sense, the meaning of acceptance may easily be confused with approval, since both require a review of the content of a certain document or proposal and signify that that document or proposal is in compliance with the applicable requirements. In other words, any use of the term 'accept' in such context should be interpreted as meaning the same as 'approval': the level of responsibility incumbent on the authority is the same.

Since legislative acts must be clear, easy to understand and unambiguous, leaving no uncertainty in the mind of the reader, the use of acceptance in this latter context should be avoided. Therefore, in determining which term should be used in a specific situation, the intention of the legislator must be analysed. If the legislator's intention is to impose an action on the authority, so that a given application is assessed and evaluated by the authority and is only valid after a positive appraisal or assessment, then the term 'accept' should be read in a specific, restricted context, as meaning the same as 'approve'. For this reason, whenever the legislator's intention is that the authority is required to assess, review and give a binding appraisal on a given document or procedure of an applicant, then the correct legal term is 'approve' and not 'accept'. If, on the other hand, the legislator's intention is to impose an obligation merely on the applicant, in the sense that the applicant should inform the authority of certain procedures, actions, documents, etc. but there is no review or assessment by the authority on the notified information, then this should be clearly established in the rule. Again, for clarity reasons, the term 'accept' should also be avoided in such context, so as not to raise doubts in the mind of the reader that the obligation and responsibility fully lay on the applicant and not on the authority. Therefore, the requirement should be drafted in a way that the obligation is put on the applicant to 'notify to the authority'. If it is desired that the authority acknowledges receipt of this notification, then here again the term 'accept' should not be used, but a reference to an 'acknowledgement' or 'notification' of receipt.

Conclusion:



- The term ‘acceptance’ is not used when establishing legal obligations, since its legal meaning is ambiguous and its use is better adapted to contractual obligations.
- When the authority is required to assess and review a given procedure, action or action of the applicant, the term ‘approval’ should be used.
- When the applicant is required to inform the authority about a given procedure, document or action, but there is no formal sanction or authoritative appraisal from the authority, the obligation set on the applicant should be to ‘notify the authority’. If an acknowledgement of receipt from the authority is envisaged, then a reference to an ‘acknowledgement’ or ‘notification’ of receipt could be used.

comment 1019

comment by: LVNL

ATM/ANS.AR.C.030

With the explicit adoption of MS and SMS in CRD to NPA 2013-08 it is assumed that these change management procedures are a part of the MS/SMS. As such there is already text on changes to the MS/SMS.

It should be noted that the title of this IR limits its scope to ATM/ANS functional systems.

Furthermore, the competent authority is required to review (a)(2) all modifications to procedures referred to in (1). This is infeasible as there may be many small changes in the management system which are insignificant to the CA.

Propose to change this to AMC level and the text to read:

AMC3 ATM/ANS.AR.C.025(b) Changes**APPROVAL OF CHANGE MANAGEMENT PROCEDURES**

(a) The competent authority should review:

(1) (1) those change management procedures submitted by the service provider in accordance with AMC1 ATM/ANS.OR.A.040(a)(2);

(2) (2) all significant modifications to the change management procedures referred to in (1); and

(3) (3) any significant deviation to the change management procedures referred to in (1) for a particular change, when requested by the service provider in accordance with AMC2 ATM/ANS.OR.A.40(a)(2).

(b) (b) The competent authority should approve the procedures, modifications and deviations referred to in (a) when it has determined that they are necessary and sufficient for the service provider to demonstrate compliance with ATM/ANS.OR.A.045, ATM/ANS.OR.C.005, ATS.OR.205 or ATS.OR.210, as applicable.

response Partially accepted

Please refer to the response to comment No 36.



comment	<p>1101</p> <p>ATM/ANS.AR.C.030</p> <p>These change management procedures should be part of the MS/SMS of the service provider. CRD 2013-08 already contains requirements regarding changes to the MS/SMS. <u>Recommend</u> that this requirement is removed but retained as AMC to ATM/ANS.AR.C.025(b) (Page 25 of CRD 2013-08 Annex A) for the approval of change management procedures which currently lacks AMC.</p>	comment by: <i>Belgocontrol</i>
response	<p><i>Not accepted</i></p> <p>The principle is that change procedures for functional system are independent of the MS/SMS at certification. They can be submitted at any time prior to their use.</p> <p>The Agency wants to make sure that they are approved by the competent authority. Considering the comment, the title of the provision is amended.</p> <p>Please refer to comment No 36 for additional clarifications.</p>	
comment	<p>1161</p> <p>A suggested rewording:</p> <p>ATM/ANS.AR.C.030 (a)(3) any deviation <u>from</u> the procedures....</p>	comment by: <i>Icetra</i>
response	<p>Accepted</p> <p>The text has been amended.</p>	
comment	<p>1178</p> <p>With the explicit adoption of MS and SMS in CRD to NPA 2013-08 it is assumed that these change management procedures are a part of the MS/SMS. As such there is already text on changes to the MS/SMS (although not explicitly procedures). It should be noted that the title of this IR limits its scope to ATM/ANS functional systems. Furthermore, the competent authority is required to review (a)(2) all modifications to procedures referred to in (1). We believes this is infeasible. Specific proposals for how to achieve this in Appendix A whereby the proposed text is made AMC to ATM/ANS.AR.C.025(b) Changes - specifically for approval of change management procedures.</p>	comment by: <i>Avinor ANS</i>



response Partially accepted
Please refer to the response to comment No 36.

3. Proposed amendments — 3.1. Draft EASA Opinion — ANNEX II — ATM/ANS.AR.C.035 Decision to review the notified change

p. 34

comment 37 *comment by: NATS National Air Traffic Services Limited*

ATM/ANS.AR.C.035

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Add 'to the functional system' to the title to aid clarity of scope given the title of ATM/ANS.AR.C.025.

Proposal: Amend title of IR to “Decision to review the notified change to the functional system”

response Accepted
The title has been amended as suggested.

comment 38 *comment by: NATS National Air Traffic Services Limited*

ATM/ANS.AR.C.035

Page 34

It is considered that Points (b) and (c) provide the means (how to) by which point (a) should be implemented and therefore be recast as AMC.

Proposal: Points (b) and (c) recast as AMC to ATM/ANS.AR.C.035 as proposed in NATS Appendix A (document attached to NATS comment number 25)

response Not accepted
The removal of ATM/ANS.AR.C.035(b) would mean that the criteria based on which the decision was made were not part of the IR, and the intent of the law would not be clear. Consequently, any criteria would be acceptable and there would be little point in having the rule. See also response to comment No 2.



comment	<p>39 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>ATM/ANS.AR.C.035 Page 34</p> <p>It does not appear feasible for the CA to meaningfully meet the requirement to decide whether or not to review the notified change in accordance with the criteria in (b)(1) given the level of information that is to be made available to the CA at the time of notification in a timely manner (likely to be insufficient). The change is notified to the CA in accordance with ATM/ANS.OR.045(a)(1). AMC2 ATM/ANS.OR.045(a) identifies the notification data including the change description. GM1 ATM/ANS.OR.A.045(a) encourages early notification, however the earlier the notification (managing risk from the service providers perspective) the less detail will be available. The GM encourages submission of the notification even if some data is unavailable. Notification updates as more data becomes available adds more risk for the service provider and consumes resource for both CA and service provider.</p>
response	<p>Not accepted</p> <p>This claim seems to be based on a flawed premise: that the complete information to make a decision is delivered with the notification. In fact, ATM/ANS.AR.C.035(a) states that ‘The competent authority shall request any additional information needed from the service provider to support this decision.’ This places no limit on the substance of the information nor does it place a time limit on its collection. The necessary data at the time of notification may be enough in most cases to make the decision. In other cases, the decision will be taken with additional information received at a later stage.</p>
comment	<p>40 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>ATM/ANS.AR.C.035(b) Page 34</p> <p>Point (b) contains two “shall” and the text needs to be amended to remove the duplication.</p> <p>Proposal: Point (b) amended as proposed in NATS Appendix A (document attached to comment 25)</p>
response	<p>Accepted</p> <p>The text has been amended to resolve the duplication.</p>
comment	<p>41 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>ATM/ANS.AR.C.035(b)(1)</p>



Page 34

Point (b)(1) contains “likelihood of the argument being unsound”. NATS suggests avoiding subjective terms like 'unsound'.

In order to determine if the “severity of the possible consequences of the change is significant” then criteria are required by which the significance can be determined. The risk definition refers to hazards, and the hazard definition is in terms of a harmful effect, therefore the “possible consequences of the change” (presumably in the context of the change being a change to the functional system) should be in terms of a harmful effect and that is what determines “significant”.

Proposal: Point (b)(1) is amended “likelihood of the of a complex or unfamiliar argument and the severity of the possible consequences of the change is significant” as proposed in NATS Appendix A (document attached to NATS Comment number 25)

response Partially accepted.

The words ‘sound’ and ‘unsound’ are used in their normal English sense. The context of their meaning is provided in Table 1 of GM to ATM.ANS.AR.C.035(b)(1). The proposed model is also described in this GM and uses the criteria suggested by the commentator. In any case, the spirit of this comment is accepted and the wording is adapted to the proposal. However, the final wording is reviewed to have a coherent sentence. Despite the fact that there was no intent either to imply mistrust in the service provider or to question its competency, the Agency has redrafted the provision to more clearly describe the elements of the risk that are intended, following the proposal of the commentator. The phrase ‘likelihood of the argument being unsound’ has been replaced by the phrase ‘likelihood of the argument being complex or unfamiliar to the service provider’, as suggested by the commentator.

Guidance on how to evaluate significant consequences is given in GM (pages 97–98). The GM should in any case be reviewed.

comment 42

comment by: *NATS National Air Traffic Services Limited*

ATM/ANS.AR.C.035(b)(2)**Page 34**

Add “documented” to point (b)(2) to align with text and intent in (b).

Proposal: Point (b)(2) amended as proposed in NATS Appendix A (document attached to Comment number 25).

response Accepted

The text has been amended as suggested.



comment	<p>43 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>ATM/ANS.AR.C.035(c) Page 34</p> <p>To aid clarity it is proposed to add “decision to review the notified change to a functional system or not” to point (c). Point (c) contains two “shall” and the text needs to be amended to remove the duplication.</p> <p>Proposal: Point (c) amended as proposed in Appendix A (document attached to Comment number 25).</p>
response	<p>Partially accepted</p> <p>The comment is partially accepted but implemented in a different way.</p>
comment	<p>73 comment by: <i>EUROCONTROL Safety Team</i></p> <p>ATM/ANS.AR.C.035</p> <ol style="list-style-type: none"> 1. <i>Unsound</i> refers to criteria that are mainly subjective 2. The current practice allows for CA to make a decision on criteria it defines (in collaboration with the SPs). It provides the CA with an overview of the changes and allows it to look for more detailed information. This is not because the CA expects that the ANSP will not be able to build a sound safety case but because the CA needs to be involved to be able to review adequately the Safety Case and finally make a decision on the go/no-go of the implementation of the change. Consequently an “unsound” safety case could be a conclusion of the review but not as a criterion for deciding to review. 3. This requirement appears to be rather infeasible. It is always a balance between “early” and “enough information”. Thus a very early notification could lead to very poor, inaccurate, incomplete information provided. This could lead to wrong decision on the review by the CA. Alternatively updates are necessary to the change notification as data becomes available. Such updates add more (management) risk to the SP because there could be more likelihood that an update was missed and could be source of confusion to all parties. Consequently such an approach requires more resources from both SP and CA to ensure its proper management. 4. The information exchanged should include some elements of the safety risk or criticality (for supporting the decision made by the CA to review or not). It will also help the SP to build a safety (support) case commensurate with the safety risk associated to the change.
response	<p>Partially accepted</p> <ul style="list-style-type: none"> — 1. Please see the response to comment No 41. — 2. Allowing the competent authority and service provider to agree on criteria is not in



the direction of harmonisation, but the CA may always use different criteria. The provision is drafted to be more clear in this sense.

- 3. The information, based on which the decision is made, is not provided at the time of notification (see ATM/ANS.AR.C.035(a)). It is collected by the competent authority. Please refer to the responses to comments Nos 376 and 39.
- 4. AMC2 ATM/ANS.OR.A.045(a) contains the elements needed in the notification. When the AMC/GM is reviewed and completed, these items will be reassessed.

comment 181

comment by: DSNA

ATM/ANS.AR.C.035 Decision to review the notified change : it is not the change that must be reviewed but the associated safety (support) assessment (or safety argument). **Proposed text : “Decision to review the safety argument of the change”**

(b)(1) :

1) “likelihood of argument being unsound” bears **an assumption of wrongdoing by the ANSP which is not acceptable in a rule** and ind a context of **continued surveillance** by AR, where the ANSP is operating under **a certificate delivered by the CA**.

2) there is no clear means available to the CA for assessing this “combination”. A rule should be more explicit.

3) severity not known at that stage

Proposal to replace “unsound” by criteria like complexity, novelty, criticality etc.. which are known and accepted criteria in aviation industry and which are **safety-related criteria**.

DSNA requests to add that **CA shall determine the need to review from the informations provided at notification by service provider**.

response

Partially accepted

1) The proposal to remove ‘unsound’ is accepted. Please see the response to comment No 41.

2) There is no assumption of wrongdoing by the service provider. In addition, there is neither mistrust on the service provider nor judgement of its competency. The clause ‘likelihood of argument being unsound’ is just about the fact that many factors influence the sufficiency of supporting evidence or inferences to support the claim made. We hope the new wording addresses your concerns — see GM1 ATM/ANS.AR.C.035(b)(1).

ATM/ANS.AR.C.040 states explicitly that it is the argument presented in the assessment that is reviewed. It is understood that reviewing a change is reviewing the argument associated. This is well explained in GM.

3) The means of assessing the risk is given in GM — GM1 ATM/ANS.AR.C.035(b)(1). AMC is expected to be developed. The rationale behind GM without AMC is given in the Explanatory Note and the RIA. The CA can always use different criteria. The criteria mentioned — complexity, novelty and criticality — are included, but the last one is related to the organisation itself (e.g. effectiveness/maturity of its SMS or similar). The associated AMC/GM



needs, in any case, refinement.

Last point: The information is unlikely to be available at the time of notification. ATM/ANS.AR.C.035(a) allows the CA to seek the information needed to make the decision. It was felt that neither this information nor its level and depth could be foreseen in the Regulation as the range of changes was too large.

comment

262

comment by: UK CAA

Page No: 34

Paragraph No: ATM/ANS.AR.C.035 (c)

Comment: The UK CAA recommends that the service provider is informed of the decision and rationale in each instance, as this information will already be recorded and held by the CA.

Justification: Improvement to transparency of process, without significant extra effort.

response

Not accepted

The Agency considers this unnecessary. The rationale backing the decision will be kept by the CA as it is inferred in the requirement. In most instances, the ANSP will not want or need the justification, but it should be provided upon request.

comment

264

comment by: UK CAA

Page No: 34

Paragraph No: ATM/ANS.AR.C.035 Decision to review the notified change

Comment: ATM/ANS.AR.C.035 (b) (2) states that 'be used in addition to (1), when the competent authority decides the need for a review based on other criteria.'

The criteria here is not defined and therefore should be for the CA to define. It is not clear that the CA may define the 'other criteria'

Justification: Clarity

Proposed Text:

Replace paragraph (2) with the following text

'Ensure that the notified change is reviewed based on other criteria which have been defined by the CA.'

response

Partially accepted

The provision has been redrafted following the commentator's suggestion.

comment

363

comment by: Air Navigation Services of the Czech Republic

We propose to delete the points (1) and (2), based on the assumption the CA would be able



to determine "specific, valid and documented criteria", as mentioned in (b), to cover the changes that might be related to higher risk.

Based on the experience in the Czech Republic, such criteria are already published in the Czech national regulation meeting the requirements of 1034/2011. The decision to review the change depends on the number of units involved, the novelty of the design, whether parameters related to the safety nets are modified, the training needed etc. (currently, 15 criteria are defined). Also, the NSA can decide to review any other change even not meeting the criteria for review, which is similar to (2). We are willing to share this experience.

We find using likelihood of the argument being unsound is mixing the risk related to operational safety (which is something we should look at) and the quality of documentation.

Proposed text:

(b) The competent authority shall determine the need for a review based on specific, valid and documented criteria.

response

Not accepted

The proposal seems to leave the criteria to evaluate the risk out of the IR. A different wording is proposed to allow using other criteria. Please refer to the responses to comments Nos 376 and 38.

comment

376

comment by: EUROCONTROL

ANNEX II — ATM/ANS.AR.C.035 Decision to review the notified change - Page 34

The notion of "unsound safety case" might be understood as what we describe today as maturity of the ANSP, experience on the technology, the change itself, etc... "Unsound" refers to criteria that are mainly subjective. The wording needs therefore improvement.

What is done currently, with the risk-based approach, allows for NSA to make decision on criteria they define (in collaboration with the ANSPs). It provides the NSA with an overview of the changes and allows them to look for more detailed information. This is not because the NSA expects that the ANSP will not be able to build a decent safety case but because the NSA needs to be involved to be able to review adequately the Safety Case and finally make a go/no-go decision on the implementation of the change. Consequently "unsound" safety case could be a conclusion of the review but not a criterion for deciding to review.

In the same area, EUROCONTROL would like to make the following observation: as it remains very unclear for ANSP's how NSA's will decide on whether or not to review a change, the following proposal has been developed to clarify both the ANSP's and NSA requirements.

Example of approach: in the FABEC Safety Risk Assessment Process (SRAP) group a method was developed to identify the Initial Safety Impact Assessment (ISIA) for changes to the functional system. In coordination between the FABEC SRAP and the Dutch NSA a proposal has been developed which is in line with the ISIA approach and aims at improving the currently defined proposal in ATM/ANS.AR.C.035 Decision to review the notified change to the functional system.

Proposal for ATM/ANS.AR.C.035 Decision to review the notified change to the functional system (page 34):



- a) Upon receipt of a notification in accordance with ATM/ANS.OR.A.045 (a) (1) the competent authority shall make a decision on whether to review the change or not.
- b) The competent authority shall determine the need for a review based on specific, valid and documented criteria.
- c) The competent authority shall inform the service provider of its decision and shall provide the associated rationale to the service provider on request.
- d) The CA may, in agreement with the ANSP, decide that changes with a relatively small safety impact are implemented without explicit acceptance of the CA. The ANSP and CA shall agree on specific criteria for which this can be applied. These criteria shall be integrated in an interface procedure between the ANSP and CA in which the procedural acceptance of the changes with a relatively small safety impact is arranged. The interface procedure shall be included in the oversight programme of the CA on a regular basis.

Proposal for corresponding AMC:

- a) The competent authority should base its decision whether to review the change or not upon documented criteria which should include at least a combination of the following criteria:

- Novelty
- Complexity
- Consequence of failure
- Effectiveness of the Safety Management

Proposed amendments – Draft EASA opinion

Section 3.1

Annex II

Subpart C

ATM/ANS.AR.C.035 and ATM/ANS.AR.C.040 Both (b) (1) of ATM/ANS.AR.C.035 (referring to “(...) the severity of the possible consequences of the change is significant”) and (b) of ATM/ANS.AR.C.040 (referring to “(...) review in a manner which is proportionate to the risk associated with the change”) tend to perpetuate the interpretation that changes only increase the risk. With such requirements a competent authority won’t review the argument for a change, say, related to a safety net (since by nature they’re not implemented to increase risks).

It is suggested to broaden the criteria to be used by a competent authority to review safety arguments/assessments/cases in both ATM/ANS.AR.C.035 and ATM/ANS.AR.C.040.

response

Partially accepted

The words ‘sound’ and ‘unsound’ are used in their normal English sense. Their context of their meaning is provided in Table 1 of GM to ATM/ANS.AR.C.035(b)(1). The proposed model is also described in this GM and uses many of the criteria suggested by the commentator (if not all).

It is not the presence or absence of the factors identified by the commentator that is at issue (most of them are actually described in the GM and included in the criteria) but their effect on the likelihood that the safety case will be unsound.

[The objective for the IR, inherited from the SES Regulations, was for a risk-based approach to](#)



the selection and review of assurance cases. The selection process is supposed to be risk based, hence the need for a 'likelihood'. The phrase 'likelihood of the argument being unsound' has been replaced by the phrase 'likelihood of the argument being complex or unfamiliar to the service provider', which seems to be closer to the meaning originally intended when the word 'unsound' was used, and incorporates the elements mentioned by the commentator. The 'mathematical approach' is a necessary consequence of the definition of risk. The NPA describes a process of validating the method proposed in the GM and then adding the description of the validated model to the AMC. Consequently, the AMC proposed here is premature.

The CA does not expect a bad/incorrect safety case but it might get one. There is no mistrust implied on the service provider or judgement of its competency.

GM1 ATM/ANS.AR.C.035(b)(1) shows how the decision will be made. The four elements proposed through this comment are the same as those proposed now in GM1 ATM/ANS.AR.C.035(b)(1). The nomenclature may need to be changed to align with more appropriate wording. This will be done at a later stage when the AMC/GM are refined.

Your proposal in point d) is also reflected in the Agency proposal. An agreement on cases that will never be reviewed and will always be reviewed is also identified in (b)(2) and is explained in GM, so there is no need to state it explicitly in the IR.

comment

399

comment by: *skyguide Corporate Regulation Management*

It does not appear feasible for the CA to meaningfully meet the requirement to decide whether or not to review the notified change in accordance with the criteria in (b)(1) given the level of information that is to be made available to the CA at the time of notification in a timely manner (likely to be insufficient). The change is notified to the CA in accordance with ATM/ANS.OR.045(a)(1). AMC2 ATM/ANS.OR.045(a) identifies the notification data including the change description. GM1 ATM/ANS.OR.A.045(a) encourages early notification, however the earlier the notification (managing risk from the service providers perspective) the less detail will be available. The GM encourages submission of the notification even if some data is unavailable. Notification updates as more data becomes available adds more risk for the service provider and consumes resource for both CA and service provider.

response

Not accepted

The information, based on which the decision is made, is not provided at the time of notification (see ATM/ANS.AR.C.035(a)). It is collected by the competent authority from that moment. Please see the response to comment No 39.

comment

528

comment by: *DGAC/DSAC - french NSA*

The french NSA has four comments related to ATM/ANS.AR.C.35 :



- Paragraph (b) :

Is is mentionned that the criteria shall be specific, **valid** and documented. We agree that the criteria upon which the decision is based should specific and documented. However, we don't understand against what those criteria should be valid. We suggest to remove the term valid unless a guidance is developed.

- Paragraph (b) (1) :

We support the approach of risk based decision as it could improve the efficiency of the competent authority oversight. However, we strongly disagree of that risk based on the likelihood of argument being unsound. Please refer to our answer to question 3 in which we developp our argumentation and propose alternative criteria. We suggest a new paragraph (b) that could be "The competent authority shall determine the need for a review based on specific and documented criteria that shall, as a minimum, include a risk based approach". This does not prevent the use by the competent authority of any other criteria if deemed necessary or adequate.

By the way, the use of qualitative term "significant" is not in line with the quantitative approach that this article wants to promote.

- Paragraph (b) (1) :

The word "argument" is introduced here. Among all the AMC and GM available, only one chapter describes what should be understood as an argument : GM1 ATM/ANS.OR.C.005(a)(2) & ATS.OR.205(a)(2) General (b). Unfortunately, the definition is too scientific to be well understood by ANSPs ans CAs. A more precise, explicit and succinct definition is expected, in the table page 123/230 for instance.

- Paragraph (c) :

This remark is a complement to the comment n°2 above. The idea behind the sentence "The CA shall provide the associated rationale" is very hard to implement as the reason can be that the provider provide unsound safety assessment. The relationship between CA and ANSP can be affected.

response Partially accepted

Comment No 1. It is not accepted. The word 'valid' is used in its normal English sense: (of an argument or point) having a sound basis in logic or fact; reasonable or cogent. It does not imply any validation of the documentation. GM1 ATM/ANS.AR.C.035(b)(1) explains the criteria and clarifies what is meant by 'valid criteria'.

Comment No 2. It is not accepted. The proposed formulation does not include the criteria to judge the risk. The possibility for the CA to use different criteria, when necessary, is also



recognised in the new requirement (c).

Comment No 3. Accepted. The definition is given at the level of IR.

Comment No 4. This comment is not understood. We do not see any issue in the CA providing the rationale when a change is not approved. Actually, the relationship may be deteriorated if it is rejected without the rationale behind the non-approval.

See also the response to comment No 1053 for additional clarifications.

comment 545

comment by: *Frasie Loredana*

b) (1) The meaning of *likelihood of the argument being unsound* must be defined despite the explanation presented in GM1 ATM/ANS.AR.035 B)1)d).

Justification

For us the meaning of *the likelihood of the argument being unsound* is more related to the cases when the ATM/ANS service provider is planning a change that is new for them or is new and complex (units involved, services / functions affected, etc). In these cases there is a probability that the safety case is weak. Otherwise, in the context of a certified organisation, the system should be able to compensate for other individual limitations. We admit that there are differences between organisations but, if certified, they are at or above the baseline.

response

Partially accepted

That is the purpose of the model definition and validation phase as described in the Explanatory Note and the RIA. Anyway, the term 'unsound' has been removed and substituted by other wording: 'likelihood of the argument being complex or unfamiliar to the service provider'.

comment 584

comment by: *Federal Office of Civil Aviation FOCA*

To determine if an argument is sound requires an assessment from the NSA. Therefore, an assessment should be performed for every notified change. Beside the significant workload increase this proposal does not contribute to an overall increase in safety. Furthermore, it may shift the safety responsibility from the service provider to the CA.

The need for a review should be based on the significance of the risk identified in relation with the change. In order to avoid that every change is subject to review, the risk significance shall be determined based on the tolerability of the effects.

Justification: As the service provider is accountable for the risks in relation with the service provided, he shall determine the acceptable limit. The CA shall verify if the limit set by the service provider does not exceed the national limit and ensure adherence if required.



response	<p>Not accepted</p> <p>The premise is inappropriate. The safety case makes the claim for safety and is written by the ATS provider. The CA reviews the safety case in order to check its validity. This is explained in GM1 ATM/ANS.AR.C.035(b)(1). This does not transfer the responsibility for the efficacy of the safety case to the CA — see legal opinion of approval in comment No 840. Furthermore, there should be no increase in the workload because not every safety case is reviewed. Once the model is built, it should be relatively straightforward to (consistently) apply the model and take the decision.</p>
comment	<p>609 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>It does not appear feasible for the CA to meaningfully meet the requirement to decide whether or not to review the notified change in accordance with the criteria in (b)(1) given the level of information that is to be made available to the CA at the time of notification in a timely manner (likely to be insufficient). The change is notified to the CA in accordance with ATM/ANS.OR.045(a)(1). AMC2 ATM/ANS.OR.045(a) identifies the notification data including the change description. GM1 ATM/ANS.OR.A.045(a) encourages early notification, however the earlier the notification (managing risk from the service providers perspective) the less detail will be available. The GM encourages submission of the notification even if some data is unavailable. Notification updates as more data becomes available adds more risk for the service provider and consumes resource for both CA and service provider. Reference to high level comment "c.i"</p>
response	<p>Not accepted</p> <p>The information, based on which the decision is made, is not provided at the time of notification (see ATM/ANS.AR.C.035(a)). It is collected by the competent authority. Please see the response to comment No 39.</p>
comment	<p>637 comment by: <i>CANSO</i></p> <p>It does not appear feasible for the CA to meaningfully meet the requirement to decide whether or not to review the notified change in accordance with the criteria in (b)(1) given the level of information that is to be made available to the CA at the time of notification in a timely manner (likely to be insufficient). The change is notified to the CA in accordance with ATM/ANS.OR.045(a)(1). AMC2 ATM/ANS.OR.045(a) identifies the notification data including the change description. GM1 ATM/ANS.OR.A.045(a) encourages early notification, however the earlier the notification (managing risk from the service providers perspective) the less detail will be available. The GM encourages submission of the notification even if some data is unavailable. Notification updates as more data becomes available adds more risk for the service provider and consumes resource for both CA and service provider.</p>



response Not accepted

The information, based on which the decision is made, is not provided at the time of notification (see ATM/ANS.AR.C.035(a)). It is collected by the competent authority. Please see the response to comment No 39.

comment 688 comment by: ROMATSA

It does not appear feasible for the CA to meaningfully meet the requirement to decide whether or not to review the notified change in accordance with the criteria in (b)(1) given the level of information that is to be made available to the CA at the time of notification in a timely manner (likely to be insufficient). The change is notified to the CA in accordance with ATM/ANS.OR.045(a)(1). AMC2 ATM/ANS.OR.045(a) identifies the notification data including the change description. GM1 ATM/ANS.OR.A.045(a) encourages early notification, however the earlier the notification (managing risk from the service providers perspective) the less detail will be available. The GM encourages submission of the notification even if some data is unavailable. Notification updates as more data becomes available adds more risk for the service provider and consumes resource for both CA and service provider.

Supporting comment to summary issues: IR does not achieve the perceived intention of the rule. In this case we do not believe that the IR can be achieved by the CA

Answer to Question 3

ROMATSA supports CANSO opinion that this is a decision for the CA. However we believe it will be very difficult to answer as the criteria for an unsound argument are very subjective. Complexity, criticality or an unfamiliar form of argument are better criteria to decide whether or not a decision to review the change by the CA should be taken.

The risk based review decision would require extensive notification/decision/coordination processes, thus requiring a lot of administration and longer lead times. More fixed review decision criteria would lower the administration for both the ANSP and the NSA. The risk based approach could still be used regarding safety overview, while following up the processes of the ANSP and their implementations. This should be included in the economic impact analysis

response Not accepted

The information, based on which the decision is made, is not provided at the time of notification (see ATM/ANS.AR.C.035(a)). It is collected by the competent authority. Please see the response to comment No 39.

Answer to Question 3: Noted

comment 842 comment by: AESA / DSANA



PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.1 <i>Draft Regulation (Draft EASA Opinion)</i> Annex II REQUIREMENTS FOR COMPETENT AUTHORITIES — SERVICE PROVISION AND NETWORK FUNCTIONS <i>(Part-ATM/ANS.AR)</i> ATM/ANS.AR.C.035(c)</p>	<p>An option to modify the decision should be included.</p>	<p>After informing the decision to not review the change, the CA may continue with the general oversight of that change before its implementation and, during this oversight, new and more detailed aspects that were not considered in the initial assessment could make the CA decide to review.</p> <p>The CA should be able to proceed in that way.</p>

response

Accepted

This is covered in ATM/ANS.AR.C.035(a) — ‘Upon receipt of a notification..., or upon receipt of modified information...’

Perhaps GM needs to be provided in the future developments to review and complete AMC/GM. The whole process is explained in GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045.

comment

855 comment by: *Navair*

This IR we proposed changed to AMC because we think that the existing rules are making changes safer. Please confer question 3

response

Not accepted

The removal of ATM/ANS.AR.C.035(b) would mean that the criteria, based on which the decision was made, were not part of the rule. Consequently, any criteria would be acceptable and there would be little point in having the rule. Please see the response to comment No 39.

comment

1024 comment by: *LVNL*

Using the wording 'likelihood of the argument being unsound' is unsatisfactory.
Propose to change the wording to:
ATM/ANS.AR.C.035 Decision to review the notified change to the functional system
 a) Upon receipt of a notification in accordance with ATM/ANS.OR.A.045(a)(1) the competent authority shall make a decision on whether to review the change or not.



- b) The competent authority shall determine the need for a review based on specific, valid and documented criteria.
- c) The competent authority shall inform the service provider of its decision and shall provide the associated rationale to the service provider on request.
- d) The CA may, in agreement with the ANSP, decide that changes with a relatively small safety impact are implemented without explicit acceptance of the CA.

This could then be complemented with AMCs as follows:

AMC ATM/ANS.AR.C.035(b)

a) The competent authority should base its decision whether to review the change or not upon documented criteria which should include at least a combination of the following:

- Novelty
- Complexity
- Consequence of failure
- Effectiveness of the Safety Management

b) In addition to (a) the competent authority may decide to review the change or not based on additional documented criteria.

AMC ATM/ANS.AR.C.035(d)

The ANSP and CA should agree on specific criteria for which (d) can be applied. These criteria should be integrated in a interface procedure between the ANSP and CA in which the procedural acceptance of the changes with a relatively small safety impact is arranged. The interface procedure shall be included in the oversight programme of the CA on a regular basis.

response

Partially accepted.

Please refer to the responses to comments No 376 and No 41.

If not clearly stated, the documented criteria identified in b) do not necessarily have to be risk-based. Consequently, this proposal goes against the established philosophy. The final wording used at IR level is: 'likelihood of the argument being complex or unfamiliar to the service provider', which can be linked to the elements proposed by the commentator. This proposal is appreciated and may be appropriate to develop the AMC and GM of the provision when the AMC/GM are reviewed and addressed.

comment

1102

comment by: *Belgocontrol*

ATM/ANS.AR.C.035

1. *Unsound* safety case is a very subjective criterion
2. The current practice permits the NSA/CA to make a decision on criteria it defines (in collaboration with the SPs). It provides the CA with an overview of the changes and allows it to look for more detailed information. This is not because the CA expects that the ANSP will not be able to build a sound safety case but because the CA needs to be involved to be able to review adequately the Safety Case and finally make a decision on the go/no-go of the implementation of the change. Consequently an



“unsound” safety case could be a conclusion of the review but not as a criterion for deciding to review.

3. This requirement appears to be rather infeasible. It is always a balance between “early” and “enough information”. Thus a very early notification could lead to very poor, inaccurate, incomplete information provided. This could lead to wrong decision on the review by the NSA/CA. Alternatively updates are necessary to the change notification as data becomes available. Requests for more information, rejection of the arguments, counter-arguments etc. requires more resources from both service provider and CA.

The information exchanged should include some elements of the safety risk or criticality (for supporting the decision made by the NSA/CA to review or not). It will also help the service provider to build a safety (support) case commensurate with the safety risk associated to the change

response

Partially accepted

- 1. Please see the response to comment No 41.
- 2. Allowing the competent authority and service provider to agree on criteria is not in the direction of harmonisation, but the CA may always use different criteria. The provision is drafted to be more clear in this sense.
- 3. The information, based on which the decision is made, is not provided at the time of notification (see ATM/ANS.AR.C.035(a)). It is collected by the competent authority. Please refer to the responses to comments Nos 376 and 39.
- 4. AMC2 ATM/ANS.OR.A.045(a) contains the elements needed in the notification. When the AMC/GM is reviewed and completed, these items will be reassessed.

comment

1162

comment by: *Icetra*

ATM/ANS.AR.C.035

response

Noted

comment

1163

comment by: *Icetra*

ATM/ANS.AR.C.035

(b)(1) (1) as a minimum ensure that the notified change is reviewed if the combination of the likelihood of the argument being unsound and the severity of the possible consequences of the change is *significant*

response

Noted

The comment is not understood.



comment	1179	comment by: <i>Avinor ANS</i>
	<p>It does not appear feasible for the CA to meaningfully meet the requirement to decide whether or not to review the notified change in accordance with the criteria in (b)(1) given the level of information that is to be made available to the CA at the time of notification in a timely manner (likely to be insufficient). The change is notified to the CA in accordance with ATM/ANS.OR.045(a)(1). AMC2 ATM/ANS.OR.045(a) identifies the notification data including the change description. GM1 ATM/ANS.OR.A.045(a) encourages early notification, however the earlier the notification (managing risk from the service providers perspective) the less detail will be available. The GM encourages submission of the notification even if some data is unavailable. Notification updates as more data becomes available adds more risk for the service provider and consumes resource for both CA and service provider.</p>	
response	<p>Not accepted</p> <p>The information, based on which the decision is made, is not provided at the time of notification (see ATM/ANS.AR.C.035(a)). It is collected by the competent authority. Please see the response to comment No 39.</p>	
comment	1194	comment by: <i>ENAIRE</i>
	<p>Everything lies on the competent authority criteria. In our opinion, the Agency should provide some criteria in order to objectify the competent authority decision.</p>	
response	<p>Not accepted;</p> <p>This has been already done.</p> <p>The criteria are given at the IR level (with the new wording): ‘likelihood of the argument being complex or unfamiliar to the service provider’ and the severity of the possible consequences of the change is significant. The elements used to estimate that likelihood and severity are described in GM1 ATM/ANS.AR.C.035(b)(1) & GM2 ATM/ANS.AR.C.035(b)(1) and the means by which these are moved into AMC is described in the Explanatory Note and the RIA.</p>	
comment	1224	comment by: <i>CAA-NL</i>
	<p>ATM/ANS.AR.C.035 Decision to review the notified change</p> <p>It is appreciated that the regulation is flexible and leaves a large amount of freedom to the service providers and CAs to interpreted and implement the requirements. This might on the</p>	



other hand compromise the wish and need for harmonization on international level. CA's therefore need more specific criteria on whether to review a change or not. Moreover, in case of FABs, these criteria need to be harmonized by regulation or at least at AMC level.

The requirement under b) includes a rather mathematical approach to risk. The Netherlands has a preference for a broader orientation to the risk concept, leading to the proposal below. Furthermore it is noticed that the NPA requires the CA to make a decision whether to review a change for every individual change.

NSA-NL has established a system where a distinction is made between Type I ("large safety impact") and Type II ("small safety impact") changes, based on clear criteria. In this system, changes with a large safety impact are notified by the ANSP on an individual basis. For these changes, the NSA decides for each change individually whether it will review the change or not, and notifies the ANSP of its decision.

For the smaller "Type II" changes, a different methodology is used. These changes are notified by means of monthly lists. The ANSP may implement these changes without explicit acceptance of the NSA, as this is arranged through procedure. The NSA verifies the safety assessment of these Type II changes on a sample basis **after** their implementation as a means of verifying the process of safety assessment.

This NPA does not seem to leave any room for such a process, which will result in an increased bureaucracy as a result of the large amount of relatively small changes having to be assessed –at least the question whether to review or not needs to be answered individually-. This process has been agreed with the Service Provider, to make this possible we also suggest an additional paragraph to this purpose. This leads to the following text suggestion for :

ATM/ANS.AR.C.035 Decision to review the notified change to the functional system

- a) Upon receipt of a notification in accordance with ATM/ANS.OR.A.045 the competent authority shall make a decision on whether to review the change or not.
- b) The competent authority shall determine the need for a review based on specific, valid and documented criteria, that shall as a minimum ensure that the notified change is reviewed if the safety risk related to the change is significant.
- c) The competent authority shall inform the service provider of its decision and shall provide the associated rationale to the service provider on request.
- d) The CA may, in agreement with the ANSP, decide that changes with a relatively small safety impact are implemented without explicit acceptance of the CA.

Further we suggest additional AMC material related to the new para's (b) and (d):

AMC ATM/ANS.AR.C.035(b)

The competent authority should base its decision whether to review the change or not upon documented criteria which should include at least a combination of the following:

- a) Novelty
- b) Complexity
- c) Consequence of failure
- d) Effectiveness of the Safety Management

In addition to (a) the competent authority may decide to review the change or not based on additional documented criteria.

AMC ATM/ANS.AR.C.035(d)



	<p>The ANSP and CA should agree on specific criteria for which (d) can be applied. These criteria should be integrated in a interface procedure between the ANSP and CA in which the procedural acceptance of the changes with a relatively small safety impact is arranged. The interface procedure shall be included in the oversight programme of the CA on a regular basis.</p>
response	<p>Partially accepted</p> <p>Please refer to the responses to comments Nos 376 and 41.</p> <p>If not clearly stated, the documented criteria identified in b) do not necessarily have to be risk-based. Consequently, this proposal goes against the established philosophy. The final wording used at IR level is: ‘likelihood of the argument being complex or unfamiliar to the service provider’, which can be linked to the elements proposed by the commentator. This proposal is appreciated and may be appropriate to develop the AMC and GM of the provision when the AMC/GM are reviewed and addressed.</p>

3. Proposed amendments — 3.1. Draft EASA Opinion — ANNEX II — ATM/ANS.AR.C.040 Risk-based review of the notified change

p. 34

comment	<p>44</p> <p>comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>ATM/ANS.AR.C.040 Page 34</p> <p>Add functional system to the title in order to aid clarity.</p> <p>Proposal: Change title to read “risk based review of the notified change to the functional system” as proposed in Appendix A (document attached to NATS Comment number 25).</p>
response	<p>Accepted</p> <p>The title has been amended.</p>
comment	<p>45</p> <p>comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>ATM/ANS.AR.C.040(a)(1) Page 34</p> <p>This point makes reference to ATM/ANS.OR.B.010, however, ATM.ANS.OR.B.010 is about approval of said procedures and any modifications. The reference should therefore be deleted. It is implicit that the procedures being used are associated with a change to the functional system given the title of the IR.</p>



	<p>Proposal: Delete the reference to ATM/ANS.OR.B.010 as proposed in Appendix A (document attached to Comment number 25).</p>
response	<p>Accepted</p> <p>See also response to comment No 34.</p> <p>ATM/ANS.AR.C.040(a)(1) has been deleted and a similar clause in ATM/ANS.AR.C.010 has been moved to AMC. The wording around the reference has been made clearer. ATM/ANS.OR.B.10 has been changed to make the reference to the procedures clearer.</p>
comment	<p>46 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>ATM/ANS.AR.C.040(a)(3) Page 34</p> <p>The “and/or” is unnecessary as the two are mutually exclusive (unless an ATS provider can produce a safety support assessment).</p> <p>Proposal: Points (a)(3) amended as proposed in Appendix A (document attached to NATS Comment number 25).</p>
response	<p>Accepted</p> <p>‘And/or’ has been changed to ‘or’.</p> <p>In the 2nd NPA, GM will be provided to explain more explicitly the relationship between safety cases and safety support cases and how they may be reviewed.</p>
comment	<p>263 comment by: <i>DSNA</i></p> <p>The concept of « risk-based » seems still immature. Shall it be kept in the IR ?</p> <p>(a)(1) : over regulated, this requirement is unnecessary, DSNA proposes to delete (a)(1).</p> <p>(a)(4) : however, a service provider answers to his own CA only. The CAs should establish their own coordination means. For example in FABEC context, the relevant CAs decide between themselves for a “lead CA” which is the sole contact point for the ANSP. FABEC ANSPs do not coordinate with other CAs.</p> <p>(b) : The “risk” is only known when the FHA phase is completed and this phase is never over when the CA has to decide to review or not the change.</p> <p>DSNA proposal : “The competent authority shall conduct the review in a manner which is proportionate to an estimation of the risk elaborated by the CA based on the description of</p>



response	<p>the change".</p> <p>Partially accepted</p> <p>(a)(1) is deleted.</p> <p>(a)(4) Accepted. Nothing indicates the contrary.</p> <p>(b) The provision is removed, so the proposal is not implemented. Note that the risk will be always an estimation (a probability has associated a degree of uncertainty).</p>
comment	<p>265 comment by: UK CAA</p> <p>Page No: 34 Paragraph No: ATM/ANS.AR.C.040 (a) (1) Comment: [The CA shall] “verify that the procedures used by the service provider, as defined in ATM/ANS.OR.B.010, were approved;” This is very difficult to determine, especially in its entirety. UK CAA suggests that it is not a feasible requirement unless the service provider is required to argue that this is true as part of the change safety case, which would be an onerous requirement. The least acceptable outcome would be that the CA merely checks that the service provider claims this is true, without supporting arguments and evidence. Justification: Practicality Proposed Text: (1) verify that the procedures used by the service provider, as defined in ATM/ANS.OR.B.010, are approved by the competent authority;</p>
response	<p>Partially accepted</p> <p>The comment is shared as the point seems reasonable. Since during the oversight there are periodical checks that the procedures are used, this clause has been removed. The AMC/GM supporting oversight (the old ATM/ANS.AR.C.010(a)) will be strengthened to make clear that the approved procedures should be checked as part of the ongoing oversight.</p>
comment	<p>266 comment by: UK CAA</p> <p>Page No: 34 Paragraph No: ATM/ANS.AR.C.040 (b) Comment: “The competent authority shall conduct the review in a manner which is proportionate to the risk associated with the change.” It is not clear to the UK CAA how this risk would be ascertained. In addition it is not made clear that if a CA conducts a review of a change safety case in a manner that is not proportionate, whether this would result in the notified change being non-compliant. Justification: Clarity</p>



response

Noted

The provision (b) has been removed due to the fact that it is immature. The main reason for this, pointed by several commentators, is that there is no AMC/GM associated with this provision as to what this risk is and how to ascertain it. The Agency has monitored the research conducted on this subject with no final result to this moment. Until further experience or development of a model to identify this risk and to modulate the review based on that risk, the Agency considers appropriate to remove this requirement from the proposal.

comment

267

comment by: UK CAA

Page No: 34**Paragraph No:** ATM/ANS.AR.C.040 (c) (1)

Comment: [The CA shall] “approve the argument referred to in ATS.OR.205(a)(2) and ATM/ANS.OR.C.005(a)(2), with conditions where applicable ...”

The concept of the CA setting ‘conditions’ is well-embedded in Regulations, but it is the UK CAA’s view that this is incorrect, as it changes something that influences the risk determined in the change safety case.

The CA would only consider setting ‘conditions’ when it considers that the risk determined in the change safety case is not acceptable. It is impractical for the CA to change the change. (This assumes that the CA can envisage the risk associated with the changed change, when the service provider would have to revise the change safety case if it proposed to do the same thing. Moreover, in doing so, the CA is also taking over responsibility for the safety of the change.

Conditions such as initially limiting traffic suggest that the assurance provided in the change safety case is inadequate for full traffic operation. In this case we suggest that the CA should reject the change safety case, and the service provider then revise the change safety case, either with additional assurance such that full traffic can be served immediately the change is in place, or to have transition stages where further assurance is gained at low traffic levels.

UK CAA recommends that all references to the CA setting ‘conditions’ should be removed

Justification: Accurate reflection of responsibilities of service provider and CA.

response

Not accepted

It might be more appropriate to approve parts of the safety case rather than insisting on the provider rewriting it. However, the approved part should be a coherent part of the change.

The CA may also approve the change yet seek more evidence, which is to be gathered during the early stages of operation, providing there is an appropriate ‘back out’ mechanism. Additional GM will be considered during the development of the proposal in the 2nd NPA.

comment

268

comment by: UK CAA



Page No: 34

Paragraph No: ATM/ANS.AR.C.040 Risk-based review of the notified change

Comment: Paragraph (a) (4) states: 'coordinate its activities with other competent authorities whenever necessary.'

This omits the requirement for the CA to coordinate its activities internally

UK CAA suggest that associated GM should be provided as in the proposed text

Justification: Where the change is likely to impact across more than one regulatory domain it is essential that the CA insures internal coordination.

Proposed Text: Associated GM

'Where the change is likely to impact across more than one regulatory domain the CA must insure it coordinates its internal activities across the relevant regulatory domains'.

response

Noted

Comments on AMC/GM will be responded to in the CRD associated with them. A considerable amount of time is needed to rework, amend and complete the AMC/GM in an appropriate and effective manner, and this cannot be done at this stage.

comment

364

comment by: *Air Navigation Services of the Czech Republic*

In (c) (1), there is a difference from the current 1034/2011, where there is the term "acceptance of the change" used.

The NPA is not clear enough whether CA would "approve the argument" or "accept the change". The terms are not used consistently.

We propose to stick to the 1034/2011 logic, where the argument is not approved (just reviewed) and the change is accepted (or not).

response

Not accepted

It is the argument (Assurance case) that is approved. It describes the change, which, once the argument has been approved, can be implemented. See GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045.

For the discussion about 'approve' vs 'accept', please see the response to comment No 840.

comment

480

comment by: *CAA CZ*

ATM/ANS.AR.C.040 b)

Supported by the CAA CZ. This approach has been introduced and implemented locally by the above mentioned/attached CAA procedure.

response

Noted

The requirement b) has been removed. There is, however, no impediment for the CA to



perform that approach if appropriate. See also the response to comment No 266.

comment 551

comment by: *Frasie Loredana*

(c) (1) To replace the term approve with accept.

Justification

The term *accept* is used in current regulations.

The term *accept* reflects better the statement used in the same sentence *...and so inform the service provider of their acceptability, or*

We believe that only the service provider change management procedures should be approved by the CA. The documentation related to changes (e.g. the argument) is in our case approved internally by the service provider and accepted by the competent authority.

Insert additional text:

(c) (3) delay the decision to accept or to reject the argument in ATS.OR.205(a)(2) and ATM/ANS.OR.C.005(a)(2) when requests additional information, until that data is provided.

Justification

Sometimes neither of the presented situations is applicable. This means that in real life the information requested by the CA is never provided and the ATM/ANS provider decides not to implement the change anymore.

response Not accepted

Please see the response to comment No 840 about the use of the term 'approve' vs the term 'accept'.

The addition is unnecessary. The assurance case is the property of the service provider and not of the CA. It contains the complete argument, claims, inferences and evidence. If it is incomplete, it could be rejected or returned for completion or updated via the delivery of additional or changed data, providing the configuration of the case is maintained. The CA should not ask for specific information but simply point out the deficiencies and allow the service provider to rectify them. It is not necessary to have a rule for this.

comment 585

comment by: *Federal Office of Civil Aviation FOCA*

ATM/ANS.AR.C.040 (a) (1): FOCA suggests to delete this requirement. Justification: Having a procedure for management of change is part of the certification process of an ANSP. Therefore, there is no benefit to check for every change proposed by the ANSP that the procedure they use has been approved. The check that the approved procedure, as part of the certification, has been appropriately followed during the development of the change (as stated in ATM/ANS.AR.C.040 (a) (2)) is sufficient. It is also covered by the amendment to ATM/ANS.OR.B.005 "Management System" as part of this NPA.



response

Accepted

The provision has been removed.

comment

622

comment by: DGAC/DSAC - french NSA

The french NSA has four comments related to ATM/ANS.AR.C.40 :

- paragraph (a) (1) :

The CA shall check as a minimum that the procedures used by the ANSP have been approved, but it shall also check that the procedures have been **correctly** used by the ANSP in order to perform the safety assessment. The CA shall also check that the procedures have been **actually** used by by the ANSP.

- paragraph (a) (2) :

In case of non-ATS provider, the CA has to review the safety support assessment with respect and ATM/ANS.OR.C.005 (a) (2). We do not understand how can the CA questions the specifications finally retained if there is no link with a safety assessment or at least with accepted safety requirements (IOP IR, ICAO, etc.). In addition, the role of a CA, in the frame of this IR, should not be to verify that a system behaves as specified.

- paragraph (a) (3) :

We do not know what is the "validity of the argument" ? Is there some principle or rule to determine whether an argument is valid or not ? At least, we ask for an explanation in GM.

- paragraph (c) :

We do not support the requirement about "approval of the argument by the competent authority". We support the notion of acceptance of the argument, almost as it is expressed in the current european regulation ("acceptance of the change"). Indeed, the approval of the argument is not compatible with a review proportionate to the risk, contrary to a acceptance. We think that, expressed like that, the requirement gives too much responsibility to the competent authority and, in addition, transfer undue responsibility in terms of safety from the service provider to the competent authority. However, we do support the use of "argument" as the scope of the change may be different than the scope of the safety assessment reviewed by the NSA. The comment is not repeated by the french NSA throughout the document (AMC and GM) but of course it is also applicable to the whole material.

In addition, uses of different terms as "approve", "reject", "acceptability", "unacceptability" together in the same article should be avoided as it could refer to different legal wording .



	<p>Consequently, we suggest the removal of "acceptability" and "unacceptability". The article could be "... and so inform the service provider" and "... and inform the service provider with supporting rationale".</p>
response	<p>Partially accepted</p> <p>Paragraph (a)(1): Not accepted. It seems infeasible to do this for every notified changed to be reviewed. This is part of the continuous oversight. We have removed the provision.</p> <p>Paragraph (a)(2): The specifications are set by the ATS needs. The safety support assessment is, of course, linked to the safety assessment (this is extensively explained in GM, e.g. GM1 ATM/ANS.OR.C.005). The principle is that the service provided by a provider other than an ATSP has to 'do what it says it will do and nothing else'. The provider does not know how the service will be used (he may provide the same or a similar service to several ATSPs, who may use it differently), consequently the safety support case cannot be linked to accepted safety requirements. When a service is used by an ATSP, he/she argues the safety of the service based on the specifications of all the services being used. It is unlikely that a CA will review only the safety support case. In any case, the review of the safety support case is not related to the appropriateness of the specification but to its validity. This can be done without reference to accepted safety requirements.</p> <p>Paragraph (a)(3): Noted. The argument is valid in the sense that the inferences and the supporting evidence are sufficient to support the claim of the argument. 'Validity' is used in its normal English sense: 'The quality of being logically or factually sound; soundness or cogency'.</p> <p>AMC/GM is provided covering many aspects of the validity of assurance cases. This can be found as AMC/GM to OR.C.005(a)(2) and ATS.210(a)(2).</p> <p>Paragraph (c): Not accepted. Please see the response to comment No 840 about the use of the term 'approve' vs the term 'accept'.</p> <p>'Acceptability' and 'unacceptability' have been removed.</p>

comment	<p>701 comment by: ROMATSA</p> <p>Answer to Question 4</p> <p>ROMATSA supports CANSO opinion that this proposal conflicts with subsidiarity principle defined in Article 5 of the Treaty on European Union. It ensures that decisions are taken as closely as possible to the citizen and that constant checks are made to verify that action at Union level is justified in light of the possibilities available at national, regional or local level. We believe the ATM/ANS.AR.B.001(c) reference is probably incorrect for the purposes of this question.</p> <p>ROMATSA fully supports CANSO recommendation not to regulate this at present, but to await sufficient experience, then evaluate need again.</p>
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response

Response to Question 4 is noted

Legal advice is that it does not conflict with the subsidiarity principle. However, it is believed that the terms proposed in the NPA are not acceptable. Through comment No 252, some terms are proposed that have been taken into account. Moreover, an additional clause just to include the arrangements has been proposed in ATM/ANS.AR.A.005.

comment

844

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.1 <i>Draft Regulation (Draft EASA Opinion)</i> Annex II REQUIREMENTS FOR COMPETENT AUTHORITIES — SERVICE PROVISION AND NETWORK FUNCTIONS (Part-ATM/ANS.AR) ATM/ANS.AR.C.040</p>	<p>This provision requires the approval of the argument by the CA when up to now and as per <i>regulation (EU) No 1034/2011</i> what was required from the CA was the acceptance.</p>	<p>This change is not considered justified as the owner of the documentation (and the one responsible for ensuring the safety or the service it provides) is the ANSP and, thus, the ANSP should be the one that approves the measures and dispositions established in its (the ANSP's) safety argument.</p> <p>The control of the CA does not reach the ANSP management to the level of deciding about the way that the ANSP handles its business as long as the ANSP meets the regulatory requirements.</p> <p>Again, we would like to stress the point on the difference between 'to approve' and 'to accept'. The approval entails a higher responsibility and the associated accountability on the content of the documentation processed.</p> <p>The reason for this modification should be clearly explained.</p>

response

Not accepted

Please see the response to comment No 840 about the use of the term 'approve' vs the term



'accept'.

comment 1026

comment by: LVNL

ATM/ANS.AR.C.040 Risk-based review of the notified change

Competent authorities should not approve the safety arguments, as this means they are taking over the responsibility from the ANSP. Therefore it is proposed to stay closer to the text in the current regulations.

It is proposed to modify c as follows:

- (c) The competent authority shall:
- (1) decide on the acceptance of the argument referred to in ATS.OR.205(a)(2) and ATM/ANS.OR.C.005(a)(2)and
 - (2) decide on the approval of the introduction into service of the change under consideration, and
 - (3) inform the service provider of its decision.

In case of non-acceptance, the competent authority shall provide the service provider with a supporting rationale.

response Not accepted

The use of the term 'approval' does not remove the responsibility from the ANSP to shift it to the CA. Please see the response to comment No 840 about the use of the term 'approve' vs the term 'accept'.

comment 1136

comment by: DSAE

The terms « approve the argument » imply new responsibilities for CAs. ANSPs are hundred percent responsible for the content of the safety cases they perform. Therefore, they should also be in charge of the approval of the safety cases. CAs do not always provide the necessary time and expertise to deem the validity of an argument.

response Not accepted

The use of the term 'approval' does not remove the responsibility from the ANSP to shift it to the CA. ANSP are responsible to carry out the assessment, but there is no need to approve it. Please see the response to comment No 840 about the use of the term 'approve' vs the term 'accept'.



comment	<p>1226</p> <p style="text-align: right;">comment by: CAA-NL</p> <p>ATM/ANS.AR.C.040 Risk-based review of the notified change</p> <p>Competent authorities should not approve the safety arguments, as this means they are taking over the responsibility from the ANSP. Therefore it is proposed to stay closer to the text in the current regulations.</p> <p>It is proposed to modify para (c) as follows:</p> <p>(c) The competent authority shall</p> <p>(1) decide on the acceptance of the argument referred to in ATS.OR.205(a)(2) and ATM/ANS.OR.C.005(a)(2)and</p> <p>(2) decide on the approval of the introduction into service of the change under consideration, and</p> <p>(3) inform the service provider of its decision.</p> <p>In case of non-acceptance, the competent authority shall provide the service provider with a supporting rationale .</p>
response	<p>Not accepted</p> <p>The use of the term ‘approval’ does not remove the responsibility from the ANSP to shift it to the CA. Please see the response to comment No 840 about the use of the term ‘approve’ vs the term ‘accept’.</p>

3. Proposed amendments — 3.1. Draft EASA Opinion — ANNEX III — ATM/ANS.OR.A.045
Changes to the functional system

p. 35

comment	<p>47</p> <p style="text-align: right;">comment by: NATS National Air Traffic Services Limited</p> <p>ATM/ANS.OR.A.045 Page 35</p> <p>It is considered that Points (b), (e) and (f) provide the means by which point (a) should be implemented and therefore be recast as AMC.</p> <p>Proposal: Points (b), (e) and (f) recast as AMC to ATM/ANS.OR.A.045 as proposed in Appendix A (document attached to NATS Comment number 25).</p>
response	<p>Not accepted</p> <p>Point (b) does not fit as AMC if notification is considered as one event that happens at one point, as opposed to the concept of a collection of actions that happens from the initial notification act and the final bit of information sent to the competent authority. Because the approach taken for the change management procedures has been to keep the notification and material modifications in the IR text, it would indicate that the notification is a single event in time, i.e. the act of notification, and to be consistent with that approach, the Agency</p>



has decided to keep it as proposed.

Points (e) and (f) cannot be moved to AMC as they set the criteria for the scope of the interactions between the stakeholder, in the case of (e) and the requirements on what shall be done in the case of (f). It is not appropriate for either of these to become AMC.

comment

48

comment by: *NATS National Air Traffic Services Limited***ATM/ANS.OR.A.045(c)****Page 35**

ATM/ANS.OR.B.010 is about submission and approval of applicable procedures and any modifications and is therefore not an appropriate cross reference. The specific rules should be directly identified in (c) and avoid ambiguous cross-referencing.

ATM/ANS.OR.B.010 also contains ATM/ANS.OR.A.045 which is not relevant for this aspect to a change to the functional system.

Proposal: Specific proposals for how to achieve this in NATS Appendix A (document attached to Comment number 25) whereby specific reference has been made to the applicable IR.

response

Partially accepted

The Agency agrees that the wording in ATM/ANS.OR.B.010 seems to be about submission, but there was an implicit intent for the service providers to use procedures to manage changes. The provision has been redrafted to make this requirement explicit, in addition to the provision about submission of procedures. Thus, the reference is now appropriate.

comment

49

comment by: *NATS National Air Traffic Services Limited***ATM/ANS.OR.A.045(e)****Page 35**

Whilst it should be feasible to reasonably determine which other service providers may be affected by the planned change it is not possible for the service provider planning a change to be absolutely sure which aviation undertakings may be affected by the change.

ATM/ANS.OR.A.045(a)(3) foresees this possibility by including “where feasible”. A similar approach is advocated for (e).

Proposal - Amend (e) to read:

“(e) When a change **is known to** affect other service providers and/or aviation undertakings the **affected** service providers should:”

Specific proposals for how to achieve this in Appendix A (document attached to NATS Comment number 25). In the proposal the text “as identified in (a)(3)” is considered



	superfluous as this is now AMC to ATM/ANS.OR.A.045.
response	<p>Partially accepted</p> <p>The use of the phrase ‘is known to’ seems unnecessary, as in (e) we are using the list of aviation undertakings identified in (a)(3), and therefore they must be known. Those that are not known, will either be identified later in the coordination with other service providers or they will never be identified. Please note that the same applies to other requirements that ask properties or elements (e.g. hazards) to be identified. The phrase ‘where feasible’ has been added to actually consider the possibility to identify all aviation undertakings where possible. Following that, the word ‘all’ has been deleted.</p> <p>(e)(2) is removed as it is considered not necessary and is already covered in the notification data (see GM1 ATM/ANS.OR.A.045(a)).</p> <p>(e)(3) is removed and the coordination is limited to determine dependencies and common assumptions and risk mitigations more implicitly in the new draft proposal.</p>
comment	<p>50 comment by: NATS National Air Traffic Services Limited</p> <p>ATM/ANS.OR.A.045(e)(1) Page 35</p> <p>Whilst it is possible to know which aviation providers are affected by the change it may not be possible to engage with them in order to determine the dependencies, if any?</p> <p>Proposal: Amend (e)(1) to read: “(e)(1) determine the dependencies with each other and, where feasible, with the affected aviation undertaking” Point (e)(1) amended as proposed in Appendix A (document attached to NATS Comment number 25).</p>
response	<p>Accepted</p> <p>The phrase ‘where feasible’ has been added.</p>
comment	<p>51 comment by: NATS National Air Traffic Services Limited</p> <p>ATM/ANS.OR.A.045(e)(3) Page 35</p> <p>It is not clear from the text as to what is the nature of the “assessment” that is to be conducted by considering the dependencies. If the dependencies are known (a) then what is the purpose of the assessment?</p>
response	<p>Accepted</p>



The purpose is to determine the existing dependencies and identify and align common assumptions and risk mitigations. The complete provision (e) has been simplified without reference to ‘assessment’ and there is only reference to ‘coordination’ in order to avoid misinterpretation of requiring a complete assessment in partnership between the service providers involved.

The assessment to be performed is that of identifying mutually dependent risks or agreeing on mitigations that resolve mutually dependent risks. However, it is accepted that the assessment is performed individually once these shared risks and mitigations have been determined. Consequently, (e)(3) has been deleted.

comment	<p>74 comment by: EUROCONTROL Safety Team</p> <p>General comment ATM/ANS.OR.A.045</p> <p>The term ‘notification of the change’ in EU 1034/2011 has been defined as the way for the ANSP to inform the NSA of a given change. In this NPA there are instances where the word ‘notification’ is used to inform stakeholders of the changes (users, other service providers...).</p>
response	<p>Accepted</p> <p>This has been amended. The action towards other service providers and aviation undertakings is ‘inform’.</p>
comment	<p>75 comment by: EUROCONTROL Safety Team</p> <p>ATM/ANS.OR.A.045 (e)</p> <p>This requirement appears to be rather infeasible because it extremely hard for the SP to be absolutely sure which aviation undertakings may be affected by the change.</p> <p>Recommend to amend text to include <i>where feasible</i>, similar to the approach in ATM/ANS.OR.A.045(a)(3).</p>
response	<p>Accepted</p> <p>The phrase ‘where feasible’ has been added.</p> <p>Please see also response to comment No 49.</p>
comment	<p>269 comment by: UK CAA</p> <p>Page No: 35</p> <p>Paragraph No: ATM/ANS.OR.A.045 (c) & (d)</p> <p>Comment: The meaning of “parts of the change” is unclear. The UK CAA requests clarification of this term in order to make meaningful comment.</p> <p>Justification: Clarity.</p>



response

Noted

What is meant by 'parts of the change' is already mentioned in GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045. 'Part' is used in its normal English sense: (OED) An amount or section which, when combined with others, makes up the whole of something. i.e. it is not the whole change. It will be reviewed during the development of AMC/GM.

comment

271

comment by: DSNA

(a) : The AMC or GM about "what is a change" should explain that changes which are immediate reactions to a failure are out of the scope of the provision ATM/ANS.OR.A.045.

(a)(2) : **proposed text** : « ... to review the safety argument of the change ».

(a)(3) : **proposed text** : **where relevant** inform service providers and aviation undertakings affected by the planned change.

(b) : **proposed text** : **when appropriate**, the service provider shall inform the competent authority whenever the information provided under (a)(1) and (2) is materially modified, and the relevant service providers and aviation undertakings whenever the information provided under (a)(3) is materially modified."

(1 (e) : whilst it should be feasible to reasonably determine which other service providers may be affected by the planned change it is not possible for the service provider planning a change to be absolutely sure which aviation undertakings may be affected by the change.

As written, being affected by a change of another ANSP implies that it triggers a safety related change and this is definitely not systematic , **proposed text** : when a change affects other **service providers** and/or aviation undertakings, as identified in (a)(3), **the service provider** affected shall:

(e)(1) : **proposed text** : **where relevant**, determine the dependencies with each other service providers and aviation undertaking ».

(e)(2) : **proposed text** : **where relevant** include in their notification to their competent authority, in accordance with (a)(1), a list of the service providers and other aviation undertakings that are **known** affected;

(3) : DSNA is working with ANSP which are not subjected to this IR (Algeria for instance) and it will be impossible for DSNA to plan and conduct a coordinated assessment if our partner disagree. DSNA would not be in a position to comply with the IR. **Proposed text** : "**where feasible**, plan and conduct a coordinated".

DSNA would like that FABEC option 2 be considered compliant with this provision and EASA develops an appropriate AMC.

response

Partially accepted

(a) Immediate reaction to failures is not included and is already described in GM (see point K



on page 60 of the NPA)

(a)(2) The word ‘argument’ has been added. The use of ‘safety argument’ is only valid in the case of ATS. It cannot be used when reviewing a safety support case. Consequently, the term ‘argument’ is used as it covers both — see GM1 ATM/ANS.OR.C.005(a)(2) & ATS.OR.205(a)(2).

(a)(3) The affected parties should be informed in order for them to e.g. to assess if they need to change their functional system too. It may be not always possible to determine the need. The term ‘affected’ is explained in GM1 ATM/ANS.OR.A.045(e), and it does not imply that changes to functional systems must be made by other providers. However, it does mean that they need to check whether they need to make a reactive change — see GM1 Annex I Definitions (35) & ATM/ANS.OR.A.045 & ATM/ANS.OR.C.005 & ATS.OR.205.

(b) The use of the phrase ‘materially modified’ covers that situation and, therefore, the phrase ‘when relevant’ is unnecessary. The implied notion is already present — the phrase ‘materially modified’ indicates the relevance.

(e)(1) It is difficult a priori to decide the relevance and to identify dependencies. They latter need to be first identified, and then it will be decided if they are relevant for the assessment.

(e)(3) has now been removed and integrated the word coordination in the requirement of dependencies and assumptions. See also the response to comment No 51.

3) We hope that the new draft proposal resolves the issue described by DSNA. Only certain coordination is required, and not a common assessment of the change. In this case the Algerian ATSP is an aviation undertaking because it is not regulated by the Basic Regulation. Consequently (e)(2) comes into play – “where feasible...”

We would be happy to integrate FABEC option 2, but we have not received it so far. If made available, we will surely assess it and integrate it in the AMC/GM, if appropriate.

comment 365

comment by: *Air Navigation Services of the Czech Republic*

(a) (3) and (e) (2) Please note, the situation would be easier if competent authority published a list of providers and undertakings. Otherwise it might be hard to agree on the parties to be informed. Also, it might be hard to prepare such a list as the "undertaking" might also be a person (by the given definition in Annex I).

(c) and (d) We propose to split a change into more smaller changes, not into parts. Then, simply, any change could enter operations only when it's accepted by the CA, provided its argument is reviewed – a clear and simple solution.

Note: in line with the current EC 1034/2011, a change is subject of acceptance by the CA. It is not used any longer here. The same applies for (d), where "CA has approved the argument to enter into operational service". Again, we propose to stick to the "change acceptance" as used by the current 1034/2011.

(e) (1) It is hardly feasible to identify "all the dependencies". We propose to delete (e) (1) and change the text of (e) as follows: “(e) When a change is known to affect other service



providers and/or aviation undertakings the affected service providers should:”

(f) Please note, that all these activities will require to prepare at least assumptions and mitigations in a common language (e.g. English), which is not the current practice in all organisations. The service providers affected by the assumptions and mitigations in (e) (4) should have an opportunity to comment and express their view in their respective risk assessment process related to the change. We propose to change the text of (f) (1) as follows: “take into account these assumptions and mitigations; and”

response Partially accepted

It is the service provider in the best place to know who is/are using its services and who provides services to them, which creates the first list of affected parties. The list is on the responsibility of the service provider and will vary from change to change. It cannot be known in advance by the CA. If there are many undertakings and informing them individually is infeasible, there is the phrase ‘where feasible’ to consider that option. There is AMC/GM available that covers these situations.

‘Acceptance vs approval’ — Please see the response to comment No 840 about the use of the term ‘approve’ vs the term ‘accept’.

The way changes can be split up is explained in GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045. The intention of this clause is to allow transitions to enter service even though the safety case for the complete change is incomplete. This is relevant when the part of the change being introduced provides evidence that supports later transitions. It could, of course, be treated as a set of individual changes but the choice depends upon the circumstances of the total change.

The word ‘all’ has been removed. This requirement is similar to that regarding the identification of hazards. It is not ‘all’ that are identified, but only those known and relevant.

f) English is not required by the regulation, although to communicate between parties it may be the easiest approach. The language used is not a matter to be regulated. The service providers do have the opportunity to comment because they must not only identify the dependencies between them (due to the change), but they must agree on any risks and mitigations that are shared in some way.

(f)(1). The agreement would include the resolution of issues which may be raised by commenting on each other’s proposals. The provision has been redrafted and simplified addressing the concerns of a number of stakeholders.

comment 400

comment by: *skyguide Corporate Regulation Management*

ATM/ANS.OR.A.045(e)

Whilst it should be feasible to reasonably determine which other service providers may be affected by the planned change it is not possible for the service provider planning a change to be absolutely sure which aviation undertakings may be affected by the change.

ATM/ANS.OR.A.045(a)(3) foresees this possibility by including “where feasible”. A similar



	<p>approach is advocated for (e). We suggest amending (e) to read: “(e) When a change is known to affect other service providers and/or aviation undertakings the affected service providers should:” Specific proposals for how to achieve this in Appendix A. In the proposal the text “as identified in (a)(3)” is considered superfluous as this is now AMC to ATM/ANS.OR.A.045.</p>
response	<p>Partially accepted</p> <p>Please see the responses to comments Nos 47, 49 and 50.</p>
comment	<p>449 comment by: EUROCONTROL</p> <p>Annex III Subpart A ATM/ANS.OR.A.045 (a) - Page 35</p> <p>The term ‘notification of the change’ in EC1034/2011 is been defined as the way for the ANSP to inform the NSA of a given change. In the NPA there are instances where the word ‘notification’ is used to inform stakeholders of the changes (users, other service providers...). It has always been a balance between “early” and “enough information”: the NPA ask for very early notification which could lead to very poor, inaccurate, incomplete information provided. This could lead to wrong decision on the review by the NSA and multiple exchange of data/information on the change between the parties (= source of confusion and not recommended management practices).</p> <p>The information exchanged should include some elements of the safety risk or criticality (for supporting the decision made by the NSA to review or not). It will also help the ANSP to build a safety case commensurate with the safety risk associated to the change.ATM/ANS.OR.A.045 (a) only relates to a change to a functional system. It does not mention the introduction of a change to a service.</p> <p>It is suggested to broaden the coverage of this NPA to change to a service related to the provision of ATM/ANS / a functional system.</p> <p>It is important to note that, if accepted, the suggestion impacts many other places in the document, basically every time “change(s) to functional system(s)” is mentioned. This comment is not repeated.ATM/ANS.OR.A.045 Changes to the functional system (a)(3)</p> <p>The notification of a change is extended to include other providers and also aviation undertakings.</p> <p>This entails a detailed look into how the change will affect other providers, etc. Such a detailed list might not be yet available at the start of assessment process and the notification stage. Consequently either the notification to the Competent Authority - CA is done knowingly with incomplete information or the notification is delayed until the safety assessment is more mature. In the latter case this could be very late in the project which means a late notification to the CA.ATM/ANS.OR.A.045 Changes to the functional system (e)(3)</p> <p>EUROCONTROL's comment</p> <p>ANSP's cannot force aviation undertakers who do not fall under the EC216/2008 regulation</p>



to conduct an assessment.

EUROCONTROL's proposal

Only the service providers or aviation undertakers which are within the scope of this NPA / regulation are required to conduct a coordinated assessment.

ATM/ANS.OR.A.045 Changes to the functional system (f)(1) and (2)

Agreement on the assumptions made and planned mitigation is necessary by the other providers affected by the change and, where feasible, by the affected aviation undertakings.

What happens in the case of no agreement? There are some references to such a scenario in the GM but the IR does not take disagreement into account.

response

Partially accepted

The term 'inform' is now used to send information about a changed to other service providers and aviation undertakings. The term used with other service providers and aviation undertakings should be 'inform'. There are no instances in IR of the use of notification, but the text in AMC/GM will be checked.

The comment from the 2nd paragraph up to "EUROCONTROL's comment" is a useful exposition but does not seem to contain any proposals for changing the IR. The Agency concurs with the idea of Eurocontrol to have some elements of the criticality in the notification. However, many service providers and CAs wish to start the notification earlier to engage the CA in the process. It does not mean that the CA will have to decide at the time the first notification is given, but only when enough information is available. For those elements of the notifications see AMC2 ATM/ANS.OR.A.045(a) and GM1 ATM/ANS.OR.A.045(a), which includes the element of criticality (point (8) in the list of that GM).

It is noted that the IR and its associated AMC/GM do indeed recognise the points being made and offer guidance on the topics raised.

This NPA does not provide process-oriented rules, but rules about the necessary outcomes of particular actions, consequently, managing the processes that necessarily produce the regulated outputs is left to the organisations concerned. The vast range of changes covered by the rule means that things like the requirement for a notification period is impractical. It is up to the service provider.

The suggestion to change from a functional system perspective to a service perspective is not accepted. The model used in the NPA is that the service of interest is delivered by a functional system. Consequently, a change to a service needs results from either a change to the functional system or a change in its operational context. The IR regulates the former, but requires the latter to be known to the service provider and, if it is necessary, to make a change to the functional system (reactive change). The opposite is not true, so focussing on the service makes adequate regulation difficult if not impossible. All of this is explained, in depth, in the GM. We concur with the fact that the list of undertakings may be initially not complete. The requirements does not imply a timeline of a process, and the list of



undertakings will need to be updated when the assessment progresses.

Coordinated assessment. It is true that aviation undertakings cannot be forced to coordinate or collaborate, as they are not subject to this Regulation. There is no requirement to force aviation undertakings to conduct an assessment. The requirement to perform an assessment is placed only on service providers — see ATM/ANS.OR.A.045(e). This is also acknowledged in AMC/GM, and that is the reason for using the term ‘aviation undertaking’ and also the reason for including the phrase ‘where feasible’. The provisions have been modified to avoid a requirement for service providers to agree or coordinate with aviation undertakings, and to limit the requirement to use only agreed assumptions and mitigations.

Aviation undertakings cannot be required to do anything within the scope of this NPA. Where feasible, the service provider (who is regulated) should seek to involve all aviation undertakings. Consequently, the intent of the comment is already implemented.

The comment implies there should be rules to resolve disagreements. This is not normally the case and the Agency did not feel it was appropriate to regulate disagreements. The rule states the outcomes required and, in some cases, this involves more than one party and so implies agreement between the parties. How that agreement is reached is not the subject of the rule and in most cases is not of concern to the law. It would be taken as too prescriptive regulation. It is up to the service provider to find the way to agree on ‘common’ assumptions or find other ways to support those common assumptions. Otherwise, they should not use them (the change may be even abandoned or modified). One example could be the use of a certain assumption on the behaviour of a pilot after the introduction of certain technology on ground and on board. If the assumption on the pilot behaviour is not agreed with pilots and/or airline operators and it turns out to be incorrect, the safety assessment of the service provider may be flawed.

comment

586

comment by: *Federal Office of Civil Aviation FOCA*

ATM/ANS.OR.045 (a) (1): FOCA suggests to add a new bullet with the following wording: "notify the competent authority of the respective country for changes affecting service provision in a delegated airspace outside the country where the organisation has its principal place of business".

Justification: In delegated airspaces the rules and regulations of the corresponding country apply. Therefore, it is the ANSPs task to seek acceptance of the safety argument of the change with the corresponding CA. By doing so, the ANSP might be in contact with different CAs with regard to a single change. Each CA will have to approve the change individually, in cooperation with the other CA or delegate the task (individually for each change or permanently) to the other CA.

response

Partially accepted

The service provider has to notify its CA of all affected service providers and aviation



undertakings (OR.A.045(e)(2). From this list, the CA can determine everyone engaged in the change. The service provider would normally only be in contact (formally) with his own CA. The CAs may need to coordinate their review of the overall change. A question about this was asked in the NPA and the response was mixed. This coordination is suggested to be regulated, but in a different place (see resulting provisions in ATM/ANS.AR.A.005).

comment

610

comment by: *DFS Deutsche Flugsicherung GmbH*

(a) (3)

It would be always "feasible" to inform aviation undertakings. We propose to change "feasible" to "necessary". It will then read: "inform service providers and, where necessary, aviation undertakings affected by the planned change."

Reference to high level comment "c.ii"

response

Not accepted

It does not seem obvious that it is always feasible to inform aviation undertakings, according to other commentators. The service provider may or may not know the use of the service by aviation undertakings, so 'necessary' is not appropriate. 'Feasible' is appropriate as it indicates an ability rather than a willingness.

comment

632

comment by: *DGAC/DSAC - french NSA*

The french NSA has four comments related to ATM/ANS.OR.A.045 :

- paragraph (a) :

The requirement stated in this paragraph is related to the changes planned by the service provider. As explained in GM1 Annex I Definitions (35) & ATM/ANS.OR.A.045 & ATM/ANS.OR.C.005 & ATS.OR.205 General, a change could be a change wished by the service provider (cf. GM (b)(1)) or a responsive change (cf. GM (b)(2)). In both cases, it is finally a planned change subject to this requirement. We suggest a clarification on this point, ideally in the requirement itself, in the GM at least.

- paragraph (a) :

Even though we can see in some parts of this NPA attempts to define "what is a change", the result is not convincing. We suggest a clear definition, if possible, in GM.

- paragraph (b) :

We do not understand the added value of using "materially modified" instead of "modified". We suggest "modified" alone or a GM to explain what can be considered as materially



	<p>modified or not.</p> <ul style="list-style-type: none"> paragraph (d) : <p>In line with our previous comment related to ATM/ANS.AR.C.40 (c), we suggest to replace "to approve the argument to enter into operational service" by "to accept the argument to enter into operational service".</p> <ul style="list-style-type: none"> paragraph (e) : <p>It will be more explicit to say that this is a change for them too ("service providers and/or aviation undertakings" affected by a change), and that they have to notify their competent authority as if they were "planning a change" (paragraph (a)).</p>
response	<p>Partially accepted</p> <ul style="list-style-type: none"> — The explanation about ‘planned’ changes is already included in paragraph (d) of GM1 Annex I Definitions (35) & ATM/ANS.OR.A.045 & ATM/ANS.OR.C.005 & ATS.OR.205 General. It will be rearranged. — The definition of a change is given and is clear: The changes which are of interest are those changes that are to be made to the functional system (people, procedures, equipment and organisation) and affect its behaviour. It might be argued that some of them have no impact on the behaviour of the service and these would not need to be notified. A description of a process that could be used to establish this is given in GM1 Annex I Definitions (35) & ATM/ANS.OR.A.045 & ATM/ANS.OR.C.005 & ATS.OR.205. The model of the functional system and what changes to it mean are given in GM2 Annex I Definitions(35). We do not see the need to redefine it. — ‘Materially’ is used in its normal English sense and means: ... ‘In a significant way’. It is not expected that every modification is ‘material’ and if a modification is not ‘material’, it would not need to be reviewed. Sending every change seems excessive. — Please see the response to comment No 840. — This is not necessarily true. They may or may not have to make a change. That is the intent of the whole requirement: to make them aware and then they should assess if they need to change their system. As explained in GM1 Annex I Definitions (35) & ATM/ANS.OR.A.045 & ATM/ANS.OR.C.005 & ATS.OR.205, not all service providers will need to make a responsive change to their functional system. However, they will be affected by the change and so the service provider proposing the change will notify all the affected stakeholders to its CA. The CAs may need to coordinate in order to see the full extent of the change — see the response to comment No 586 for information on proposed change to cover CA coordination.

comment 638

comment by: *CANSO*

	<p>ATM/ANS.OR.A.045(e)</p> <p>Whilst it should be feasible to reasonably determine which other service providers may be affected by the planned change it is not possible for the service provider planning a change to be absolutely sure which aviation undertakings may be affected by the change. ATM/ANS.OR.A.045(a)(3) foresees this possibility by including “where feasible”. A similar approach is advocated for (e). CANSO suggests amending (e) to read: “(e) When a change is known to affect other service providers and/or aviation undertakings the affected service providers should:” Specific proposals for how to achieve this in Appendix A. In the proposal the text “as identified in (a)(3)” is considered superfluous as this is now AMC to ATM/ANS.OR.A.045.</p>
response	<p>Partially accepted</p> <p>Please see the responses to comments Nos 47, 49 and 50.</p>
comment	<p>689 comment by: ROMATSA</p> <p>ATM/ANS.OR.A.045(e)</p> <p>Whilst it should be feasible to reasonably determine which other service providers may be affected by the planned change it is not possible for the service provider planning a change to be absolutely sure which aviation undertakings may be affected by the change. ATM/ANS.OR.A.045(a)(3) foresees this possibility by including “where feasible”. A similar approach is advocated for (e). ROMATSA supports CANSO suggestion to amend (e) to read: “(e) When a change is known to affect other service providers and/or aviation undertakings the affected service providers should:” Specific proposals for how to achieve this in Appendix A. In the proposal the text “as identified in (a)(3)” is considered superfluous as this is now AMC to ATM/ANS.OR.A.045.</p> <p>Supporting comment to summary issue: The IR is not feasible, i.e., impractical to meet in practice.</p>
response	<p>Partially accepted</p> <p>Please see the responses to comments Nos 47, 49 and 50.</p>
comment	<p>755 comment by: CAA Norway</p> <p>ATM/ANS.OR.A.045 (e) (3):</p> <p>To plan and conduct a coordinated assessment with all affected aviation undertakings, may turn out to be infeasible. CAA Norway therefore suggest to add "where feasible" to the requirement.</p>



response Accepted

The assessment is normally performed by service providers, not by aviation undertakings. Anyway, provisions have been amended to account for this situation.

comment 846 comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.1 <i>Draft Regulation (Draft EASA Opinion)</i> Annex III COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR) ATM/ANS.OR.A.045(a)(3)</p>	<p>A clarification on what is actually sought with this report to other service providers and aviation undertakings should be included.</p> <p>In a more pragmatic level, we wonder:</p> <p>a) whether this activity should be carried out prior to the notification of the change to the CA or simultaneously with the notification;</p> <p>b) what is the purpose of this communication;</p> <p>c) whether this activity implies the start of the coordinations required further on;</p> <p>d) whether this activity allows other organizations to participate actively in the development and implementation of the change almost from the very beginning; and</p> <p>e) how the process that relates provision (a)(3) to (e) looks like.</p>	<p>We would welcome clarification on these points in order to better understand and assess this NPA.</p>

response Noted

a) The regulation does not describe processes and, hence, makes no requirements on when activities occur. It would seem sensible for these activities to occur both prior to and after the act of notification. However, in identifying all the dependencies, some early development work may be needed and, as a result, new stakeholders could be identified. In such a case,



the information to the CAs would be ‘materially modified’ and so the CAs would have to be informed.

b) The purpose of the notification is to make the CA aware of the planned change and its extent.

c) The notification does not imply the start of any process. It is an action that is necessary at some point. It is assumed that some coordinated activity has taken place prior to the notification — see above.

d) It is expected that as stakeholders who will be affected are identified, they are immediately brought into coordination to contribute to the identification of dependencies.

e) While no guidance is given on the process for identifying dependencies (and therefore stakeholders affected), GM1 ATM/ANS.OR.A.045(e)(1) provides detailed guidance on the kinds of dependencies being sought. GM proposed for the 2nd NPA may provide more process-oriented guidance.

comment

857

comment by: Naviair

Regarding AMC1 ATM/ANS.OR.A.045(a)(3)

Even where known it is not feasible to individually notify all known service providers and aviation undertakings. For certain changes this could many may be hundreds of notifications. There will be a significant number of changes that has no effect on any other service provider or aviation undertaking yet (b) would require that they are published – even to those not affected.

Regarding AMC1 ATM/ANS.OR.A.045(e)(3)

(e)(3) requires “However, no matter how many individual changes to service providers’ functional systems are part of the change, they should be coordinated. An overarching safety argument, coherent with the arguments of the individual changes, that claims the complete change is safe should be provided.”

This is not feasible given that each service provider will have argued the safety acceptability of their changes to their functional system against prescribed safety criteria and regulations.

response

Noted

Comments on AMC/GM will be responded to in the CRD associated with them. A considerable amount of time is needed to rework, amend and complete the AMC/GM in an appropriate and effective manner, and this cannot be done at this stage. Future work is planned to review the comments on the AMC/GM and complete the CRD in due time.

[Regarding AMC1 ATM/ANS.OR.A.045\(a\)\(3\), the comment is partially accepted that it may not](#)



be feasible to inform all aviation undertakings; however, it seems feasible to inform all service providers affected by the change. In the case of aviation undertakings, GM is provided on this issue (GM1 ATM/ANS.OR.A.045(f)(2)) which states that 'When the number of aviation undertakings affected by the change is large, the service providers may not need to involve every individual stakeholder. If a body can represent the views of a group of affected aviation undertakings, it may suffice to involve that representative body to obtain the supporting evidence to move forward with the assessment of the change'. The AMC has been altered to reflect this.

Regarding AMC1 ATM/ANS.OR.A.045(e)(3), the comment is not accepted. Whilst each service provider must argue the safety consequences or the trustworthiness of the change he/she makes, this will depend fundamentally on the way the change is introduced into service and the way this changed service interacts with all other services within the system of interest, whether changed or not. This safe transition of all services being changed cannot be the responsibility of each service provider; it must be co-ordinated. Equally, the overall safety of the system cannot be argued by each service provider individually. This is the purpose of the overarching safety case. So, even if the acceptability of each individual change is done against prescriptive safety criteria, those safety criteria may well be dependent on the way the change is introduced.

comment 885

comment by: Naviair

**ANNEX III
COMMON REQUIREMENTS FOR SERVICE PROVIDERS
(Part-ATM/ANS.OR)**

SUBPART A — GENERAL COMMON REQUIREMENTS (ATM/ANS.OR.A)

ATM/ANS.OR.A.045. Changes to the functional system

(a) A service provider planning a change to its functional system shall:

- (1) notify their competent authority of the change;
- (2) provide the competent authority, if requested, with any additional information that allows the competent authority to decide whether or not to review the change; and
- (3) inform service providers and, where feasible, aviation undertakings affected by the planned change.

(b) The service provider shall only allow the parts of the change, for which the activities required by ATM/ANS.OR.C.005, ATS.OR.205 and ATS.OR.210 as applicable have been completed, to enter operational service.

(c) If the change is subject to competent authority review in accordance with ATM/ANS.AR.C.035, the service provider shall only allow the parts of the change for which the competent authority has approved the argument to enter into operational service.

AMC1 ATM/ANS.OR.A.045. Changes to the functional system

CHANGE TO INFORMATION PROVIDED

Having notified a change, the service provider should inform the competent authority whenever the information provided under ATM/ANS.OR.A.045(a) and (b) is materially



modified, and the relevant service providers and aviation undertakings whenever the information provided under ATM/ANS.OR.A.045(c) is materially modified.

AMC2 ATM/ANS.OR.A.045. Changes to the functional system

CHANGE AFFECTS OTHER SERVICE PROVIDERS AND/OR AVIATION UNDERTAKINGS

(a) When a change is known to affect other service providers and/or aviation undertakings the affected service providers should:

(1) determine all the dependencies with each other and, where feasible, with the affected aviation undertakings;

(2) include in their notifications to their competent authorities, in accordance with ATM/ANS.OR.A.045(a), a list of the service providers and other aviation undertakings that are affected;

(3) plan and conduct a coordinated assessment considering the dependencies as determined in (a); and

(4) determine the assumptions and risk mitigations that relate to more than one service provider or aviation undertaking.

(b) Those service providers affected by the assumptions and mitigations in (a)(4) should:

(1) mutually agree and align these assumptions and risk mitigations; and

(2) where feasible, mutually agree and align these assumptions and risk mitigations with the aviation undertakings affected by them.

AMC1 ATM/ANS.OR.A.040(a)(2). Changes – general

CHANGE MANAGEMENT PROCEDURES

Procedures that will be used by a service provider to manage, assess, and, if necessary, mitigate the impact of changes to their functional systems in accordance with ATM/ANS.OR.A.045, ATM/ANS.OR.C.005, ATS.OR.205, ATS.OR.210, or any material modifications to those procedures should:

(a) be submitted, for approval, by the service provider to the competent authority; and

(b) not be used until approved by the competent authority.

AMC2 ATM/ANS.OR.A.040(a)(2). Changes - general

CHANGE MANAGEMENT PROCEDURES – DEVIATION FROM THE APPROVED PROCEDURES

When the approved procedures referred to in AMC1 ATM/ANS.OR.A.040(a)(2) are not suitable for a particular change to the functional system, the service provider should:

(a) make a request to the competent authority to deviate from the approved procedures;

(b) provide the details of the deviation and the justification for its use to the competent authority; and

(c) not use the deviation before being approved by the competent authority.

SUBPART C — SPECIFIC ORGANISATIONAL REQUIREMENTS FOR SERVICE

PROVIDERS OTHER THAN ATS PROVIDERS (ATM/ANS.OR.C)

ATM/ANS.OR.C.001. Scope

This Subpart establishes the requirements to be met by service providers other than air traffic services providers with respect to additional responsibilities to those established in Subparts A and B.

ATM/ANS.OR.C.005. Safety support assessment and assurance of changes to the functional system

A service provider other than an air traffic services provider shall:



(a) ensure that a safety support assessment is carried out; and
 (b) provide assurance, with sufficient confidence, via a complete, documented and valid argument that the service will behave and will continue to behave only as specified in the specified context,
 for any change they have notified in accordance with ATM/ANS.OR.A.045(a).

AMC1 ATM/ANS.OR.C.005. Safety support assessment and assurance of changes to the functional system

SAFETY SUPPORT ASSESSMENT

A service provider other than an air traffic services provider shall ensure that the safety support assessment comprises:

- (a) the definition of the scope of the change consisting of:
 - (1) the equipment, procedural and human elements being changed;
 - (2) interfaces and interactions between the elements being changed and the remainder of the functional system;
 - (3) interfaces and interactions between the elements being changed and the context in which it is intended to operate; and
 - (4) the life cycle of the change from definition to operations including transition into service and planned degraded modes;
- (b) verification that:
 - (1) the change conforms to the scope that was subject to safety support assessment; and
 - (2) the service behaves only as specified in the specified context; and
 - (3) the way the service behaves complies with and does not contradict any applicable requirements of this Regulation placed on the services provided by the changed functional system;
- (c) the specification of the monitoring requirements necessary to demonstrate that the service delivered by the changed functional system will continue to behave only as specified in the specified context.

SUBPART D — SPECIFIC ORGANISATIONAL REQUIREMENTS FOR ANS AND ATFM PROVIDERS AND THE NETWORK MANAGER (ATM/ANS.OR.D)

response

Partially accepted

 This proposal seems to be the same as the one submitted by CANSO (very difficult to identify as changes are not highlighted). Please see the responses to comments Nos 47, 49 and 50.

comment

905 comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.1 Draft Regulation	We wonder whether the partial approval of a change introduced in this new provision	The change is presented as an integral project composed of several interrelated parts.



<p><i>(Draft EASA Opinion) Annex III COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR)</i></p>	<p>ATM/ANS.OR.A.045(c) & (d) is a sensible way to proceed.</p>	<p>The partial approval of some of these parts, although presented as an improvement for the sake of flexibility, can finally result in a higher risk to the project if the full review results in parts not being approved or changes required to the still-not-approved parts that have consequential effects on the parts already approved.</p>
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response

Not accepted

This comment implies a change to (c) & (d)

A partial approval of a change is intended to allow for the introduction of parts of a change. A part of a change would be the same as a transition phase as described in GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045. The part concerned must have been assessed and an assurance case must exist for the part being made operational (OR.B.010). This approach may be used when there is a need to gather evidence for the assurance of a later part of the change. Moreover, as described in GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045, in these circumstances, a 'back out plan' will be part of the safety case and so should the partial change not provide sufficient supporting evidence, the change can be halted, modified or reversed in order to keep the system safe.

The CA will have seen the whole safety case before the partial change takes place and can, therefore, take a view as to whether the partial change is safe enough and that in the event of not achieving its goal, the system can be made safe enough. The example given by the commentator would not be possible.

comment

907

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.1 <i>Draft Regulation (Draft EASA Opinion) Annex III COMMON</i></p>	<p>A similar requirement should be included to prevent service providers to introduce a change before the CA has informed of its decision on</p>	<p>If this requirement is not in place, it could happen that a service provider notifies a change to the CA and, instead of waiting for the CA's answer, starts the implementation of the change as approval is only required in</p>



REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR) ATM/ANS.OR.A.045 (d)	whether to review or not.	case of an explicitly declared review.
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response Not accepted

ATM/ANS.OR.B.045(c) provides for this safeguard.

comment 1050

comment by: LVNL

ATM/ANS.OR.A.045 Changes to the functional system

This is quite a specific regulation, and in line with my earlier comment on staying at a sufficiently high level, it is proposed to split this into one IR and several AMCs.

Whilst it should be feasible to reasonably determine which other service providers may be affected by the planned change it is not possible for the service provider planning a change to be absolutely sure which aviation undertakings may be affected by the change.

The list of details needed for the notification should be at GM level.

It is proposed to change the IR as follows:

ATM/ANS.OR.A.045 Changes to the functional system

(a) A service provider planning a change to its functional system shall:

- (1) notify their competent authority of the change;
- (2) provide the competent authority, if requested, with any additional information that allows the competent authority to decide whether or not to review the change; and
- (3) inform service providers and, where feasible, aviation undertakings affected by the planned change.

(b) The service provider shall only allow the parts of the change, for which the activities required by ATM/ANS.OR.C.005, ATS.OR.205 and ATS.OR.210 as applicable have been completed, to enter operational service.

(c) If the change is subject to competent authority review in accordance with ATM/ANS.AR.C.035, the service provider shall only allow the parts of the change for which the competent authority has approved the argument to enter into operational service.

Subsequently, this would be the proposed AMC:

AMC1 ATM/ANS.OR.A.045 Changes to the functional system

CHANGE TO INFORMATION PROVIDED

Having notified a change, the service provider should inform the competent authority whenever the information provided under ATM/ANS.OR.A.045(a) and (b) is materially modified, and the relevant service providers and aviation undertakings whenever the information provided under ATM/ANS.OR.A.045(c) is materially modified.



AMC2 ATM/ANS.OR.A.045 Changes to the functional system

CHANGE AFFECTS OTHER SERVICE PROVIDERS AND/OR AVIATION UNDERTAKINGS

(a) When a change is known to affect other service providers and/or aviation undertakings the affected service providers should:

(1) determine all the dependencies with each other and, where feasible, with the affected aviation undertakings;

(2) include in their notifications to their competent authorities, in accordance with ATM/ANS.OR.A.045(a), a list of the service providers and other aviation undertakings that are affected;

(3) plan and conduct a coordinated assessment considering the dependencies as determined in (a); and

(4) determine the assumptions and risk mitigations that relate to more than one service provider or aviation undertaking.

(b) Those service providers affected by the assumptions and mitigations in (a)(4) should:

(1) mutually agree and align these assumptions and risk mitigations; and

(2) where feasible, mutually agree and align these assumptions and risk mitigations with the aviation undertakings affected by them.

AMC3**ATM/ANS.OR.A.045(a)**

NOTIFICATION

DATA

The notification of a change should contain the following information:

a) a description of the change under consideration

b) an initial safety impact assessment covering at least the following criteria:

- Novelty
- Complexity
- Consequence of failure

And this would be the GM:

GM for AMC2 ATM/ANS.OR.A.045(a) sub a)

The notification of a change is not considered complete until the following information is provided:

a) Name of the organisation notifying the change;

b) Title of the change;

c) Unique identifier of change;

d) Version number of notification;

e) Date of the submission of the original of this change notification;

f) Specific description of the change to the functional system;

g) Time planning, including scheduled date of entry into service;

h) Entity in charge of the assurance case; and

i) Contact details of the point of contact for communications with the CA.

response

Partially accepted

It is unclear which earlier comment the commentator refers to (No 1024?). Please see the responses to comments Nos 47, 49 and 50, which address your points. Your proposal for AMC/GM seems interesting and it may be incorporated when the AMC/GM is reviewed and



completed.

Changes to the IR and creation of AMC have been agreed. It is not precisely as described but the intent has been met, except:

- The determination of dependencies, assumptions and risk mitigations remains in the IR as it describes criteria.
- The notification is included in the notification data AMC.
- Planning and conducting co-ordinated assessments has been removed from the IR but the outcome of such an activity is included in paragraph (f) of ATM/ANS.OR.A.045.

comment 1103

comment by: *Belgocontrol*

ATM/ANS.OR.A.045 (e)

This requirement is rather infeasible as it is extremely hard for the service provider to be absolutely sure which aviation undertakings may be affected by the change.

Recommend to include *where feasible*

response Accepted

It has been added to the provision. Please see the response to comment No 50.

comment 1180

comment by: *Avinor ANS*

Whilst it should be feasible to reasonably determine which other service providers may be affected by the planned change it is not possible for the service provider planning a change to be absolutely sure which aviation undertakings may be affected by the change.

ATM/ANS.OR.A.045(a)(3) foresees this possibility by including “where feasible”. A similar approach is advocated for (e).

We suggests amending (e) to read: “(e) When a change is known to affect other service providers and/or aviation undertakings the affected service providers should:” Specific proposals for how to achieve this in Appendix A. In the proposal the text “as identified in (a)(3)” is considered superfluous as this is now AMC to ATM/ANS.OR.A.045.

response Partially accepted

Please see the responses to comments Nos 47, 49 and 50.

comment 1227

comment by: *Frasie Loredana*

a) Modify the text: *A service provider planning a change to its functional system shall: to A service provider planning a safety related change to its functional system shall:*



Modify AMC1 ATM/ANS.OR.A.045(a) Changes to the functional system accordingly.

Justification

As CA we do not need to be notified of those changes that are not safety related and therefore do not necessitate safety or safety support assessment, as those presented in Table 3 under GM1 Annex I Definitions (35) & ATM/ANS.OR.A.045 & ATM/ANS.OR.C.005 & ATS.OR.205 General (page 81). According to the new rule all changes must be notified. In our view this cannot be complied with.

response Not accepted

All the changes to the functional system are potentially safety-related. A priori, it is impossible to identify what is safety-related. The amount of the effect can only be found out by assessing the risk of the proposed change. Thus, the IR is generic for changes to functional system, but there is flexibility for the CA to agree with the service providers what changes do not need to be reviewed, and, therefore, can be notified much later. There are many examples of different approaches in GM2 ATM/ANS.OR.A.045(a) and GM3 ATM/ANS.OR.A.045(a)

3. Proposed amendments — 3.1. Draft EASA Opinion — ANNEX III — ATM/ANS.OR.B.005 Management system

p. 36

comment 52

comment by: *NATS National Air Traffic Services Limited*

ATM/ANS.OR.B.005(a)(5)

Page 36

Point (a)(5) seems to duplicate the proposed CRD 2013-08 ATM/ANS.OR.B.005 (a)(4). Additionally, the requirement is only to plan changes to the functional system and not to actually implement them. “Circumstances” “that may” is open to wide interpretation and is not appropriate at the level of IR. It is difficult to see a formal process that would be capable of fulfilling this requirement with any degree of confidence and the cost is likely to outweigh the benefit. It is noted that EASA has not proposed any AMC or GM on this topic. Until such time as the requirement is adequately understood and is supported by AMC and/or GM it should be deleted.

Proposal: Delete ATM/ANS.OR.B.005 (a)(5) as proposed in Appendix A (document attached to NATS Comment number 25)

response Accepted

Even though a certain overlap might exist, the Agency believed that this requirement was more appropriate to be drafted in the form proposed in NPA 2014-13 to cover circumstances related to the organisation and the context. Several commentators have pointed that it is



very difficult to show compliance with this new wording, so the Agency has amended the current requirement ATM/ANS.OR.B.005 (4) in CRD to NPA 2013-08 to cover the intent of this provision, i.e. to cover drivers for change within the organisation and the context.

Planning a change includes the intent of the provider to implement the change.

comment

53

comment by: *NATS National Air Traffic Services Limited***ATM/ANS.OR.B.005(a)(6)****Page 36**

Point (a)(6) requires ANSPs to consider changing their functional system if it is technically and economically feasible to improve performance by doing so.

“Consider” is not appropriate wording for IR. Furthermore, the IR implies a requirement to document why changes have not been made. This is unreasonable and may lead to a risk of prosecution for not having considered a change that might have been technically and economically feasible in the eyes of the CA.

Especially for service providers, other than ATS providers, any “improvement” in the performance would necessitate updating their safety support assessment (at cost) for no tangible benefits if they are already meeting the performance requirements of their users. There is an argument for ATS providers to seek safety improvement however this is an aspect of their SMS and not MS. In terms of changes to the functional system it is the safety criteria that determine the acceptability of the change

It is difficult to see a formal process that would be capable of fulfilling this requirement with any degree of confidence and the cost is likely to outweigh the benefit. It is noted that EASA has not proposed any AMC or GM on this topic. Until such time as the requirement is adequately understood and is supported by AMC and/or GM it should be deleted.

Proposal: Delete ATM/ANS.OR.B.005 (a)(6) as proposed in NATS Appendix A (document attached to Comment number 25)

response

Accepted

Based on the arguments provided by this and other commentators, the Agency has decided to remove these provisions until a more thorough analysis is carried out, and at least AMC/GM are developed and available to be evaluated together with the requirement in the IR. The decision is to remove the intent of the provision from the common requirement and possibly move it (in a different form) to AMC on SMS of ATS providers, where many commentators suggest it belongs. A considerable amount of time is needed to rework, amend and complete the AMC/GM in an appropriate and effective manner, and this cannot be done at this stage. Future work is planned to review and complete the AMC/GM in due time.



comment	<p data-bbox="359 235 391 280">54</p> <p data-bbox="821 235 1498 280">comment by: <i>NATS National Air Traffic Services Limited</i></p> <p data-bbox="359 324 646 369">ATM/ANS.OR.B.005(d)</p> <p data-bbox="359 369 470 414">Page 36</p> <p data-bbox="359 414 1498 526">The definition of substandard performance is too subjective for inclusion in IR. Furthermore substandard performance is not always a valid change driver for a change – it may still be good enough.</p> <p data-bbox="359 571 1498 772">This requirement is already addressed in ATM/ANS.OR.B.005(c) whereby there is a function to monitor compliance with relevant requirements which will include the monitoring as per ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7). In addition ATM/ANS.OR.B.005(c) contains a requirement for corrective actions as required which would include initiating a change or provide a valid argument.</p> <p data-bbox="359 817 1498 907">Proposal: Delete ATM/ANS.OR.B.005 Para (d)(1) and (d)(2) as proposed in NATS Appendix A (document attached to Comment number 25)</p>
response	<p data-bbox="359 929 582 974">Partially accepted</p> <p data-bbox="359 996 1498 1444">The Agency believes there is a misunderstanding of the term ‘substandard’ as no subjectivity is implied by the term. The acceptable performance of the service is known to the provider (it must be specified what is considered standard), and substandard can be specified clearly when performance is below the acceptable (standard) boundaries of performance. The intent of the requirement is to monitor the performance and when it does not reach a defined value between defined bounds, it would trigger an action and potentially a change. The term has been replaced by ‘underperformance’ believing that this will resolve the issue of subjectivity. AMC will be developed in the near future to ensure that the intent is clear. The requirement for the management system of service providers to monitor the functional system has been simplified and redrafted. In particular, it has been reduced to one single provision to monitor the behaviour of the functional system.</p> <p data-bbox="359 1467 1498 1668">Moreover, the monitoring requirements are included in the safety assessments and safety support assessments as per the new ATM/ANS.OR.C.005(b)(2) and ATS.205(b)(6) related to the definition of the criteria, but there needs to be a process to actually monitor the defined properties, and compare them against the acceptable reference values and act when they are not met.</p> <p data-bbox="359 1691 1498 1848">We disagree that ATM/ANS.OR.B.005(c) covers this intent, as that requirement aims at checking compliance with the requirements stated in this proposed regulation. There is nothing in the regulation that check the level of performance of the functional system against the acceptable values.</p> <p data-bbox="359 1870 1498 1957">The (d)(2) clause can be moved to AMC as this is part of the underperformance limited to the monitoring criteria of changes.</p>



comment	<p data-bbox="363 241 395 271">76</p> <p data-bbox="975 241 1485 271" style="text-align: right;">comment by: <i>EUROCONTROL Safety Team</i></p> <p data-bbox="363 331 671 360">ATM/ANS.OR.B.005 (a)(5)</p> <ol data-bbox="411 376 1485 651" style="list-style-type: none"> 1. This requirement is very similar to what is mandated in CRD 2013-08 ATM/ANS.OR.B.005 (a)(4), in fact it looks like a duplicate. 2. The requirement is unbounded and uses subjective language. Words such as <i>Circumstances, that may</i> can be interpreted in several ways. 3. The formulation of any formal process that fulfils this requirement with any degree of confidence is difficult because the requirement addresses only to plan changes to the functional system and not implementation. <p data-bbox="363 663 1485 730">This requirement is thus rather unclear and somewhat infeasible. Furthermore no AMCs or GM are provided on this topic.</p> <p data-bbox="363 741 1011 770">Recommend to delete ATM/ANS.OR.B.005 Para (a)(5).</p>
response	<p data-bbox="363 808 475 837">Accepted</p> <p data-bbox="363 871 890 900">Please see the response to comment No 52.</p>
comment	<p data-bbox="363 987 395 1016">77</p> <p data-bbox="975 987 1485 1016" style="text-align: right;">comment by: <i>EUROCONTROL Safety Team</i></p> <p data-bbox="363 1077 671 1106">ATM/ANS.OR.B.005 (a)(6)</p> <ol data-bbox="411 1155 1485 1576" style="list-style-type: none"> 1. The requirement is unbounded and uses subjective language. <i>Consider</i> can be interpreted in several ways. 2. The formulation of any formal process that fulfills this requirement with any degree of confidence is difficult because the SP would need to document why changes have not been made. 3. It is appropriate that ATSPs seek safety improvement but this part of their SMS. Thus any such requirement should be included in CRD 2013-08 Annex IV Specific requirements for the provision of ATS. 4. This requirement implies that SPs other than ATSPs would need to improve their performance even though the performance requirements of their users are already met. This would have no tangible benefit while increasing costs for SPs other than ATSPs. <p data-bbox="363 1626 1485 1693">This requirement is thus somewhat infeasible. Furthermore no AMCs or GM are provided on this topic.</p> <p data-bbox="363 1704 1011 1733">Recommend to delete ATM/ANS.OR.B.005 Para (a)(6).</p>
response	<p data-bbox="363 1767 475 1796">Accepted</p> <p data-bbox="363 1830 890 1859">Please see the response to comment No 53.</p>
comment	<p data-bbox="363 1946 395 1975">78</p> <p data-bbox="975 1946 1485 1975" style="text-align: right;">comment by: <i>EUROCONTROL Safety Team</i></p>



	<p>ATM/ANS.OR.B.005 (d)</p> <ol style="list-style-type: none"> 1. The requirement is uses subjective language because <i>substandard performance</i> is not defined. 2. This requirement is very similar to what is mandated in CRD 2013-08 ATM/ANS.OR.B.005 (c) which also mandates corrective actions as required which would include initiating a change or providing a valid argument. <p>Recommend to delete ATM/ANS.OR.B. .005 Para (d)(1) and (d)(2).</p>
response	<p>Partially accepted</p> <p>Please see the response to comment No 54.</p>
comment	<p>79 comment by: EUROCONTROL Safety Team</p> <p>ATM/ANS.OR.B.005(d)</p> <p>There is a discrepancy between this requirement and the EN. The requirement is that <i>a service provider shall monitor the behaviour of the functional system</i> but the EN refers to <i>monitor the behaviour of the service</i>.</p> <p>Monitoring, as explained by the EN, at the level of the service (which naturally includes the behaviour of the function system) is preferable. The requirement for monitoring at the level of a change to a functional system (as implied by (d)(2)) would be resource intensive for little benefit.</p> <p>Recommend to adjust text to require <i>monitoring the behaviour of the service</i>.</p>
response	<p>Not accepted</p> <p>Please see the response to comment No 680.</p>
comment	<p>272 comment by: DSNA</p> <p>(a)(5) :</p> <ol style="list-style-type: none"> 1. "Circumstances" "that may", the text here is too subjective and it is open to wide interpretation. AMC or GM are needed. 2. It is not appropriate at the level of IR. 3. It is difficult to see a formal process that would be capable of fulfilling this requirement with any degree of confidence and the cost is likely to outweigh the benefit. 4. The requirement is not supported by AMC and/or GM 5. <u>DSNA suggests to delete ATM/ANS.OR.B.005 Para (a)(5)</u> or at the very least suggest to move to AMC and develop appropriate GM. <p>(a)(6) :</p>



1. The requirement implies to document why changes have not been made. This is both unfeasible and may lead to a risk of prosecution for not having considered a change that might have prevented it.
2. There is an argument for ATS providers to seek safety improvement however this is an aspect of their SMS and not MS. In terms of changes to the functional system it is the safety criteria that determine the acceptability of the change.
3. It is difficult to see a formal process that would be capable of fulfilling this requirement with any degree of confidence and the cost is likely to outweigh the benefit.
4. The requirement is not supported by AMC and/or GM
5. **DSNA suggests to delete ATM/ANS.OR.B.005 Para (a)(6).**

(d)(1) :

1. the definition of substandard performance is too subjective for inclusion in IR.
2. A substandard performance is not always a valid change driver for a change.
3. This requirement is already addressed in ATM/ANS.OR.B.005(c) whereby there is a function to monitor compliance with relevant requirements which will include the monitoring as per ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7). In addition ATM/ANS.OR.B.005(c) contains a requirement for corrective actions as required which would include initiating a change or provide a valid argument.
4. **DSNA suggests to delete ATM/ANS.OR.B.005 Para (d)(1) and (d)(2).**

(d)(2) : see previous comment

response

Partially accepted

(a)(5) has been deleted, but a current requirement in CRD to NPA 2013-08 has been amended to include the intent of this requirement. Please see the response to comment No 52.

(a)(6) has been deleted, as suggested. Please see the response to comment No 53.

(d)(1) has been redrafted to address the commentators' concern. Please see the response to comment No 54.

(d)(2) has been removed.

comment

337

comment by: *ATCEUC - Air Traffic Controllers European Unions Coordination***ATM/ANS.OR.B.005 (d) Management System**

ATCEUC strongly supports the inclusion in the IR of the monitoring requirements as part of the safety assessment plan and the change design.

response

Noted

The comment is appreciated. The requirement — redrafted — remains in the IR.



comment 381

comment by: skyguide Corporate Regulation Management

ATM/ANS.OR.B.005(a)(5)

Point (a)(5) seems to duplicate the proposed CRD 2013-08 ATM/ANS.OR.B.005 (a)(4).

Additionally, the requirement is only to plan changes to the functional system and not to actually implement them. “Circumstances” “that may” is open to wide interpretation and is not appropriate at the level of IR. It is difficult to see a formal process that would be capable of fulfilling this requirement with any degree of confidence and the cost is likely to outweigh the benefit. It is noted that EASA has not proposed any AMC or GM on this topic. Until such time as the requirement is adequately understood and is supported by AMC and/or GM it should be deleted.

We suggest to delete ATM/ANS.OR.B.005 Para (a)(5) as proposed in Appendix A

ATM/ANS.OR.B.005(a)(6)

Point (a)(6) requires ANSPs to consider changing their functional system if it is technically and economically feasible to improve performance by doing so.

“Consider” is not appropriate wording for IR. Furthermore, the IR implies a requirement to document why changes have not been made. This is both unfeasible and may lead to a risk of prosecution for not having considered a change that might have prevented it.

Especially for service providers, other than ATS providers, any “improvement” in the performance would necessitate updating their safety support assessment (at cost) for no tangible benefits if they are already meeting the performance requirements of their users. There is an argument for ATS providers to seek safety improvement however this is an aspect of their SMS and not MS. In terms of changes to the functional system it is the safety criteria that determine the acceptability of the change.

It is difficult to see a formal process that would be capable of fulfilling this requirement with any degree of confidence and the cost is likely to outweigh the benefit. It is noted that EASA has not proposed any AMC or GM on this topic. Until such time as the requirement is adequately understood and is supported by AMC and/or GM it should be deleted.

We suggest to delete ATM/ANS.OR.B.005 Para (a)(6) as proposed in Appendix A.

To improve performance **and safety** (or to improve performance without degrading safety – we think it’s important to keep the focus on safety)

ATM/ANS.OR.B.005(d)

There is a discrepancy between this explanation and the IR itself. The explanation refers to monitor the behavior of the service, whereas the related IR considers monitoring the behavior of the functional system. Monitoring at the level of the service (which would encompass the behavior of the functional system) is preferable as measuring at the level of a change to a functional system (as implied by (d)(2)) would be resource intensive for little benefit.

The definition of substandard performance is too subjective for inclusion in IR. Furthermore substandard performance is not always a valid change driver for a change – it may still be good enough.

This requirement is already addressed in ATM/ANS.OR.B.005(c) whereby there is a function to monitor compliance with relevant requirements which will include the monitoring as per



	<p>ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7). In addition ATM/ANS.OR.B.005(c) contains a requirement for corrective actions as required which would include initiating a change or provide a valid argument. We suggest to delete ATM/ANS.OR.B.005 Para (d)(1) and (d)(2) as proposed in Appendix A. This may have important impact (time & resources) to develop/describe the monitoring processes.</p>
response	<p>Partially accepted</p> <p>(a)(5) has been deleted, but a current requirement in CRD to NPA 2013-08 has been amended to include the intent of this requirement. Please see the response to comment No 52.</p> <p>(a)(6) has been deleted, as suggested. Please see the response to comment No 53.</p> <p>(d)(1) has been redrafted to address the commentator's concern about 'substandard'. Please see the response to comment No 54. For the clarifications about the level of monitoring (i.e. at service or functional system level), please see the response to comment No 680.</p> <p>(d)(2) has been removed.</p>
comment	<p>427 comment by: <i>Air Navigation Services of the Czech Republic</i></p> <p>The point (a) (5) duplicates the CRD 2013-08 point (a) (4). The formal process to meet this requirement is considered to be hardly feasible. Also, the terms with not clear interpretation like "circumstances" and "may affect" should not be used at the IR level. The point (a) (6) also requires a formal process that is considered to be hardly feasible. It might even require documenting why changes have not been made and not considering a change that might prevent something might be considered as breaking the rule. Furthermore, EASA provides no AMC or GM to this topic. We propose to delete the points (a) (5) and (a) (6). We also propose to delete the points (d) (1) and (d) (2) as it duplicates ATM/ANS.OR.B.005 (c). Also, the term "substandard performance" is not clear enough to be used at the IR level.</p>
response	<p>(a)(5) has been deleted, but a current requirement in CRD to NPA 2013-08 has been amended to include the intent of this requirement. Please see the response to comment No 52.</p> <p>(a)(6) has been deleted, as suggested. Please see the response to comment No 53.</p> <p>(d)(1) has been redrafted to address the commentator's concern about 'substandard'. Please see the response to comment No 54. For the clarifications about the level of monitoring (i.e. at service or functional system level), please see the response to comment No 680.</p> <p>(d)(2) has been removed.</p>



comment	<p>481</p> <p>CAA CZ suggest to make the provisions of para 5 and 6 even more descriptive by adding word “documented” such in: <i>„(5) a formal documented process to identify circumstances...”</i> <i>„(6) a formal documented process to consider changing...”</i></p>	comment by: CAA CZ
response	<p>Not accepted</p> <p>This seems to be unnecessary as every procedure has to be documented. In any case, these provisions have been removed. Please see the responses to comments No 52 and 53 for additional clarifications.</p>	
comment	<p>573</p> <p>(d) (2) Referring to Question 6 Eliminate the provision: <i>or provide a valid argument.</i> Justification If following the monitoring activities it is found that an argument associated with a change is unsound, a valid argument for that change cannot be provided without changing the functional system. Almost every time, only a component of the argument is unsound and only this should be reanalysed by the service provider. In our view the provision requires that the service provider has to update every Safety Case/ Safety Support Case when the real data, partially, is different from that presented in the previous version of the Safety Case/ Safety Support Case. In this case the workload will increase and will become a factor that will block the service provider from initiating and documenting the necessary measures and with the CA acceptance implement the measures. According to the regulation, in case that an unforeseen situation (situation stated in the people personal characteristics explanation) occurs, the argument for a change/ or changes related to that component affected by the situation has to be modified. The effect of this will be an increase in the workload. No GM on ATM/ANS.OR.B.005 Management system (d)</p>	comment by: <i>Frasie Loredana</i>
response	<p>Accepted</p> <p>(d)(2) has been removed.</p>	
comment	<p>611</p> <p>(a) (5)</p>	comment by: <i>DFS Deutsche Flugsicherung GmbH</i>



response	<p>Point (a)(5) seems to duplicated CRD to NPA 2013-08 ATM/ANS.OR.B.005(a)(4). Reference to high level comment "b"</p> <p>Accepted</p> <p>Please see the response to comment No 52.</p>
comment	<p>612 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>(a) (5) The wording "circumstances" and "that may" opens the IR to wide interpretation. Reference to high level comment "c.iii"</p>
response	<p>Accepted</p> <p>Please see the response to comment No 52.</p>
comment	<p>613 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>Point (a)(6) requires ANSPs to "consider" changing their functional system if it is technically and economically feasible to improve performance by doing so. This is both unfeasible and may lead to a risk of prosecution for not having considered a change that might have prevented it. Reference to high level comment "c.iii"</p>
response	<p>Accepted</p> <p>Please see the response to comment No 53.</p>
comment	<p>614 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>(a) (6) Additional GM for this requirement is missing. Reference to high level comment "c.v"</p>
response	<p>Noted</p> <p>Since the requirement is removed, the GM is not needed in this part of the regulation. It will be assessed if something is needed as AMC/GM to the SMS requirements.</p>
comment	<p>615 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>(d)</p>



	<p>The definition of <u>substandard performance</u> is too subjective for use in IR. Furthermore substandard performance is not always a valid change driver for a change – it may still be good enough.</p> <p>Reference to high level comment "c.iii"</p>
response	<p>Partially accepted</p> <p>Please see the response to comment No 54.</p>
comment	<p>616 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>(d)</p> <p>This requirement is already addressed in ATM/ANS.OR.B.005(c) whereby there is a function to monitor compliance with relevant requirements which will include the monitoring as per ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7). In addition, ATM/ANS.OR.B.005(c) contains a requirement for corrective actions as required which would include initiating a change or provide a valid argument.</p> <p>Reference to high level comment "b"</p>
response	<p>Not accepted</p> <p>Please see the response to comment No 54.</p>
comment	<p>639 comment by: <i>CANSO</i></p> <p>ATM/ANS.OR.B.005(a)(5)</p> <p>Point (a)(5) seems to duplicate the proposed CRD 2013-08 ATM/ANS.OR.B.005 (a)(4). Additionally, the requirement is only to plan changes to the functional system and not to actually implement them. "Circumstances" "that may" is open to wide interpretation and is not appropriate at the level of IR. It is difficult to see a formal process that would be capable of fulfilling this requirement with any degree of confidence and the cost is likely to outweigh the benefit. It is noted that EASA has not proposed any AMC or GM on this topic. Until such time as the requirement is adequately understood and is supported by AMC and/or GM it should be deleted.</p> <p>CANSO suggests to delete ATM/ANS.OR.B.005 Para (a)(5) as proposed in Appendix A</p>
response	<p>Accepted</p> <p>Please see the response to comment No 52.</p>
comment	<p>640 comment by: <i>CANSO</i></p> <p>ATM/ANS.OR.B.005(a)(6)</p>



Point (a)(6) requires ANSPs to consider changing their functional system if it is technically and economically feasible to improve performance by doing so.

“Consider” is not appropriate wording for IR. Furthermore, the IR implies a requirement to document why changes have not been made. This is both unfeasible and may lead to a risk of prosecution for not having considered a change that might have prevented it.

Especially for service providers, other than ATS providers, any “improvement” in the performance would necessitate updating their safety support assessment (at cost) for no tangible benefits if they are already meeting the performance requirements of their users. There is an argument for ATS providers to seek safety improvement however this is an aspect of their SMS and not MS. In terms of changes to the functional system it is the safety criteria that determine the acceptability of the change

It is difficult to see a formal process that would be capable of fulfilling this requirement with any degree of confidence and the cost is likely to outweigh the benefit. It is noted that EASA has not proposed any AMC or GM on this topic. Until such time as the requirement is adequately understood and is supported by AMC and/or GM it should be deleted.

CANSO suggests to delete ATM/ANS.OR.B.005 Para (a)(6) as proposed in Appendix A.

response

Accepted

Please see the response to comment No 53.

comment

641

comment by: CANSO

ATM/ANS.OR.B.005(d)

The definition of substandard performance is too subjective for inclusion in IR. Furthermore substandard performance is not always a valid change driver for a change – it may still be good enough.

This requirement is already addressed in ATM/ANS.OR.B.005(c) whereby there is a function to monitor compliance with relevant requirements which will include the monitoring as per ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7). In addition ATM/ANS.OR.B.005(c) contains a requirement for corrective actions as required which would include initiating a change or provide a valid argument.

CANSO suggests to delete ATM/ANS.OR.B.005 Para (d)(1) and (d)(2) as proposed in Appendix A.

response

Partially accepted

Please see the response to comment No 54.

comment

680

comment by: ROMATSA

ATM/ANS.OR.B.005(d)

There is a discrepancy between this explanation and the IR itself. The explanation refers to



	<p>monitor the behavior of the service, whereas the related IR considers monitoring the behavior of the functional system. Monitoring at the level of the service (which would encompass the behavior of the function system) is preferable as measuring at the level of a change to a functional system (as implied by (d)(2)) would be resource intensive for little benefit.</p> <p>Supporting comment to summary issue: Explanatory Note – does not support the Implementing Rule</p>
response	<p>Not accepted</p> <p>The discrepancy is acknowledged. The wording in the proposed rule is the correct one, as it would cover both monitoring at the service level and also monitoring at the level of the functional system wherever the monitoring criteria are set as per ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7).</p> <p>Monitoring criteria defined as per ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7) need to be monitored and followed-up . This will be at the appropriate defined level, either at the level of service or at the level of the functional system (see GM1 ATM/ANS.OR.C005(b)(3) and GM1 ATS.OR.205(b)(7)). Monitoring at the level of the service may in some cases require very long period of times to get data and to evaluate against the monitoring requirements, thus, it will be more convenient to monitor properties at the level of subsystems of the functional system.</p>
comment	<p>690 comment by: ROMATSA</p> <p>ATM/ANS.OR.B.005(a)(5)</p> <p>Point (a)(5) seems to duplicate the proposed CRD 2013-08 ATM/ANS.OR.B.005 (a)(4).</p> <p>Supporting comment to summary issue: Specific Example of MS / SMS Split</p> <p>Additionally, the requirement is only to plan changes to the functional system and not to actually implement them.</p> <p>“Circumstances” “that may” is open to wide interpretation and is not appropriate at the level of IR. It is difficult to see a formal process that would be capable of fulfilling this requirement with any degree of confidence and the cost is likely to outweigh the benefit. It is noted that EASA has not proposed any AMC or GM on this topic. Until such time as the requirement is adequately understood and is supported by AMC and/or GM it should be deleted.</p> <p>ROMATSA supports CANSO suggestion to delete ATM/ANS.OR.B.005 Para (a)(5) as proposed in Appendix A.</p> <p>Supporting comment to summary issue: The IR is unbounded and uses subjective language and is not appropriate for inclusion in the IR.</p> <p>ATM/ANS.OR.B.005(a)(6)</p>



Point (a)(6) requires ANSPs to consider changing their functional system if it is technically and economically feasible to improve performance by doing so.

“Consider” is not appropriate wording for IR. Furthermore, the IR implies a requirement to document why changes have not been made. This is both unfeasible and may lead to a risk of prosecution for not having considered a change that might have prevented it.

Especially for service providers, other than ATS providers, any “improvement” in the performance would necessitate updating their safety support assessment (at cost) for no tangible benefits if they are already meeting the performance requirements of their users. There is an argument for ATS providers to seek safety improvement however this is an aspect of their SMS and not MS. In terms of changes to the functional system it is the safety criteria that determine the acceptability of the change

It is difficult to see a formal process that would be capable of fulfilling this requirement with any degree of confidence and the cost is likely to outweigh the benefit. It is noted that EASA has not proposed any AMC or GM on this topic. Until such time as the requirement is adequately understood and is supported by AMC and/or GM it should be deleted.

ROMATSA supports CANSO suggestion to delete ATM/ANS.OR.B.005 Para (a)(6) as proposed in Appendix A.

Supporting comment to summary issue: This is an unbounded and subjective requirement and not appropriate for inclusion in the IR.

Additionally the GM for this requirement is missing.

response

Partially accepted

(a)(5) has been deleted, but a current requirement in CRD to NPA2013-08 has been amended to include the intent of this requirement. Please see the response to comment No 52.

(a)(6) has been deleted, as suggested. Please see the response to comment No 53.

comment

691

comment by: ROMATSA

ATM/ANS.OR.B.005(d)

The definition of substandard performance is too subjective for inclusion in IR. Furthermore substandard performance is not always a valid change driver for a change – it may still be good enough.

Specific comment to summary issue: Subjective requirement not appropriate for inclusion in IR.

This requirement is already addressed in ATM/ANS.OR.B.005(c) whereby there is a function to monitor compliance with relevant requirements which will include the monitoring as per ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7). In addition ATM/ANS.OR.B.005(c) contains a requirement for corrective actions as required which would include initiating a change or provide a valid argument.



ROMATSA supports CANSO suggestion to delete ATM/ANS.OR.B.005 Para (d)(1) and (d)(2) as proposed in Appendix A.

Specific comment to summary issue: Specific example of MS/SMS split.

Answer to Question 5

We agree on the general principle which should be part of the management system. However this NPA needs an update for proactive performance management.

Answer to Question 6

ROMATSA supports CANSO opinion that monitoring effectiveness is already part of the overall SMS requirements listed in CRD 2013-08 and that this should not be part of this NPA on the risk assessment of changes. We agree that monitoring the performance of the functional system is a good thing, but disagree to monitoring the effectiveness of any individual change as this is likely not always achievable and incurs significant cost.

response

Partially accepted

(d)(1) has been redrafted to address the commentator’s concern about ‘substandard’. Please see the response to comment No 54. For the clarifications about the level of monitoring (i.e. at service or functional system level), please see the response to comment No 680.

(d)(2) has been removed.

The responses to Questions 5 and 6 are noted. The Agency is of the opinion that the proposal (e.g. change drivers, monitoring the functional system) pursues a proactive approach to safety. These proposals are not reactive in any sense.

comment

908

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.1 <i>Draft Regulation (Draft EASA Opinion) Annex III</i> COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR) ATM/ANS.OR.B.005(d)(1)	It should state <i>'substandard performance is identified, (...) and, if necessary, shall initiate a change to eliminate or mitigate such causes'</i> .	Maybe the implications of such substandard performance are neither relevant for the behaviour of the service provided nor for the safety so that no additional change needs to be performed.



response Not accepted

'Substandard performance' (now 'underperformance') means exactly that the performance monitoring is not acceptable. The service provider has to define the acceptable bounds. There is no need to add 'if necessary' as the limits defined should consider that already. The term has been updated to 'underperformance', which should include again a limit and acceptable bounds. AMC/GM should be developed accordingly.

comment 1056

comment by: LVNL

Point (a)(5) duplicates the proposed CRD 2013-08 ATM/ANS.OR.B.005 (a)(4). Therefore it is proposed to delete ATM/ANS.OR.B.005 Para (a)(5)

response Accepted

Please see the response to comment No 52.

comment 1058

comment by: LVNL

Point (a)(6) requires ANSPs to consider changing their functional system if it is technically and economically feasible to improve performance by doing so.

"Consider" is not appropriate wording for IR. Furthermore, the IR implies a requirement to document why changes have not been made. This is both unfeasible and may lead to a risk of prosecution for not having considered a change that might have prevented it. Especially for service providers, other than ATS providers, any "improvement" in the performance would necessitate updating their safety support assessment (at cost) for no tangible benefits if they are already meeting the performance requirements of their users. There is an argument for ATS providers to seek safety improvement however this is an aspect of their SMS and not MS. In terms of changes to the functional system it is the safety criteria that determine the acceptability of the change

It is difficult to see a formal process that would be capable of fulfilling this requirement with any degree of confidence and the cost is likely to outweigh the benefit. It is noted that EASA has not proposed any AMC or GM on this topic. Until such time as the requirement is adequately understood and is supported by AMC and/or GM it should be deleted. It is suggested to delete ATM/ANS.OR.B.005 Para (a)(6)

response Accepted

Please see the response to comment No 53.



comment	<p data-bbox="363 271 427 309">1059</p> <p data-bbox="1257 271 1498 309" style="text-align: right;">comment by: LVNL</p> <p data-bbox="363 360 1498 663">The definition of substandard performance is too subjective for inclusion in IR. This requirement is already addressed in ATM/ANS.OR.B.005(c) whereby there is a function to monitor compliance with relevant requirements which will include the monitoring as per ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7). In addition ATM/ANS.OR.B.005(c) contains a requirement for corrective actions as required which would include initiating a change or provide a valid argument. It is suggested to delete ATM/ANS.OR.B.005 Para (d)(1) and (d)(2)</p>
response	<p data-bbox="363 663 576 701">Partially accepted</p> <p data-bbox="363 730 1498 808">'substandard performance' has been substituted by 'underperformance'. Please see the response to comment No 54.</p>
comment	<p data-bbox="363 887 427 925">1104</p> <p data-bbox="1161 887 1498 925" style="text-align: right;">comment by: Belgocontrol</p> <p data-bbox="363 976 671 1014">ATM/ANS.OR.B.005 (a)(5)</p> <ol data-bbox="363 1021 1498 1301" style="list-style-type: none"> 1. This requirement looks like a duplicate to what is mandated in CRD 2013-08 ATM/ANS.OR.B.005 (a)(4). 2. Words such as <i>Circumstances, that may</i> is subjective language and can be interpreted in several ways. 3. The formulation of any formal process that fulfils this requirement with any degree of confidence is difficult because the requirement addresses only to plan changes to the functional system and not implementation. <p data-bbox="363 1308 1498 1386">This requirement is thus rather unclear and somewhat infeasible. Furthermore no AMCs or GM are provided on this topic.</p> <p data-bbox="363 1393 1011 1431"><u>Recommend</u> to delete ATM/ANS.OR.B.005 Para (a)(5).</p>
response	<p data-bbox="363 1473 480 1512">Accepted</p> <p data-bbox="363 1541 890 1579">Please see the response to comment No 52.</p>
comment	<p data-bbox="363 1653 427 1691">1105</p> <p data-bbox="1161 1653 1498 1691" style="text-align: right;">comment by: Belgocontrol</p> <p data-bbox="363 1742 671 1780">ATM/ANS.OR.B.005 (a)(6)</p> <ol data-bbox="411 1832 1498 2049" style="list-style-type: none"> 1. The requirement is unbounded and uses subjective language. <i>Consider</i> can be interpreted in different ways. 2. The formulation of any formal process that fulfills this requirement with any degree of confidence is difficult because the SP would need to document why changes have not been made. 3. It is appropriate that ATSPs seek safety improvement but this part of their SMS. Thus



any such requirement should be included in CRD 2013-08 Annex IV Specific requirements for the provision of ATS.

4. This requirement implies that SPs other than ATSPs would need to improve their performance even though the performance requirements of their users are already met. This would have no tangible benefit while increasing costs for SPs other than ATSPs.

This requirement is thus somewhat infeasible. Furthermore no AMCs or GM are provided on this topic.

Recommend to delete ATM/ANS.OR.B.005 Para (a)(6).

response

Accepted

Please see the response to comment No 53.

comment

1106

comment by: *Belgocontrol*

ATM/ANS.OR.B.005 (d)

1. The requirement uses subjective language: *substandard performance* is not defined.
2. CRD 2013-08 ATM/ANS.OR.B.005 (c) also mandates corrective actions as required which would include initiating a change or providing a valid argument.

Recommend to delete ATM/ANS.OR.B. .005 Para (d)(1) and (d)(2).

response

Partially accepted

Please see the response to comment No 54.

comment

1108

comment by: *Belgocontrol*

ATM/ANS.OR.B.005(d)

There is a discrepancy between the requirement and the explanatory note. The requirement states '*a service provider shall monitor the behaviour of the functional system*' but the explanatory note refers to '*monitor the behaviour of the service*'.

Monitoring, as explained by the explanatory note, is preferred as it also includes the behaviour of the functional system. Monitoring at the level of a change to a functional system would ask a lot of resource for little benefit.

Recommend to adjust to '*monitoring the behaviour of the service*' in the explanatory note.

response

Partially accepted

For the clarifications about the level of monitoring (i.e. at service or functional system level), please see the response to comment No 680.



comment	<p data-bbox="363 271 427 309">1181</p> <p data-bbox="1177 271 1498 309" style="text-align: right;">comment by: <i>Avinor ANS</i></p> <div data-bbox="363 365 1482 757" style="border: 1px solid black; padding: 5px;"> <p>Point (a)(5) seems to duplicate the proposed CRD 2013-08 ATM/ANS.OR.B.005 (a)(4). Additionally, the requirement is only to plan changes to the functional system and not to actually implement them. “Circumstances” “that may” is open to wide interpretation and is not appropriate at the level of IR. It is difficult to see a formal process that would be capable of fulfilling this requirement with any degree of confidence and the cost is likely to outweigh the benefit. It is noted that EASA has not proposed any AMC or GM on this topic. Until such time as the requirement is adequately understood and is supported by AMC and/or GM it should be deleted.</p> <p>We suggest to delete ATM/ANS.OR.B.005 Para (a)(5) as proposed in Appendix A</p> </div>
response	<p data-bbox="363 824 478 862">Accepted</p> <p data-bbox="363 884 890 922">Please see the response to comment No 52.</p>
comment	<p data-bbox="363 1048 427 1086">1182</p> <p data-bbox="1177 1048 1498 1086" style="text-align: right;">comment by: <i>Avinor ANS</i></p> <p>Point (a)(6) requires ANSPs to consider changing their functional system if it is technically and economically feasible to improve performance by doing so.</p> <p>The IR implies a requirement to document why changes have not been made. This is both unfeasible and may lead to a risk of prosecution for not having considered a change that might have prevented it.</p> <p>Especially for service providers, other than ATS providers, any “improvement” in the performance would necessitate updating their safety support assessment (at cost) for no tangible benefits if they are already meeting the performance requirements of their users. There is an argument for ATS providers to seek safety improvement however this is an aspect of their SMS and not MS. In terms of changes to the functional system it is the safety criteria that determine the acceptability of the change</p> <p>It is difficult to see a formal process that would be capable of fulfilling this requirement with any degree of confidence and the cost is likely to outweigh the benefit. It is noted that EASA has not proposed any AMC or GM on this topic. Until such time as the requirement is adequately understood and is supported by AMC and/or GM it should be deleted.</p> <p>We suggest to delete ATM/ANS.OR.B.005 Para (a)(6) as proposed in Appendix A.</p>
response	<p data-bbox="363 1821 478 1859">Accepted</p> <p data-bbox="363 1881 890 1919">Please see the response to comment No 53.</p>



comment	1183	comment by: <i>Avinor ANS</i>
	<p>The definition of <u>substandard performance</u> is too subjective for inclusion in IR. Furthermore substandard performance is not always a valid change driver for a change – it may still be good enough.</p> <p>This requirement is already addressed in ATM/ANS.OR.B.005(c) whereby there is a function to monitor compliance with relevant requirements which will include the monitoring as per ATM/ANS.OR.C.005(b)(3) or ATS.OR.205(b)(7). In addition ATM/ANS.OR.B.005(c) contains a requirement for corrective actions as required which would include initiating a change or provide a valid argument.</p> <p>We suggests to delete ATM/ANS.OR.B.005 Para (d)(1) and (d)(2) as proposed in Appendix A.</p>	
response	<p>Partially accepted</p> <p>Please see the response to comment No 54.</p>	
comment	1228	comment by: <i>CAA-NL</i>
	<p>ATM/ANS.OR.B.005 Management system</p> <p>We suggest some different wording for ATM/ANS.OR.B.005 Management system (d)(2) which in our opinion better clarifies the intent of this part of the monitoring function related to the outcome of the change rather than the process that leads to it.</p> <p>(d) The service provider shall monitor the behaviour of the functional system and where:</p> <p>(2) the actual behaviour of a change is found different from its predicted behaviour, the service provider will determine the cause and when the outcome of a change is below expectations, initiate corrective actions.</p> <p>Furthermore we are of the opinion that the word "formal" in (a) (5) and (6) does not have any added value and could lead to misunderstanding of the status of processes. All processes are described in the manuals and have the same status. This remark is equally applicable to items (4) until (9).</p>	
response	<p>Partially accepted</p> <p>(d) has been reworded taking the spirit of the comment into account, and (d)(2) is removed from the IR. It is accepted that the word 'formal' does not add anything, but the provisions have been removed.</p>	
comment	1235	comment by: <i>Icetra</i>
	<p>(d)</p>	



It is recommended that the ANSP be required to inform the CA if substandard performance is identified. Or if he identifies that the safety case contains unsound arguments. This might be an "implicit" requirement but it is suggested that EASA considers making it explicit in the provision.

A revision is suggested to the provision (2) as it is unclear whether the verb "change" refers to the "functional system" or to the "argument".

(2) it is found that an argument associated with a change to that functional system is unsound, the service provider shall provide a valid argument for that functional system.

It is implicit, that if the argument can not be made it might be necessary to initiate a new change to the system.

response Not accepted

It seems unnecessary. If the monitoring of performance indicates that something needs to be done, it may require a new change (or the update of a previous one), which will be notified to the CA as per the current requirements.

comment 1272

comment by: *European Transport Workers Federation - ETF*

ETF consider the performance management out of the scope of the Agency and propose to delete the paragraph ATM/ANS.OR.B.005(a)(6) "*a formal process to consider changing their functional system if it is technically and economically feasible to improve performance by doing so*"

response Accepted

Please see the response to comment No 53.

comment 1276

comment by: *European Transport Workers Federation - ETF*

ATM/ANS.OR.B.005 (d)

ETF welcomes the monitoring requirements to identify substandard performance, and the consequent mitigation measures

response Noted



The comment is appreciated. The requirement — redrafted — remains in the IR.

3. Proposed amendments — 3.1. Draft EASA Opinion — ANNEX III — ATM/ANS.OR.B.010 Change management procedures

p. 36

comment

55

comment by: *NATS National Air Traffic Services Limited*

ATM/ANS.OR.B.010

Page 36

This IR is a specific instantiation of the general procedures for change that is already covered by CRD 2013-08 ATM/ANS.OR.B.010.

Proposal: Move ATM/ANS.OR.B.010 as specific AMC to ATM/ANC.OR.040(2) as proposed in NATS Appendix A (document attached to Comment number 25)

response

Not accepted

The philosophy is that change procedures may be independent of the MS/SMS at certification. They can be submitted at any time prior to their use. The actual intent of the proposed provisions for management of change procedures of functional system is to allow those procedures to be managed independently of the MS/SMS at the time of certification. There are two reasons for this: to ensure their review and approval by the competent authority every time they are changed, and to provide flexibility to service providers to develop them and receive approval at any time after certification, but always prior to their use. In any case, if the service provider wishes to have them reviewed and approved at the time of certification and as part of the MS/SMS, that is also possible and the provision does not prevent this from happening. The provisions have been kept as proposed.

comment

286

comment by: *DSNA*

(a) : **proposed text** : procedures that will be used by a service provider to manage, assess changes to their functional systems in accordance with ATM/ANS.OR.A.045, ATS.OR.205, ATS.OR.210, ATM/ANS.OR.C.005 or any material modifications to those procedures shall:

response

Partially accepted

The wording has been aligned, but not exactly in the same way. The provision has been redrafted to make this requirement to use procedures explicit, in addition to the provision about submission of procedures.



comment

344

comment by: ATCEUC - Air Traffic Controllers European Unions Coordination

ATM/ANS.OR.B.010(b) Change Management Procedures

This provision includes the possibility to deviate from an approved procedure if the Service Provider finds that they are not suitable for a particular change. However, it doesn't say how the CA shall evaluate the change... It just says that the provider will make the request and provide the justification for the deviation, not being able to use it until the CA approves the deviation, but something should be said as to what the CA must do to guarantee that the deviation doesn't compromise safety.

A good solution would be to introduce the requirement in AMC to make an additional assessment similar to the one required when there is a change in a FS. (see ATM/ANS.AR.C.035 Decision to review the notified change and ATM/ANS.AR.C.040 Risk based review of the notified change)

An alternative is to modify **GM1 ATM/ANS.OR.B.010(a)(c)** and include "deviation" in order to be consistent with the rest of the text, and move this provision to AMC level.

~~(c)~~ **AMC3 ATM/ANS.OR.B.010**

When requested for a deviation from the approved procedures, the competent authority should carry out an assessment as established in ATM/ANS.AR.C.035 Decision to review the notified change and ATM/ANS.AR.C.040 Risk based review of the notified change

OR

~~GM1~~ **AMC3 ATM/ANS.OR.B.010(a)(c) Change management procedures**

GENERAL

(c) A service provider and its CA should coordinate so as to reach a common agreement about guidance on when modifications and/or deviations of an already approved procedure are not considered material, and, therefore, does not require a new notification and/or approval. This guidance will detail criteria to consider whether a modification of an already approved procedure either:

- (1) requires a new approval before use;
- (2) requires only notification; or
- (3) does not need to be notified.

response

Noted

This comment addresses AMC/GM. Comments on AMC/GM will be responded to in the CRD associated with them. A considerable amount of time is needed to rework, amend and complete the AMC/GM in an appropriate and effective manner, and this cannot be done at this stage. Future work is planned to review the comments on the AMC/GM and complete the CRD in due time.

The commentator seems confused about what is being reviewed when a deviation is requested. The deviation from the procedures when taken together with the remaining (undeviated) procedures should still comply with the requirements of ATM/ANS.OR.A.045, ATM/ANS.OR.C.005, ATS.OR.205, or



ATS.OR.210 and be reviewed by the CA in compliance with ATM/ANS.AR.C.030. A deviation has nothing to do with the CA's decision to review a change or its review of the change. The proposed GM tackles a completely different issue.

comment 454

comment by: EUROCONTROL

ATM/ANS.OR.B.010 (a) Change management procedures - Page 36EUROCONTROL's comment

When reading this requirement, EUROCONTROL understands that the change management procedures that require approval are limited to the procedures / processes related to safety assessments, development of safety cases, safety criteria and notification to NSA (i.e. the procedures to show compliance to this NPA).

However, the current text lacks clarity. For example, do the "management, development and testing procedures for change" also require prior approval?

In addition, when reviewing Table 3 of page 81, other examples of changes / circumstances that may not require safety or safety support assessment can be found, in particular those under footnotes 79 and 81 which are both referring to pre-approved procedures. With these examples the scope of change management procedures seems to be extended to maintenance and operational procedures.

Where to draw the limit or, in other words, which of our MMS processes / procedures require now NSA approval? It seems that, in the past, the NSA had to approve the SMS, but not the MMS.

EUROCONTROL's proposal

EUROCONTROL's proposal is therefore to recommend the incorporation of a clarification of the scope of the change management procedures which require approval as there are in the current document some confusing and possibly contradicting examples.

response Not accepted

It seems that there is a misinterpretation of the proposed text. Those testing procedures are not included in the procedures to manage changes of this provision, but the safety assessment and the safety support assessment methods are. See GM1 ATM/ANS.OR.B.010(a) for clarification.

Footnotes 79–81 do not extend maintenance and operational procedures to these procedures, but are procedures that are approved before their use (with their corresponding SA/SSA), so they can be implemented at any time. These are not parts of the procedures of ATM/ANS.B.010.

comment 909

comment by: AESA / DSANA



PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.1 <i>Draft Regulation (Draft EASA Opinion)</i> <i>Annex III</i> COMMON REQUIREMENTS FOR SERVICE PROVIDERS <i>(Part-ATM/ANS.OR)</i> ATM/ANS.OR.B.010(a)</p>	<p>The sentence "(...) or any material modifications to those procedures shall be submitted, for approval, by the service provider to the CA (...)" constitutes a very ambiguous requirement.</p>	<p>For the purpose of standardisation, more GM should be provided in addition to GM1 ATM/ANS.OR.B.010(a)-(c).</p> <p>Leaving the definition of "material modification" in hands of every State through common agreements between every service provider and the CA would produce very different procedures.</p> <p>This would in fact bring more disharmony than harmony into the EU landscape.</p>

response Noted

It is not possible to define these modifications a priori. Every accepted modification considered as non-material has to be supported by a rationale. During the review of the AMC/GM, this aspect will be revisited.

comment 910

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.1 <i>Draft Regulation (Draft EASA Opinion)</i> <i>Annex III</i> COMMON REQUIREMENTS FOR SERVICE PROVIDERS <i>(Part-ATM/ANS.OR)</i></p>	<p>We wonder in which manner is the suitability for a particular change of the approved procedures assessed as required by provision ATM/ANS.OR.B.010 (b).</p>	<p>We see this term as too vague and subjective.</p> <p>This could open the gate to divergence in the assessment of changes within one ANSP and/or one CA and the rest of ANSPs and/or CAs.</p> <p>If this procedure is seen as exceptional this should be clearly stated in the provision.</p>



response Partially accepted

The criteria used by the CA are the same as those included in ATM/ANS.AR.C.030 (b).

The word 'exception' has been added.

comment 1236 comment by: *Icetra*

ATM/ANS.OR.B.010 (b)

This provision is very „open“ as there is no set criteria for when he can decide that the procedures are „not suitable“?
the following is suggested:

(b) When a service provider is not able to follow the approved procedures, the service provider shall:

(1) no change suggested
(2) provide the details of the deviation and arguments why the approved procedures can not be followed to the CA; and
(3) no change suggested

response Not accepted

The need to approve the deviation is covered in ATM/ANS.AR.C.030(a)(2), and the criteria are already covered in ATM/ANS.AR.C.030(b).

comment 1277 comment by: *European Transport Workers Federation - ETF*

ETF propose to establish a procedure to verify if the requested deviation complies with safety requirements. It should also specify how the CA will asses this. We would suggest the creation of appropriate AMC to describe this process.

response Not accepted

The need to approve the deviation is covered in ATM/ANS.AR.C.030(a)(2), and the criteria are already covered in ATM/ANS.AR.C.030(b).



comment	<p>56 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>ATM/ANS.OR.C.001 Page 37</p> <p>The scope appears to not foresee for the possibility of an ATS provider producing a safety support assessment. Whilst an ATS provider could also be, for example, a CNS provider and would produce a safety support assessment can it be determined that there is never an instance whereby an ATS provider needs to produce a safety support assessment? The convention is to use air traffic service provider in full rather than ATS provider.</p> <p>Proposal: Amend text to read “...other than an air traffic services provider...”</p>
response	<p>Accepted</p> <p>The text has been amended. ATS can produce a safety support assessment, but there is no need to produce it as a separate assessment, as it will produce the argument and evidence of the safety support assessment as part of the safety assessment.</p>
comment	<p>93 comment by: <i>EUROCONTROL Safety Team</i></p> <p>Subpart C General Comments</p> <ol style="list-style-type: none"> 1. There is no clear definition of who is considered as regulated or not. 2. The concept of safety support assessment is welcomed because it formalises the obligation of external services and suppliers to provide the required data feeding the Safety Case. 3. A safety support assessment, as described in the GM, would only deal with quality, requirement identification and verification (and to a limited extend validation). There are no safety elements in this. The wording of Safety Support Assessment could therefore be limited to Support Assessment.
response	<p>Partially accepted</p> <ol style="list-style-type: none"> 1. This subpart is applicable to services providers other than ATS, that is ATFM, ASM, CNS, MET, DAT, AIS, are regulated in Subpart C. 2. The support is appreciated. 3. We preferred to use the term ‘safety support assessment’, as the evaluation of performance is carried out to support a safety assessment.
comment	<p>270 comment by: <i>UK CAA</i></p> <p>Page No: 37 Paragraph No: ATM/ANS.OR.C.001 Scope</p>



	<p>Comment: There is no requirement for the paragraph to include reference to subparts A and B</p> <p>Justification: The UK CAA suggests that there is no requirement for the reference to subparts A and B as this is implicit in the scope described in the titles of subparts A and B.</p> <p>Proposed Text: Replace paragraph text with: 'This Subpart establishes the requirements to be met by service providers other than ATS providers'</p>
response	<p>Accepted</p> <p>The text has been amended accordingly.</p>
comment	<p>1111 comment by: <i>Belgocontrol</i></p> <p>Subpart C General Comments</p> <ol style="list-style-type: none"> 1. There is no clear definition of who is considered as service provider other than ATS providers. 2. The safety support assessment concept is welcomed as it formalizes the need of external services and suppliers to provide the required data for our Safety Case. <p>The safety support assessment described in the GM only deals with quality, requirement identification and verification (and to a limited extend validation). There are no safety elements in this. The wording of Safety Support Assessment could therefore be limited to Support Assessment.</p>
response	<p>Partially accepted</p> <ol style="list-style-type: none"> 1. This subpart is applicable to services providers other than ATS, that is ATFM, ASM, CNS, MET, DAT, AIS, are regulated in Subpart C. 2. The support is appreciated. <p>In reference to the last part of your comment, we preferred to use the term 'safety support assessment', as the evaluation of performance is carried out to support a safety assessment.</p>

3. Proposed amendments — 3.1. Draft EASA Opinion — ANNEX III — ATM/ANS.OR.C.005 Safety support assessment and assurance of changes to the functional system

p. 37

comment	<p>57 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>ATM/ANS.OR.C.005(a) Page 37</p>
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response	<p>The convention is to write ATS in full.</p> <p>Proposal: Amend text to read “...an air traffic services provider...”</p> <p>Accepted</p> <p>The text has been amended.</p>
comment	<p>58 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>ATM/ANS.OR.C.005(b) Page 37</p> <p>It is considered that point (b) provides the means by which point (a) should be implemented and therefore be recast as AMC.</p> <p>Proposal: Point (b) recast as AMC to ATM/ANS.OR.C.005 as proposed in NATS Appendix A (document attached to Comment number 25).</p>
response	<p>Not accepted</p> <p>The requirement in (b) does provide the elements of a safety support assessment (SSA). Without these elements, there are no criteria in the IR to assess the SSA, or a definition of the SSA would be needed in Annex I. The approach to define the elements of the SSA here seems more sensible. Please see also the response to comment No 2 for clarification on what should or not be at the level of IR. The provision has been rearranged to move the scope to (a) to avoid these elements being part of the SSA, but part of the scope.</p>
comment	<p>59 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>ATM/ANS.OR.C.005(b) Page 37</p> <p>The convention is to write ATS in full.</p> <p>Proposal: Amend text to read “...an air traffic services provider...” as proposed in NATS Appendix A (document attached to Comment number 25)</p>
response	<p>Accepted</p> <p>The text has been amended.</p>
comment	<p>60 comment by: <i>NATS National Air Traffic Services Limited</i></p>



	<p>ATM/ANS.OR.C.005(b)(1) Page 37 It is considered better grammar to change “...,which consists of...” to “...consisting of...”</p> <p>Proposal: Amend text as proposed in NATS Appendix A (document attached to Comment number 25)</p>
response	<p>Accepted</p> <p>The text has been amended.</p>
comment	<p>140 comment by: <i>ENAIRE</i></p> <p>We cannot find in this section any safety criteria or safety acceptability to be included in the safety support assessment to be performed. What are these criteria? In GM 2 ATM/ANS.OR.C005(a)2 Safety support assessment and assurance of changes to the functional systems, deals with assurance levels and propose those as a possible methods, but this does not establish nor specific criteria or who is responsible for establishing safety acceptability. There is not mandatory requirements for the relations among different providers ATS, CNS, etc.</p>
response	<p>Noted</p> <p>Safety support requirements are not necessary at the level of the IR. There is already material available for this (see AMC2 ATM/ANS.OR.C005(a)(2)).</p> <p>The specifications for the service are the requirements that the SSA should meet.</p> <p>The safety support assessment was chosen because of the implications those services can cause in the safety of aircraft operations (either through the ATS or directly to the aircraft).</p> <p>Development of GM which will be proposed in due time, to clarify this aspect is needed.</p>
comment	<p>287 comment by: <i>DSNA</i></p> <p>(a)(2):proposed text : “provide assurance, with sufficient confidence, via a complete, documented and valid argument that <u>the service will behave as specified in the specified context...</u>” because engineering processes (specification, design, production, tests and evaluation) are here to give confidence in the behaviour of the system but they cannot guarantee 100% .In particular, software assurance level methods consider that software will eventually fail at one point. Engineering and development process are adapted to the level of risk, corrective maintenance processes are in place in case of failure. Another important point is that the service may evolve in the future and will be subject to future safety assessments.</p>



(2)(ii):**proposed text** :“ the service behaves as specified in the specified context; and”

(2)(iii):**proposed text** :“the way the service behaves complies with and does not contradict procedures approved by the competent authority”.

(3):**proposed text** :“the specification of the monitoring requirements necessary to demonstrate that the service delivered by the changed functional system will continue to behave as specified in the specified context.”

response

Not accepted

The argument about guarantee of 100 % of confidence is true.

The behaviour of the service does not imply 100 % perfection and it is not expected to be 100 % reliable. The behaviour of the service includes failure modes as part of the assurance as well. In this instance, confidence is about the accuracy of the service provider’s statements about reliability.

Any future evolution of the service will be via a change that will have to be assessed.

The need to keep in the text the phrase ‘and continue to behave’ prevents that limited testing is being performed, and the assessment needs to show confidence in the continued behaviour of the service.

Development of GM which will be proposed in due time, to clarify this aspect is needed.

comment

380

comment by: UK CAA

Page No: 37

Paragraph No: ATM/ANS.OR.C.005 **Safety support assessment and assurance of changes to the functional system**

Comment: Paragraph (a) contains an unnumbered sub paragraph

(a) (2) is shown as two separate subparagraphs i.e.

‘(a) (2) provide assurance, with sufficient confidence, via a complete, documented and valid argument that the service will behave and will continue to behave only as specified in the specified context,

for any change they have notified in accordance with ATM/ANS.OR.A.045(a)(1).’

The layout of the text makes it misleading and hard to comprehend.

Justification: Clarity and comprehension.

Proposed Text:

‘a) (2) **provide assurance, with sufficient confidence, via a complete, documented and valid argument that the service will behave and will continue to behave only as specified in the specified context, for any change they have notified in accordance with ATM/ANS.OR.A.045(a)(1).**’



response	<p>Partially accepted</p> <p>The numbering is correct, but the provision has been amended following the advice to avoid misleading interpretations.</p>
comment	<p>383 comment by: UK CAA</p> <p>Page No: 37 Paragraph No: ATM/ANS.OR.C.005(b)(1)(iv) Comment: [partial statement of the safety support assessment] “the life cycle of the change from definition to operations including transition into service and planned degraded modes” The “planned degraded modes” is not a concept related to the “life cycle of the change”. UK CAA suggests splitting this sentence and making planned degraded modes item (v). Justification: Consistency and clarity. Proposed Text: (iv) the life cycle of the change from definition to operations including transition into service (v) planned degraded modes</p>
response	<p>Accepted</p> <p>The sentence is split.</p>
comment	<p>453 comment by: EUROCONTROL</p> <p>Annex III Subpart C There is no clear definition of who is considered as regulated or not. The concept of safety support assessment is welcomed because it formalises the obligation of external services and suppliers to provide the required data feeding the Safety Case. Why not making use of these words: “external services”, “suppliers”? A safety support assessment, as described in the GM, would only deal with quality, requirement identification and verification (and to a limited extent validation). There are no safety elements in this. The wording of Safety Support Assessment could therefore be limited to Support Assessment. ATM/ANS.OR.C.005 Safety support assessment and assurance of changes to the functional system EUROCONTROL's following question relates to the whole section ATM/ANS.OR.C.005: what is the added benefit for asking for a support safety assessment when the ANSP remains responsible for the safety of its services? ATM/ANS.OR.C.005 (a) (2) 1. It is not clear what the service in question really is: is it ATM, AIS, etc.? 2. It should be acknowledged that e.g. an AIS provider does not necessarily know for what purposes an ATM system might use AIS data or in what specific environment.</p>



	<p>As a result, (2) as a whole may lead to misinterpretation about what to argue and from what viewpoint in the argument.</p> <p>It is therefore suggested to make clearer the definition of “service” in that context as well as what needs to be argued and from what viewpoint in the safety argument.</p>
response	<p>Noted</p> <p>It is considered clear by the title and the scope of the Subpart that the regulated service providers are the service providers other than ATS. The use of a different word would require a new definition, which was avoided.</p> <p>The term ‘safety support assessment’ was chosen because of the implications those services can have in the safety of aircraft operations (either through the ATS or directly to the aircraft).</p> <p>The benefit is that the ATS providers do not have to ensure that these services meet the required specifications in the specified context, which would be too burdensome for them (or not possible).</p> <p>The context of a service is ‘where’ that service is provided, not in the ATM context where its data is used by ATS. In this example, the context of the AIS would be, for instance, the context of the information provided by the AIS, meaning the format used to transmit the information (e.g. paper, electronic, protocol used, etc.)</p>
comment	<p>483 comment by: CAA CZ</p> <p>The regulation proposal does not make totally clear whether an ANSP that is at the same time CNS shall provide safety assessment, safety support assessment or both.</p>
response	<p>Noted</p> <p>This aspect will be made clear in the AMC/GM to be developed. The intention is, however, to have SSA only when the service other than ATS is provided by a different organisation; otherwise the SSA is just part of the safety assessment.</p>
comment	<p>484 comment by: CAA CZ</p> <p>The CAA CZ expresses support to the implementation of requirements in (iii) under provisions of points 1 and 3 of paragraph b.</p>
response	<p>Noted</p> <p>The Agency appreciates the support of the commentator.</p>



comment	574 comment by: <i>Frasie Loredana</i>
	b)
	Modify the requirements for the content of the safety support assessment to include provisions on safety support requirements.
	Justification
	The requirements for the content of the safety case is not in line with ATM/ANS.OR.C.005 (a) (2) and GM4 ATM/ANS.OR.C.005 (a) (2) regarding the Safety Support Requirements.
	There are no requirements to include Safety Support Requirements in the Safety Support Assessment.
response	Noted
	The proposal in the comment is not well understood. Safety support requirements are not necessary to be explicitly mentioned at the level of the IR. There is already material available for this (see AMC2 ATM/ANS.OR.C005(a)(2)).
	The specifications are the requirements. The safety support requirement is to demonstrate that the service meets its specifications in the specified context, which is already included in the proposed regulation.
	The term ‘safety support assessment’ was chosen because the possible implications of those services in the safety of aircraft operations (either through the ATS or directly to the aircraft).
comment	587 comment by: <i>Federal Office of Civil Aviation FOCA</i>
	ATM/ANS.OR.C.005 (b) (2): the notion of "evidence" shall be added under (2) in order to avoid that the argument solely relies on expert judgment. The intent is to demonstrate that the system will behave as intended. Therefore, evidence is required to support the argumentation.
	Additionally, the concept of "supporting evidence" before the implementation of the change avoids that tests are performed in the operational environment.
response	Not accepted
	Even though the concern is legitimate, it seems unnecessary to include ‘evidence’ in the text. The argument contains evidence already. The definition of argument is added in the IR.
comment	650 comment by: <i>DGAC/DSAC - french NSA</i>
	The french NSA has three comments related to ATM/ANS.OR.C.005 :
	<ul style="list-style-type: none"> • general :



The French NSA strongly disagree with the idea of safety support assessment required for non ATS service providers. In this requirement, there is no link to the users of the service. That is to say that the specifications could not integrate the needs of the users specially in terms of safety (case of ATS providers). It should be stated in the regulations (and not only in GM) that such specifications must take into account the needs of the ATS provider to finally ensure safety (or any other users when the service is provided directly to them without an ATS provider involvement).

- general :

This article is a major change compared to the current regulation. The French NSA is not in line with all the material and guidance given through AMC and GM on this particular topics (safety support assessment) which aims to explain why an ATS provider has to perform a safety assessment and why a non-ATS provider has to perform a support safety assessment.

But, if we could understand the global picture of safety insured by a support safety assessment provided by a non-ATS provider taken into account by an ATS provider in the own safety assessment, we really think that services given directly to aircraft by non ATS provider should be first regulated by this IR and secondly should be in line with the requirements for an ATS provider. If not, there is a gap which may lead to unsafe situations.

As we do not want to question the works and analysis done so far on which this NPA is based, we suggest to add the following paragraph (c) which, in our opinion, fill the potential gap mentioned above :

"A service provider other than an ATS provider which provides direct services to aircraft should comply with ATS.OR.205, unless it can prove that the safety of its services is completely covered by another assessment."

- paragraph (a) (2) :

What is the difference between assurance and confidence ? It should be explained, at least in the GM.

response

Not accepted

Please see case 1 and case 2 in GM1 ATM/ANS.OR.C005.

The changes in the specifications will naturally accommodate the legitimate needs of the ATS provider. If there is a contestable environment, the ATS can decide to change supplier or if there is monopoly, the State must regulate the conditions of the service supplied. Either way, the requirements must be such that satisfy the ATS needs.

The proposal is already covered by ATM/ANS.OR.C.005(b)(2)(iii), on the requirements imposed on the services other than ATS, which the specifications must meet.



The terms ‘assurance’ and ‘confidence’ are used in their normal English meaning (OED):

- assurance: a positive declaration intended to give confidence
- confidence: the feeling or belief that one can have faith in or rely on someone or something

comment

913

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.1 <i>Draft Regulation (Draft EASA Opinion) Annex III COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR)</i></p>	<p>We wonder whether the "sufficient confidence" required by provision <i>ATM/ANS.OR.C.005 (a)(2)</i> is really <u>sufficient</u>.</p>	<p>We see this term as too vague and subjective.</p> <p>This could open the gate to divergence in the assessment of changes within one ANSP and/or one CA and the rest of ANSPs and/or CAs.</p> <p>We would suggest to develop AMC on the use of the concept of 'assurance level' in order to reduce the subjectiveness of this provision.</p> <p>We kindly refer EASA to our comments on GM2 ATM/ANS.OR.C.005(a)(2) and GM2 ATS.OR.(a)(2).</p>

response

Noted

Comments on AMC/GM will be responded to in the CRD associated with them. A considerable amount of time is needed to rework, amend and complete the AMC/GM in an appropriate and effective manner, and this cannot be done at this stage. Future work is planned to review the comments on the AMC/GM and complete the CRD in due time.

comment

1167

comment by: LfV

There need to be a clear definition of what is technical ATS services and what is CNS services, since the regulation differs between them.

What equipment is defined to be a part of the ATS functional system, and what equipment



	<p>to be a part of the CNS functional system? Should e.g. according to NPA 2014-13 a technical ATS Service Provider, providing services to another ATS Provider, produce a safety assessment or a safety support assessment? Or will all equipment supporting the ATS functional system be considered CNS services, and the CNS-regulation apply?</p>
response	<p>Noted</p> <p>The second interpretation seems to be the correct one; depending on what ‘technical ATS service’ means.</p>
comment	<p>1202 comment by: ENAIRE</p> <p>According to (a.1) a CNS/ATS provider has to establish a safety support assessment (CNS) and a safety assessment (ATS) separately. In our opinion, it should be possible to get them together in a single assessment.</p>
response	<p>Noted</p> <p>The interpretation is not correct. This applies only in the case of separate organisations. If both types of services are provided by the same organisation, they will be presented as a safety case, and the content of what has been called SSA, will be part of the evidence supporting the safety assessment.</p>
comment	<p>1229 comment by: CAA-NL</p> <p>ATM/ANS.OR.C.005 We suggest to replace the words “Safety support assessment” throughout the article with “Quality assurance assessment”. Organisations other than ATS providers do not have to comply with the SMS requirements but do have to comply with the requirements for a management system. As such they have to assure that their service will continue to behave as specified, also when a change is incorporated. To assure the quality and integrity of their service a “Quality assurance assessment” relates better to the management principles applicable to these organisations where the current wording used might give the impression of something that is not required. When this comment is accepted, similar changes have to be made to the related AMC/GM.</p>
response	<p>Not accepted</p> <p>Although the arguments are correct, the assessment is performed to support the safety assessment conducted by the ATS. The term was chosen for that reason and seems appropriate.</p>



comment 1237

comment by: *Icetra*

The concept of a "safety support assessment" (is the term "support" referring to "safety" or to "assessment"?) to be carried out by service providers other than ATS providers is not supported.

The rationale provided for lessening the demands on providers other than ATS providers are not fully understood. For example the rationale provided stating that "it is only the ATS provider that can perform a safety assessment and provide a safety case" is not understood (p.54). ATS is not in all cases controlling separation between aircraft. FIS for instance is „just“ flight information service, not controlling separation and in such cases the ATS provider does not necessarily have a plan (navigational plan (a plan controlling separation) for all a/c receiving an ATS) to adhere to and to modify to ensure that all a/c remain safe. Using the same rationale as is done on p.54 one might come to the conclusion that the ATS provider can only provide a safety case for ATC provision and nothing else.

It is the definition of the scope of a safety assessment that stipulates what can and needs to be taken into account in the assessment. Hence, the scope of the safety assessment provided by a CNS provider does not necessarily include the "user" of the service whereas the scope of a safety assessment of ATC service will include the user since the ATC service has full (or almost full) control of how the service is used. A safety "support assessment" (or is it "safety support" assessment?) degrades the assessment and has the risk of the service provider not taking ownership of the risk of the services he provides. When an ATS/ATM provider avails himself of services provided by other service providers he can thus use as an input into his own safety case, the safety assessment provided by those services of which he uses in his own service provision. Again, it is the scope that is the important issue and the CA must in all cases ensure that the entire scope of the end service is covered in the safety case provided.

It is suggested that the current provisions of requiring CNS/ATS providers to perform a safety assessment be retained, but an emphasis be put on the importance of defining/describing the scope of the assessments made each time. It is furthermore supported that the requirement of safety assessment be extended to other service providers such as is proposed in this NPA.

response Noted

‘Support’ refers to ‘safety’.

Requirements are not lessened for service providers other than ATS, but they have been made appropriate to what they can manage or to whomever has the best ‘view’ of safety. In the example, FIS may still be in the best position to assess safety risks as FIS may have the most complete situation awareness of the traffic. The ability to perform a safety assessment because they are in the best position to understand the traffic situation does not mean they have the responsibility for the safety of operations. The safety assessment has to be conducted in coordination with the aircraft operator.

There is a need for AMC/GM to clarify the scope of the safety assessment and the safety



support assessment.

3. Proposed amendments — 3.1. Draft EASA Opinion — ANNEX IV — ATS.OR.201 Safety management system

p. 38

comment

61

comment by: *NATS National Air Traffic Services Limited*

ATS.OR.201(b)

Page 38

As previously commented the explanation (in 2.4.5) that “the set of safety criteria, as a whole, shall satisfy the “objective for safety”” is taken to mean that in ATS.OR.201(b) “objective for the safety” is the safety criteria.

NATS therefore understands that the objective for safety cannot be that the service will be at least as safe after the change as it was before and that satisfaction of the safety criteria is sufficient.

This view would appear to be further supported by ATS.OR.210 whereby (a) makes it explicit that safety criteria determine the safety acceptability of a change to a functional system. That said ATS.OR.205 appears to imply in (b)(7) that the safety criteria are associated with the changed functional system rather than the change itself.

Notwithstanding the above comments it is foreseen that some changes could result in a slightly increased risk and still be within the risk budget for the overall service. For example, with this type of requirement it would be difficult to justify the deployment of safety nets whereby there is definite increase in risk from such a deployment and yet the safety benefits of such a deployment will be measured against a different set of measures making the assertion that it will be at least as safe after the change as before a difficult argument to make.

Proposal: Delete ATS.OR.201(b) & (c) as proposed in NATS Appendix A (document attached to Comment number 25).

response

Partially accepted

The objective for safety sets the top-level goal. The safety criteria are used to decompose this goal into the parts of the change. In this sense, the acceptability of the change depends on the satisfaction of the safety criteria, but these criteria must collectively meet that goal. Consequently, without the ‘goal’, the validity of the set of safety criteria cannot be established. The only validity that can be established is their internal validity, i.e. that they are individually ‘well formed’. The objective for safety was included in the SMS, but after assessing all the comments, it has been moved to ATS.OR.210 to more clearly show the link



between the objective for safety of a change and the safety criteria. The relationship between the objective for safety and the safety criteria has been clarified (ATS.OR.210(b)(2)), but it has also been redefined to account for situations where some changes could result in a slightly increased risk and still be within the risk budget for the overall service. The requirement for the objective for safety of a change has been redrafted to make sure that the safety criteria collectively 'ensure that the change does not create an unacceptable risk to the safety of the service'. Then the former objective 'as safe as before the change' would be one option to comply with this requirement, and other means can be developed.

comment 94 comment by: EUROCONTROL Safety Team

ATS.OR.201(b) is seemingly in conflict with the EN (2.4.5, page 30) because the EN explains that the safety criteria are *used to decide the safety acceptability of a change to a functional system*. In such a case then the objective for the safety is understood to mean that it is necessary to satisfy the safety criteria. Therefore the objective for safety cannot be that the service will be at least as safe after the change as it was before.
Recommend that ATS.OR.201(b)&(c) are deleted.

response Not accepted

Please see the response to comment No 61.

comment 288 comment by: DSNA

(b):The objective of the safety assessment is to demonstrate that the change is acceptably safe. **Proposed text** : "The air traffic service provider shall ensure as part of its SMS that the objective for the safety of a planned change to a functional system that has been notified in accordance with ATM/ANS.OR.A.045(a)(1), shall be that the service **remain acceptably safe**"
This is coherent with ICAO concept of SMS acceptable level of safety.
The notion "at least as safe as" may be an acceptable objective **from an academic approach of safety but cannot be measured and does not reflect reality.**

response Partially accepted

The wording '**remain acceptably safe**' has been changed to 'avoid introducing unacceptable risk', but the spirit is the same. The Agency, however, disagrees with the statement that the notion 'at least as safe as' is academic, but it recognises that other approaches can also be possible to ensure no unacceptable risk is introduced. That is the same as 'leave the service acceptably safe'.

comment 339 comment by: ATCEUC - Air Traffic Controllers European Unions Coordination



ATS.OR.201 Safety Management System

The objective for safety in this NPA will be that the safety level of the service provided after a change in FS is at least the same as before the change. When this may not be achieved the SP might agree with the CA that the situation will be temporary and that eventually they will return to the original levels of safety, and in the meantime there should be measures to minimize the impact of that decrease in safety.

We can easily imagine the situation where a radar is to be disconnected because it is going to be replaced by a new one. The system will be less safe for a period of time during which mitigation measures should be enforced (for instance, in the example proposed, these measures could be reducing the capacity of the sector)

ATS.OR.201

(c) Where (b) cannot be achieved, the ATS provider shall reach agreement with the competent authority on a subsequent course of action including, at least, mitigation measures.

response

Not accepted

In the example, the time between removing the radar and installing a new one is covered by the safety case and so the provider would have to show the mitigations needed for the short period of time. The CA would agree with them via their approval of the safety case. If the CA agreed to this short period of higher risk, then they would approve the safety case and signify their agreement to the subsequent course of action.

On the other hand, the provider may be arguing a reduction in safety based on an increased benefit for which there is no mitigation foreseen. The CA's choice is then to either accept the risk because the benefit is seen to outweigh it or to stop the change. In the former case, the subsequent course of action may be to initiate some studies to find ways of reducing the risk in the long term. Instead, in the latter case, the benefit will not be realised. Most CAs would adopt the former approach.

In any case, the proposed provision has been amended and moved to ATS.OR.210(b). Please see the responses to comments Nos 61 and 288.

comment

360

comment by: *Finavia*

b) The air traffic service provider shall ensure as part of its SMS that the objective for the safety of a planned change to a functional system that has been notified in accordance with ATM/ANS.OR.A.045(a)(1), shall be that the service will be at least as safe after the change as it was before the change.

Finavia comment:

The end of paragraph should be modified so that the requirement is to ensure that '...the service after the change is reaching acceptable level of safety taking into account the total effects in overall safety of the entire system.'



	<p>Arguments for the comment:</p> <ol style="list-style-type: none"> 1) The original requirement “at least as safe as before the change” would require reliable and comprehensive evidence of the level of safety that was existing before the change. This is in many cases very difficult to verify in a reliable way taking into account the complexity of the total functional system. 2) The original requirement “at least as safe as before the change” may lead to misconception to assess only a small component/part of the system. 3) The original requirement “at least as safe as before the change” is not described enough deep to give an unambiguous understanding of how the requirement should be understood or interpreted. 4) The requirement should support the use of specified safety criteria (acceptable level of safety) instead of setting some single statements of the required level of safety. 5) Serious problems may occur in connection with modifications on some old systems or procedures that may due to historical reasons have heavily oversized arrangements to ensure the safety. The original operational concept and the meaning of the original procedure/equipment may have changed in the functional entity.
response	<p>Partially accepted</p> <p>Please see the responses to comments Nos 61 and 288.</p> <ol style="list-style-type: none"> 1) Yes, but this is part of the change. Moreover, if there is uncertainty about the safety of the part of the system being changed, how can there be certainty about the safety of that part after the change. The argument needed is a relative one which only needs sufficient confidence in the difference in safety, not in its absolute value. In any case, the proposed provision has been amended following the spirit of this comment and moved to ATS.OR.210(b). 2) No, the requirement in 205(a)(1) states that any part of the system that is affected by the change is within the scope of the change and so no analysis is needed for those parts of the system unaffected by the change and it is assumed, because of this, that they contribute the same level of risk after the change as they did before. 3) It should show that the total risk after the change is the same as the total risk before the change. 4) Please see the response to comment No 61. 5) In that case, it can be discussed with the CA as part of the original provision proposed in ATS.201(c). This provision has been removed, anyway.
comment	<p>367 comment by: <i>Air Navigation Services of the Czech Republic</i></p> <p>The approach proposed here is not consistent with ATS.OR.210, where the safety acceptability is linked to safety criteria, not any other objective.</p> <p>There is no commonly agreed approach to express the level of safety therefore it would not be feasible to assess the compliance with the proposed IR.</p>



	<p>Also, we consider the point (b) as not feasible. E.g. temporary changes might decrease the level of safety (construction works at aerodrome), yet it might be acceptably safe all the time.</p> <p>We propose to remove point ATS.OR.201 (b) from the IR.</p>
response	<p>Partially accepted</p> <p>Please see the responses to comments Nos 61 and 288.</p>
comment	<p>382 comment by: <i>skyguide Corporate Regulation Management</i></p>
	<p>ATS.OR.201(b) & (c)</p> <p>The explanation that “the set of safety criteria, as a whole, shall satisfy the “objective for safety”” (middle Page 30) is taken to mean that in ATS.OR.201(b) “objective for the safety” is the safety criteria. The safety criteria are “used to decide the safety acceptability of a change to a functional system” (middle Page 30).</p> <p>sg therefore considers that the objective for safety cannot be that the service will be at least as safe after the change as it was before and that satisfaction of the safety criteria must be sufficient and recommend that ATS.OR.201(b)&(c) are deleted as shown in Appendix A.</p>
response	<p>Partially accepted</p> <p>Please see the responses to comments Nos 61 and 288.</p>
comment	<p>386 comment by: <i>UK CAA</i></p>
	<p>Page No: 38</p> <p>Paragraph No: ATS.OR.201 Safety management system</p> <p>Comment:. UK CAA suggests that there is no requirement to include the reference to ATM/ANS.OR.A.045(a)(1) in this paragraph as a planned change to a functional system is a planned change to a functional system, therefore the reference is considered superfluous.</p> <p>Justification: superfluous reference.</p> <p>Proposed Text: ‘ (b) The air traffic service provider shall ensure as part of its SMS that the objective for the safety of a planned change to a functional system shall be that the service will be at least as safe after the change as it was before the change’</p>
response	<p>Not accepted</p> <p>Not applicable as the requirement has been removed. Please see the responses to comments Nos 61 and 288.</p>
comment	<p>387 comment by: <i>UK CAA</i></p>



	<p>Page No: 38</p> <p>Paragraph No: ATS.OR.201 Safety management system</p> <p>Comment: Paragraph (c) states ‘Where (b) cannot be achieved, the ATS provider shall reach agreement with the competent authority on a subsequent course of action’. In the absence of AMC on the criteria for subsequent action the UK CAA recommends that the need for affirmative action by the CA is clearly stated in this paragraph.</p> <p>Justification: Clarification of responsibility for determining the criteria for subsequent action.</p> <p>Proposed Text: ‘Where (b) cannot be achieved, the competent authority shall determine the subsequent course of action in consultation with the ATS provider.’</p>
response	<p>Not accepted:</p> <p>Not applicable as the requirement has been removed. Please see the responses to comments Nos 61 and 288. Besides that, the clause requires agreement to be reached with the CA, who in this case can insist on the criteria, if necessary, because ultimately it can refuse to approve the argument.</p>
comment	<p>389 comment by: UK CAA</p>
	<p>Page No: 38</p> <p>Paragraph No: ATS.OR.201(c)</p> <p>Comment: “Where (b) cannot be achieved, the ATS provider shall reach agreement with the competent authority on a subsequent course of action”</p> <p>The UK CAA recommends that an equivalent provision on the CA for this activity, stating the responsibility for establishing the criteria for this “subsequent course of action is included.</p> <p>Justification: Clarity and sufficiency of requirement</p> <p>Proposed Text: ‘Where (b) cannot be achieved, the competent authority shall determine the subsequent course of action in consultation with the ATS provider.’</p>
response	<p>Not accepted</p> <p>Not applicable as the requirement has been removed. Please see the responses to comments Nos 61 and 288.</p>
comment	<p>560 comment by: EUROCONTROL</p>
	<p>Annex IV</p> <p>Subpart A</p> <p>ATS.OR.201 (b) Safety management system - Page 38</p> <p>First, EUROCONTROL believes that, like in other places in the NPA, it is not clear what the service in question really is in “(...) the service will be at least as safe after the change as it was before the change.”</p> <p>Secondly, depending on how the safety criterion for the change is being defined (i.e. per</p>



flight, per approach, etc.), “at least as safe as before” might lead to in fact an overall increase in safety risks (in terms e.g. of the absolute number of accidents) if the change is associated to an increase in traffic.

It is therefore suggested to:

- make clearer the definition of “service” in that context;
- add after “(...) the service will be at least as safe after the change as it was before the change”, “irrespective of change-enabled evolutions in the traffic level”.

EUROCONTROL also shares the view that as long as the change is acceptably safe it should be considered acceptable for implementation, although this could mean a slight reduction against the current safety levels (possibly only for a short period after implementation during which experience can be gained).

In ATS.OR.201(b) EUROCONTROL therefore proposes to replace:

‘The air traffic service provider shall ensure as part of its SMS that the objective for the safety of a planned change to a functional system that has been notified in accordance with ATM/ANS.OR.A.045(a)(1), shall be that the service will **be at least as safe after the change as it was before the change**’.

by

‘The air traffic service provider shall ensure as part of its SMS that the objective for the safety of a planned change to a functional system that has been notified in accordance with ATM/ANS.OR.A.045(a)(1), shall be that the service will **meet the safety criteria**’.

response

Partially accepted

1) This is not of importance. The requirement in ATS.OR.210(b) is that any part of the system that is affected by the change is within the scope of the change and so no analysis is needed for those parts of the system unaffected by the change. It is assumed that they do not contribute at all to the change and have the same level of risk after the change as they did before. Consequently, the requirement could be thought to cover the changed part of the service or the whole service. In any case, it would yield the same result.

2) The evolution of the traffic level is a change driver as described now in ATM/ANS.OR.B.005(a)(4) and is, therefore, taken into account as part of the change — it is a responsive change (please see GM1 Annex I definitions (35) & ATM/ANS.OR.A.0345 & ATM/ANS.OR.C.005 & ATS.OR.205).

3) Partially incorporated into the final proposal. Please see the responses to comments Nos 61 and 288.

comment

588

comment by: *Federal Office of Civil Aviation FOCA*

ATS.OR.201 (b): FOCA suggests the following change in wording:
The air traffic service provider shall ensure as part of its SMS that the objective for the safety of a planned change to a functional system that has been notified to the respective competent authority in accordance with ATM/ANS.OR.A.045 (a)(1), shall be that the service will be proven as being acceptably safe in light of the overall safety level.



response	<p>Justification: It is not relevant if the safety level is equal to or better than the existing safety level. It is solely relevant if the change is acceptably safe in the overall safety.</p> <p>Partially accepted</p> <p>Please see the responses to comments Nos 61 and 288.</p>
comment	<p>589 comment by: <i>Federal Office of Civil Aviation FOCA</i></p> <p>ATS.OR.201 (c): FOCA suggests to delete this requirement. If the overall safety level is reached, there is no use for such a coordination. See also comment to ATS.OR.201 (b)</p>
response	<p>Accepted</p> <p>The requirement has been deleted.</p>
comment	<p>617 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>(b) - (c) was added after the closure of the group and not agreed on in RMT.</p> <p>"service will be at least as safe after the change as it was before the change"</p> <p>We are aware that this requirement is meant to display the requirements from ESARR3, which DFS is already fulfilling.</p> <p>But there are interpretations of this requirement (by the CA) possible, which could be relating the "as safe as" to "zero risk" for a single change e.g. That would be impossible to fulfil at the moment (without significant increase of the effort by introducing success cases). None of the current certified ANSP safety assessment methods would fulfil it.</p> <p>We strongly suggest to remove this new paragraph again and address the intended requirement on a different level (i.e. in CRD to NPA 2013-08).</p> <p>Although the EN was very helpful with regard to the intention of being comparable to ESARR3, there is not information like that found in IR/AMC and there is also some confusion regarding the terms "set of safety criteria" and "objective for safety" as used on page 30. Reference to high level comment "c.i"</p>
response	<p>Partially accepted</p> <p>Please see the responses to comments Nos 61 and 288.</p>
comment	<p>618 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p>



	<p>(b) We suggest to turn the expression "risk analysis of the effects" into "analysis of the effects" (delete the word "risk") to avoid confusion with the later used term "risk evaluation". Reference to high level comment "c.ii"</p>
response	<p>Noted</p> <p>Not applicable in the final proposal.</p>
comment	<p>682 comment by: ROMATSA</p> <p>ATS.OR.201 (b) & (c)</p> <p>The explanation that “the set of safety criteria, as a whole, shall satisfy the “objective for safety” is taken to mean that in ATS.OR.201(b) “objective for the safety” is the safety criteria. The safety criteria are “used to decide the safety acceptability of a change to a functional system” (page 30)</p> <p>ROMATSA supports CANSO opinion and understands that the objective for safety cannot be that the service will be at least as safe after the change as it was before and that satisfaction of the safety criteria is sufficient and recommend that ATS.OR.201(b)&(c) are deleted as shown in Appendix A.</p> <p>Supporting comment to summary issue: IR does not achieve the perceived intention of the rule. In this case the IR is in conflict with ATS.OR.210.</p>
response	<p>Partially accepted</p> <p>Please see the responses to comments Nos 61 and 288.</p>
comment	<p>887 comment by: Navair</p> <p style="text-align: center;">ANNEX IV SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS)</p> <p style="text-align: center;">SUBPART A — ADDITIONAL ORGANISATION REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (ATS.OR) Section 1 — General requirements</p> <p>...</p> <p style="text-align: center;">Section 2 — Safety of services</p> <p>ATS.OR.205. Safety assessment and assurance of changes to the functional system An air traffic services provider providing air traffic services shall:</p> <p>(a) ensure that a safety assessment is carried out; and</p> <p>(b) provide assurance, with sufficient confidence, via a complete, documented and valid</p>



argument that the safety criteria are valid, will be satisfied and will remain satisfied for any change they have notified in accordance with ATM/ANS.OR.A.045(a).

AMC1 ATS.OR.205. Safety assessment and assurance of changes to the functional system

SAFETY ASSESSMENT AND ASSURANCE

An air traffic services provider providing air traffic services should ensure that the safety assessment comprises:

(a) the definition of the scope of the change consisting of:

(1) the equipment, procedural and human elements being changed;

(2) interfaces and interactions between the elements being changed and the remainder of the functional system;

(3) interfaces and interactions between the elements being changed and the context in which it is intended to operate; and

(4) the life cycle of the change from definition to operations including transition into service and planned degraded modes;

(b) identification of hazards;

(c) determination of the safety criteria applicable to the change in accordance with ATS.OR.210;

(d) risk analysis of the effects related to the change;

(e) risk evaluation and, if required, risk mitigation for the change such that it can meet the applicable safety criteria;

(f) verification that the change:

(1) conforms to the scope that was subject to safety assessment; and

(2) meets the safety criteria; and

(g) the specification of the monitoring requirements necessary to demonstrate that the service delivered by the changed functional system will continue to meet the safety criteria.

ATS.OR.210. Safety criteria

An air traffic services provider shall determine the safety acceptability of a change to a functional system using specific and verifiable safety criteria, where each criterion is expressed in terms of safety risk or other measures that relate to safety.

AMC1 ATS.OR.210. Safety criteria

SAFETY CRITERIA

(a) An air traffic services provider should specify the safety criteria with reference to one or more of the following:

(1) explicit quantitative acceptable levels of safety risk or other measures related to safety risk;

(2) recognised standards and/or codes of practice;

(3) proxies; and

(4) the safety performance of the existing functional system or a similar functional system elsewhere.

(b) An air traffic services provider should ensure that the safety criteria:

(1) are justified for the specific change, taking into account the type of change; and

(2) support the improvement of safety whenever reasonably practicable.



response Noted

It seems difficult to identify the changes and the rationale. It is assumed that this is the same proposal as that of CANSO. Please see the responses to comments Nos 61 and 288.

comment 914 comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.1 <i>Draft Regulation (Draft EASA Opinion)</i> Annex IV SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES <i>(Part-ATS)</i> ATS.OR.201(c)	We wonder in which cases the implementation by the service provider of a change that makes the system <u>less safe than it was before the change</u> might be acceptable for the CA. . Further to this, we wonder what kind of agreement could be reached in that situation that would be acceptable for the CA. Some GM should be provided.	We would welcome clarification on these points in order to better understand and assess this NPA.

response Noted

Increasing the risk of operations, even by a small margin, would make the service less safe. However, considering the comments received, the final proposal has been amended. Please see the responses to comments Nos 61 and 288.

comment 1274 comment by: European Transport Workers Federation - ETF

ETF agree on the need to identify an overall objective for safety offering the possibility to take mitigating measures in case safety should be affected during and after the changes to functional systems. It means also that a continuous assessment process should be put in place.

response Noted

The ETF support is appreciated. Please note that the objective for safety has been changed and moved to ATS.OR.210(b). Please see the responses to comments Nos 61 and 288.



comment	<p>1278 comment by: <i>European Transport Workers Federation - ETF</i></p> <p>ETF propose to modify the paragraph (c) as follows:</p> <p><i>Where (b) cannot be achieved, the ATS provider shall reach agreement with the competent authority on a subsequent course of action including temporary mitigation and contingency measures to minimise the decrease in safety, and to identify terms and procedures to return to the level of safety before the changes introduced to the functional system.</i></p>
response	<p>Not accepted</p> <p>With the final proposal, this requirement has been removed. Please see the responses to comments Nos 61 and 288.</p>

3. Proposed amendments — 3.1. Draft EASA Opinion — ANNEX IV — ATS.OR.205 Safety assessment and assurance of changes to the functional system p. 38-39

comment	<p>62 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>ATS.OR.205 Page 38</p> <p>It is considered that point (b) provides the means by which point (a) should be implemented and should therefore be recast as AMC.</p> <p>Each instance of ATS should be replaced by air traffic services to comply with the convention used in the rule.</p> <p>Proposal: Point (b) recast as AMC to ATS.OR.205 as proposed in NATS Appendix A (document attached to Comment number 25).</p>
response	<p>Not accepted</p> <p>The requirement in (b) does provide the elements of a safety assessment. Without these elements, there are no criteria in the IR to assess this safety assessment; otherwise, a definition of the safety assessment would be needed in Annex I. The approach to define the elements of the safety assessment here seems more sensible. Please see also the response to comment No 2 for clarification of what should be or not at the level of IR. The provision has been rearranged to move the scope to (a) to avoid these elements being part of the safety assessment, instead of the scope.</p>



comment	<p data-bbox="360 241 395 271">63</p> <p data-bbox="820 241 1485 271" style="text-align: right;">comment by: <i>NATS National Air Traffic Services Limited</i></p> <p data-bbox="360 331 576 360">ATS.OR.205(b)(1)</p> <p data-bbox="360 376 459 405">Page 38</p> <p data-bbox="360 416 1406 445">It is considered better grammar to change "...,which consists of..." to "...consisting of..."</p> <p data-bbox="360 499 1485 566">Proposal: Amend text as proposed in NATS Appendix A (document attached to Comment number 25)</p>
response	<p data-bbox="360 600 475 629">Accepted</p> <p data-bbox="360 667 703 696">The text has been amended.</p>
comment	<p data-bbox="360 792 395 822">64</p> <p data-bbox="820 792 1485 822" style="text-align: right;">comment by: <i>NATS National Air Traffic Services Limited</i></p> <p data-bbox="360 882 576 911">ATS.OR.205(b)(7)</p> <p data-bbox="360 927 459 956">Page 39</p> <p data-bbox="360 967 1485 1034">Point (b)(7),"the specification of monitoring requirements necessary to demonstrate that the service delivered by the changed functional system will continue to meet the safety criteria."</p> <p data-bbox="360 1088 1485 1200">As previously commented the explanation (in 2.4.5) that "the set of safety criteria, as a whole, shall satisfy the "objective for safety"" is taken to mean that in ATS.OR.201(b) "objective for the safety" is the safety criteria.</p> <p data-bbox="360 1254 1485 1366">NATS therefore understands that the objective for safety cannot be that the service will be at least as safe after the change as it was before and that satisfaction of the safety criteria is sufficient.</p> <p data-bbox="360 1420 1485 1576">This view would appear to be further supported by ATS.OR.210 whereby (a) makes it explicit that safety criteria determine the safety acceptability of a change to a functional system. That said ATS.OR.205 appears to imply in (b)(7) that the safety criteria are associated with the changed functional system rather than the change itself.</p>
response	<p data-bbox="360 1646 576 1675">Partially accepted</p> <p data-bbox="360 1713 895 1742">Please see the response to comment No 61.</p>
comment	<p data-bbox="360 1827 411 1856">289</p> <p data-bbox="1246 1827 1485 1856" style="text-align: right;">comment by: <i>DSNA</i></p> <p data-bbox="360 1910 1485 1977">(a):proposed text : " for any safety related change they have notified in accordance with ATM/ANS.OR.A.045(a)(1)."</p>



	<p>(b)(1)(iii):"context" need for explanations. Need an GM.</p> <p>(2):identification of hazards implies here that proxy alone is not accepted to expressed the risk. But AMC p 160 stress that we may identify hazard OR proxies. According to the AMC, identification of hazards is not necessary when proxies are used.</p> <p>(6)(i):It is too detailed and shall be removed or moved to a GM.</p> <p>(7):proposed text : "the specification of the monitoring requirements necessary to demonstrate <u>that the change will continue to meet the safety criteria</u>".</p>
response	<p>Not accepted</p> <p>(a) All the changes to the functional system are potentially safety-related. The amount of the effect can only be found out by assessing the risk of the proposed change.</p> <p>(b)(1)(iii) Comments on AMC/GM will be responded to in the CRD associated with them.</p> <p>(2) The commentator misunderstood the concept of proxies. Proxies do not substitute hazards, but they are a surrogate of safety risk. <i>Whilst it is true that the use of proxies may remove the need to evaluate the value of the risk and a proxy could be seen as a hazard, there is no implication that hazards need not be identified if using proxies.</i> This means that the safety criteria can be expressed in terms of these indicators or proxies. Please see examples in GM2 ATS.OR.205(b)(4).</p> <p>(6)(i) <i>The fact that a single requirement requires extensive GM or AMC is the result of the complexity of the concept/requirement that the Regulation is dealing with. There is nothing that limits the AMC/GM if it is considered useful for the applicability or understanding of the requirement. This is perfectly acceptable.</i></p>
comment	<p>346 comment by: ATCEUC - Air Traffic Controllers European Unions Coordination</p> <p>ATM/ANS.OR.B.005 (d) Management System We strongly support the inclusion of the monitoring criteria as part of the requirements for the safety assessment. See our answer to Q6.</p>
response	<p>Noted</p> <p>The Agency appreciates the ATEUC's support.</p>
comment	<p>390 comment by: UK CAA</p> <p>Page No: 38 Paragraph No: ATS.OR.205(b)(1)(iv) Comment: [partial statement of the safety assessment] "the life cycle of the change from</p>



	<p>definition to operations including transition into service and planned degraded modes” The “planned degraded modes” is not a concept related to the “life cycle of the change”. [Equivalent to comment made for ATM/ANS.OR.C.005(b)(1)(iv)].</p> <p>Justification: Clarity</p> <p>Proposed Text: ‘(iv) the life cycle of the change from definition to operations including transition into service (v) planned degraded modes’</p>
response	<p>Accepted</p> <p>The text has been changed.</p>
comment	<p>590 comment by: <i>Federal Office of Civil Aviation FOCA</i></p> <p>ATS.OR.205 (2) (b): FOCA suggests to add under par. (2) the notion of "evidence" in order to avoid that the argument solely relies on expert judgment. The idea is to demonstrate that the system will behave as intended. Therefore, evidence is required to support the argumentation.</p> <p>Additionally, the concept of "supporting evidence" before the implementation of the change avoids that tests are performed in the operational environment (in live trials).</p>
response	<p>Not accepted</p> <p>Even though the concern is legitimate, it seems unnecessary to include ‘evidence’ in the text. The argument contains evidence already. The definition of argument is added in the IR.</p>
comment	<p>608 comment by: <i>EUROCONTROL</i></p> <p>ATS.OR.205 (b) (7) – Safety assessment and assurance of changes to the functional system - Page 39</p> <p>The need to identify monitoring requirements is welcomed by EUROCONTROL.</p> <p>However, a question exists as to whether the follow-up of these monitoring requirements has to be embedded within the safety assessment process for changes as the monitoring criteria (see page 162, AMC1 ATS.OR.205 (b)), or can be included in another process e.g. occurrence process or a specific follow-up of monitoring requirements.</p> <p>EUROCONTROL therefore proposes not to limit the follow-up process of these monitoring requirements to the safety assessment process for changes, but to leave each ANSP decide on how to incorporate this follow up process in an appropriate place in their SMS / MMS.</p>
response	<p>Accepted</p> <p>The Agency concurs with the statements of Eurocontrol as this is exactly the intention of the requirement ATM/ANS.OR.B.005 (d). That is the actual monitoring act of the values and their follow-up. The requirements are not prescriptive, as it is up to the ANSP how to implement</p>



it.

comment

624

comment by: EUROCONTROL

ATS.OR.205 – Safety assessment and assurance of changes to the functional system - Page 38

Reading this requirement does not better explain how and when proxies can be used.

Again here, EUROCONTROL recommends to clarify the guidance material on the use of proxies.

Moreover, by having ATS.OR.205 as a whole suggesting a “piecemeal” approach to change management, the problem could be twofold:

- firstly, there is no assurance (except from continually changing, historical evidence of safety achievement) that what is about to be changed had been actually safe in itself;
- secondly, there is a limit to how many times changes can be made before either one loses track of what is being changed and / or different but interacting changes produce conflicting safety requirements. It is therefore suggested to add a requirement related to the need for ATS provider to develop and maintain an up-to-date safety/risk baseline.

ATS.OR.205 (a) (2)

In current and past regulations, there was no explicit regulatory requirement to produce Safety Cases, with the result, as currently, of little or no take-up of the idea by ANSPs.

Since the NPA does not fix this regulatory problem EUROCONTROL suggests that this NPA mentions that suitable Safety Cases are one way of satisfying the regulatory requirements quoted in this section.

ATS.OR.205 (b)

Although not explicit, it seems that the scope of the safety assessment of a change as per this NPA is limited to the identification of change-generated hazards and risks (that is, those caused by failure of the change under assessment) and risk mitigation. Obviously in the cases of safety criteria being related to e.g. (1) maintaining a similar safety level irrespective of an increase in traffic/airport throughput; or (2) an improvement in safety, it is hard to understand how such an approach could provide a meaningful argument about satisfying the safety criteria.

In addition, it seems that the safety practitioners within those ATS providers would still be receiving a designed change rather than being part of an interdisciplinary approach to enable the realisation/operation of successful systems. In doing so, the NPA seems to miss the point that there was no equivalent to ARP 4754 in ATM.

EUROCONTROL therefore suggests to:

1. Promulgate a system-engineering approach to safety assessment whereby the overall objective of the safety assessment is twofold:
 - maximizing the ATM/ANS positive contribution to aviation safety, whilst
 - minimizing its contribution to the risk of an [aviation] accident
2. Clearly broaden the definition of hazard as suggested for Annex I i.e. covering both relevant pre-existing aviation hazards (which the ATM/ANS functional system relevant to the



change has to mitigate) and generated hazards which are created by failure of the change to the ATM/ANS functional system.

3. Make clear that the resulting functional/performance properties of the changed service/functional system will both provide mitigation of the pre-existing risks as well as capturing the mitigations of the risks related to the change-generated hazards.

ATS.OR.205 (b) (3)

It is hard to understand why the determination and justification of the safety criteria does not come earlier in the list.

EUROCONTROL therefore suggests bringing the determination and justification of the safety criteria forward in the list.

In addition, since of the one perceived objective of this NPA is to address a currently existing shortcoming in regulation that is suggesting over-proceduralized, processed-based approach to safety assessment, it is not clear why the NPA does not require an ATS provider to develop, as an initial step before carrying out the safety assessment, a safety argument enabling to define the safety assessment/assurance activities to be conducted and the type of evidence required (with appropriate rigour/quality).

It is suggested to add the requirement for an ATS provider to develop at the earliest stage of an assessment a safety argument providing the overall strategy for the safety assessment to be conducted.

If the above suggestion is accepted, this should come in the list immediately after the definition of the safety criteria since they not only define what is tolerably or acceptably safe but also determine the way by which the Safety Argument (giving the safety strategy) is developed.

response

Partially accepted

‘ firstly, there is no assurance (except from continually changing, historical evidence of safety achievement) that what is about to be changed had been actually safe in itself’:

The Agency agrees with this statement. However, that is an irrelevant argument as it seems infeasible to estimate what level of safety is achieved by each ATS provider and then agree on an adequate level of safety and, finally, get those providers who are below that level to come up to that level.

‘secondly,’:

This is not the case in this proposed regulation, given that each change has to be assured and part of that assurance is to establish the boundaries of the change, i.e. not just what is changed but what effect the changed part has on the rest of the system. If a part is not changed but affected by a change (the relationship between the parts is changed), then it is included in the change.

Safety Cases:

It is explained in GM (page 122) that a safety case is ‘a structured argument , supported by a body of evidence that...’ and because what the service providers have to provide is a complete, documented and valid argument to provide assurance of the change, the



requirement for a safety case is effectively a means.

Eurocontrol suggestion in points 1, 2, 3.

The spirit is accepted, but the Agency believes that it is more appropriate to promote those ideas in AMC and GM. The comment that the proposal only promotes the analysis of change-induced hazards seems unfounded. There is nothing in the text that restricts the assessment of positive contribution to safety of changes. The graph on page 187 makes that clear, and the description in GM1 ATS.OR.205(b)(4) about risk analysis and hazards and accidents does not lead to that conclusion. There is, however, a resistance in the service providers' community to assess the positive contribution of changes in safety. Following that, the introduction of this in AMC/GM rather than at IR level is recommended.

Please note that the proposal does not describe a timeline of steps to follow. The regulation does not describe processes and, hence, makes no requirements on when they occur.

comment

764

comment by: DGAC/DSAC - french NSA

The french NSA has three comments related to ATS.OR.205 :

- paragraph (a) (2) :

The term "safety criteria" is not defined before this paragraph, nor in the definition part. The reader only knows the meaning at the part "ATS.OR.210 Safety Criteria". It would be preferable to introduce it before.

- paragraph (b) (6) (ii) :

The word "and" at the end of the paragraph shall be deleted.

- paragraph (b) (7) :

We suggest to clarify, at least in the associated GM, the term "monitoring requirements" as it could be interpreted as indicators only and not as the whole means necessary to maintain the level of safety as needed (preventive actions for instance are include in these actions).

response

Partially accepted

The order the safety criteria are introduced does not seem to be important in the regulation.

Deletion of 'and' at the end is accepted.

The monitoring criteria (the name has been changed) are values, and the actions are embedded in the management system (requirement ATM/ANS.B.005(d)).

comment

916

comment by: AESA / DSANA



PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.1 <i>Draft Regulation (Draft EASA Opinion)</i> <i>Annex IV</i> SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS)</p>	<p>We wonder whether the "sufficient confidence" required by provision <i>ATS.OR.205 (a)(2)</i> is really <u>sufficient</u>.</p>	<p>We see this term as too vague and subjective.</p> <p>This could open the gate to divergence in the assessment of changes within one ANSP and/or one CA and the rest of ANSPs and/or CAs.</p> <p>We would suggest to develop AMC on the use of the concept of 'assurance level' in order to reduce the subjectiveness of this provision.</p> <p>We kindly refer EASA to our comments on GM2 ATM/ANS.OR.C.005(a)(2) and GM2 ATS.OR.(a)(2).</p>

response

Noted

Comments on AMC/GM will be responded to in the CRD associated with them. A considerable amount of time is needed to rework, amend and complete the AMC/GM in an appropriate and effective manner, and this cannot be done at this stage. Future work is planned to review the comments on the AMC/GM and complete the CRD in due time.

comment

1170

comment by: LfV

There need to be a clear definition of what is technical ATS services and what is CNS services, since the regulation differs between them.

What equipment is defined to be a part of the ATS functional system, and what equipment to be a part of the CNS functional system?

Should e.g. according to NPA 2014-13 a technical ATS Service Provider, providing services to another ATS Provider, produce a safety assessment or a safety support assessment?

Or will all equipment supporting the ATS functional system be considered CNS services, and the CNS-regulation apply?

response

Noted

The second interpretation seems to be the correct one; depending on what 'technical ATS service' means.



comment	1199	comment by: ENAIRE
	In our opinion, at least (b.2), identification of hazards, (b.4), risk analysis of the effects related to the change, and (b.5), risk evaluation, should be included in CNS safety support assessment.	
response	Not accepted	
	The commentator does not provide any rationale to support the proposal, and the Agency has provided extensive GM supporting the approach. In simple terms, they cannot assess the risks, so it is not sensible to impose these requirements on these service providers.	
comment	1279	comment by: European Transport Workers Federation - ETF
	Human resources are the only element of functional systems able to provide useful feedback to monitor the level of safety, after the introduction of a change to the system. For this reason ETF proposes to include in the IR ATS.OR.205 the paragraph (c) <i>“staff affected by the change shall be consulted during the safety assessment and assurance of changes to functional systems.”</i> ETF propose to include a GM to the ATS.OR.C.205 to describe the procedures of consultation and to identify the staff affected by the change, e.g. trade unions, staff representatives, etc.	
response	Not accepted	
	The Agency does agree to include requirements at the IR level to have the operational staff consulted during the safety assessment. The assessment has to be performed involving the operational staff; otherwise it is difficult, if not impossible, to gather robust evidence that provide enough confidence to approve the change.	

3. Proposed amendments — 3.1. Draft EASA Opinion — ANNEX IV — ATS.OR.210 Safety criteria

p. 39

comment	65	comment by: NATS National Air Traffic Services Limited
	ATS.OR.210 Page 39	
	It is considered that Points (b) and (c) provide the means by which point (a) should be implemented and therefore be recast as AMC.	
	Each instance of ATS should be replaced by air traffic services to comply with the convention used in the rule.	



	<p>Proposal: Points (b) and (c) recast as AMC to ATS.OR.210 as proposed in NATS Appendix A (document attached to comment number 25).</p>
response	<p>Partially accepted</p> <p>The idea of moving the elements in (b) is accepted. The criteria in (b)(1) have been moved to ATS.OR.210(a) as there was already overlap between the two provisions. We agree that following this, (b)(2) & (3) are converted to AMC material and, consequently, they have been moved. Point (c) is not accepted as AMC, as it defines the basis on which the safety criteria are valid.</p>
comment	<p>66 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>ATS.OR.210(b) Page 39</p> <p>It is noted that the proxy approach is missing from point (b) although it is discussed extensively in the GM.</p> <p>Proposal: Amend (b) in to add: “(3) proxies; and” as proposed in NATS Appendix A (document attached to Comment number 25)</p>
response	<p>Partially accepted</p> <p>The concept of proxies was present at the level of IR, but encapsulated in the term ‘others measures related to risks’. Proxies were not explicitly described at the level of the IR, but are defined in AMC1 ATS.OR.205(b) in points (d) and (e): ‘A proxy is some measurable property that can be used to represent the value of something else. In the safety assessment of functional systems, the value of a proxy may be used as a substitute for a value of risk,...’ Explanation can be found in GM1 ATS.OR.205(b)(3) & GM2 ATS.OR.205(b)(4).</p> <p>Proxies have been added explicitly to the AMC stemming from comment No 65.</p>
comment	<p>67 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>ATS.OR.210(b)(3) Page 39</p> <p>It is considered that point (b)(3) should refer to the <u>functional</u> system.</p> <p>Proposal: Amend (b)(3) to read the safety performance of the existing <u>functional</u> system or similar <u>functional</u> system elsewhere” as proposed in NATS Appendix A (document attached to comment number 25).</p>



response	Accepted The text will be amended when the AMC is published
comment	95 comment by: EUROCONTROL Safety Team The GM discusses at length the proxy approach but this is not included in the requirement. Recommend to add text in (b) (3) proxies; and.
response	Partially accepted Please see the response to comment No 66.
comment	290 comment by: DSNA DSNA suggests/proposes to keep (a) and to move in the AMC (b) and (c) which are too detailed and paraphrase the dedicated AMC. If this DSNA's comment is not accepted see next comments below on (b)(1), (b)(3) (b)(1): proposed text : “explicit quantitative <u>or qualitative</u> acceptable safety levels” to be consistent with AMC p160. (b)(3): proposed text : “the safety performance of the existing <u>functional system</u> or a similar system elsewhere”.
response	Partially accepted Please see the response to comment No 65. If the purpose of the comment is to introduce ‘qualitative’ safety levels, this is neither supported in the AMC nor in the IR. The evaluation of safety risks is advocated to be quantitative, despite the fact that it will have uncertainty associated with it. This may lead to the evaluation of risks using categorisations of scalar values. Categorisations of scalar values (e.g. from value ‘a’ to value ‘b’, the risk is estimated as ‘high’) are treated as ‘quantitative’. The interpretation of ‘qualitative’ being used in the IR/AMC/GM is equivalent to ‘subjective’ and it is not accepted. The use of the term ‘functional’ is accepted.
comment	368 comment by: Air Navigation Services of the Czech Republic We propose to add a new bullet for (b), (4) proxies; the use of proxies is extensive in the GM (also 2.4.5), yet it is not reflected in the IR itself.
response	Partially accepted



Please see the response to comment No 66. The provision is moved to AMC.

comment 384 comment by: *skyguide Corporate Regulation Management*

It is noted that the proxy approach is missing from point (b) although it is discussed extensively in the GM.

Amend (b) in to add: “(3) proxies; and” as proposed in Appendix A

response Partially accepted

Please see the response to comment No 66.

comment 391 comment by: *UK CAA*

Page No: 39

Paragraph No: AT.S.OR.210(b) Safety criteria

Comment: The UK CAA recommends - Insert new AT.S.OR.210(b)(4): ‘exceptionally, other measures as agreed with the competent authority’

Justification: The AT.S may not be able to specify the safety criteria with reference to one or more of the proposed measures (or at least may in certain circumstances not be able to *adequately* specify the safety criteria in accordance with the listed measures. The proposed text therefore presents the a degree of flexibility to the AT.S provider, subject to the agreement of the competent authority, to exceptionally present their arguments by other means.

Proposed Text:

(b) (4) exceptionally, other measures as agreed with the competent authority.

response Not accepted

Since the measure of safety is defined as safety risk and AT.S.OR.210(a) gives the flexibility of ‘other measures that relate to safety risk’ how does ‘other measures as agreed with the competent authority’ relate to safety? If it does not, why is a change with no relationship to safety to be allowed? The Agency believes that the phrase ‘other measures that relate to safety risk’ covers all potential measures and that any further detail should be in AMC.

comment 621 comment by: *EUROCONTROL*

AT.S.OR.210 (b) (2) – Page 39

Some guidance, or a usable list of standards and/or codes of practices which meet this requirement would be welcomed. EUROCONTROL assumes that not all standards and codes of practices that can be found on this topic are of the proper quality and therefore meet this requirement.

EUROCONTROL therefore proposes that some examples of accepted standards and/or codes



	of practices are added.
response	<p>Accepted</p> <p>The Agency agrees with the comment and the proposal. However, this comment has no impact on the IR. Comments on AMC/GM will be responded to in the CRD associated with them.</p>
comment	<p>623 comment by: EUROCONTROL</p> <p>ATS.OR.210 (a) Safety criteria - Page 39</p> <p>As there is neither AMC material, nor guidance or recognised standards (ED 125) on how an ANSP should define quantitative values of risk / quantitative acceptable levels of safety risk, EUROCONTROL presumes that any classification scheme currently defined and approved by the relevant NSA is still acceptable to meet this requirement.</p>
response	<p>Noted</p> <p>Risk is the severity of the consequences of an accident and the probability of its occurrence. The concept is simple enough and explained in GM1 ATS.OR.205(b)(4). The practical difficulty lies in evaluating it to a high degree of certainty, i.e. the risk bounds will be quite large. However, this has not prevented some service providers, like LVNL and NATS, from using it.</p> <p>Standards that calculate risks and follow the GM are presumed to be compliant.</p>
comment	<p>683 comment by: ROMATSA</p> <p>It is noted that the proxy approach is missing from point (b) although it is discussed extensively in the GM.</p> <p>Amend (b) in to add:“(3) proxies; and” as proposed in Appendix A.</p> <p>Supporting comment to summary issue: IR does not achieve the perceived intention of the rule.</p>
response	<p>Partially accepted</p> <p>Please see the response to comment No 66.</p>
comment	<p>760 comment by: CAA Norway</p> <p>ATS.OR.210 (b):</p> <p>CAA Norway would have expected proxies to be listed as one of the safety criteria mentioned in (b) since extensive GM have been provided on the topic.</p>



response Partially accepted
Please see the response to comment No 66.

comment 771 comment by: DGAC/DSAC - french NSA

The french NSA has only one comment related to ATS.OR.210 :

This article gives the ATS provider many possibilities for the safety criteria upon which the safety acceptability will be determined : quantitative acceptable levels of safety, other measures related to safety risk (proxies), standards, comparison to existing or similar systems, etc.

Even if "the ATS provider shall ensure that the safety criteria support the improvement of safety whenever reasonably practicable" (cf. (c) (2)), nothing prevents the provider to choose the more convenient criteria for its assessment, not taking into account the safety as a priority (comparative approach instead of absolute approach, proxy instead accepted safety risks levels, etc.). If this articles is kept unchanged, a GM (for CA and provider) must be provided, as a minimum, to promote the safety as main objective for the choice of safety criteria and, consequently, to give CAs some tools to question the choices made by the provider in this matter.

response Accepted

The objective for safety has been added in ATS.OR.210(b)(3) to ensure that the safety criteria do not introduce unacceptable risks.

comment 917 comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.1 <i>Draft Regulation (Draft EASA Opinion)</i> <i>Annex IV</i> SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS)	We don't fully understand the concept of ' <i>safety criteria</i> ' introduced by provision <i>ATS.OR.210</i> .	We wonder whether this provision will bring in fact more disharmony than harmony into the EU landscape.



response Noted

The Agency believes that this approach is an acceptable balance between the needs of the industry, including flexibility to assess changes, and the safety and harmonisation objectives pursued by the proposed regulation. It is not clear why the commentator believes it will bring disharmony. The IR narrows the current set of 'things' that can be used to claim adequate safety to those measures based on risk. This alone should improve harmony. Clearly, there is no intent to impose uniformity in the way the risk is measured. Therefore, providing that the measure used to claim safety is appropriately related to risk (see AMC1 ATS.OR.205(b)(d)), the use of that measure should be allowed.

comment 1112

comment by: *Belgocontrol*

The proxy approach is discussed at length in the GM, however this is not included in the requirement.

Recommend to add text in (b) (3) proxies; and.

response Partially accepted

Please see the response to comment No 66.

comment 1241

comment by: *Icetra*

ATS.OR.210

It is not clear what is meant by "other measures that relate to safety". This needs to be clarified.

The use of "safety criteria" as partly a replacement for "safety requirement" as per current regulations is not supported. It has been found very useful to require the ANSP to define safety requirements and require him to distinguish between risk mitigations that have to be in place in order for the system to be sufficiently safe, and other risk mitigations that are not. Safety requirement is further a good term that denotes that which is required and should be retained.

response Partially accepted

This has been clarified by the clause "other measures must relate to safety risk". The definition of them can be found in AMC1 ATS.OR.205(b) and the new AMC created from ATS.OR.210(b). In addition to that, proxies are further explained in GM1 ATS.OR.205(b)(3).

No further explanation is provided for the other suggested measures. GM will be provided in the 2nd NPA.



This proposal does not replace safety requirements by safety criteria. Safety requirements are dealt with in AMC/GM. They are considered to be at too low a level to be included in the IR. Instead, the concept of 'safety criteria' is introduced, which can be thought of as the highest-level safety requirements that are related to the implementation of the change. And the objective for safety of a change (i.e. unacceptable risk is not introduced) being the highest level safety requirement related to the change as a whole.

comment 1290

comment by: EUROCONTROL

Annex IV**Subpart A****ATS.OR.210 (a) Safety criteria - Page 39**

The safety criteria should not only be specific and verifiable but also appropriate and correct for the operational environment specified and for the scope of the safety assessment / safety case.

It is suggested to refine the sentence as follows: "(...) appropriate, correct, specific and verifiable safety criteria (...)"

ATS.OR.210 (c)(2)

The following wording is not understood:

"(...) support the improvement of safety whenever reasonably practicable".

While obviously welcoming that the NPA acknowledges that the primary purpose of ATM is to prevent accidents, not merely to avoid causing them (which should be more explicitly acknowledged in ATS.OR.205 (b)), the wording of (c) (2) reads strangely. Indeed if a change is safety-driven (e.g. Conformance monitoring for the airport surface, automation to support ATC conflict identification/resolution, etc.), the safety criteria should not only "(...) support the improvement of safety whenever reasonably practicable" but specify a net safety improvement. Similarly if a change should end-up with a least a neutral safety level while there is an increase in traffic, the safety criteria should explicitly mention the need to boost the safety performance for the change.

EUROCONTROL suggests to refine the wording accordingly.

response Partially accepted

These attributes are covered in ATS.OR.205(a)(2): '...the safety criteria are valid', and adding more criteria here would overlap with that provision. The properties identified in the comment are part of the validity of each criterion.

The idea behind this clause (c)(2) is tactical 'alarp', i.e. no matter what the objective for safety is, if during the change development it is seen that the criteria can be changed so as to improve safety, then they should be.

We agree that this point, i.e. the improvement of safety, is not explicitly made in the GM. This will be improved as part of the 2nd NPA.



3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to Cover Regulation — GM2
Article 2 (2) Definitions

p. 40-44

comment	<p>80 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>GM2 Article (2) Definitions.</p> <p>There should be no need for several pages of explanation about definitions. The text in this section also refers to internal structures and management systems and should be deleted as it is not relevant. If this much explanation is required to understand a definition then it follows that the definition must be flawed. We recommend deleting the guidance</p>
response	<p>Partially accepted</p> <p>The guidance is not an elaboration on the definition, but on the implications of the definition and interactions of functional services of service providers. In any case, the material has been reallocated and it is not associated with a particular definition, but with a section that expands on the functional system concept and the organisational model of service providers. See section 2.1 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities.</p>
comment	<p>81 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>The definition of functional system Annex I (35) does not support the description in this GM. According to the definition the functional system performs a function within the context of ATM/ANS whereas the GM states that services are produced by a functional system.</p> <p>The GM states that “a service provider delivers ATM/ANS services” and yet the scope of service providers and ATM/ANS is different (see earlier comment on definitions). ATM/ANS is used throughout the GM.</p> <p>At (b) there is a reference to GM1 Article 2(2) Definitions which is not found.</p> <p>The figure at (d) is confusing insofar as it includes service/organization/operational (functional) system but not service provider and the introductory text claims that this is a complete representation of a functional system.</p> <p>Footnote 18 attempts to clarify the distinction between function and services however it is considered by NATS that the view of services in 216/2008 should prevail.</p> <p>There appears to be GM totally unrelated to service provider definition. For example (g), (h) (partly), (i) appear related to the service providers’ MS and if thought necessary the GM should be moved to a more suitable location.</p> <p>Point (j) is totally incomprehensible and needs to be rewritten or deleted.</p> <p>The inconsistencies and contradictions in this GM make it unsuitable for its intended purpose.</p>
response	<p>Partially accepted</p>



A functional system performs a function and delivers a service. There is no contradiction between the definition in Annex I and the model used in the guidance material. As indicated in footnote 18, the term used throughout this GM is 'service' for simplicity. Article 8b(2) of Regulation EC (No) 216/2008 makes it clear that ATM/ANS providers provide services. This IR takes the view that these services are provided by the service provider's functional system as described in the GM. The distinction between function and services is not present in Regulation EC (No) 216/2008 and so the GM provides a model of a functional system where the distinction is clear: A service provider functional system delivers services to the outside world; this is its function.

The scope of service providers is, as suggested by the commentator, ATM/ANS and other ATM network functions, but the GM does not distinguish between ATM/ANS services and other ATM network functions and it uses the term ATM/ANS as a shorthand.

The figure is fixed now.

The reference to GM1 Article 2(2) Definitions was a typo. It has been amended now and it points to the new Section 2.1.1 of Appendix I to GM1 to Article 5 & Article 6(c), where the functional system model is introduced.

This GM relates to the organisation of service providers and has been moved to a different location, so that now it does not relate directly to the definition of functional system.

Point (j) has been redrafted and it is hopefully more comprehensible now.

comment

96

comment by: EUROCONTROL Safety Team

The GM is not consistent with the IR:

1. The definition of functional system in Annex I (35) states that the functional system performs a function within the context of ATM/ANS. However, the GM states that services are produced by a functional system.
2. GM states that *a service provider delivers ATM/ANS services* but the scope of service providers and ATM/ANS is different.
3. ATM/ANS is used throughout the GM.

response

Not accepted

Please see the response to comment No 81.

comment

97

comment by: EUROCONTROL Safety Team

GM2 Article 2 (2)(b)

Reference is made to *GM1 Article 2(2) Definitions* which is not found.



response	<p>Accepted</p> <p>The reference to GM1 Article 2(2) Definitions was a typo. It has been amended now and it points to the new Section 2.1.1 of Appendix I to GM1 to Article 5 & Article 6(c), where the functional system model is introduced.</p>
comment	<p>98 comment by: EUROCONTROL Safety Team</p> <p>GM2 Article 2 (2)(d) It is claimed that this figure is a complete representation of a functional system. However, it includes service/organisation/operational (functional) system but not service provider.</p>
response	<p>Accepted</p> <p>The figure has been amended.</p>
comment	<p>99 comment by: EUROCONTROL Safety Team</p> <p>GM2 Article 2 Footnote 18 The distinction between function and services is already found in EC 216/2008. Consequently this view should prevail and Footnote 18 should refer to this regulation.</p>
response	<p>Not accepted</p> <p>Please see the response to comment No 81.</p>
comment	<p>100 comment by: EUROCONTROL Safety Team</p> <p>GM2 Article 2 (2)(g), (h), (i) These paragraphs do not address service provider definition. In fact they seem to address more the management system. Recommend that these paragraphs are removed or, at least, relocated to a more suitable place in the document, if they are considered to be absolutely essential.</p>
response	<p>Not accepted</p> <p>Please see the response to comment No 81.</p>
comment	<p>101 comment by: EUROCONTROL Safety Team</p> <p>GM2 Article 2 (2)(j)</p>



	<p>Very difficult to understand, to say the least. Recommend that this paragraph is deleted or, at least, re-written if considered absolutely essential.</p>
response	<p>Not accepted</p> <p>Please see the response to comment No 81. The paragraph has been amended.</p>
comment	<p>127 comment by: ENAIRE</p> <p>After reading this NPA, in our case, we have neither a clear view of the different means of compliance with the rules, nor the guidance material available to achieve it.</p>
response	<p>Noted</p> <p>Without more explicit indication, it is not possible to identify what is missing or could be explained more clearly.</p>
comment	<p>129 comment by: ENAIRE</p> <p>AMCs included in this NPA are far from precisely describing a method/way to implement a requirement. AMC should describe clearly steps to be performed.</p>
response	<p>Not accepted</p> <p>The AMC does not necessarily describe a method. Without more explicit indication, it is not possible to identify what is missing or could be explained more clearly.</p>
comment	<p>130 comment by: ENAIRE</p> <p>There are missing AMCs, what contributes to have a confused image/view of the whole NPA.</p>
response	<p>Noted</p> <p>Without more explicit indication, it is not possible to identify what is missing. The AMC are means to comply with the regulation and they are not necessary in all situations.</p>
comment	<p>291 comment by: DSNA</p> <p><u>DSNA question</u> : Could an organization which is multi-service-provider apply the regulations as an AIS provider, then as a CNS provider or ATS ? An organization multi-service-provider should have a certification for each type of service</p>



provided?

An organization multi-service-provider should have specific structures according to the services it provides?

The definition of functional system Annex I (35) does not support the description in this GM. According to the definition the functional system performs a function within the context of ATM/ANS whereas the GM states that services are produced by a functional system.

“a legal basis” in a guidance material ?

(b) : “range of the scope”, there is a reference to GM1 Article 2(2) Definition, which is not found ?

Figures are confusing and over complicated.

Footnote 18 attempts to clarify the distinction between function and services, the goal is missed.

(j) is totally incomprehensible and needs to be rewritten or deleted.

The inconsistencies and contradictions in this GM make it unsuitable for its intended purpose. Suggest to rephrase the GM to manageable proportions and size in coherence with the rest of the IR/AMC/GM.

response

Partially accepted

1. A multi-service provider can provide a range of services. It does not do so sequentially but all together. The certificate for a multi-service provider covers the scope of the services provided. Separate certificates are unnecessary. The organisation does not need separate structures provided it can demonstrate that it meets all the requirements for all the services it provides. Guidance on management structures, including the necessary isolation between structures that are regulated by the IR and those that are not can be found in (g) (h) & (i)
2. Yes, the GM describes the way service providers may be organised and explains the legal basis for the regulation.
3. The figures describe a range of organisations many of which already exist. It is difficult to understand in what way they are ‘over complicated’ without more specific comments.
4. It is not understood in what way the goal of footnote 18 is missed.



1.5. (j) has been redrafted.

comment

392

comment by: UK CAA

Page No: 40

Paragraph No: GM2 Article 2 (2) Definitions (d)

Comment: The symbol used to denote “Operational Context” here and in other diagrams gives no indication as to what an Operational Context is.

There needs to be a clear definition of “Operational Context”, or else it should be removed from the diagrams (it is not mentioned in the supporting text).

Justification: Clarity.

response

Not accepted

Operational context is described in the GM before this: [Section 2.1.1 of Appendix 1 to GM1 to Article 5 Service Providers and Article 6\(2\) Oversight capabilities.](#)

comment

465

comment by: skyguide Corporate Regulation Management

The definition of functional system Annex I (35) does not support the description in this GM. The definition of *Function* and *Services* are unclear since the NPA does not provide how they relate to each other.

According to the definition the functional system performs a function within the context of ATM/ANS whereas the GM states that services are produced by a functional system.

The GM states that “a service provider delivers ATM/ANS services” and yet the scope of service providers and ATM/ANS is different (see earlier comment on definitions). ATM/ANS is used throughout the GM.

At (b) there is a reference to GM1 Article 2(2) Definitions which is not found.

The figure at (d) is confusing insofar as it includes service/organization/operational (functional) system but not service provider and the introductory text claims that this is a complete representation of a functional system.

Footnote 18 attempts to clarify the distinction between function and services however it is considered that the view of services in 216/2008 should prevail.

There appears to be GM totally unrelated to service provider definition. For example (g), (h) (partly), (i) appear related to the service providers MS and if thought necessary the GM should be moved to a more suitable location.

Point (j) is totally incomprehensible and needs to be rewritten or deleted.

The inconsistencies and contradictions in this GM make it unsuitable for its intended purpose.

response

Not accepted



[Please see the response to comment No 81.](#)

comment

619

comment by: *DFS Deutsche Flugsicherung GmbH*

The definition of "functional system" Annex I (35) does not support the description in this GM. According to the definition the "functional system" performs a function within the context of ATM/ANS whereas the GM states that services are produced by a "functional system". The GM states that "a service provider delivers ATM/ANS services" and yet the scope of service providers and ATM/ANS is different (see earlier comment on definitions). ATM/ANS is used throughout the GM. At (b) there is a reference to GM1 Article 2(2) Definitions which is not found. The figure at (d) is confusing insofar as it includes service/organization/operational (functional) system but not service provider and the introductory text claims that this is a complete representation of a functional system. Footnote 18 attempts to clarify the distinction between function and services however it is considered that the view of services in 216/2008 should prevail. There appears to be GM totally unrelated to service provider definition. For example (g), (h) (partly), (i) appear related to the service providers MS and if thought necessary the GM should be moved to a more suitable location. Point (j) is totally incomprehensible and needs to be rewritten or deleted. The inconsistencies and contradictions in this GM make it confusing and not useful for its intended purpose.

Reference to high level comment "c.v"

response

[Partially accepted](#)

[Please see the response to comment No 81.](#)

comment

620

comment by: *DFS Deutsche Flugsicherung GmbH*

(h)

How is „managed independently“ defined? Does it have to be managed independently in every way or just with regard to safety?

Please add definition or explanation.

Reference to high level comment "c.v"

response

[Partially accepted](#)

[As the phrase uses normal English and it is not a technical term, it is not defined.](#)

[The organisation must be managed in such a way that the management of the non-ATM/ANS parts does not interfere with the compliance of the ATM/ANS part with these regulations.](#)

[The GM has been clarified in this respect in paragraph \(j\).](#)



comment	<p data-bbox="359 271 411 309">642</p> <p data-bbox="1227 271 1498 309" style="text-align: right;">comment by: <i>CANSO</i></p> <p data-bbox="359 360 571 398">GM2 Article 2 (2)</p> <p data-bbox="359 405 1498 517">The definition of functional system Annex I (35) does not support the description in this GM. According to the definition the functional system performs a function within the context of ATM/ANS whereas the GM states that services are produced by a functional system.</p> <p data-bbox="359 524 1498 636">The GM states that “a service provider delivers ATM/ANS services” and yet the scope of service providers and ATM/ANS is different (see earlier comment on definitions). ATM/ANS is used throughout the GM.</p> <p data-bbox="359 642 1278 680">At (b) there is a reference to GM1 Article 2(2) Definitions which is not found.</p> <p data-bbox="359 687 1498 799">The figure at (d) is confusing insofar as it includes service/organization/operational (functional) system but not service provider and the introductory text claims that this is a complete representation of a functional system.</p> <p data-bbox="359 806 1498 889">Footnote 18 attempts to clarify the distinction between function and services however it is considered that the view of services in 216/2008 should prevail.</p> <p data-bbox="359 896 1498 1008">There appears to be GM totally unrelated to service provider definition. For example (g), (h) (partly), (i) appear related to the service providers MS and if thought necessary the GM should be moved to a more suitable location.</p> <p data-bbox="359 1014 1246 1052">Point (j) is totally incomprehensible and needs to be rewritten or deleted.</p> <p data-bbox="359 1059 1498 1135">The inconsistencies and contradictions in this GM make it unsuitable for its intended purpose.</p>
response	<p data-bbox="359 1153 576 1191">Partially accepted</p> <p data-bbox="359 1227 890 1265">Please see the response to comment No 81.</p>
comment	<p data-bbox="359 1355 411 1393">692</p> <p data-bbox="1187 1355 1498 1393" style="text-align: right;">comment by: <i>ROMATSA</i></p> <p data-bbox="359 1444 571 1482">GM2 Article 2 (2)</p> <p data-bbox="359 1489 1498 1601">The definition of functional system Annex I (35) does not support the description in this GM. According to the definition the functional system performs a function within the context of ATM/ANS whereas the GM states that services are produced by a functional system.</p> <p data-bbox="359 1608 1498 1720">The GM states that “a service provider delivers ATM/ANS services” and yet the scope of service providers and ATM/ANS is different (see earlier comment on definitions). ATM/ANS is used throughout the GM.</p> <p data-bbox="359 1727 1278 1765">At (b) there is a reference to GM1 Article 2(2) Definitions which is not found.</p> <p data-bbox="359 1771 1498 1883">The figure at (d) is confusing insofar as it includes service/organization/operational (functional) system but not service provider and the introductory text claims that this is a complete representation of a functional system.</p> <p data-bbox="359 1890 1498 1973">Footnote 18 attempts to clarify the distinction between function and services however it is considered that the view of services in 216/2008 should prevail.</p> <p data-bbox="359 1980 1498 2018">There appears to be GM totally unrelated to service provider definition. For example (g), (h)</p>



	<p>(partly), (i) appear related to the service providers MS and if thought necessary the GM should be moved to a more suitable location. Point (j) is totally incomprehensible and needs to be rewritten or deleted. The inconsistencies and contradictions in this GM make it unsuitable for its intended purpose.</p> <p>Specific comment to summary issue:Missing, incorrect and more focused Guidance material.</p>
response	<p>Partially accepted</p> <p>Please see the response to comment No 81.</p>
comment	<p>848 comment by: <i>DGAC/DSAC - french NSA</i></p> <p>This article refers to GM1 Article 2 (2) Definition not found in this NPA nor in CRD to NPA 2013-08.</p>
response	<p>Accepted</p> <p>The reference to GM1 Article 2(2) Definitions was a typo. It has now been amended and it points to the new Section 2.1.1 of Appendix I to GM1 to Article 5 & Article 6(c), where the functional system model is introduced.</p>
comment	<p>1114 comment by: <i>Belgocontrol</i></p> <p>GM2 Article 2 (2)(b) Reference to <i>GM1 Article 2(2) Definitions</i>: not found.</p>
response	<p>Accepted</p> <p>The reference to GM1 Article 2(2) Definitions was a typo. It has been now amended and it points to the new Section 2.1.1 of Appendix I to GM1 to Article 5 & Article 6(c), where the functional system model is introduced.</p>
comment	<p>1115 comment by: <i>Belgocontrol</i></p> <p>GM2 Article 2 (2)(j) Very difficult to understand. <u>Recommend</u> that this paragraph re-written or even deleted</p>
response	<p>Accepted</p>



[The paragraph has been redrafted and hopefully is clearer now.](#)

comment 1187

comment by: *Avinor ANS*

The definition of functional system Annex I (35) does not support the description in this GM. According to the definition the functional system performs a function within the context of ATM/ANS whereas the GM states that services are produced by a functional system. The GM states that “a service provider delivers ATM/ANS services” and yet the scope of service providers and ATM/ANS is different (see earlier comment on definitions). ATM/ANS is used throughout the GM.

At (b) there is a reference to GM1 Article 2(2) Definitions which is not found.

The figure at (d) is confusing insofar as it includes service/organization/operational (functional) system but not service provider and the introductory text claims that this is a complete representation of a functional system.

Footnote 18 attempts to clarify the distinction between function and services however it is considered that the view of services in 216/2008 should prevail.

There appears to be GM totally unrelated to service provider definition. For example (g), (h) (partly), (i) appear related to the service providers MS and if thought necessary the GM should be moved to a more suitable location.

Point (j) is totally incomprehensible and needs to be rewritten or deleted.

The inconsistencies and contradictions in this GM make it unsuitable for its intended purpose.

response [Partially accepted](#)

[Please see the response to comment No 81.](#)

comment 1204

comment by: *ENAIRE*

Disagree with the diagram because navigation service is not delivered to ATS; it is delivered to A/C directly.

response [Not accepted](#)

[The navigation information is delivered to the aircraft, but the navigation service is used by the ATS, and, in that sense, the service is delivered to ATS. Please see explanation in section 2.3 of Appendix 1 to GM1 to Article 5 Service Providers and Article 6\(2\) Oversight capabilities.](#)

comment 1291

comment by: *EUROCONTROL*



Section 3.2**AMC/GM to Cover Regulation****GM2 Article 2 (2) Definitions - Page 40****SERVICE PROVIDERS**

It is appreciated that GM2 Article 2 (2) Definitions (b) acknowledges that ATM/ANS services are needed to enable aircraft to travel safely. As a result, section 3.1 should make more explicit that the combination of a “success”- and “failure”-based approach is required. The reading tends to make think that only the latter is within the scope of the safety assessment. It is suggested to make appropriate adjustments in section 3.1 to ensure that safety assessments explicitly demonstrate that the right functionality and performance is embedded within the design of the change to deliver the maximum positive contribution to safety (which might or might not be a net safety benefit depending on the performance driving the need for the change).

response

Partially accepted

It is accepted that the GM does not make it clear that the IR supports a combination of success- and failure-based assessments. The approach forms part of the guidance on the use of proxies in GM2 ATS.OR.205(b)(4) and the use of mitigations in the bow tie model (in section 5.1 of Appendix 1 to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities) implies such an approach; however, it is neither explicitly stated nor appropriately described. This will be rectified in the 2nd NPA 2, although it is unlikely to take the form suggested in the comment.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX I — Definitions of terms used in ANNEXES II to XIII — GM1 Annex I Definitions(35)

p. 45-47

comment

82

comment by: *NATS National Air Traffic Services Limited*

GM1 Annex 1 Definitions – it is not appropriate to define definitions in the GM. These should be deleted or placed into IR

response

Accepted

The Agency agrees that when the term is used in the IR, the definition should be given at the IR level. However, the use of definitions in GM is acceptable, as far as the term is not used in the IR.

In any case, the definitions of this GM have been removed as SW and HW have been explicitly included in the element ‘equipment’ as part of the functional system in the definition of functional system at the IR level. Thus, the set of definitions is not needed.



comment	<p data-bbox="359 235 391 280">83</p> <p data-bbox="821 235 1498 280" style="text-align: right;">comment by: <i>NATS National Air Traffic Services Limited</i></p> <p data-bbox="359 324 758 369">GM1 Annex I Definitions (35)(a)</p> <p data-bbox="359 369 1498 649">The term “computer” is only found in GM. It is used in the software definition which is confusing especially if you substitute the definition of “computer” into the software definition and “software” into the computer definition. For example at (a)(4) “‘Software’ is a constituent part of a (computer) hardware constituent that provides the operational environment for the software and contains the software itself.” It is understood that the use of a definition is “shorthand” and the definition text can be substituted at any time for the definition and the sentence should still make sense.</p> <p data-bbox="359 649 1498 772">Given that (1) defines equipment in terms of hardware and (2) defines hardware itself then software appears to be left out of the definition of a functional system (definition of functional system includes equipment).</p> <p data-bbox="359 772 1498 862">Whilst it is possible for equipment (without software, as is implied by the definitions) to exhibit behavior is this what is intended?</p> <p data-bbox="359 862 1498 952">Given the definitions then software is the behavior emerging from the computer whereas hardware is the behavior emerging from the equipment. This is confusing.</p>
response	<p data-bbox="359 963 438 996">Noted</p> <p data-bbox="359 1030 1498 1153">The definitions of this GM have been removed as SW and HW have been explicitly included in the element ‘equipment’ as part of the functional system in the definition of functional system at the IR level. Thus, the set of definitions is not needed.</p>
comment	<p data-bbox="359 1243 406 1276">292</p> <p data-bbox="1244 1243 1498 1276" style="text-align: right;">comment by: <i>DSNA</i></p> <p data-bbox="359 1332 1268 1366">The definition of equipment is overcomplicated and difficult to understand.</p> <p data-bbox="359 1411 1498 1489">For DSNA, “equipment” is a part of the functional system which includes hardware and software.</p> <p data-bbox="359 1534 1498 1612">The definition of context is not clear and this affects the rest of the document, and the examples in (e)(2) are not helpful (e.g wearther in an airspace ...)</p> <p data-bbox="359 1657 869 1691">The figure page 46 cannot be understood.</p> <p data-bbox="359 1736 901 1769">(k) is over complicated. Suggest to rephrase.</p>
response	<p data-bbox="359 1814 582 1848">Partially accepted</p> <p data-bbox="359 1881 1498 1993">The definitions of this GM have been removed as SW and HW have been explicitly included in the element ‘equipment’ as part of the functional system in the definition of functional system at the IR level. Thus, the set of definitions is not needed.</p>



comment	<p data-bbox="363 271 411 309">393</p> <p data-bbox="1225 271 1498 309" style="text-align: right;">comment by: UK CAA</p> <p data-bbox="363 360 507 398">Page No: 45</p> <p data-bbox="363 405 1385 443">Paragraph No: AMC/GM to ANNEX I — Definitions of terms used in ANNEXES II to XIII</p> <p data-bbox="363 450 1498 734">Comment: The UK CAA recommends that the definitions are included in the IR not the GM. Five of the proposed definitions refer to words contained in the proposed IR, therefore should be incorporated in the IR and not supporting GM. The sixth ('computer programmes') appears once in the proposed GM (see page 145/230 'GM1 ATM/ANS.OR.C.005(b)(1)(iv) & ATS.OR.205 (b)(1)(iv) General') and rather than introduce the term within the IR we suggest that it is replaced by the single use of the term with another example that does not require definition (or is already defined).</p> <p data-bbox="363 741 1498 808">Justification: Inappropriate placing of definitions: definitions are binding not advisory, therefore must be incorporated into IR not GM</p> <p data-bbox="363 815 1034 853">Proposed Text: Move proposed definitions to IR Annex I</p>
response	<p data-bbox="363 875 523 913">Not accepted</p> <p data-bbox="363 943 890 981">Please see the response to comment No 82.</p>
comment	<p data-bbox="363 1055 411 1093">394</p> <p data-bbox="1225 1055 1498 1093" style="text-align: right;">comment by: UK CAA</p> <p data-bbox="363 1167 507 1205">Page No: 45</p> <p data-bbox="363 1211 1225 1249">Paragraph No: GM1 Annex I Definitions(35) FUNCTIONAL SYSTEM (a) (1)</p> <p data-bbox="363 1256 1498 1413">Comment: This section does not seem to provide a satisfactory definition of the parts of an equipment. No rationale is given for treating a 'cover' as different from 'hardware'. If 'cover' is required, why not 'strut', 'mounting pillar', and other hardware items that are necessary for a physical assembly, but only contribute to the physical properties of the assembly?</p> <p data-bbox="363 1420 608 1458">Justification: Clarity.</p>
response	<p data-bbox="363 1464 443 1503">Noted</p> <p data-bbox="363 1532 890 1570">Please see the response to comment No 82.</p>
comment	<p data-bbox="363 1644 411 1682">395</p> <p data-bbox="1225 1644 1498 1682" style="text-align: right;">comment by: UK CAA</p> <p data-bbox="363 1756 507 1794">Page No: 45</p> <p data-bbox="363 1800 1225 1839">Paragraph No: GM1 Annex I Definitions(35) FUNCTIONAL SYSTEM (a) (4)</p> <p data-bbox="363 1845 1498 2002">Comment: The footnote does not adequately explain why this statement supports the conclusion in footnote 25. It is particularly unclear what the first word of the footnote refers to when it says "It". The reasoning seems to depend on the precise meaning of the term 'constituent part', which is not defined here.</p> <p data-bbox="363 2009 608 2047">Justification: Clarity.</p>



response

[Noted](#)[Please see the response to comment No 82.](#)

comment

401

comment by: UK CAA

Page No: 45**Paragraph No:** AMC/GM to ANNEX I — Definitions of terms used in ANNEXES II to XIII**Comment:** ‘Computer programmes’: the accepted spelling of the word ‘programmes’ is, in this context, ‘programs’**Justification:** Correct spelling of terminology

response

[Noted](#)[The working language of the Agency is British English. In any case, this part of the GM has been removed. Please see the response to comment No 82](#)

comment

402

comment by: UK CAA

Page No: 46**Paragraph No:** GM1 Annex I Definitions(35) FUNCTIONAL SYSTEM (a) (6)**Comment:** The figure below (6) shows several items whose definition is not given locally. UK CAA recommends that cross references are given, so that the relationships can be properly understood.**Justification:** Clarity.

response

[Noted](#)[In any case, this part of the GM has been removed. Please see the response to comment No 82.](#)

comment

403

comment by: UK CAA

Page No: 46**Paragraph No:** GM1 Annex I Definitions(35) FUNCTIONAL SYSTEM (a) (6)**Comment:** The UK CAA recommends that cross references are given to the definition of ‘environment’ and ‘physical environment’, so that the relationships can be properly understood.**Justification:** Clarity.

response

[Noted](#)

In any case, this part of the GM has been removed. Please see the response to comment No 82.

comment

629

comment by: EUROCONTROL

GM1 Annex I Definitions (35) – page 45

FUNCTIONAL SYSTEM

EUROCONTROL finds that the definitions given to computer in (a)(3), software in (a)(4) and computer programmes in (a)(5) are too limited.

For instance, software also includes the requirements and design aspects which should fall under the safety management elements of an ATM/ANS functional system.

Moreover, the human element and procedures should be further developed like for the equipment in (a)(1).

Finally, the relevant interactions between the various elements of a functional system should also be addressed.

response

Partially accepted

The definitions are no longer considered necessary. Please see the response to comment No 82.

comment

704

comment by: DFS Deutsche Flugsicherung GmbH

Definitions contradicting: the definition of "equipment" on page 45 does not contain "software", only indirectly as part of the functional system; but on page 46 "equipment" does contain "software (as sub-part of "hardware" which is not going along the understanding taught at universities) ((applies to the rest of the document as well; e.g. page 47 GM1 Annex I Definitions (35) (b)))

Reference to high level comment "c.v"

response

Noted

In any case, this part of the GM has been removed. Please see the response to comment No 82.

comment

761

comment by: ENAIRE

GM1 Annex I Definitions(35): It is not clear the meaning of "Cover" and "Framework". What is the reason to eliminate the Human Machine Interface? Why is the "Software" included in "Computer" and "Hardware"?

response

Noted



In any case, this part of the GM has been removed. Please see the response to comment No 82.

comment 918

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.2. Draft Acceptable Means of Compliance and Guidance Material (Draft EASA Decision) GM1 Annex I Definitions(35)</p>	<p>These definitions should be included within <i>Annex I "Definitions"</i> of the Opinion instead of publishing them as GM to the functional system as they are important enough to deserve a place at regulation level.</p>	<p>'Equipment', 'hardware', 'software',... are important terms which should be treated within the regulation itself as it should be clear what is the full scope of the regulation.</p> <p>The regulation itself should be enough to know what is affected by it.</p>

response Partially accepted

In any case, this part of the GM has been removed. Please see the response to comment No 82.

comment 1158

comment by: Hugues BONNIN

The decomposition of a functional system into a tree of elements, is a limitative view of the technical systems.

Indeed, it supposes that the software is included in a computer, which is included in a hardware, which is included in an equipment. Nowadays, these elements are more and more not included into each other : equipment can be standardized servers, which have the ability to execute one or another software, depending of global load balancing algorithm ; software can be executed on multiple computers, with parallelized subtasks ; software is not really included in one computer, at least it depends on its state (i.e. running as active, running as passive, dormant, etc). This "desincluded" vision is even more true in the context of "virtualization technologies" and "cloud computing technologies".

So in the perspective of a more general view of the functional systems, it is suggested to present "hardware" and "software(s)" at the same level, included and just below "equipment" ; and suppressing the term computer, which seems not to have an added value.



The definitions must be changed consistently :
 'software' is a set of programs and configuration data, which provide an emerging behaviour of an equipment, when executing on hardware connected to or included in that equipment.
 'computer' => suppress
 'computer programs' (or 'programs' or 'software programs') : are sequences of instructions written to perform specified tasks when executed on compatible hardware.

response [Noted](#)

[In any case, this part of the GM has been removed. Please see the response to comment No 82.](#)

comment

1205

comment by: *ENAIRE*

From our view, these definitions are extremely wide and imprecise. Something more delimited is expected from GM.

response

[Partially accepted](#)

[In any case, this part of the GM has been removed. Please see the response to comment No 82.](#)

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX I — Definitions of terms used in ANNEXES II to XIII — GM2 Annex I Definitions(35)

p. 47-50

comment

84

comment by: *NATS National Air Traffic Services Limited*

GM1 Annex I Definitions (35)(c)

Unlike (b) which refers to a computer which, by definition, contains software, (c) asserts that the hardware including its contained software is applicable; however by definition equipment includes hardware but not software.

response

[Partially accepted](#)

[Please see the response to comment No 82.](#)

comment

85

comment by: *NATS National Air Traffic Services Limited*

GM2 Annex I Definitions(35)(f)

This GM is confusing as GM2 Article 2 (2) (d) claims to portray a complete representation of a



functional system and the notion of a functional system model is introduced here which appears to extend to include the aircraft. When the term “functional system” is used in the rule can it be assumed that the definition prevails and it is not meant to be the functional system model? At (f) Figure 1 is titled “The functional system model” yet “The System” appears to be the content of the Figure. Which is it?

response [Partially accepted](#)

There are two functional systems depicted in the figure, both have a circle around them, and they do not include the aircraft. The more general system referred in the figure is ‘the system of interest’, i.e. the air traffic system, as explained in the text. The title of the figure has been updated to indicate that the functional system is depicted within a more general ‘system’ of interest.

comment

86

comment by: *NATS National Air Traffic Services Limited*

GM2 Annex I Definitions(35)(f)

It is claimed that “a complete representation of the system...” is shown in Figure 1 and yet footnote 30 (which is associated with this text) states “but is not actually complete”- which is true?

response [Accepted](#)

Wording in the footnote was changed from ‘not actually complete’ to ‘not actually the most complex one’.

comment

87

comment by: *NATS National Air Traffic Services Limited*

GM2 Annex I Definitions(35)(g)

Figure 2 is a simplified functional system model and is very similar to GM2 Article 2 (2) (d). Is one meant to be the functional system and the other the functional system model? If so what is the difference?

response [Noted](#)

Both figures are the representation of a functional system model. It is not intended to be two different representations. The word ‘model’ is not systematically used throughout the GM, but every time the functional system is represented, it corresponds to the model used in the GM. With the current structure of the GM, it is clearer that in this section the model of a functional system is presented, and used later in the Regulation.

comment

405

comment by: *UK CAA*



	<p>Page No: 47 Paragraph No: GM1 Annex I Definitions(35) FUNCTIONAL SYSTEM (b) Comment: Text can be clarified. Justification: Clarity. Proposed Text: Suggest start the paragraph with “This regulation does not refer to assurance of ‘Hardware’ and ‘Software’ because ...” or</p>
response	<p>Noted</p> <p>In any case, this part of the GM has been removed. Please see the response to comment No 82.</p>
comment	<p>406 comment by: UK CAA</p> <p>Page No: 47 Paragraph No: GM1 Annex I Definitions(35) FUNCTIONAL SYSTEM (c) Comment: It is the UK CAA’s view that it is insufficient to only denote this concept as guidance. Either the rule text or the AMC must make this principle clear, and set associated mandatory requirements for the assurance case arguments and evidence, and for the CA’s review of them. Justification: Clarity of requirement. If not clearly mandated, SPs and CAs will reduce the effort and expertise applied to assurance of the hardware and software, making only very high level arguments.</p>
response	<p>Partially accepted</p> <p>Please see the response to comment No 82. With the current definition of functional system, it is clear that SW and HW are part of the functional system, and any requirement concerning equipment will necessitate to cover all constituents parts of the equipment; otherwise, the service provider will most likely not be able to produce the evidence for a convincing argument.</p>
comment	<p>407 comment by: UK CAA</p> <p>Page No: 48 Paragraph No: GM2 Annex I Definitions(35) FUNCTIONAL SYSTEM (f) Figure 1 Comment: The diagram is inconsistent in the way it represents context. There are three different representations – the operational context on the left and top is shown by bold lines across the service, on the right it is a large shaded box, and in the middle ‘FS Context’ appears to be represented by the edge of a circle. This last representation is particularly unclear. Justification: Clarity.</p>
response	<p>Noted</p>



The figure should be read in conjunction with the text. The text clarifies that there are two types of contexts: one that surrounds the elements of each functional system (depicted by the circle and named 'FS context') and the operational context where each service is delivered (depicted by three different operational contexts where each type of service is delivered).

comment 408

comment by: UK CAA

Page No: 49**Paragraph No:** GM2 Annex I Definitions(35) FUNCTIONAL SYSTEM (g) Figure 2

Comment: The diagram is inconsistent in the way it represents context. There are two different representations – the operational context on the left and right is shown by bold lines across the service, and in the middle 'FS Context' appears to be represented by the edge of a circle. This last representation is particularly unclear.

Justification: Clarity.

response Noted

Please see the response to comment No 407.

comment 658

comment by: EUROCONTROL

GM2 Annex I Definitions (35)

FUNCTIONAL SYSTEM

EUROCONTROL is of the opinion that the different descriptions of a functional system, as given in the current version of the NPA, create some confusion and should therefore be either left out or simplified.

In addition, some explanations on how systems currently work are unclear and sometimes inconsistent. In general there is too much guidance information for the user to be able to follow and understand the NPA.

EUROCONTROL therefore recommends simplifying and clarifying the guidance material.

response Not accepted

The commentator is not specifying what the complicated and confusing parts are, so it is difficult to identify what parts of that GM need to be simplified or removed. Without any GM, it is difficult to convey the complexities of the concept of functional system. The new structure gives less emphasis on this part of the GM, and the reader can find details only when needed.

comment 659

comment by: EUROCONTROL



GM2 Annex I Definitions (35)

FUNCTIONAL SYSTEM

(g)

EUROCONTROL confirms that it is not the change that propagates, but it is the effect that the change has caused. The text should be corrected accordingly.

response

Accepted

The text has been amended.

comment

853

comment by: *DGAC/DSAC - french NSA*

In paragraph (e) (2), the term "physical environment" seems to be too restricted. We simply suggest "environment" instead.

response

Partially accepted

Any reference to the environment is removed.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX I — Definitions of terms used in ANNEXES II to XIII — GM1 Annex I Definitions(35) & ATM/ANS.OR.C.005 & ATS.OR.205 General

p. 50-54

comment

88

comment by: *NATS National Air Traffic Services Limited*

Definitions (35) is "functional system". This GM appears to relate to service providers and attempts to justify who produces a safety assessment and who produces a safety support case. This is not GM to the definition rather it is an explanation justifying the approach in the IR. It is therefore superfluous to the NPA and should be deleted (or included in the EN as it is explanatory) as it is of no benefit to the reader as the IR casts in stone what has to be done and this explanation does not help to implement the IR. Whilst this text may have been useful to EASA to inform its rulemaking activity, now that the IR exists it is no longer relevant.

response

Partially accepted

It is included because it is Guidance that explains the circumstantial background to the IR, e.g. the reason for the law or the underlying reasons for the scope and approach taken in an AMC. It is not superfluous in the NPA or EN material as it provides a useful reference model that can be used in the future, when the NPA is history. The Agency considered the material relevant to the understanding of the IR/AMC/GM, but agrees that it may not be the GM normally published. Thus, the material has been moved to an Appendix for reference only. It may be deleted in the future when the concepts have been absorbed by stakeholders.



The GM has been restructured. This GM is now in Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities.

comment 293

comment by: DSNA

Suggest to rephrase the GM to manageable proportions and size in coherence with the rest of the IR/AMC/GM.

SERVICES, INFORMATION AND THE RESPONSIBILITY FOR SAFETY : over complicated.

AIR TRAFFIC SERVICE — VIEW OF SAFETY : over complicated.

CHANGE TO FUNCTIONAL SYSTEM AND ITS ASSESSMENT - (f) drivers for changes : Is it helpful ?

response Partially accepted

Unfortunately, the commentator does not give details as to why the GM is thought to be 'over complicated'. The Agency believes it is at the right level to provide Guidance that explains the circumstantial background to the IR, e.g. the reason for the law or the underlying reasons for the scope and approach taken in an AMC.

The GM has been restructured. This GM is now in Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities.

The proportions are more manageable in this section of the GM.

comment 410

comment by: UK CAA

Page No: 50

Paragraph No: GM1 Annex I Definitions(35) & ATM/ANS.OR.C.005 & ATS.OR.205

Comment: Throughout this section, and others, the abbreviation 'a/c' is used to denote aircraft. Additionally the abbreviation IR is used at least in this section. We suggest that these abbreviations are unsuitably informal, and that there is consistency in the use of abbreviations

Justification: Inappropriate style plus textual consistency.

response Accepted

The text has been updated.

comment 411

comment by: UK CAA



response	<p>Page No: 51 Paragraph No: GM1 Annex I Definitions(35) & ATM/ANS.OR.C.005 & ATS.OR.205 (c) Comment: The diagram should be formally referenced, e.g. "Figure 3 below" Justification: Clarity.</p> <p>Accepted</p> <p>The text has been updated.</p>
comment	<p>412 comment by: UK CAA</p> <p>Page No: 51 Paragraph No: GM1 Annex I Definitions(35) & ATM/ANS.OR.C.005 & ATS.OR.205 footnote 41 Comment: The text erroneously states "that that", when it means "than that". Justification: Typographical error.</p>
response	<p>Accepted</p> <p>The text has been updated.</p>
comment	<p>413 comment by: UK CAA</p> <p>Page No: 51 Paragraph No: GM1 Annex I Definitions(35) & ATM/ANS.OR.C.005 & ATS.OR.205 footnote 41 Comment: The second sentence is making a hidden assumption about the confidence required from the safety support case and the safety case. The means to determine the level of confidence required in each case is unknown, and in any case the level of confidence required depends on the use of the required services. Therefore the sentence is technically incorrect, even though the point it is trying to make is justified. Justification: Accuracy Proposed Text: Suggest that second sentence is amended to begin: "The difference also does not lower the level of confidence required ..."</p>
response	<p>Accepted</p> <p>Footnote changed: 'Nor should it be taken to mean that there should necessarily be any lower degree of confidence needed...'</p>
comment	<p>660 comment by: EUROCONTROL</p> <p>GM1 Annex I Definitions(35) & ATM/ANS.OR.C.005 & ATS.OR.205 General – Page 50 SERVICES, INFORMATION AND THE RESPONSIBILITY FOR SAFETY</p>



	<p>EUROCONTROL has one comment to make.</p> <p>The guidance material under this heading states that ANSPs are solely responsible for the safety in their area of responsibility. This is questionable since, not being able to control everything within its area of responsibility (e.g. unpredictable action taken by pilot), an ANSP cannot be solely responsible.</p>
response	<p>Not accepted</p> <p>The commentator is incorrect in his claim. There is no statement that ANSPs are solely responsible for safety. The GM simply points out their responsibilities in terms of the services they provide and the type of assessment they must perform because of their best ability to manage aircraft trajectories.</p> <p>Paragraph (e) and footnote 50 of GM2 Annex I Definitions (35) & ATM/ANS.OR.C.005 & ATS.OR.205 (this has become now the new Section 2.3 in in Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities) specifically state that the ATS provider is not responsible for safety but is made responsible for the assessment and assurance of safety for the services he delivers. Being responsible for the assessment of safety, because they are better placed to understand and evaluate the safety consequences, is not the same thing as being responsible for safety.</p>
comment	<p>873 comment by: DGAC/DSAC - french NSA</p> <p>The paragraph (h) and the analysis inside are the main argumentation which supports the concept of differences of responsibilities between ATS provider and other providers (CNS, etc.). However, we are not in line with this analysis. The a/c is always the user of the navigation service which permits the safe guidance along the chosen or imposed routes / trajectories. ATS (in fact ATC) only defines where the a/c should go by taking into account all available information (except in case of radar vectoring).</p>
response	<p>Not accepted</p> <p>The reason why the navigation service provider cannot produce a safety assessment is given in section 2.3 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities.</p> <p>The commentator may be under the impression that producing a safety case makes the service provider the only one responsible for safety. It does not. It simply makes him responsible for safety assessment and assurance. The ATS provider is in a position to assess safety, the navigation provider is not, even though he is responsible for delivering a service that is fit for purpose and that has a great deal of safety impact. While that purpose relates to safety, it is not the sole contributor to safety. The ATS provider can see the 'big' picture and can also dynamically adjust the service delivered.</p> <p>As indicated by the commentator, the aircraft is directly using the navigation service to</p>



navigate, but the ATC is also using that service (indirectly) as it relies on the aircraft to move in the directions indicated by it without unexpected deviations, which depends on the navigation service, among other factors.

comment 1206 comment by: ENAIRE

Disagree with rationale behind safety support assessments instead of safety assessments are required from CNS providers.

response **Noted**

Nevertheless, since no detail is provided, it is difficult to address the commentators implied concern.

comment 1210 comment by: ENAIRE

Disagree with footnote #41.

We believe there is no need to make such a change (safety support case vs safety case).

If separation were provided by a machine, would it be produced a safety support case or a safety case? What if ATS provider cannot provide separation (AFIS)?

Not every risk can be solved by means of more separation, by example, a complete ILS signal loss.

Disagree with 'the ATS provider is using its knowledge of the navigational service provided to the A/C and other information available to him, in creating and communicating its own navigational plan for the whole airspace'.

Disagree with 'it is only the ATS provider that can perform a safety assessment and provide a safety case. All other service providers can only perform safety support assessments and provide safety support cases'.

Problems with this view:

- AFIS cannot provide separation service, therefore an AFIS (ATS) provider could not provide a safety case.
- In some cases, like ILS signal loss, the ATS provider cannot produce a safety case.
- It is possible to have a scenario in which it is necessary to produce several safety support cases for each of the N providers, several ones for each of the C providers, several ones for each of the S providers and a safety case for the ATS provider, and there are not any indication about how this scenarios should/must be managed.

response **Not accepted**

The fact that separation is provided by a machine is not relevant, since someone is responsible for the design and use of the machine. Safety is an emergent property of a system (which in this case includes the machine) and depends upon the behaviour of the service (delivered by the machine) and the context in which it is used. Both of these are



known by the ATSP but not by a CNS provider (unless it is the CNS who is managing the machine, which effectively makes them an ATSP)

There is no difficulty in the ATS provider forecasting ILS signal loss and in providing procedures to accommodate the loss. However, the provider of the ILS signal is not able to propose what contingency procedures can be used to separate the aircraft, and assess their effect on the risk mitigation. The safety of ILS loss can therefore be assessed by the ATS provider, but hardly by the navigation signal provider. It is more efficient if the Nav provider focuses their analysis on the performance of its service and the ATS on the assessment of the risks.

The disagreement over the use of the ATS providers knowledge is not detailed and cannot therefore be responded to.

The reason why only the ATS provider can produce a safety assessment is given in Section 2.3 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities. The commentator does not state why he disagrees with the reasoning.

Problems with the view:

- Paragraph (e) explains that the GM relates strictly to ATC but there are circumstances when other ATS services, e.g. AFIS, may be relevant as well — see footnote 43.
- Not Accepted — see above.
- This scenario is dealt with in the multi-actor change GM (see Section 2.4 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities.) and does not defeat the argument for separating ATS from other services for the purposes of safety assessment and assurance.

In addition, please see the responses to other comments on the same issue, e.g. comment No 873.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX I — Definitions of terms used in ANNEXES II to XIII — GM2 Annex I Definitions(35) & ATM/ANS.OR.C.005 & ATS.OR.205 General

p. 55-57

comment 89

comment by: *NATS National Air Traffic Services Limited*

Definitions (35) is “functional system”. This GM appears to relate to service providers and their view of safety. This is not GM to the definition rather it is an explanation justifying the approach in the IR. It is therefore superfluous to the NPA and should be deleted (or included in the EN as it is explanatory) as it is of no benefit to the reader as the IR casts in stone what has to be done and this explanation does not help to implement the IR. . Whilst this text may



response	<p>have been useful to EASA to inform its rulemaking activity, now that the IR exists it is no longer relevant.</p> <p>Partially accepted</p> <p>Please see the response to comment No 88.</p>
comment	<p>414 comment by: UK CAA</p> <p>Page No: 57 Paragraph No: GM2 Annex I Definitions(35) & ATM/ANS.OR.C.005 & ATS.OR.205 General Comment: The figure has dynamic and static or semi-static SERVICES, whereas the text discusses dynamic and static or semi-static DATA. Justification: Inconsistency.</p>
response	<p>Accepted</p> <p>The figure has been removed as a result of merging two sections.</p>
comment	<p>415 comment by: UK CAA</p> <p>Page No: 57 Paragraph No: GM2 Annex I Definitions(35) & ATM/ANS.OR.C.005 & ATS.OR.205 General Comment: The figure introduces ‘Transmission Service Providers’, who are not discussed in the text. Justification: Inconsistency.</p>
response	<p>Accepted</p> <p>An explanatory paragraph has been added.</p>
comment	<p>485 comment by: CAA CZ</p> <p>The CAA CZ appreciates the AMC/GM diagram (page 57) depicting and suggesting that the services provided by CSP (ARINC and SITA) are subject to certification.</p>
response	<p>Noted</p> <p>Nevertheless, the certification or not of the CSP is not implied by the figure. In fact, it is the other way around; the figure assumes that the CNS are certified service providers, without arguing that CSP are subject to certification. The figure has been in any case removed, as result of merging two sections.</p>



3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX I — Definitions of terms used in ANNEXES II to XIII — GM1 Annex I Definitions (35) & ATM/ANS.OR.A.045 & ATM/ANS.OR.C.005 & ATS.OR.205 General

p. 58-81

comment	90	comment by: <i>NATS National Air Traffic Services Limited</i>
	<p>Point (b)(2)(ii) & (iii) – there is a potential for much confusion here whereby electrical power supplier is seen as providing a “service” and is not a service provider (given the definition in CRD 2013-08). 216/2008 (Basic Regulation) at Annex Vb 2. stipulates the essential requirements for each service. Therefore the GM identifies a service (by way of example) that is not a service in the BR. Furthermore (iii) reinforces this view as it implies that in (ii) the electrical power supplier is a service provider otherwise (iii) itself would not be required (not regulated and not a service provider). The GM needs to be much clearer and the use of the term “service” for a “service” not provided by a service provider needs to be carefully considered.</p>	
response	<p>Not accepted</p> <p>The word ‘service’ is used as a normal English word and not specifically as a definition of something delivered by a regulated service provider. Consequently, ‘service provider’ is an overloaded term but this cannot be rectified without rewriting the rules of English. In general, the meaning is clear because of the context of the terms used.</p>	
comment	91	comment by: <i>NATS National Air Traffic Services Limited</i>
	<p>Figure 1 – the second decision box appears to assume that any change that impacts unacceptably would result in a change to service provider B functional system. A viable alternative could be that, if the change has an unacceptable impact, that service provider B consults with the initiator of the change and “renegotiates” the change so as to have a lesser, or no, impact</p>	
response	<p>Accepted</p> <p>The commentator is correct, and this is mentioned in the GM, within the new footnote 61. It is not reflected in the diagram, as it would clutter too much the diagram and would not illustrate the point of view of a service provider changing its functional system due to some external factor.</p>	
comment	102	comment by: <i>EUROCONTROL Safety Team</i>



response	<p>No clear definition of change is provided, only examples.</p> <p>Not accepted</p> <p>The Agency assumes that the commentator is requesting the introduction of a definition of a change to functional system. The NPA argues that a simple definition of change that is complete, correct and unambiguous was not believed to be possible. Consequently, there are many examples of changes given in order to help the reader understand how change is used in the regulation.</p> <p>A simple description (not a definition) is that a change is any alteration to the elements of the functional system or the context in which it operates that has the potential to affect the behaviour of the service(s) provided.</p> <p>This is fully explained in the GM on the functional system — see the new Section 2.1.1 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities.</p>
comment	<p>294 comment by: DSNA</p> <p>Examples of ATS changes in the GM are sometimes irrelevant and do not provide clear explanations on “what is a change” to the point where they become ambiguous. Suggest to rephrase the GM to manageable proportions and size in coherence with the rest of the IR/AMC/GM.</p>
response	<p>Not accepted</p> <p>The table was developed by the RMT.0469 Rulemaking Group, which consisted of a number of experienced ATS service providers.</p> <p>The examples are not intended to provide a definition of what a change is, but simply support the Explanatory Next above.</p> <p>It is difficult to respond further when no specific instances of the irrelevant or ambiguous examples is given by the commentator.</p>
comment	<p>417 comment by: UK CAA</p> <p>Page No: 59 and others Paragraph No: GM1 Annex I Definitions (35) & ATM/ANS.OR.A.045 & ATM/ANS.OR.C.005 & ATS.OR.205 General (f)(2), and others Comment: The words ‘environment’ and ‘environmentally’ is used in several contexts. It is accepted that this is unavoidable to a degree, however in certain areas use of the term ‘operational</p>



environment' (or 'operating environment' as appropriate) is necessary to prevent misunderstanding. That page 27 of 230 refers to 'the specified environment (operational environment)' indicates the need for greater clarity of terminology. Further qualified use of the term 'environment' (e.g. 'physical environment', 'regulatory environment') may be necessary throughout the proposed AMC and GM to further enhance clarity.

The critical term is 'environmentally-driven'; this can be interpreted in one of two ways – driven by operational circumstances (i.e. the operational environment) or environmental (i.e. geo- or biophysical) considerations. GM1 Annex I Definitions (35) & ATM/ANS.OR.A.045 & ATM/ANS.OR.C.005 & ATS.OR.205 General (f)(2) refers to 'environmental features' in the context of 'environmentally-driven change'.

Page 62/230 includes a flow chart that refers to 'environmental change'. Again this could mean operational, geophysical or biophysical environment – it is not clear.

Page 66/230 Table 1 line 1 'Change description' refers to 'Increase in traffic in airspace (Environmentally triggered change) when it should more precisely refer to either 'operationally-driven change' or 'change to operating environment'. See also references to 'Airspace reorganisation' within the same table – use of the word 'environmentally' needs to be reconsidered or qualified in each case. The same is true of similar use of the word/term throughout the entire regulatory package.

See also use of terminology in Table 3 at page 81/230.

Justification: Improved textual clarity.

response

Accepted

Where feasible, 'environment' and similar terms have been replaced by 'context' which is defined in GM and is a much wider term. Its use is explained in the GM on the Functional System – see Section 2.1.1 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities.

comment

418

comment by: UK CAA

Page No: 63

Paragraph No: GM1 Annex I Definitions (35) & ATM/ANS.OR.A.045 & ATM/ANS.OR.C.005 & ATS.OR.205 General (p)

Comment: It is UK CAA's view that there needs to be a requirement for the CA to review impact assessments that did not lead to a change. At present ATM/ANS.AR.C.010 only requires the CA to review changes made (to the functional system).

Justification: Completeness.

response

Not accepted

The IR does not include, as the commentator suggests, any provision that requires reviewing those impact assessments. This need is not justified, and it is not considered necessary.



comment	<p>486</p> <p>The last sentence of the point 3 paragraph f seems to be too prescriptive. The CAA CZ proposes the service provider is to be responsible for safety relevance assessment of the change in line with change management procedure approved by the CA.</p>	comment by: CAA CZ
response	<p>Accepted</p> <p>Safety improvement is a fundamental safety management concept and is embedded in the IR at ATS.OR.200(a)(2)(iii).</p> <p>Improvements in trustworthiness are not required by the IR so they have been removed.</p>	
comment	<p>487</p> <p>The scope of unforeseeable changes provide for by the point k seems to narrow down to the changes “organized” by the State. The examples suggested here and many other such conflict, strikes and natural disasters are cover by the contingency planning.</p>	comment by: CAA CZ
response	<p>Not accepted</p> <p>The examples given are not ‘organised’ by the State, e.g. volcanic ash. The examples given by the commentator should already be covered in the contingency plan (as indicated by the writer) and so do not meet the criteria of this section. They would do so only if the activity were not foreseen by the contingency plan.</p>	
comment	<p>577</p> <p>d) Replace the term <i>approve</i> with <i>accept</i>. k) We support the provisions contained in the NPA referring to unplanned/unforeseen changes due to unforeseen urgent circumstances, when these changes are outside of the service provider operating envelope and therefore are a change to the functional system. Justification d) The same paragraph refers to acceptability. Align with our proposal for Annex II, ATM/ANS.AR.C.040 c) 1)</p>	comment by: <i>Frasie Loredana</i>
response	<p>Not accepted</p> <p>‘Approve’ is the correct term — see legal justification in response to comment No 840.</p> <p>The acceptability of the change referred to here is that the change is predicted by the assurance case to meet its criteria. The CA will approve the assurance case if it is convinced that it is valid, i.e. the criteria must be valid and the argument that the implementation will</p>	



satisfy the criteria must be valid.

comment

661

comment by: EUROCONTROL

Definition of a “change”: No clear definition is provided, only examples.

Examples of changes for ATS providers that may require safety assessment (and perhaps supervision), i.e. those within the scope of ATS.OR.205 – Page 67 & 68

Concerning the 2nd remark that starts at the end of Table on page 67, viz. ‘This is not intended to include the like-for-like replacement of a piece of equipment. However, it does include the replacement of a component with a similar but not identical one i.e. a component having similar functionality but whose design is different (including different software) as demonstrated by having a different part number’, EUROCONTROL makes the following observation: the part number will always change but not the specifications of that part.

The remark should therefore be rephrased.

response

Not accepted

For a response regarding the definition of change, please see comment No 102.

If the part number changes, then it is to be assumed that something in the equipment has changed, even though specifications may remain the same. Consequently, there needs to be assurance that the behaviour, in the context of use, has not changed. There are often errors in specifications. The safety support assurance confirms that the specification is trustworthy.

comment

705

comment by: DFS Deutsche Flugsicherung GmbH

The table contains some changes to CNS systems for which a safety support assessment would be necessary. It is unclear why these changes appear in table 1 “Examples of changes for
ATS providers...”.

The dividing line between safety support assessments for non-ATS providers and safety assessments for ATS providers should be clarified.

Reference to high level comment "c.v"

response

Not accepted

The table contains CNS changes because they may have an impact on the ATS service and so a safety assessment should be made and, if necessary, a responsive change made by the ATS provider (‘Potential change’ column). The CNS provider also has to make a safety support assessment of the change. Such changes are multi-actor changes.

The dividing line between safety assessment and safety support assessment is defined in the



Implementing Rule: ATM/ANS.OR.C.005 applies to ATM/ANS providers other than ATS providers, while ATS.OR.205 applies only to ATS providers. There is enough supporting GM.

comment

762

comment by: *ENAIRE*

Table 3 – Examples of changes that may not require safety or safety support assessment: What is the content of the safety support assessment? Is there any template in GM depending on the type of changes? When should it be provided? It is still unclear why minor functional changes (with minimal operational impact) , or low level components changes (such as keyboard replacements or firmware updates) are not included in this Table.

response

Noted

For changes that do not require assessment, the content of the assessment is 'nil'. For those that do, the content is described in ATM/ANS.OR.C.005 and ATS.OR.205 and associated AMC/GM.

Even apparently minor functional changes can have an impact on the behaviour of the functional system and so should be assessed. The assessment only needs to go as far as confirming there is no behavioural impact on the service. For minor changes, this may require very little effort. Note that the CA may agree certain changes that will not be reviewed, but this does not mean they should not be assessed (regardless of the simplicity of the assessment).

Note that the rule does not regulate effort. It regulates the outcome, i.e. there is no size of assessment or assurance implied by the rule.

comment

877

comment by: *DGAC/DSAC - french NSA*

- paragraph (q) :

If the impact analysis includes the items (1) (2) (3), it seems to be very close to a safety assessment.

- paragraph (i) & (m) & figure 1 :

"Would the proposed change alter the way the service delivered by Service provider B behaves" is the only question that should be considered. If the answer is yes, this implies a change to its functional system. The second question about the acceptability of the impact is



	in contradiction with the requirements.
response	<p>Not accepted</p> <p>(q) the commentator is correct, and this is recognised in footnote 60.</p> <p>(i) is simply providing a case where it is assumed that the service will not behave differently after the change (a replacement on a like-for-like basis). The maintenance procedure does have to be assessed. This is covered in (j).</p> <p>It also states that if the behaviour of the service does alter during the maintenance activity, it should be assessed.</p>
comment	<p>1116 comment by: <i>Belgocontrol</i></p> <p>There is no clear definition for ‘change’ provided, only examples.</p>
response	<p>Not accepted</p> <p>Please see the response to comment No 102.</p>
comment	<p>1282 comment by: <i>Per Ove Torsteinsson</i></p> <p>Refer “GM1 Annex 1 Definitions(35) & ATM/ANS.OR.C.005 & ATS.OR.205 General”.</p> <p>In this GM (under SERVICES, INFORMATION AND THE RESPONSIBILITY FOR SAFETY), it is explained why different responsibilities for safety between an ATS provider and other types of service providers (e.g. CNS provider) exist, where the ATS provider is responsible for safety assessments and other service providers are responsible for safety support assessments.</p> <p>Based on the fact that ATS is also provided at airports – separating aircraft on the maneuvering area (on runways and taxiways) – it is assumed that the same arguments and principles are valid at an airport.</p> <p>In the same GM (under AIR TRAFFIC SERVICE – VIEW OF SAFETY), there is no information regarding the ATS provided at airports.</p> <p>How is the role of an airport operator with regard to safety defined in this context?</p> <p>Should the airport operator be responsible for safety support assessments when implementing changes which may affect the ATS provision at the airport – while the ATS provider should provide the safety assessment?</p>
response	<p>Noted</p> <p>Where ATS are provided at airports, then the rules applying to ATS from the ATM IR are</p>



applied to the ATS services.

The aerodrome operator abides by Regulation (EU) No 314/2014, which is the regulation that governs aerodromes. From the point of view of the current proposal, they are considered as aviation undertakings, and there are no requirements imposed on them.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX II — Requirements for competent authorities — Service provision and network functions (Part-ATM/ANS.AR) — GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045 General p. 82-91

comment 92 comment by: *NATS National Air Traffic Services Limited*

GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045

Though this material is GM, less mature authorities and organisations will feel pressurized to show compliance against the GM. This will drive up the cost to service providers and increase the regulatory burden on CAs. Please reduce the volume of information in the GM to a more proportionate and appropriate level of detail.

response **Not accepted**

It is not clear what aspects of this guidance the commentator feels will 'drive up the costs'.

The GM does not cover the process to a very great depth and covers in a general manner different approaches to implement changes (e.g. including transitions) and it is hard to see what can be left out and still leave the GM complete enough.

comment 419 comment by: *UK CAA*

Page No: 84

Paragraph No: GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045 General (c) (8)

Comment: If the statement "any part ... cannot be started until a valid assurance case for the change exists" is meant to mean that the valid assurance case must exist for the WHOLE change, then this needs to be stated explicitly. If an alternative meaning is the case then that should be stated explicitly.

Justification: Clarity.

response **Partially accepted**

Transitional changes are dealt with in section (d).

There are two methods proposed but these are not intended to be the only ways of performing change, just two contrasting ways. In the first, no change should be implemented



until a valid safety case for it exists and, if necessary, it has been approved. In the second case, the intention is that the safety case covers all transitions before any of them are implemented (as described in paragraph (d)). However, the IR allows change to be implemented providing a valid safety case exists for the part of the change being implemented. This could include a partial implementation of the type of change foreseen in (d)(2)(ii).

No changes seem to be required in the GM text for (d), as what the commentator is asking for is already present; however, (c)(8) has been clarified.

comment 420

comment by: UK CAA

Page No: 84**Paragraph No:** GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045 General (c) (11)

Comment: It is accepted that the CA would, during regular oversight, verify that monitoring is taking place, and the results are being reviewed by the service provider. However, there appears to be no reason for the CA to concern itself to the extent that it wishes to be “informed about its results”, as the CA will only have approved the assurance case as valid if it provides sufficient confidence in the safety of the changed functional system without further evidence.

Justification: The recommended activity is unnecessary.

response Not accepted

The wording is ‘may wish to review...’ leaves it up to the CA to decide and is not a general recommendation. It is an allowable part of regular oversight and is included for completeness.

comment 421

comment by: UK CAA

Page No: 85**Paragraph No:** GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045 General (c) (12)

Comment: UK CAA suggests that it is not the “assessment of the monitoring activities identified above” that leads to monitoring requirements, but the need for evidence to support the validity of the assurance case.

Justification: Accuracy.

response Accepted

The text has been amended accordingly.



comment	422	comment by: UK CAA
	<p>Page No: 85 Paragraph No: GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045 General (c) (13) Comment: The term ‘chance’ is used here. It is not used elsewhere – probability is used. The use of a different term implies something other than probability is meant. If this is deliberate, the reason for this different term needs to be explicitly stated. Otherwise we recommend that ‘probability’ should be used instead. Justification: Clarity.</p>	
response	<p>Accepted</p> <p>The word ‘chance’ is replaced by the word ‘probability’.</p>	
comment	423	comment by: UK CAA
	<p>Page No: 85 Paragraph No: GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045 General (c) (13) Comment: There is a random full stop after “requirements, then”. Justification: Typo. Proposed Text: delete full stop</p>	
response	<p>Accepted</p> <p>The text has been corrected.</p>	
comment	424	comment by: UK CAA
	<p>Page No: 85 Paragraph No: GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045 General (c) (13) Comment: There is a forward reference to “back out or recovery plan” which is explained in (d) (5) Justification: Clarity.</p>	
response	<p>Partially accepted</p> <p>The definition of a back out plan is provided here so it is not strictly a forward reference. However, a footnote is added to point the reader to (d)(5).</p>	
comment	425	comment by: UK CAA
	<p>Page No: 86</p>	



response

Paragraph No: GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045 General (d) (5)

Comment: The second sentence appears to make too weak a requirement/recommendation and also requires clarification.

Justification: Sufficiency and clarity.

Proposed Text: The UK CAA recommends that the second sentence is replaced with these two sentences. "Following a transition, the changed system may not behave in accordance with the criteria, established in the assurance case, required to continue with the next transition towards the intended service. Therefore, as part of the transition planning, the service provider should establish a way to returning to an acceptable service."

Partially accepted

Apart from the grammar of the second proposed sentence, the proposal itself is not correct. The criteria are not intended to continue with the next transition but are intended to show that the current transition is or is not performing satisfactorily.

The wording has been changed, in the spirit of the comment, and a footnote added.

comment

426

comment by: UK CAA

Page No: 86

Paragraph No: GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045 General (d) (6)

Comment: The UK CAA disagrees with the approach in the first and last sentences of this clause.

1) The service provider must provide a rationale as to why it is acceptable to have a transitional stage that leads to a reduction of safety. 2) The CA must not change the service provider's assurance case by imposing conditions or adding mitigations. If the assurance case is not sufficient, it is the responsibility of the service provider to identify conditions or further mitigations. 3) All conditions and mitigation must be incorporated into the risk analysis in the assurance case, so that their effect on risk is determined.

There is nothing to stop the CA making suggestions for the service provider to consider, but their adoption and the assessment of the resulting risk against the safety criteria is the service provider's decision.

If no further conditions or mitigations are possible or practical, then the service provider may have to argue why reduced safety criteria are valid. (Safety criteria are derived for a change in accordance with the service provider's approved procedures. The service provider can seek to establish that the criteria were set too conservatively, or else seek the CA's approval for another valid means of establishing safety criteria.) If this cannot be done, all options have been exhausted (no further risk reduction is possible, and it is not possible to accept lower levels of safety), and the change must either be withdrawn or implemented differently.

The rule text makes no provision for a CA to accept an invalid safety case.

Justification: Appropriate allocation of responsibilities between CA and service provider.



response Not accepted

The GM does not suggest that the rationale behind the reduction on safety being acceptable has not been provided. The safety case must declare that the safety of a transition is worse than that without the transition. It is unlikely that a CA would approve such a case if it did not accept the rationale for the reduction in safety.

The CA is not changing the safety case, it is simply adding conditions, as it is allowed to do by the IR.

There is no notion of the safety case being insufficient. It is simply that it records the fact that safety levels will decrease.

If there is to be a change in some aspect of the operation as a result of conditions proposed by the CA, then presumably it would not approve the safety case until the safety assessment on those changed aspects had been performed and shown (argued) to be acceptable in the safety case. This limits the CA's conditions to those that have no impact on the safety case.

In general, the commentator's arguments are accepted and it is true that the CA cannot approve an invalid safety case. However, they seem to be reflected in the paragraph already, except for the statement that a CA cannot accept lower levels of safety, which is not true. Consequently, no change has been made to the text.

comment 428 comment by: UK CAA

Page No: 88
Paragraph No: GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045 General (e) (2) (ii)
Comment: The UK CAA suggest the CA's default view should be that a review is required until the CA has received sufficient information to demonstrate that the change does not meet the selection criteria.
Justification: Rigour of approach.

response Not accepted

The view proposed by the IR is that the CA will decide based upon the evidence it sees. This either comes as part of the notification or the CA seeks sufficient evidence to make an appropriate decision (in accordance with ATM/ANS.AR.C.035(a)). There is no notion of a default view and the rigour is already implied in the regulation.

comment 429 comment by: UK CAA

Page No: 88
Paragraph No: GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045 General (e) (3) (i)
Comment: The second sentence, as written, suggests that normally only large, complex or



	<p>novel changes will be reviewed. As the way that CAs set selection criteria is yet to be established, the sentence should avoid this, perhaps inadvertent, implication.</p> <p>Justification: Clarity.</p> <p>Proposed Text: “When large, complex or novel changes are selected for review, the CA would be well advised ...”</p>
response	<p>Not accepted</p> <p>The implication is not inadvertent. It provides the rationale behind the early engagement of the CA in the change process.</p>
comment	<p>432 comment by: UK CAA</p> <p>Page No: 91</p> <p>Paragraph No: GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045 General (f) (6) (i)</p> <p>Comment: The use of the word ‘any’ make it unclear whether it is intended that the CA will check every change, or just a sample of changes. Footnote 115 makes it clear that the CA does not do this at every visit, but not the scope of the activity when it does take place.</p> <p>Justification: Clarity.</p>
response	<p>Accepted</p> <p>The word ‘any’ has been removed.</p>
comment	<p>489 comment by: CAA CZ</p> <p>The requirement under point 2.c paragraph c seems to be too prescriptive. The CAA CZ proposes the service provider is to be responsible for safety relevance assessment of the change in line with change management procedure approved by the CA.</p>
response	<p>Partially accepted</p> <p>It is understood that the comment is against (c)(2)(iii). The GM accurately reflects the IR. Please see the comments and responses related to the notification and involvement of the CA in the review. The text has been amended to reflect the fact that the CA may decide the degree of involvement or not in the change process.</p>
comment	<p>490 comment by: CAA CZ</p> <p>Support to the requirement provided for by point 13 of paragraph c.</p>
response	<p>Noted</p>



comment	<p>491 comment by: CAA CZ</p> <p>The requirements under 4.i and 4.ii of the paragraph (e) are not totally clear. While point 4.i requires CA to approve safety case the point 4.ii requires the CA to approve functional system change.</p>
response	<p>Partially accepted</p> <p>It is the assurance case that is approved or rejected — see footnote 96. The change has not been performed when this happens and cannot therefore be approved or rejected. However, since approval of the assurance case allows the change to go ahead, while its rejection means that the change will not go ahead, approval/rejection of the assurance case is used as a metaphor for approval/rejection of the change. (e)(4)(ii) and (ii) have been amended to clarify this.</p>
comment	<p>578 comment by: <i>Frasie Loredana</i></p> <p>c) For the CA, replace the term <i>approve</i> with <i>accept</i> in regard to the acceptability of the safety (support) case and of the change. Justification Align with our proposal for Annex II, ATM/ANS.AR.C.040 c) 1) and GM1 Annex I Definitions (35) & ATM/ANS.OR.A.045 & ATM/ANS.OR.C.005 & ATS.OR.205 General CHANGE TO FUNCTIONAL SYSTEM AND ITS ASSESSMENT (d)</p>
response	<p>Not accepted</p> <p>The appropriate term is 'approve'. Please see the response to comment No 840 for a legal justification of the use of 'approve'.</p>
comment	<p>662 comment by: EUROCONTROL</p> <p>GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045 General (f) (6) (i) (C) – Page 91 EUROCONTROL considers that in the case there are no clear requirements for an ANSP on when a CA review is needed, as such a decision lies with the CA, an ANSP is not able to define the properties that determine whether a change should or should not be reviewed. EUROCONTROL therefore suggests adding a requirement for CA to communicate to the ANSP's the properties that determine whether a change needs to be reviewed or not.</p>



response	<p>Noted</p> <p>The comment while valid does not seem to indicate that a change is needed to this GM.</p> <p>The properties that determine when a change will be reviewed do not need to be communicated to every service provider by every CA as they will be published as an AMC and its associated GM to ATM/ANS.AR.C.035(b).</p>
comment	<p>706 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>(c) (2) (iii) "If the CA decides to review the change, the CA <u>will</u> be involved in the change process."</p> <p>This should not be stated as necessary ("will"), but as an option ("may"). In general this is an unnecessary statement, since the CA can be involved in any process whenever it wants.</p> <p>Reference to high level comment "c.ii"</p>
response	<p>Accepted</p> <p>Agreed that it is strictly an unnecessary statement; however, it is included here for completeness. The proposed text is amended as suggested.</p>
comment	<p>707 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>(2) (ii)</p> <p>„changes, those that carry very low levels of risk, will not be reviewed, the notification carries <u>sufficient</u> information to identify these cases without further interaction” => This can result in problems for service providers depending on the interpretation of the CA, since it is not defined what is "sufficient". Therefore, huge amounts of information might be required by the CAs.</p> <p>In addition this kind of process encloses the problem that the CA might take very long to decide (and to process that huge amount of data). This might cause problems for the service providers planning processes.</p> <p>Reference to high level comment "c.v"</p>
response	<p>Partially accepted</p> <p>It is agreed that the information required for the CA to make the decision has not yet been fully defined. However, that is part of an ongoing activity and the part of the rule governing the decision will not be enforced until two years after the rest of the IR has been enforced.</p> <p>However, the IR, AMC and GM relating in detail to the decision to review the safety case is not intended to be covered by this GM so it is difficult to see what change the commentator</p>



would like.

A change has been introduced in AMC, where it now states that the decision-making by the CA has to be done without ‘undue delay’.

comment

708

comment by: *DFS Deutsche Flugsicherung GmbH*

(3) (i)

“This will allow the CA to acquire knowledge of the safety aspects and the details of the change slowly via workshops, attending [...]”

This is an unnecessary statement, since the CA can be involved whenever it wants. We propose to take out this sentence to give the CAs full flexibility to decide when to attend.

overregulation

Reference to high level comment "c.i"

response

Not accepted

While it is strictly true that the statement is unnecessary, it has been included for completeness and clarification. It also indicates an expectation rather than a requirement.

comment

920

comment by: *AESA / DSANA*

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i></p> <p>ANNEX II REQUIREMENTS FOR COMPETENT AUTHORITIES — SERVICE PROVISION AND NETWORK FUNCTIONS (Part-ATM/ANS.AR)</p> <p>GM1 ATM/ANS.AR.C.035 & ANS.OR.A.045</p>	<p>c.2.i.: a minimum/maximum period of time should be established for the CA decision to review.</p>	<p>A minimum period of time that allows the CA to apply its procedures in an orderly and systematic manner without being subject to external pressures (deadlines, political commitments,...).</p> <p>A maximum period of time that helps the ANSP assess the duration of this activity (<i>CA deciding whether to review or not</i>) in order to define the timeframe for the introduction of the change within the plan for the implementation of the change.</p>



response Partially accepted

The IR has been updated to include the notion of a timely response to a timely request. This GM already reinforces this notion so that nothing here has been changed.

It is not possible to set minimum/maximum periods as the range of changes being selected is too large.

comment 921

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX II REQUIREMENTS FOR COMPETENT AUTHORITIES — SERVICE PROVISION AND NETWORK FUNCTIONS (Part-ATM/ANS.AR) GM1 ATM/ANS.AR.C.035 & ANS.OR.A.045</p>	<p>c.2.ii.: It is understood that there is a difference between the concept 'review of a change' and the concept 'general oversight of a change'.</p> <p>A review directly implies the need of approval while the general oversight allows to ask for the remediation of any non-compliance related to a specific change once the CA has decided not to approve but to oversight it before the implementation.</p>	<p>It is important to keep the option of an oversight <u>before the implementation of the change</u> even if a non-review decision has been taken.</p> <p>A risk-based decision to review assumes that some changes are neither so relevant that they require an approval nor so irrelevant as to be passed without some kind of overview (and some modifications of the argument if necessary).</p> <p>In our particular case, we work with a specific level of 'review' for this type of change which has shown to be very useful since the concept was first applied.</p>

response Not accepted

The IR imposes no requirements on the CA to oversee a change that is not to be reviewed. The CA will, at the same time as the change is being developed, be overseeing the service



provider making a change. The content of this oversight activity is regulated by the oversight regulations and does not directly refer to changes being developed. This does not prevent the CA from overseeing any aspect of the developing change; however, no guidance on this is provided.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX II — Requirements for competent authorities — Service provision and network functions (Part-ATM/ANS.AR) — AMC1 ATM/ANS.AR.030 Approval of change management procedures for ATM/ANS functional systems

p. 91-92

comment	103	comment by: <i>EUROCONTROL Safety Team</i>
	<p>AMC1 ATM/ ANS.AR.030(c) This text states that service providers comply with ATM/ANS.OR.A.045, ATS.OR.205, ATS.OR.210 and ATM/ANS.OR.C.005 through their AMC or through Alternative means of compliance, if any. However, despite the voluminous material, there are very limited AMCs specified for ATM/ANS.OR.A.045, ATS.OR.205 and while ATS.OR.210 has no AMC.</p>	
response	<p>Partially accepted Please see the response to comment No 643.</p>	
comment	148	comment by: <i>NATS National Air Traffic Services Limited</i>
	<p>The reference for this AMC should be AMC1 ATM/ANS.AR.C.030 and corrected in (b) and (e) and (h).</p>	
response	<p>Accepted The text has been amended.</p>	
comment	149	comment by: <i>NATS National Air Traffic Services Limited</i>
	<p>The last reference under (b) is not found AMC1 ATM/ANS.OR.B.015(a).</p>	
response	<p>Accepted The reference should be to AMC1 ATM/ANS.OR.B.010(a)(b), and has been amended</p>	



accordingly.

comment 150 comment by: *NATS National Air Traffic Services Limited*

Point (c) states that compliance with ATM/ANS.OR.A.045, ATS.OR.205, ATS.OR.210 and ATM/ANS.OR.C.005 is through their AMC or AltMoC, if any. However ATM/ANS.OR.A.045 has limited AMC; ATS.OR.205 has very limited AMC; ATS.OR.210 has no AMC; ATM/ANS.OR.C.005 has very limited AMC. Note that this summary is based upon the contents list.

This lends weight to NATS' general comment that the detail in the current IR should be recast as AMC and that the possibility to propose AltMoC is very limited.

response Partially accepted

Please see the response to comment No 643.

comment 151 comment by: *NATS National Air Traffic Services Limited*

CA should have time limit for responding, otherwise changes may have indefinite response times.

Suggest add para (i) to AMC1 ATM/ANS.AR.C.030 to read:

"(i) The CA should provide a response to the service provider's notification of change referred to in ATM/ANS.OR.A.045 (a) within 30 days of its receipt."

response Partially accepted

While the need of limiting the response time is acknowledged, the introduction of a precise time limit seems not appropriate, as given the vast range of different services provided, setting a fixed time limit would be infeasible. Anyway, text has been introduced (i.e. 'without undue delay') to avoid unreasonable time to response.

comment 433 comment by: *UK CAA*

Page No: 91

Paragraph No: AMC1 ATM/ANS.AR.030 Approval of change management procedures for ATM/ANS functional systems GENERAL (c)

Comment: The notion that the 'procedures are capable of initiating ...' is too weak. The criteria should be in the form of 'procedures make mandatory provisions ...'

Justification: Rigour of approach

Proposed Text: "The CA should check that the procedures make mandatory provisions that require actions are undertaken and all required evidence is produced to comply with ..."



response [Accepted](#)

[The text has been amended accordingly.](#)

comment 469 comment by: *skyguide Corporate Regulation Management*

Point (c) states that compliance with ATM/ANS.OR.A.045, ATS.OR.205, ATS.OR.210 and ATM/ANS.OR.C.005 is through their AMC or AltMoC, if any. However ATM/ANS.OR.A.045 has limited AMC; ATS.OR.205 has very limited AMC; ATS.OR.210 has no AMC; ATM/ANS.OR.C.005 has very limited AMC. Note that this is based upon the contents list. This lends weight to our general comment that the detail in the current IR should be recast as AMC and that the possibility to propose Alt MoC is very limited.

response [Partially accepted](#)

[Please see the response to comment No 643.](#)

comment 493 comment by: *CAA CZ*

Not clear. Is the requirement identified here as AMC1 ATM/ANS.OR.B.015(a) referring to amalgamated ATM/ANS.OR.B.005(a) in CRD NPA 2013-08 or is missing?

response [Accepted](#)

[The reference should be to AMC1 ATM/ANS.OR.B.010\(a\)\(b\), and has been amended accordingly.](#)

comment 494 comment by: *CAA CZ*

Practical implementation is not quite obvious.

response [Noted](#)

[The analysis of service provider's change management procedures is not an easy task, but it is not obvious what is difficult from the commentator's perspective.](#)

comment 643 comment by: *CANSO*

AMC1 ATM/ANS.AR.030(c)

Point (c) states that compliance with ATM/ANS.OR.A.045, ATS.OR.205, ATS.OR.210 and ATM/ANS.OR.C.005 is through their AMC or AltMoC, if any. However ATM/ANS.OR.A.045 has



limited AMC; ATS.OR.205 has very limited AMC; ATS.OR.210 has no AMC; ATM/ANS.OR.C.005 has very limited AMC. Note that this is based upon the contents list. This lends weight to CANSO's general comment that the detail in the current IR should be recast as AMC and that the possibility to propose AltMoC is very limited.

response [Partially accepted](#)

The intent was to check compliance either directly with the IR or through AMC/AltMOC if any of these exist. The text has been changed to reflect this intent. The fact that currently there are very few AMCs related to these provisions is irrelevant to the question of moving IR text to AMC. It merely indicates that we consider that the law relates directly to current circumstances and that it does not need a specific means to be complied with.

comment

693

comment by: *ROMATSA*

AMC1 ATM/ANS.AR.030(c)

Point (c) states that compliance with ATM/ANS.OR.A.045, ATS.OR.205, ATS.OR.210 and ATM/ANS.OR.C.005 is through their AMC or AltMoC, if any. However ATM/ANS.OR.A.045 has limited AMC; ATS.OR.205 has very limited AMC; ATS.OR.210 has no AMC; ATM/ANS.OR.C.005 has very limited AMC. Note that this is based upon the contents list.

General comment: the detail in the current IR should be recast as AMC and the possibility to propose AltMoC is very limited.

Supporting comment to summary issue: Missing AMC.

response [Partially accepted](#)

[Please see the response to comment No 643.](#)

comment

709

comment by: *DFS Deutsche Flugsicherung GmbH*

Point (c) states that compliance with ATM/ANS.OR.A.045, ATS.OR.205, ATS.OR.210 and ATM/ANS.OR.C.005 is through their AMC or AltMoC, if any. However ATM/ANS.OR.A.045 has limited AMC; ATS.OR.205 has very limited AMC; ATS.OR.210 has no AMC; ATM/ANS.OR.C.005 has very limited AMC.

Reference to high level comment "c.iv"

response [Partially accepted](#)

[Please see the response to comment No 643.](#)

comment

1069

comment by: *LVNL*

AMC1

ATM.ANS.AR.030

(p.

91)



(a) The life cycle of the change to be managed excludes the decommissioning since decommissioning is interpreted as a change in itself. Therefore this is not the complete life cycle. Proposal to delete the word “complete”

response

Accepted

The life cycle of the change is defined in the new requirements ATM/ANS.OR.C.005(a)(1)(iv) and ATS.OR.205(a)(1)(iv). It does not include decommissioning. The reason for the use of the word ‘complete’ in the AMC is to emphasise the completeness of the lifecycle as defined within the IR. It is acknowledged that complete lifecycles can include decommissioning, and thus ‘complete’ has been removed and references to the defined lifecycle have been added.

comment

1185

comment by: Avinor ANS

Point (c) states that compliance with ATM/ANS.OR.A.045, ATS.OR.205, ATS.OR.210 and ATM/ANS.OR.C.005 is through their AMC or AltMoC, if any. However ATM/ANS.OR.A.045 has limited AMC; ATS.OR.205 has very limited AMC; ATS.OR.210 has no AMC; ATM/ANS.OR.C.005 has very limited AMC. Note that this is based upon the contents list. The detail in the current IR should be recast as AMC (as proposed in the Annex 1) and that the possibility to propose AltMoC is very limited.

response

Partially accepted

Please see the response to comment No 643.

comment

1230

comment by: CAA-NL

AMC1 ATM.ANS.AR.030

(a) To be precise the life cycle of the change to be managed excludes the decommissioning since decommissioning is interpreted as a change in itself. Therefore this is not the complete life cycle. Proposal to delete the word “complete”

response

Accepted

The life cycle of the change is defined in the new requirements ATM/ANS.OR.C.005(a)(1)(iv) and ATS.OR.205(a)(1)(iv). It does not include decommissioning. The reason for the use of the word ‘complete’ in the AMC is to emphasise the completeness of the lifecycle as defined within the IR. It is acknowledged that complete lifecycles can include decommissioning, and thus ‘complete’ has been removed and references to the defined lifecycle have been added.



3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX II — Requirements for competent authorities — Service provision and network functions (Part-ATM/ANS.AR) — GM1 ATM/ANS.AR.030 Approval of change management procedures for ATM/ANS functional systems

p. 92

comment 152 comment by: *NATS National Air Traffic Services Limited*

The reference for this GM should be GM ATM/ANS.AR.C.030.

response [Accepted](#)

comment 434 comment by: *UK CAA*

Page No: 92

Paragraph No: AMC1 ATM/ANS.AR.030 Approval of change management procedures for ATM/ANS functional systems GENERAL (h)

Comment: Clarity is required on the status of previously approved change management procedures when there are changes to the Implementing Rule, associated AMC or GM.

Justification: Clarity.

response [Noted](#)

[If a change to the IR/AMC/GM affects previously approved change procedures, this issue will be tackled at that time. The extent and nature of future changes cannot be predicted.](#)

comment 435 comment by: *UK CAA*

Page No: 92

Paragraph No: AMC1 ATM/ANS.AR.030 Approval of change management procedures for ATM/ANS functional systems (h)

Comment: The relationship of the CA's cross-reference to the service provider's compliance matrix mentioned in (b) (and AMC1 ATM/ANS.OR.B.015(a)) is unclear. Is this duplication? If not, it is unclear what the difference is.

If the difference is entirely captured in GM1 ATM/ANS.AR.030 (which also appears on p92 of the NPA), then this should be made clear.

Justification: Clarity and possibly removal of duplicated effort.

response [Accepted:](#)

[They are the same. Both AMCs now use the term 'compliance matrix' and](#)



AMC1 ATM/ANS.AR.C.030(b)(b) points to AMC2 ATM/ANS.OR.B.010(a)(b).

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX II — Requirements for competent authorities — Service provision and network functions (Part-ATM/ANS.AR) — p. 92-99
GM1 ATM/ANS.AR.C.035(b)(1) Decision to review the notified change

comment 104 comment by: EUROCONTROL Safety Team

GM1 ATM/ ANS.AR.C.035(b)(1) Point (a)(1) on Page 92

The GM is theoretically correct but not borne out by real life situations. It is not always possible to complete the safety case prior to implementation. There are at times when assurance activities, particularly those relating to Human Factors, which are predicted to be successful. The change is implemented then through a comprehensive transition plan which includes criteria for go/no go decisions.

response Not accepted

The safety case is an argument predicting that the change, when implemented, will be safe enough. If it is to be reviewed, then the safety case must be approved before any part of the change that can have an effect on the operation of the service is implemented. It is both practical and necessary. The GM on CA/ANSP interaction during change in Section 3.2.1 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities describes how a change develops and differentiates between the implementation of the parts of the change that will not affect operations and those that will. Most of the issues raised here are covered in that GM.

It also covers ((c)(13)) the case where the predicted criteria are not actually met during operation (c)(13).

The commentator seems to imply that certain elements are not assessed prior to implementation, and that part of the evidence of assurance is collected during implementation. This is what the material covers as temporary monitoring during transitions. The GM also differentiates (please see (c)(12) in the above-mentioned GM) between criteria that show that transitions in the change have been implemented correctly (potentially used to obtain certain evidence and build confidence in the assurance case) and those criteria that show that the change as a whole meets the claims in the safety case.

Specific guidance (footnote 77) is given relating to HF assurance.

comment 105 comment by: EUROCONTROL Safety Team

GM1 ATM/ ANS.AR.C.035(b)(1) Point (d)(2)(i) on page 96



	<p>Another unrealistic GM which seems to presuppose that the CA is all-knowing and competent or, at least, more competent than the service provider who, in many cases, is actually providing the service on H24 basis. While this view might be true for the smaller (non-complex) providers, real life shows that this is not so for the bigger SPs. If an SP lacks the required expertise/knowledge to perform the change, the chances are that the CA faces the same problem.</p> <p>Recommend to delete (d)(2)(i).</p>
response	<p>Not accepted</p> <p>The issue of who is more competent is not relevant to the argument of what may cause the production of an unsound safety case. The CA does not produce the safety case, but the service provider does produce the safety case and so may produce an unsound one. The argument presented here is that the probability increases if the difficulty of the change increases (see figure in this GM). It is difficult to see why the commentator believes this may not be true.</p>
comment	<p>106 comment by: EUROCONTROL Safety Team</p> <p>GM1 ATM/ ANS.AR.C.035(b)(1) Point (d)(2)(ii) on Page 96</p> <p>The provider need to meet a minimum standard in order to be certified and these standards maintained to retain certification. If the CA has doubts, properly documented, about the capability of the provider then the CA needs to take action not only limited to a particular change.</p> <p>Recommend to delete (d)(2)(ii).</p>
response	<p>Not accepted</p> <p>The CA gains the necessary knowledge via its periodic oversight activities. The CA's perception is already the basis for performance-based review and so must be in a form and level of objectivity that could withstand legal scrutiny.</p>
comment	<p>107 comment by: EUROCONTROL Safety Team</p> <p>GM1 ATM/ ANS.AR.C.035(b)(1) Point (d)(2)(iii) on Page 97</p> <p>This is incorrect and without any legal basis because safety culture is not a requirement of certification.</p> <p>Recommend to delete (d)(2)(iii).</p>
response	<p>Not accepted</p> <p>'Safety culture' is used as shorthand for the level of performance of the organisation against its SMS.</p>



Where a service provider has consistently performed at a higher level than the minimum regulatory standard, it is argued that the probability of that organisation producing an unsound safety case is reduced.

comment 153 comment by: *NATS National Air Traffic Services Limited*

Point (a)(1) – it is not always that the safety case is complete ahead of a change to the functional system. This in the sense that there may be outstanding assurance activities which the safety case predicts will be successful and the actual change will be managed through a transition plan that has agreed assurance activities and go/no go criteria. A typical assurance activity that cannot be complete before the change has been implemented is HF assurance gleaned from real world operations that would provide assurance for HF hazards. If this were not to be allowed then no significant operational changes could ever take place.

response Not accepted

Please see the response to comment No 104.

comment 154 comment by: *NATS National Air Traffic Services Limited*

Point (d) (1) – the probability that an unsound safety case will be developed. NATS believe that the list provided (changes in number of hazards, hazard rates, mitigation etc.) are not an accurate indicator of an unsound safety case – they may in fact be an indicator of a more mature analysis.

As stated in a previous comment the use of the term “unsound” is not appropriate.

We suggest deleting the text in (d)(1) as it is not a true indicator of a potential unsound safety case.

response Partially accepted

While it is accepted that the premise may be true, the conclusion is not necessarily as implied by the comment.

(d)(1) deals with the risk creators, assuming the same level of maturity of analysis, and it does not deal with their relationship with the elaboration of an indicator that relates to the elaboration of a complex or unfamiliar safety case. This is dealt with in (d)(2). The maturity of the analysis is handled by (d)(2); specifically by (d)(2)(ii)(A).

The term ‘unsound’ has been removed and aligned with the IR text.

comment 155 comment by: *NATS National Air Traffic Services Limited*



	<p>Point (d)(2)(i) – given the criteria in (i) why would the CA be in a better position than the service provider to estimate the likelihood that service provider will develop an unsound safety case? The CA will equally lack relevant experience. At least the service provider may well be contracting a supplier who is well versed in the proposed change. This, at best, will be subjective and has no basis in a legal framework.</p> <p>The GM appears to have an underlying theme that the CA will always know better and will always be deemed competent – not always true.</p> <p>Suggest deleting (d)(2)(i).</p>
response	<p>Not accepted</p> <p>The issue is not who is in the best position to identify whether a safety case will be unsound or not, which as the commentator suggests is usually the service provider, but that the decision to review the safety case is that of the CA and not that of the service provider. The service provider is supposed to review the safety case before submission and implementation.</p>
comment	<p>156 comment by: <i>NATS National Air Traffic Services Limited</i></p>
	<p>Point (d)(2)(ii) – how does the CA gain knowledge of the capability of the service provider? The service provider, if certificated, must meet a minimum level of capability. Given that the CA must document this perception of service provider capability it could lead to legal challenge from the service providers. This, at best, will be subjective and has no basis in a legal framework.</p> <p>Suggest deleting (d)(2)(ii).</p>
response	<p>Not accepted</p> <p>Please see the response to comment No 106.</p>
comment	<p>157 comment by: <i>NATS National Air Traffic Services Limited</i></p>
	<p>Point (d)(2)(iii) – within the rules associated with the certification of a service provider there is no requirement for an ATS provider to have a safety culture. Use of the performance rule regarding safety culture could be punitive as in many case it is the States themselves that limit the claim by the ATS provider. The quality of the SMS must meet the necessary minimum standard if certified. This, at best, will be subjective and has no basis in a legal framework.</p> <p>Suggest deleting (d)(2)(iii).</p>
response	<p>Partially accepted</p> <p>The comment about the ‘performance rule’ and the safety culture, it is not well understood.</p>



'Safety culture' is used as a shorthand for the level of performance of the organisation against its SMS, and it does not have a specific meaning in terms of how to measure it. It is only an indication of the degree of effectiveness of the provider's SMS. The phrase 'safety culture has been changed by to 'The effectiveness of safety management' to avoid confusion.

It is accepted that to be certified, all service providers' SMS must achieve a minimum standard. That does not, however, preclude differences in the quality of their SMS, as a minimum standard does not imply an identical standard of achievement.

Where a service provider has consistently performed at a higher level than the minimum standard, it is argued (see figure of the GM) that the probability of that organisation producing an unsound safety case is reduced.

comment 295

comment by: DSNA

(a)(1) : it is not always that the safety case is complete ahead of a change to the functional system. This in the sense that there may be outstanding assurance activities which the safety case predicts will be successful and the actual change will be managed through a transition plan that has agreed assurance activities and go/no go criteria. A typical assurance activity that cannot be complete before the change has been implemented is HF assurance gleaned from real world operations that would provide assurance for HF hazards. If this were not to be allowed then no significant operational changes could ever take place.

(a)(1) seems inconsistent with ATM/ANS.OR.A.045.

response Not accepted

Please see the response to comment No 104.

It is not apparent how (a)(1) is inconsistent with ATM/ANS.OR.A.045.

comment 296

comment by: DSNA

(d):why would the CA be in a better position than the service provider to estimate the likelihood that service provider will develop an unsound safety case?

The CA will equally lack relevant experience. At least the service provider may well be contracting a supplier who is well versed in the proposed change. This, at best, will be subjective and has no basis in a legal framework.

The GM appears to have an underlying theme that the CA will always know better and will always be deemed competent – not always true.

DSNA proposes:



1. to delete **ALL** (d)
2. and to define new criteria, see comment on ATM/ANS.AR.C.035 Decision to review the notified change (b)(1).

(d)(2)(ii): how does the CA gain knowledge of the capability of the service provider? The service provider, if certificated, must meet a minimum level of capability. Given that the CA must document this perception of service provider capability it could lead to legal challenge from the service providers. This, at best, will be subjective and has no basis in a legal framework.

The CA cannot meet this requirement.

Additionally the IR comes in to conflict with the ANSPs certificate which requires a minimum standard to be met.

DSNA proposes to delete (d)(2)(ii).

response

Not accepted

The issue is not who is in the best position to identify whether a safety case will be unsound or not, which as the commentator suggests is usually the service provider, but that the decision to review the safety case is that of the CA and not that of the service provider. The service provider is supposed to review the safety case before submission and implementation. The CA should decide if the review is to be made or not based on its own (objective) criteria.

With regard to how the CA gains knowledge of the capability of the service provider, please refer to response to comment No 106.

comment

297

comment by: *DSNA*

(d)(2)(iii): within the rules associated with the certification of a service provider there is no requirement for an ATS provider to have a safety culture. Use of the performance rule regarding safety culture could be punitive as in many case it is the States themselves that limit the claim by the ATS provider. The quality of the SMS must meet the necessary minimum standard if certified. This, at best, will be subjective and has no basis in a legal framework.

DSNA proposes to delete (d)(2)(iii).

response

Partially accepted

Please see the response to comment No 157.



comment	<p>436</p> <p>Page No: 95 Paragraph No: GM1 ATM/ANS.AR.C.035(b)(1) Decision to review the notified change REVIEW W CRITERIA – ATS PROVIDERS (c) Comment: The UK CAA suggests that the text should include a clause to prevent CAs from using the creation of the selection criteria as an excuse to drastically reduce the number of changes it reviews. Justification: Adequacy of requirement on CA. Proposed Text: Addition of a clause, probably between (3) and (4) “it should not result in a significant reduction in the number of safety cases reviewed compared with arrangements that preceded this rule;”</p>	comment by: UK CAA
response	<p>Not accepted</p> <p>There is no evidence that the current review rate is appropriate. Furthermore, the appropriateness of the proposed criteria is to be reviewed in line with the goals of (c)(4). Consequently, the issue raised appears to be addressed.</p>	
comment	<p>438</p> <p>Page No: 95 Paragraph No: GM1 ATM/ANS.AR.C.035(b)(1) Decision to review the notified change REVIEW W CRITERIA – ATS PROVIDERS (c) Comment: The UK CAA suggests that the text includes a clause to prevent CAs from using the creation of the selection criteria to review far too few changes (failure to regulate adequately), or far too many changes (inefficient over-regulation). Justification: Adequacy of requirement on CA, consistency across CAs. Proposed Text: Addition of a clause stating that the requirement “should not result in a significant reduction in the number of safety cases reviewed compared with arrangements that preceded this rule;”</p>	comment by: UK CAA
response	<p>Not accepted</p> <p>Providing that the evaluation of ‘significant’ is correct, then the right number of changes should be reviewed.</p> <p>The aim of ATM/ANS.AR.C.035(c), on other criteria, is to validate this evaluation.</p> <p>In addition, the Agency will undertake some work to build and validate a model for review selection, including the validity of selection criteria.</p>	
comment	<p>439</p>	comment by: UK CAA



	<p>Page No: 95</p> <p>Paragraph No: GM1 ATM/ANS.AR.C.035(b)(1) Decision to review the notified change REVIEW W CRITERIA – ATS PROVIDERS (c)</p> <p>Comment: The UK CAA recommends that the CA should be required to submit its selection criteria to EASA for comment.</p> <p>Justification: Adequacy of requirement on CA, consistency across CAs.</p>
response	<p>Not accepted</p> <p>The review criteria will be harmonised via an AMC that will be developed later (approximately two years after the Opinion has been published). This is covered in the RIA of the NPA.</p> <p>Periodic oversight by EASA standardisation will seek to ensure that CAs are applying the criteria consistently.</p>
comment	<p>440 comment by: UK CAA</p>
	<p>Page No: 96</p> <p>Paragraph No: GM1 ATM/ANS.AR.C.035(b)(1) Decision to review the notified change REVIEW W CRITERIA – ATS PROVIDERS (c) (4)</p> <p>Comment: The two sub-clauses (i) and (ii) are obscure. It is not at all clear what is meant in either case. UK CAA requests clarification .</p> <p>Justification: Clarity.</p>
response	<p>Noted</p> <p>The information used to evolve the process should contain at the minimum:</p> <ol style="list-style-type: none"> 1) whether the change has proven to be unacceptable (with or without review by the CA), or its safety has been challenged by the CA based on evidence; and 2) whether the review of a change resulted in approval or rejection or withdraw..
comment	<p>441 comment by: UK CAA</p>
	<p>Page No: 96</p> <p>Paragraph No: GM1 ATM/ANS.AR.C.035(b)(1) Decision to review the notified change REVIEW W CRITERIA – ATS PROVIDERS (d) (1) (i)</p> <p>Comment: It is unclear whether this is meant to be a change in the number of hazards for the whole functional system, or that part changed or impacted by the change, or both. UK CAA requests clarification.</p> <p>Justification: Clarity.</p>



response

Noted

It is the increase in the number of the hazards associated with the change. Since hazards can only increase by either changing the functional system or by a contextual change affecting the functional system, which would require a responsive change to the functional system and since any change must be encompassed within the scope of the change, then the distinctions drawn by the commentator are irrelevant.

comment

442

comment by: UK CAA

Page No: 96**Paragraph No:** GM1 ATM/ANS.AR.C.035(b)(1) Decision to review the notified change REVIEW W CRITERIA – ATS PROVIDERS (d) (1)**Comment:** In the closing 'Note', we understand that 'In all cases' is probably meant to apply only to the list in this section, although its point is notionally universally applicable.**Justification:** Clarity.**Proposed Text:** Suggest change "In all cases ..." to "In this list ..."

response

Accepted

comment

443

comment by: UK CAA

Page No: 96**Paragraph No:** GM1 ATM/ANS.AR.C.035(b)(1) Decision to review the notified change REVIEW W CRITERIA – ATS PROVIDERS (d) (1) (v) Footnote 120**Comment:** The footnote uses the term 'hazardous event', whereas the text uses the term 'hazard'.**Justification:** Consistency.

response

Not accepted

The footnote is correct. The explanation for the use of hazardous events over hazards when dealing with accident trajectories may be found in GM1 ATS.OR.205.(b)4 Safety assessment and assurance of changes to the functional system.

comment

444

comment by: UK CAA

Page No: 96**Paragraph No:** GM1 ATM/ANS.AR.C.035(b)(1) Decision to review the notified change REVIEW W CRITERIA – ATS PROVIDERS (d) (2) (i)**Comment:** The properties of the system being changed can also dictate the probability of the

change being unsound. A quite simple and small change can fail due to the size and complexity of the system of the system to which it is being made. UK CAA recommend that a new (d) (2) (ii) is inserted between the existing (i) and (ii) to address this.

Justification: Completeness.

Proposed Text: '(ii) The system being changed or impacted

(A) Its size

(B) Its complexity

(C) Its novelty

(D) Its span (the range of other systems it interacts with)'

response

Partially accepted

The argument is accepted; however, the change has been implemented via a footnote.

comment

474

comment by: *skyguide Corporate Regulation Management*

Point (a)(1) – it is not always that the safety case is complete ahead of a change to the functional system. This in the sense that there may be outstanding assurance activities which the safety case predicts will be successful and the actual change will be managed through a transition plan that has agreed assurance activities and go/no go criteria. A typical assurance activity that cannot be complete before the change has been implemented is HF assurance gleaned from real world operations that would provide assurance for HF hazards. If this were not to be allowed then no significant operational changes could ever take place.

Point (d)(2)(i) – given the criteria in (i) why would the CA be in a better position than the service provider to estimate the likelihood that service provider will develop an unsound safety case? The CA will equally lack relevant experience. At least the service provider may well be contracting a supplier who is well versed in the proposed change. This, at best, will be subjective and has no basis in a legal framework.

The GM appears to have an underlying theme that the CA will always know better and will always be deemed competent – not always true.

We propose to delete (d)(2)(i).

Point (d)(2)(ii) – how does the CA gain knowledge of the capability of the service provider? The service provider, if certificated, must meet a minimum level of capability. Given that the CA must document this perception of service provider capability it could lead to legal challenge from the service providers. This, at best, will be subjective and has no basis in a legal framework.

We propose to delete (d)(2)(ii).

Point (d)(2)(iii) – within the rules associated with the certification of a service provider there is no requirement for an ATS provider to have a safety culture. Use of the performance rule regarding safety culture could be punitive as in many case it is the States themselves that limit the claim by the ATS provider. The quality of the SMS must meet the necessary minimum standard if certified. This, at best, will be subjective and has no basis in a legal framework.



response	<p>We propose to delete (d)(2)(iii).</p> <p>Not accepted</p> <p>Point (a)(1): Please see the response to comment No 104.</p> <p>Point (d)(2)(i): Please see the response to comment No 155.</p> <p>Point (d)(2)(ii): Please see the response to comment No 106.</p> <p>Point (d)(2)(iii): Please see the response to comment No 157.</p>
comment	<p>514 comment by: EUROCONTROL</p> <p>GM1 ATM/ANS.AR.C.035(b)(1) Decision to review the notified change – Page 92</p> <p>EUROCONTROL makes several comments.</p> <ul style="list-style-type: none"> • It is found that there should be more guidance on how an NSA should review the safety argument with a view to deciding whether it's good or not and, therefore, the change subject to approval. • The current version of the NPA talks about “complete arguments”. For those routinely using GSN safety arguments, the topic should be self-explanatory. However, major issues may be foreseen for smaller ANSPs or those less advanced in arguing safety. • The notion of “unsound safety case” as presented in Table 1 on page 93 might be (wrongly) understood as being what we describe today in terms of ANSP maturity, experience of the technology, the change itself, etc. Besides a possible wrong understanding there is an aspect that is essential: an “unsound” safety case could be a conclusion of the review but not a criterion for deciding to review. In addition, the wording is inappropriate since “unsound” usually refers to criteria that are mainly subjective. • What is done currently, with the risk-based approach, allows for NSAs to make decisions on the basis of criteria that they define (in collaboration with the ANSPs). This approach provides the NSAs with an overview of the changes and allows them to dig “where it might hurt”, not because they fear the ANSPs will not be able to build a decent safety case but because the NSAs need to be involved to be able to review adequately the Safety Case and finally take a go/no-go decision on implementation of the change.
response	<p>Partially accepted</p> <p>1) The need for more guidance on how to perform the review is recognised and it will be tackled in the 2nd NPA.</p> <p>2) The comment about the ‘complete argument’ is agreed; however, covering this topic fully is not possible in this GM. It is probably best addressed via education and training, or</p>



possibly in the future update of material.

3) The comment about the 'unsound safety case' is not accepted.

Table 1 describes what is meant by 'unsound'.

The actual nature of the safety case is, indeed, determined by the review itself. However, the commentator is missing the point, that the decision is based on a prediction of whether the safety case will or will not be unsound, not its actual state.

4) The final point being made is unclear. The GM on CA/ANSP interaction during change in Section 3.2.1 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities identifies and resolves the issues raised by the commentator. The decision to review a safety case comes before the development has progressed to the point where the issues raised could be resolved, using the means suggested, and so they are irrelevant to this GM.

comment

644

comment by: CANSO

GM1 ATM/ANS.AR.C.035(b)(1)

Point (a)(1) – it is not always that the safety case is complete ahead of a change to the functional system. This in the sense that there may be outstanding assurance activities which the safety case predicts will be successful and the actual change will be managed through a transition plan that has agreed assurance activities and go/no go criteria. A typical assurance activity that cannot be complete before the change has been implemented is HF assurance gleaned from real world operations that would provide assurance for HF hazards. If this were not to be allowed then no significant operational changes could ever take place.

response

Not accepted

Point (a)(1): Please see the response to comment No 104.

comment

645

comment by: CANSO

GM1 ATM/ANS.AR.C.035(b)(1)

Point (d)(2)(i) – given the criteria in (i) why would the CA be in a better position than the service provider to estimate the likelihood that service provider will develop an unsound safety case? The CA will equally lack relevant experience. At least the service provider may well be contracting a supplier who is well versed in the proposed change. This, at best, will be subjective and has no basis in a legal framework.

The GM appears to have an underlying theme that the CA will always know better and will always be deemed competent – not always true.

CANSO proposes to delete (d)(2)(i).



response [Not accepted](#)

[Point \(d\)\(2\)\(i\): Please see the response to comment No 155.](#)

comment **646**

comment by: *CANSO*

GM1 ATM/ANS.AR.C.035(b)(1)

Point (d)(2)(ii) – how does the CA gain knowledge of the capability of the service provider? The service provider, if certificated, must meet a minimum level of capability. Given that the CA must document this perception of service provider capability it could lead to legal challenge from the service providers. This, at best, will be subjective and has no basis in a legal framework.

CANSO proposes to delete (d)(2)(ii).

response [Not accepted](#)

[Point \(d\)\(2\)\(i\): Please see the response to comment No 106.](#)

comment **647**

comment by: *CANSO*

GM1 ATM/ANS.AR.C.035(b)(1)

Point (d)(2)(iii) – within the rules associated with the certification of a service provider there is no requirement for an ATS provider to have a safety culture. Use of the performance rule regarding safety culture could be punitive as in many case it is the States themselves that limit the claim by the ATS provider. The quality of the SMS must meet the necessary minimum standard if certified. This, at best, will be subjective and has no basis in a legal framework.

CANSO proposes to delete (d)(2)(iii).

response [Partially accepted](#)

[Point \(d\)\(2\)\(iii\): Please see the response to comment No 157.](#)

comment **694**

comment by: *ROMATSA*

Point (a)(1) – it is not always that the safety case is complete ahead of a change to the functional system. This in the sense that there may be outstanding assurance activities which the safety case predicts will be successful and the actual change will be managed through a transition plan that has agreed assurance activities and go/no go criteria. A typical assurance activity that cannot be complete before the change has been implemented is HF assurance gleaned from real world operations that would provide assurance for HF hazards. If this were not to be allowed then no significant operational changes could ever take place.



response	Supporting comment to summary issue: Unfeasible requirement on the ANSP in the real world.
	<p>Not accepted</p> <p>Point (a)(1): Please see the response to comment No 104.</p>

comment	comment by: <i>ROMATSA</i>
	<p>695</p> <p>Point (d)(2)(i) – given the criteria in (i) why would the CA be in a better position than the service provider to estimate the likelihood that service provider will develop an unsound safety case? The CA will equally lack relevant experience. At least the service provider may well be contracting a supplier who is well versed in the proposed change. This, at best, will be subjective and has no basis in a legal framework.</p> <p>The GM appears to have an underlying theme that the CA will always know better and will always be deemed competent – not always true.</p> <p>ROMATSA supports CANSO suggestion to delete (d)(2)(i).</p> <p>Supporting comment to summary issue: Unfeasible requirement on the CA as evidenced by the world experience.</p> <p>Point (d)(2)(ii) – how does the CA gain knowledge of the capability of the service provider? The service provider, if certificated, must meet a minimum level of capability. Given that the CA must document this perception of service provider capability it could lead to legal challenge from the service providers. This, at best, will be subjective and has no basis in a legal framework.</p> <p>ROMATSA supports CANSO suggestion to delete (d)(2)(ii).</p> <p>Supporting comment to summary issue: Unfeasible requirement on the CA. Additionally the IR comes in to conflict with the ANSPs certificate which requires a minimum standard to be met.</p> <p>Point (d)(2)(iii) – within the rules associated with the certification of a service provider there is no requirement for an ATS provider to have a safety culture. Use of the performance rule regarding safety culture could be punitive as in many case it is the States themselves that limit the claim by the ATS provider. The quality of the SMS must meet the necessary minimum standard if certified. This, at best, will be subjective and has no basis in a legal framework.</p> <p>ROMATSA supports CANSO suggestion to delete (d)(2)(iii).</p>



Supporting comment to summary issue: Incorrect GM. Safety culture is not a requirement of certification. It is addressed in the Performance Implementing Rule and should not be introduced here.

response **Not accepted**

Point (d)(2)(i): Please see the response to comment No 155.

Point (d)(2)(ii): Please see the response to comment No 106.

Point (d)(2)(iii): Please see the response to comment No 157.

comment **710** comment by: *DFS Deutsche Flugsicherung GmbH*

Point (d) (2) (iii)
 - within the rules associated with the certification of a service provider there is no requirement for an ATS provider to have a safety culture. Use of the performance rule regarding safety culture could be punitive as in many case it is the States themselves that limit the claim by the ATS provider. The quality of the SMS must meet the necessary minimum standard if certified. This, at best, will be subjective and has no basis in a legal framework.

We suggest to delete (d)(2)(iii).
 Reference to high level comment "c.v"

response **Partially accepted**

Please see the response to comment No 157.

comment **902** comment by: *DGAC/DSAC - french NSA*

Refer to french NSA answer to question 3.

response **Noted**

comment **923** comment by: *AESA / DSANA*

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.2 Draft AMC & GM (Draft EASA	(a)(1): "As the change to the functional system will only start being implemented	These concepts should be perfectly clear before the development of the other



<p>Decision) ANNEX II REQUIREMENTS FOR COMPETENT AUTHORITIES — SERVICE PROVISION AND NETWORK FUNCTIONS (Part- ATM/ANS.AR) GM1 ATM/ANS.AR.C.035(b)(1)</p>	<p>once the safety case is complete and in some cases approved..."</p> <p>This statement contradicts the ideas exposed in some sections before (e.g. implementation may start before the approval in parallel with the development of the safety case).</p>	<p>requirements in the implementing rule, since they represent the base of the process.</p> <p>Further to this, this NPA is quite important for the functioning of the whole system and it should be as clear as possible in order to avoid present and future misunderstandings.</p>
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response Partially accepted

The statement does not contradict other GM. The GM on CA/ANSP interaction during change in Section 3.2.1 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities describes how a change develops and differentiates between the implementation of the parts of the change that will not affect operations and those that will (c) & (d).

The safety case must be approved before any part of the change that can have an effect on the operation of the service is implemented.

There are two ways of performing a change described in the GM but these are not intended to be the only ways of performing change, just two contrasting ways. In the first, no change should be implemented until a valid safety case for it exists and, if necessary, it has been approved. In the second case, the intention is that the safety case covers all transitions before any of them are implemented. However, the IR allows change to be implemented providing a valid safety case exists for the part of the change being implemented. This could include a partial implementation of the type of change foreseen in (d)(2)(ii).

Since this GM follows the GM on change interactions, it was not felt necessary to be complete as the ground rules have already been established. However, the text has been clarified and a footnote has been added to aid the reader.

comment 925

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION



<p>Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX II REQUIREMENTS FOR COMPETENT AUTHORITIES — SERVICE PROVISION AND NETWORK FUNCTIONS (Part-ATM/ANS.AR) GM1 ATM/ANS.AR.C.035(b)(1)</p>	<p>(a)(2) Table 1 (Case Not adequately safe - Sound): it is stated that, in this case, "the change will be abandoned and the safety case will not be submitted for review".</p> <p>This option is not clear enough and does not seem to make sense: irrespective of the case, the change would not be abandoned but sent back to the ANSP for new iterations until an acceptable level of safety is reached.</p> <p>Further to this, there is no provision within the NPA that requires that only cases that are adequately safe can be notified.</p>	<p>The inclusion of a provision that explicitly forbids the introduction of changes "Not adequately safe" (and its notification to the CA) by an ANSP is fundamental in order to ensure the soundness of the notifications sent to the CA.</p>
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response **Not accepted**

The table is a State table and does not seek to represent a process. Clearly, if the service provider makes the case that the change is not adequately safe and the safety case is sound, then he will not pursue this particular change and will not submit the safety case to the CA. Consequently, the change is 'abandoned'.

comment 926

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i></p>	<p>(a)(5): a minimum/maximum period of time should be established for the CA</p>	<p>A minimum period of time that allows the CA to apply its procedures in an orderly and systematic manner without being</p>



<p>ANNEX II <i>REQUIREMENTS FOR COMPETENT AUTHORITIES — SERVICE PROVISION AND NETWORK FUNCTIONS (Part-ATM/ANS.AR)</i> GM1 ATM/ANS.AR.C.035(b)(1)</p>	<p>review.</p>	<p>subject to external pressures (deadlines, political commitments,...).</p> <p>A maximum period of time that helps the ANSP assess the duration of this activity (CA <i>deciding whether to review or not</i>) in order to define the timeframe for the introduction of the change within the plan for the implementation of the change.</p>
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response Partially accepted

While the need for limiting the response time is acknowledged, the introduction of a precise time limit seems not appropriate, as, given the vast range of different services provided setting a fixed (minimum or maximum) time limit, would be infeasible. In any case, text has been introduced (i.e. 'without undue delay') at the AMC level to avoid unreasonable time to response (see AMC1 ATM/ ANS.AR.030(c)).

comment 927

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX II <i>REQUIREMENTS FOR COMPETENT AUTHORITIES — SERVICE PROVISION AND NETWORK FUNCTIONS (Part-ATM/ANS.AR)</i> GM1 ATM/ANS.AR.C.035(b)(1)</p>	<p>(d): we fully agree with this provision as the criteria furnished are quite similar to the ones defined in the <i>EUROCONTROL Guidelines for the Safety Oversight of Changes to ATM (EAM 1 / GUI 4)</i>.</p> <p>In order to further enhance this provision, we would only suggest that some examples are provided that show both how these criteria can lead the decision to review or not to review.</p>	<p>We have been using these criteria for some time now and it is a fact that they give a certain idea of the probability of a safety argument being reliable.</p>



response **Noted**

The proposal, in the NPA, is for the proposed method to be validated in future activities and AMC created to establish a means of evaluating the risk, based on the criteria suggested in the NPA.

This would involve looking at the means suggested by EUROCONTROL as well as any other candidates.

comment 929

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX II <i>REQUIREMENTS FOR COMPETENT AUTHORITIES — SERVICE PROVISION AND NETWORK FUNCTIONS (Part-ATM/ANS.AR)</i> GM1 ATM/ANS.AR.C.035(b)(1)</p>	<p>(e): The whole section including <i>Figure 3</i> are much unclear.</p> <p>In a more pragmatic level, we wonder: a) about what a '<i>demand rate</i>' is; and b) whether the service provider shall include the value of these parameters in the notification of the change.</p> <p>Finally, it is understood that providing this information about '<i>severity of the consequences</i>' of the change corresponds to the service provider. Would this not be the case, we wonder how the CA could estimate them with just coarse-grained information.</p>	<p>This NPA is quite important for the functioning of the whole system and it should be as clear as possible in order to avoid present and future misunderstandings.</p>



response **Noted**

a) 'Demand rate' is the rate at which demands are made of the part of the system being changed. For example, if an ILS were being changed, then the demand rate for part of the service would be the aircraft arrival rate.

b) It is not necessary for this information to be included in the change notification; however, it will be needed before the decision to review the safety case is made. This is explained in GM1 ATM/ANS.OR.A.045(a) Changes to the functional system NOTIFICATION DATA (b)

c) It is provided by the service provider (see the response to (b)). If the service provider does not provide it, the CA can request it in accordance with ATM/ANS.AR.C.035(a).

The NPA accepts that the selection criteria are not complete and provides for their completion via a proposal to validate the model described in this GM. It is likely therefore that the GM is not completely clear. This will be addressed as part of the proposed validation exercise.

comment 930

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX II <i>REQUIREMENTS FOR COMPETENT AUTHORITIES — SERVICE PROVISION AND NETWORK FUNCTIONS (Part-ATM/ANS.AR)</i> GM1 ATM/ANS.AR.C.035(b)(1)</p>	<p>(f): more GM should be provided in order to help in the quantification of both parameters ('severity of the consequences' and 'probability of unsound safety case') when using the risk matrix.</p>	<p>The use of the risk matrix in a real situation is not clear.</p> <p>Further to this, the difference between the cases when the CA is deciding whether to review or not (1) a safety case and (2) a safety support case is not clear.</p>

response **Noted**

The NPA accepts that the selection criteria are not complete and provides for their completion via a proposal to validate the model described in this GM. It is likely therefore



that the GM is neither complete nor clear. This will be addressed as part of the proposed validation exercise.

The criteria for the review decision will be defined in AMC once the validation exercise is complete. This should also help to clarify the decision model.

comment

1117

comment by: *Belgocontrol*

GM1 ATM/ ANS.AR.C.035(b)(1) Point (a)(1) on Page 92

It is not always possible to complete the safety case before the start of the implementation.

response

Not accepted

Point (a)(1): Please see the response to comment No 104.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX II — Requirements for competent authorities — Service provision and network functions (Part-ATM/ANS.AR) — GM2 ATM/ANS.AR.C.035(b)(1) Decision to review the notified change

p. 99-100

comment

158

comment by: *NATS National Air Traffic Services Limited*

The risk matrices showing the criteria to review for different levels of risk will require significant development to be useful. Suggest deletion until such time as there is a reasoned and justified proposal that has been subject to consultation.

Other selection criteria are in ATM/ANS.AR.C.035(b)(2) not (b)(1).

Please delete the text in GM2 ATM/ANS.AR.C.035 (b) (1)

response

Not accepted

It is true that the risk matrices will take significant development. This has been foreseen in the NPA. The GM has been provided so that CAs and service providers have sight of the intended way the material will develop and so may take it into account before the material has been actually developed. This will be part of future work by the Agency. While there is some likelihood that the evaluation of the risk may not be as predicted, it is thought that this is small and the GM will therefore remain roughly as it is. Consequently, publishing it now is thought to be useful.



comment	298	comment by: <i>DSNA</i>
	<p><u>This GM is unhealthy.</u> The relationship between AR and a certified OR is <u>based on trust</u>, not suspicion.</p> <p><u>DSNA proposes to delete this GM.</u></p>	
response	<p>Not accepted</p> <p>The relationship between service providers and CAs, which is certainly based on trust, has nothing to do with the fact that not all safety cases will be perfect. If they were, there would be no need for a CA to review any of them. In order to minimise the effort of the CA and hence the cost to the industry, some means of identifying those safety cases that pose a significant risk of not being perfect and also a substantial safety risk, is needed. This GM explains the proposed way of identifying such safety cases.</p>	

comment	903	comment by: <i>DGAC/DSAC - french NSA</i>
	<p>Refer to french NSA answer to question 3.</p> <p>The title should be GM2 ATM/ANS.AR.C.035 (b)(2) instead of (b)(1) .</p>	
response	<p>Partially accepted</p> <p>The title is wrong but has not been changed in the way suggested because the IR has been altered.</p> <p>In relation to the answer to Question 3, please see the response to comment No 1053.</p>	

<p>3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM1 ATM/ANS.AR.C.035 & ATM/ANS.OR.A.045 General</p>	<p>p. 101</p>
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comment	763	comment by: <i>CAA Norway</i>
	<p>AMC1 ATM/ANS.OR.A.045(a) Point (b):</p> <p>The meaning of the last sentence in (b): "In any case, the notification should be legally binding", is unclear.</p>	
response	<p>Accepted</p> <p>The text has been removed.</p>	



comment	<p>1119</p> <p>AMC1 ATM/ANS.OR.A.045 (a) Point (a) Service providers are required to notify their planned changes to other service providers which are expected to be impacted by this planned change. However, a regulated or unregulated body (which are not bound by this rule) would not necessarily notify the service provider of their planned changes. Therefore this AMC is practically not possible. It may be incorporated as GM but only after it has been re-written to reflect the requirement that the service provider notifies the NSA/CA about known changes.</p>	comment by: <i>Belgocontrol</i>
response	<p>Not accepted</p> <p>The commentator seems to have misinterpreted the provision. The AMC is about the service provider notifying the CA about a change he/she wishes to make, not about changes other service providers wish to make.</p> <p>Section (a) of the AMC has been removed as it was causing confusion and added little to the IR.</p>	
comment	<p>1121</p> <p>AMC1 ATM/ ANS.OR.A.045(a) Point (b) What is meant by <i>notification means should be legally binding</i>? <u>Recommend</u> to remove <i>In any case, the notification means should be legally binding.</i></p>	comment by: <i>Belgocontrol</i>
response	<p>Accepted</p> <p>The text has been removed.</p>	
comment	<p>1189</p> <p>Point (a)(1) – it is not always that the safety case is complete ahead of a change to the functional system. This in the sense that there may be outstanding assurance activities which the safety case predicts will be successful and the actual change will be managed through a transition plan that has agreed assurance activities and go/no go criteria. A typical assurance activity that cannot be complete before the change has been implemented is HF assurance gleaned from real world operations that would provide assurance for HF hazards. If this were not to be allowed then no significant operational changes could ever take place.</p>	comment by: <i>Avinor ANS</i>
response	<p>Not accepted</p> <p>The comment seems to be misplaced and be related to GM1 ATM/ANS.AR.C.035(b)(1).</p>	



Please see the response to comment No 104.

comment 1190

comment by: *Avinor ANS*

Point (d)(2)(i) – given the criteria in (i) why would the CA be in a better position than the service provider to estimate the likelihood that service provider will develop an unsound safety case? The CA will equally lack relevant experience. At least the service provider may well be contracting a supplier who is well versed in the proposed change. This, at best, will be subjective and has no basis in a legal framework.

The GM appears to have an underlying theme that the CA will always know better and will always be deemed competent – not always true.

We proposes to delete (d)(2)(i).

response Not accepted

The comment seems to be misplaced and be related to GM1 ATM/ANS.AR.C.035(b)(1).

Please see the response to comment No 155.

comment 1192

comment by: *Avinor ANS*

Point (d)(2)(ii) – how does the CA gain knowledge of the capability of the service provider? The service provider, if certificated, must meet a minimum level of capability. Given that the CA must document this perception of service provider capability it could lead to legal challenge from the service providers. This, at best, will be subjective and has no basis in a legal framework.

We proposes to delete (d)(2)(ii).

response Not accepted

The comment seems to be misplaced and be related to GM1 ATM/ANS.AR.C.035(b)(1).

Please see the response to comment No 106.

comment 1193

comment by: *Avinor ANS*

Incorrect GM. Safety culture is not a requirement of certification. It is addressed in the Performance Implementing Rule and should not be introduced here.

response Not accepted

The comment seems to be misplaced and be related to GM1 ATM/ANS.AR.C.035(b)(1).



Please see the response to comment No 157.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — AMC1 ATM/ANS.OR.A.045(a) Changes to the functional system p. 101

comment 108 comment by: EUROCONTROL Safety Team

AMC1 ATM/ANS.OR.A.045 (a) Point (a)

Service providers are required to notify, where known, other SPs of their planned changes however, a regulated or unregulated body (which are not bound by this rule) would not necessarily inform the SP of their planned changes. In such a case how could the SP judge the impact of the change? Consequently this AMC is practically infeasible. At best it could be incorporated as GM but only after it had been re-written to reflect the requirement that the SP notifies the CA about **known** changes.

response Not accepted

The commentator seems to have misinterpreted the provision. The AMC is about the service provider notifying the CA about a change he/she wishes to make, not about changes other service providers wish to make.

Section (a) of the AMC has been removed as it was causing confusion and added little to the IR.

comment 109 comment by: EUROCONTROL Safety Team

AMC1 ATM/ ANS.OR.A.045(a) Point (b)

Infeasible and possibly illegal in some states.

What is meant by *notification means should be legally binding*? This sounds ominous.

Recommend to delete *In any case, the notification means should be legally binding*.

response Accepted

The text has been removed.

comment 159 comment by: NATS National Air Traffic Services Limited

In point (a) it is unclear how an ANSP would necessarily know that a change originated by another service provider or another regulated or unregulated body would impact them.



Whilst other service providers are required to notify, where known, other service providers of their planned changes it is difficult to see how either a regulated or unregulated body (who are not bound by this rule) would necessarily inform the service provider of their planned changes.

This is not risk based regulation. It is proposed that the AMC is moved to Guidance Material and re-worded to say:

“A service provider should notify its CA of all known changes proposed by the provider itself or stemming from the impact of any other change proposed by another service provider or by another regulated or unregulated body that affect the following:”

response

Partially accepted

How a service provider establishes if a change proposed by someone else affects the service they provide is dealt with in Section 3.1.1 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities.

The commentator seems to have misinterpreted the provision. The AMC is about the service provider notifying the CA about a change he/she wishes to make, and therefore is about known changes (please note that a planned change is imperative to be known), not about changes other service providers wish to make.

Section (a) of the AMC has been removed as it was causing confusion and added little to the IR for clarity.

comment

160

comment by: NATS National Air Traffic Services Limited

Para (a)(2) refers to the way the services of the service provider behave. The services are not likely to change. Rather the functional system to deliver the (same) services will change.

Suggest change to paragraph to read:

the way the functional systems of the service provider behave to deliver the service

response

Not accepted

The way the service behaves can be also changed if the environment in which the service is delivered changes. This is not a change to the functional system.

comment

161

comment by: NATS National Air Traffic Services Limited

Point (b), “A service provider should submit the notification of changes in a manner agreed between the provider and the CA. Until an agreement is reached, the CA will prescribe the means of submission. In any case, the notification means should be legally binding.”

The requirement for a legally binding notification means cannot be placed as a requirement on service providers; this rule should detail the necessary obligation and not attempt to



	<p>defer the issue by other means. Suggest change the text to read: A service provider should submit the notification of changes in a manner agreed between the provider and the CA. Until an agreement is reached, the CA will prescribe the means of submission. In any case, the notification means should be legally binding.</p>
response	<p>Accepted</p> <p>The text has been removed.</p>
comment	<p>299 comment by: <i>DSNA</i></p> <p>DSNA : proposes to move this AMC to Guidance Material and re-worded to say: “A service provider should notify its CA of all changes proposed by the provider itself or stemming from the impact of any other known change proposed by another service provider or by another regulated or unregulated body that affect the following:”</p>
response	<p>Not accepted</p> <p>The commentator seems to have misinterpreted the provision. The AMC is about the service provider notifying the CA about a change he/she wishes to make, regardless the driver of that change, and not about changes other service providers wish to make.</p> <p>Section (a) of the AMC has been removed as it was causing confusion and added little to the IR for clarity.</p>
comment	<p>362 comment by: <i>Finavia</i></p> <p>A definition should exist to indicate which kind of changes in functional system will or will not trigger the service providers obligation to notify the CA. Minor changes with no impact to safety or functionality of the system should be allowed to be excluded from this process.</p> <p>Argument for the comment: Without definition, every single minor change with no impact to functionality or safety can be understood as a change to be notified, which might unnecessarily burden both the service provider and CA.</p>
response	<p>Not accepted</p> <p>There is no absolute definition of a change other than any change to the functional system that may cause a change in the behaviour of the service. This is explained in more detail in Section 3.1.1 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities. All changes with the potential to modify the behaviour of the service need to be notified, but only some will need review and approval. It is explained in GM that the</p>



competent authority may agree with the service provider a list of changes that will not be reviewed and that the service provider can implement without waiting for the approval of the CA. Those changes can be notified collectively with an agreed frequency (e.g. once every month or every year). The service provider has to assess them, in any case, and keep a log of them.

comment 482

comment by: skyguide Corporate Regulation Management

In **point (a)** it is unclear how an ANSP would necessarily know that a change originated by another service provider or another regulated or unregulated body would impact them. Whilst other service providers are required to notify, where known, other service providers of their planned changes it is difficult to see how either a regulated or unregulated body (who are not bound by this rule) would necessarily inform the service provider of their planned changes. We propose that the AMC is moved to Guidance Material and re-worded to say:

“A service provider should notify its CA of all known changes proposed by the provider itself or stemming from the impact of any other change proposed by another service provider or by another regulated or unregulated body that affect the following:”

Point (b), “A service provider should submit the notification of changes in a manner agreed between the provider and the CA. Until an agreement is reached, the CA will prescribe the means of submission. In any case, the notification means should be legally binding.”

The requirement for a legally binding notification means cannot be placed as a requirement on service providers.

Change the text to read:

A service provider should submit the notification of changes in a manner agreed between the provider and the CA. Until an agreement is reached, the CA will prescribe the means of submission. ~~In any case, the notification means should be legally binding.~~

response

Partially accepted

Point (a) is partially accepted. Please see the response to comment No 159.

Point (b) is accepted and the text has been removed.

comment 648

comment by: CANSO

In point (a) it is unclear how an ANSP would necessarily know that a change originated by another service provider or another regulated or unregulated body would impact them. Whilst other service providers are required to notify, where known, other service providers of their planned changes it is difficult to see how either a regulated or unregulated body (who are not bound by this rule) would necessarily inform the service provider of their planned changes.



	<p>CANSO proposes that the AMC is moved to Guidance Material and re-worded to say: “A service provider should notify its CA of all known changes proposed by the provider itself or stemming from the impact of any other change proposed by another service provider or by another regulated or unregulated body that affect the following.”</p>
response	<p>Partially accepted</p> <p>Please see the response to comment No 159.</p>

comment	<p>649 comment by: <i>CANSO</i></p>
	<p>Point (b), “A service provider should submit the notification of changes in a manner agreed between the provider and the CA. Until an agreement is reached, the CA will prescribe the means of submission. In any case, the notification means should be legally binding.”</p> <p>The requirement for a legally binding notification means cannot be placed as a requirement on service providers.</p> <p>Change the text to read:</p> <p>A service provider should submit the notification of changes in a manner agreed between the provider and the CA. Until an agreement is reached, the CA will prescribe the means of submission. In any case, the notification means should be legally binding.</p>
response	<p>Accepted</p> <p>The text has been removed.</p>

comment	<p>696 comment by: <i>ROMATSA</i></p>
	<p>In point (a) it is unclear how an ANSP would necessarily know that a change originated by another service provider or another regulated or unregulated body would impact them. Whilst other service providers are required to notify, where known, other service providers of their planned changes it is difficult to see how either a regulated or unregulated body (who are not bound by this rule) would necessarily inform the service provider of their planned changes.</p> <p>ROMATSA supports CANSO suggestion that the AMC is moved to Guidance Material and re-worded to say:</p> <p>“A service provider should notify its CA of all <u>known</u> changes proposed by the provider itself or stemming from the impact of any other change proposed by another service provider or by another regulated or unregulated body that affect the following.”</p> <p>Supporting comment to summary issue: This is not feasible and is not Performance Based Regulation.</p>



Point (b), “A service provider should submit the notification of changes in a manner agreed between the provider and the CA. Until an agreement is reached, the CA will prescribe the means of submission. In any case, the notification means should be legally binding.”

The requirement for a legally binding notification means cannot be placed as a requirement on service providers.

Change the text to read:

“A service provider should submit the notification of changes in a manner agreed between the provider and the CA. Until an agreement is reached, the CA will prescribe the means of submission. ~~In any case, the notification means should be legally binding.~~”

Supporting comment to summary issue: Not feasible.

AMC1 ATM/ANS.OR.A.045(a)(3)

Even where known it is not feasible to individually notify all known service providers and aviation undertakings. For certain changes this could run into hundreds if not thousands of notifications. There are generic publications that are currently used to promulgate the change and its impact. The onus should be on the other service providers and aviation undertakings to read these publications.

There will be a significant number of changes that has no effect on any other service provider or aviation undertaking yet (b) would require that they are published - with no-one interested.

Supporting comment to summary issue: Unfeasible requirement in the real world.

response

Partially accepted

Point (a) is partially accepted. Please see the response to comment No 159.

Point (b) is accepted and the text has been removed.

The comment on AMC1 ATM/ANS.OR.A.045(a)(3) is accepted. It is accepted that it may not be feasible to inform all aviation undertakings; however, it is feasible to inform all service providers affected by the change, as their number is much more reduced and it is feasible to inform them. In the case of aviation undertakings, GM is provided on this issue (GM1 ATM/ANS.OR.A.045(f)(2)) which states that ‘When the number of aviation undertakings affected by the change is large, the service providers may not need to involve every individual stakeholder. If a body can represent the views of a group of affected aviation undertakings, it may suffice to involve that representative body to obtain the supporting evidence to move forward with the assessment of the change’. The AMC has been altered to reflect this and the text is amended to individually notify the service providers only, as their number will be reduced, and through other means to aviation



undertakings (e.g. through a publication site). Note that if the change has no effect on any other service provider, it is not necessary to notify them.

comment 711 comment by: *DFS Deutsche Flugsicherung GmbH*

“(a) A service provider should notify its CA of all changes”

That requires that the service provider knows about it, but if not? E.g. when an aviation undertaking that is not regulated by this IR/AMC changes something and doesn't inform the service provider.

In point (a) it is not clear how an ANSP would necessarily know that a change originated by another service provider or another regulated or especially of an unregulated body would impact them. Whilst other service providers are required to notify, where known, other service providers of their planned changes it is difficult to see how either a regulated or unregulated body (who are not bound by this rule) would necessarily inform the service provider of their planned changes.

suggestion: “(a) A service provider should notify its CA of all planned changes”.
The AMC can even be moved to Guidance Material.

Reference to high level comment "c.ii"

response Partially accepted

Please see the response to comment No 159.

comment 712 comment by: *DFS Deutsche Flugsicherung GmbH*

(b) "Until an agreement on the manner to notify the change is reached, the CA will prescribe the means of submission."

We suggest to delete it or move it to GM level, since it only gives information.
Reference to high level comment "a"

response Not accepted

It is not GM since it authorises the CA to declare the means of notification when reaching agreement is protracted.

comment 713 comment by: *DFS Deutsche Flugsicherung GmbH*

“(b) [...] In any case, the notification means should be legally binding”



What does "legally binding" mean? A notification needs to be repealed or be changeable, if necessary.

This looks like interference with competence of national authorities due to the state's sovereignty for regulation of formal administrative procedures. Meaning: legal bindingness of paper, electronic or other means is a matter of national regulation. Additionally, there is no requirement to which that sentence could be a means of compliance

We suggest to delete the sentence to avoid overregulation.
Reference to high level comment "c.ii"

response

[Accepted](#)[The text has been removed.](#)

comment

1061

comment by: LVNL

In point (a) it is unclear how an ANSP would necessarily know that a change originated by another service provider or another regulated or unregulated body would impact them. Whilst other service providers are required to notify, where known, other service providers of their planned changes it is difficult to see how either a regulated or unregulated body (who are not bound by this rule) would necessarily inform the service provider of their planned changes.

It is proposed that the AMC is moved to Guidance Material and re-worded to say: "A service provider should notify its CA of all known changes proposed by the provider itself or stemming from the impact of any other change proposed by another service provider or by another regulated or unregulated body that affect the following:"

response

[Partially accepted](#)[Please see the response to comment No 159.](#)

comment

1062

comment by: LVNL

Point (b), "A service provider should submit the notification of changes in a manner agreed between the provider and the CA. Until an agreement is reached, the CA will prescribe the means of submission. In any case, the notification means should be legally binding."

The requirement for a legally binding notification means cannot be placed as a requirement on the service providers.

Change the text to read:

A service provider should submit the notification of changes in a manner agreed between the provider and the CA. Until an agreement is reached, the CA will prescribe the means of



	submission. In any case, the notification means should be legally binding.
response	<p>Accepted</p> <p>The text has been removed.</p>
comment	<p>1195 comment by: <i>Avinor ANS</i></p> <p>In point (a) it is unclear how an ANSP would necessarily know that a change originated by another service provider or another regulated or unregulated body would impact them. Whilst other service providers are required to notify, where known, other service providers of their planned changes it is difficult to see how either a regulated or unregulated body (who are not bound by this rule) would necessarily inform the service provider of their planned changes.</p> <p>We proposes that the AMC is moved to Guidance Material and re-worded to say: “A service provider should notify its CA of all <u>known</u> changes proposed by the provider itself or stemming from the impact of any other change proposed by another service provider or by another regulated or unregulated body that affect the following:”</p>
response	<p>Partially accepted</p> <p>Please see the response to comment No 159.</p>
comment	<p>1196 comment by: <i>Avinor ANS</i></p> <p>Point (b), “A service provider should submit the notification of changes in a manner agreed between the provider and the CA. Until an agreement is reached, the CA will prescribe the means of submission. In any case, the notification means should be legally binding.”</p> <p>The requirement for a legally binding notification means cannot be placed as a requirement on service providers.</p> <p>Change the text to read: A service provider should submit the notification of changes in a manner agreed between the provider and the CA. Until an agreement is reached, the CA will prescribe the means of submission. In any case, the notification means should be legally binding.</p>
response	<p>Accepted</p> <p>The text has been removed.</p>
comment	<p>1198 comment by: <i>Avinor ANS</i></p> <p>Even where known it is not feasible to <u>individually</u> notify all known service providers and</p>



	<p>aviation undertakings. For certain changes this could run into hundreds if not thousands of notifications. There are generic publications that are currently used to promulgate the change and its impact. The onus should be on the other service providers and aviation undertakings to read these publications.</p> <p>There will be a significant number of changes that has no effect on any other service provider or aviation undertaking yet (b) would require that they are published - with no-one interested.</p>
response	<p>Accepted</p> <p>This comment seems to be misplaced. It probably refers to AMC1 ATM/ANS.OR.A.045(a)(3).</p> <p>It is accepted that it may not be feasible to inform all aviation undertakings; however, it is feasible to inform all service providers affected by the change, as their number is much more reduced and it is feasible to inform them.</p> <p>In the case of aviation undertakings, GM is provided on this issue (GM1 ATM/ANS.OR.A.045(f)(2)) which states that 'When the number of aviation undertakings affected by the change is large, the service providers may not need to involve every individual stakeholder. If a body can represent the views of a group of affected aviation undertakings, it may suffice to involve that representative body to obtain the supporting evidence to move forward with the assessment of the change'.</p> <p>The AMC has been altered to reflect this and the text is amended to individually notify the service providers only, as their number will be reduced, and through other means to aviation undertakings (e.g. through a publication site).</p> <p>Note that if the change has no effect on any other service provider, it is not necessary to notify them.</p>

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — AMC2 ATM/ANS.OR.A.045(a) Changes to the functional system	p. 101
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comment	<p>404</p> <p>Page 101 GM for AMC2 ATM/ANS.OR.A.045(a) sub b) Use of ISIA for novelty, complexity and consequence of failure Use of Performance Monitoring for EoSM Proposal for corresponding AMC2: NOTIFICATION DATA The notification of a change should contain the following information:</p>	comment by: EUROCONTROL
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a) a description of the change under consideration
 b) an initial safety impact assessment covering at least the following criteria:

- Novelty
- Complexity
- Consequence of failure

(c) Name of the organisation notifying the change;
 (d) Unique identifier of change;
 (e) Version number of notification;
 (f) Title of the change;
 (g) Date of the submission of the original of this change notification;
 (h) Scheduled date of entry into service (even if only approximate);
 (i) Change description;
 (j) Entity in charge of the assurance case; and
 (k) Identity of a point of contact for communications with the CA.

The notification of a change cannot be considered complete if the above information has not been provided.
 The ISIA process could also be included as GM for AMC 2.

response

Not accepted

Proposed GM: These elements are not necessary for every change (they may delay the notification unnecessarily). The associated GM contains additional details of the change that will be used by the CA to make the decision.

Proposed AMC: The data defined in a) & b) is already covered in (i) and is expanded on in GM1 ATM/ANS.OR.A.045(a) paragraph (b).

comment

445

comment by: UK CAA

Page No: 101

Paragraph No: AMC2 ATM/ANS.OR.A.045(a) Changes to the functional system NOTIFICATION DATA (g)

Comment: The item 'Change description' could be misleading, as it suggests a very brief description, rather than the extensive information in GM1 ATM/ANS.or.A045(a) (b) on page 102.

An alternative description should be used, which is more suggestive of the extent of information necessary, perhaps "Details of the change and its impact"

Justification: Clarity.

response

Accepted

The text has been amended with the suggested sentence.



comment 933

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX III COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR) AMC2 ATM/ANS.OR.A.045(a)	<p>According to <i>ATM/ANS.OR.A.045(e)(2)</i>, the notification data shall include a list of the service providers and other aviation undertakings that are affected.</p>	<p>This list shall appear as a part of the information listed in <i>AMC2 ATM/ANS.OR.A.045(a)</i>.</p>

response [Accepted](#)

[In any case, this clause has been now removed from the IR.](#)

comment 1231

comment by: CAA-NL

Related to the suggested change of *ATM/ANS.AR.C.035* Decision to review the notified change to the functional system we also suggest to change the following AMC material into AMC and GM.

AMC2 ATM/ANS.OR.A.045(a) Changes to the functional system

In our view the list of details needed for the notification should be at GM level, to get the flexibility for CA and providers to manage the process appropriately. There may be the need to manage the process for providers with a lot of changes differently from the providers with scarce changes. So we propose the following:

AMC2 ATM/ANS.OR.A.045(a) Changes to the functional system

NOTIFICATION DATA

The notification of a change should contain the following information:

- a) a description of the change under consideration
- b) an initial safety impact assessment covering at least the following criteria:
 - Novelty
 - Complexity
 - Consequence of failure

And:

GM1 for ATM/ANS.OR.A.045(a)



The notification of a change is not considered complete until the following information is provided:

- a) Name of the organisation notifying the change;
- b) Title of the change;
- c) Unique identifier of change;
- d) Version number of notification;
- e) Date of the submission of the original of this change notification;
- f) Specific description of the change to the functional system;
- g) Time planning, including scheduled date of entry into service;
- h) Entity in charge of the assurance case; and
- i) Contact details of the point of contact for communications with the CA.

GM2 for ATM/ANS.OR.A.045(a)

· Please Insert a reverence to FABEC ISIA method for novelty, complexity en consequence of failure. <FABEC ANSP method to determine the safety impact in an early stage of the change>

response

Not accepted

Different ways of handling change notification are described in GM3 ATM/ANS.OR.A.045(a). They do not affect the notification data described in the AMC.

The proposed AMC for notification data does not include the elements in the proposed GM1 and therefore the GM would be invalid and useless.

The AMC already includes the description of the change, the data for which is given in GM3 ATM/ANS.OR.A.045(a).

The proposal for GM2 is not relevant here since this clause is about notification data and not about the selection of a change for review. It would be more appropriate to include it in GM1 ATM/ANS.AR.C.035(b)(1); however, it is already covered there.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM1 ATM/ANS.OR.A.045(a) Changes p. 102-103 to the functional system

comment

162

comment by: *NATS National Air Traffic Services Limited*

Points (b)(6) & (7) – it does not appear reasonable to expect the service provider initiating the change to be in a position to fully identify let alone inform those other service providers and aviation undertakings so early in the change lifecycle. When a solution becomes apparent then it should be possible, where feasible, to identify and inform other service providers and, especially, aviation undertakings. See previous comment on ability to provide sufficient information at the earliest opportunity.



response	<p>Not accepted</p> <p>Clearly, a solution has already become ‘apparent’ before notification since (b)(4) & (5) seek details of that solution. Consequently, other service providers and aviation undertakings ought to have been identified.</p> <p>It is accepted that, as the change progresses, it may be realised that other service providers or aviation undertakings are affected by the proposed change. However, this is already accounted for in the IR (ATM/ANS.OR.A.045(b)).</p>
comment	<p>163 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>Point (f) refers to (b)(9) which does not appear to exist. Should it be (b)(8)?</p>
response	<p>Accepted</p> <p>The reference has been amended.</p>
comment	<p>164 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>Point (g) refers to “field 9 of the table in AMC2 ATM/ANS.OR.A.045(a)”. There is no table in AMC2 ATM/ANS.OR.A.045(a).</p>
response	<p>Accepted</p> <p>The text has been changed to indicate Item (j) in the list.</p>
comment	<p>446 comment by: <i>UK CAA</i></p> <p>Page No: 102 Paragraph No: GM1 ATM/ATS.OR.A.045(a) Changes to the functional system NOTIFICATION DATA (b) (8) Comment: The term “Consequence of the change” is not suggestive of the information required Justification: Clarity. Proposed Text: Suggest replace with: “Preliminary assessment of risk or criticality”</p>
response	<p>Partially accepted</p> <p>The consequence of the change is the severity of the effects of the change as in the definition of risk. Whilst these will be known early, the probabilities will not be and so risk cannot be part of the notification.</p>



A reference to the risk definition will be added to clarify the meaning of 'consequences'. Please see also (f).

comment

447

comment by: UK CAA

Page No: 103**Paragraph No:** GM1 ATM/ATS.OR.A.045(a) Changes to the functional system NOTIFICATION DATA (f)**Comment:** The cross reference to (b)(9) is incorrect**Justification:** Accuracy.**Proposed Text:** "(b)(8)"

response

Accepted

The reference has been amended.

comment

448

comment by: UK CAA

Page No: 103**Paragraph No:** GM1 ATM/ATS.OR.A.045(a) Changes to the functional system NOTIFICATION DATA (g)**Comment:** The phrase "focal point for the CA" could be more clearly stated.**Justification:** Clarity.**Proposed Text:** Suggest amend to read: '...provides a focal point for the CA to contact when seeking....'

response

Accepted

The text has been amended as suggested.

comment

714

comment by: DFS Deutsche Flugsicherung GmbH

"(f) [...] For service providers other than ATS providers, the consequences should be expressed in terms of criticality of the change"

That sentence should be removed, since the criticality can only be assessed by the end user, which is an ATS/ATM provider in NPA 2014-13

Reference to high level comment "c.ii"

response

Partially accepted

It is not accepted that criticality can only be assessed by the end user. However, criticality



has connections with safety that were not intended and so has been removed. The sentence has been left in but in a modified form.

comment 904

comment by: DGAC/DSAC - french NSA

- paragraph (f) :

Article (b)(9) referenced to is missing

- paragraph (h) :

It should be "Field i" instead of "field 9".

response Accepted

The reference has been amended.

The text has been changed to indicate Item (j) in the list.

comment 934

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX III COMMON REQUIREMENTS FOR SERVICE PROVIDERS <i>(Part-ATM/ANS.OR)</i> GM1 ATM/ANS.OR.A.045(a)	(a): This paragraph should be in <i>AMC2 ATM/ANS.OR.A.045(a)</i> and not in this <i>GM1 ATM/ANS.OR.A.045(a)</i> .	A change shall be notified as soon as the required data is available.

response Partially accepted

Putting such a clause in the AMC may make matters worse, since notification could be



delayed until all info is available. This is not advisable for the reasons described in (c).

It is proposed to add a timeliness clause to the AMC for ATM/ANS.AR.C.035. A similar clause is considered for the AMC associated with this clause.

comment 936

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX III COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR) GM1 ATM/ANS.OR.A.045(a)</p>	<p>(b): The data listed in this section should be in AMC2 ATM/ANS.OR.A.045(a) and not in this GM1 ATM/ANS.OR.A.045(a).</p>	<p>The explanation provided in <i>section (c)</i> has no sense. Every data listed in <i>section (b)</i> is essential for both the service provider to plan and design the change and the CA to decide on whether to review it or not.</p> <p>If the service provider is not able to provide that data <u>before the introduction of the change</u> we would strongly recommend, as CA, not to implement it. Any delay due to the lack of this information is fully justified.</p> <p>Further to this, a preliminary notification with data required in AMC2 ATM/ANS.OR.A.045(a) would automatically result in the CA requiring the data indicated in GM1 ATM/ANS.OR.A.045(a) in order to have enough information before taking its decision on whether to review or not which, in turn, directly results in an unnecessary increase of the communications between CA and service provider (and an unnecessary higher workload).</p> <p>The arguments stated in <i>section (d)</i> are aligned with this idea.</p>



response Partially accepted

Some of the data listed in (b) has been moved to AMC2.

The GM provides an expansion of AMC2 ATM/ANS.OR.B.045(a)(g). While all the information is expected to be useful, it may not be necessary in all cases. Furthermore, it may not be necessary for it to be available when first notifying the CA. It could be gradually provided later. The service provider will be aware that delaying the information may delay the decision but will also be aware that the some information is more important than other.

There is no justification for the claim that this GM would mean that some necessary data would not be delivered before the introduction of the change. The emphasis in the guidance is on delivering that which is necessary for the CA to come to a correct and speedy decision. It is not true that this must be everything and furthermore there may be other things not listed that will help that CA come to a decision, hence the need for ATM/ANS.AR.C.035(a).

comment 938

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX III COMMON REQUIREMENTS FOR SERVICE PROVIDERS <i>(Part-ATM/ANS.OR)</i> GM1 ATM/ANS.OR.A.045(a)</p>	<p>(f): A mention is made to a preliminary safety assessment in order to allow the ATS providers to determine the consequences of the change in terms of safety risks.</p> <p>That sort of safety assessment (and any GM referring to it) does not appear in the rest of the NPA.</p> <p>Some more GM should be developed about this point.</p>	<p>This development is required to assist the service provider in developing a trustworthy preliminary safety assessment with the coarse-grained information it knows at the moment of the notification.</p> <p>In the case that the service provider has not developed a preliminary safety assessment, the development would assist the service provider in assessing the consequences of the change.</p>



response Partially accepted

The full safety assessment is described in ATS.OR.205(b) and the associated AMC and GM. There is no need to describe a preliminary safety assessment as it clearly comprises an incomplete assessment and may take many forms.

However, it is accepted that the meaning of (f) could be clearer and this has been taken care of.

comment 1149

comment by: EUROCONTROL

GM1 ATM/ANS.OR.A.045 (a) Changes to the functional system – Page 102

Concerning Article (b) EUROCONTROL makes the following comments:

Finding the right balance between “early provision” and “provision of enough information” is not new. The NPA asks for very early notification, but this could lead to the provision of poor, inaccurate and incomplete information. This could in turn lead to wrong decision on the review by the NSA and, consequently, to multiple exchanges of data/information on the change between the parties, thus creating confusion and awkward management practices.

In addition to data to be contained in the change description, as listed from (1) to (8), it is proposed to include also some elements on the safety risk or criticality (for supporting the decision made by the NSA to review or not). Such elements will also help the ANSP to build a safety case commensurate with the safety risk associated to the change.

response Not accepted

The data passed to the CA as part of notification will be updated if found to be inaccurate or incomplete (ATM/ANS.OR.A.045(b)).

The CA, if not sure about the change, can seek additional information (ATM/ANS.AR.C.035(a)), which will also be updated if found to be inaccurate or incomplete. Consequently, whilst it is acknowledged that finding the right balance is difficult, it is primarily a matter of the CA being confident that it has sufficient, correct material in order to make the decision. Clearly, if the proposed change is altered and new or modified information arrives after the decision, then it will have to be reviewed. It does not seem to be the case that the IR/AMC/GM alters the situation in a negative sense. It is hoped that by making the process clearer, the confusion referred to will occur less frequently than in the past.

The data proposed in the second paragraph is already present in the GM. Item (8) of that GM requests the consequences of the change. This is equivalent to the ‘criticality’ mentioned.



3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM2 ATM/ANS.OR.A.045(a) Changes to the functional system

p. 103

comment	110	comment by: EUROCONTROL Safety Team
	<p>GM2 ATM/ ANS.OR.A.045(a) (b) Having such a list is desirable. However, this formal list should be periodically reviewed.</p>	
response	<p>Partially accepted</p> <p>The coordination referred to will result in a formal agreement that will become part of the change procedures. The application of these procedures is overseen by the CA and covered in AMC1 ATM/ANS.AR.C.010(a). Consequently, it will be periodically reviewed.</p> <p>This explanation will be included in the GM.</p>	
comment	165	comment by: NATS National Air Traffic Services Limited
	<p>GM2 ATM/ANS.OR.A.045(a) This GM appears to contradict the intent of ATM/ANS.AR.C.035 (Decision to review the notified change) which does not foresee the possibility for the approach advocated in the GM for routine changes. NATS fully supports the notion that not every change needs to be reviewed however the IR does not appear to foresee this possibility. If the intent is correct then similar GM would be appropriate for the AR as this GM has implications in it for the CA.</p>	
response	<p>Not accepted</p> <p>A decision to review a change (ATM/ANS.AR.C.035(a)) implies that the decision may go either way, i.e. some assurance cases are reviewed while others are not. The criteria for the choice are given in ATM/ANS.AR.C.035(b).</p> <p>Other selection criteria are allowed by ATM/ANS.AR.C.035(c).</p>	
comment	450	comment by: UK CAA
	<p>Page No: 103 Paragraph No: GM2 ATM/ATS.OR.A.045(a) Changes to the functional system ROUTINE CHANGES Comment: This section does not provide sufficient guidance on what types of changes this is appropriate for. [GM3 ATM/ANS.OR.A.045(a) Changes to the functional system MEANS OF NOTIFICATION does not suffice.]</p>	



	<p>Justification: Adequacy of guidance.</p>
response	<p>Partially accepted</p> <p>The first sentence has been moved to GM1 ATM/ANS.AR.C.035(c) which describes more thoroughly the types of changes that can use criteria other than those described in ATM/ANS.AR.C.035(a).</p>
comment	<p>1293 comment by: EUROCONTROL</p> <p>GM2 ATM/ANS.OR.A.045(a)(b) Changes to the functional system - Page 103 Having such a list is desirable. However, this formal list should be periodically reviewed.</p>
response	<p>Partially accepted</p> <p>The coordination referred to will result in a formal agreement that will become part of the change procedures. The application of these procedures is overseen by the CA and covered in AMC1 ATM/ANS.AR.C.010(a). Consequently, it will be periodically reviewed.</p> <p>This explanation will be included in the GM.</p>

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM3 ATM/ANS.OR.A.045(a) Changes to the functional system p. 103-106

comment	<p>111 comment by: EUROCONTROL Safety Team</p> <p>GM3 ATM/ ANS.OR.A.045(a) (b) (2) Periodic notification on Page 104 A notification every 3 months may not be frequent enough to capture all the planned changes at the appropriate time for notification to CA. There is contradiction with GM3 ATM/ANS.OR.A.045(a) (b) (3) Short lead time notifications because the example provided in the mentioned GM is based on monthly notification.</p>
response	<p>Not accepted</p> <p>The 3-month period is an example. It should not be taken to imply a requirement.</p> <p>There is no contradiction. There is no requirement for a defined period. A monthly notification is still an example of a periodic notification. The CAs should decide the periods and the process of notification that suit them best.</p>



comment	<p data-bbox="359 235 406 280">112</p> <p data-bbox="973 235 1484 280" style="text-align: right;">comment by: <i>EUROCONTROL Safety Team</i></p> <p data-bbox="359 324 1133 369">GM3 ATM/ ANS.OR.A.045(a) (b) (3) Short lead time notifications</p> <ol data-bbox="406 403 1484 728" style="list-style-type: none"> 1. This GM contradicts GM3 ATM/ANS.OR.A.045(a) (b) (2) Periodic Notification because the quarterly notification could increase the number of short lead notifications. This point is actually raised in the 5th paragraph where the author of the GM uses a monthly periodic notification as an example of how short lead times some changes have. 2. The procedure should be clearly established and the means for it should be in place. It is surprising to see in the 4th paragraph that a direct phone call is being considered as a formal notification. A phone call would neither allow for a factual information gathering and decision making nor traceability.
response	<p data-bbox="359 784 582 817">Partially accepted</p> <p data-bbox="359 851 1484 1097">Firstly, the quarterly notification period is not mandatory; it is simply an example. There is no contradiction because (3) specifically states that short lead time notifications should be the exception, not the norm. The frequency of short lead time notifications is related to the rate of changes needed by a service provider, which should not correlate with the notification period referred to in (2). If it does, then this could be a concern to a CA because the rate of change of the service is likely to correlate with ill-considered changes.</p> <p data-bbox="359 1131 1484 1209">A phone call is not an appropriate notification. However, it could be used as an alert so that the CA is aware of the problem and will respond optimally to the notification when it arrives.</p>
comment	<p data-bbox="359 1288 406 1332">133</p> <p data-bbox="1220 1288 1484 1332" style="text-align: right;">comment by: <i>ENAIRE</i></p> <p data-bbox="359 1377 1484 1467">The introduction of examples is welcome, specially the concept of short lead notification, but we understand a phone call as a notification doesn't fit for an NPA/regulation.</p>
response	<p data-bbox="359 1489 478 1523">Accepted</p> <p data-bbox="359 1556 1484 1646">A phone call is not an appropriate notification. However, it could be used as an alert so that the CA is aware of the problem and will respond optimally to the notification when it arrives.</p>
comment	<p data-bbox="359 1713 406 1758">451</p> <p data-bbox="1220 1713 1484 1758" style="text-align: right;">comment by: <i>UK CAA</i></p> <p data-bbox="359 1814 526 1848">Page No: 103</p> <p data-bbox="359 1859 1484 1937">Paragraph No: GM3 ATM/ANS.OR.A.045(a) Changes to the functional system MEANS OF NOTIFICATION</p> <p data-bbox="359 1937 1484 2016">Comment: This section does not appear to provide sufficient guidance to be useful, except perhaps in (3).</p>



response	<p>Justification: Adequacy of guidance.</p> <p>Not accepted</p> <p>The guidance is deliberately high level and it is considered adequate as it covers all the main issues. It is expected that lower-level more detailed guidance will be written by CAs as it will depend on the service providers within their jurisdiction and the types of changes most commonly made.</p>
comment	<p>906 comment by: DGAC/DSAC - french NSA</p> <p>In paragraph (3), CA should not, in any case, take into account the business risk to decide a review. This mention must be deleted.</p>
response	<p>Not accepted</p> <p>There is no reason why a CA should not take business arguments into account in its decision to review a change. This would be the case if the safety risk was relatively small and the business risk considerable. Note that the CA does not have to accept the short lead time notification.</p>
comment	<p>1135 comment by: bmvit/CAA/NSA</p> <p>Practical implementation of notification is no clear.</p>
response	<p>Not accepted</p> <p>Please see the response to comment No 451.</p>
comment	<p>1150 comment by: EUROCONTROL</p> <p>GM3 ATM/ANS.OR.A.045 (a) Changes to the functional system – Page 103</p> <p>Concerning Article (b) (2) on page 104 EUROCONTROL makes the following comments: A notification every 3 months may not be frequent enough to capture all the planned changes at the appropriate time for notification to the Competent Authorities.</p> <p>Concerning Article (b) (3) on page 105 EUROCONTROL makes the following comments: This GM contradicts the previous as the quarterly notification could increase the number of short lead notifications. This point is actually raised in the 5th paragraph where the author of the GM uses a monthly periodic notification as an example of how short lead times some changes have. The procedure shall be clearly established and the means for it shall be in place.</p> <p>It is surprising to see in the 4th paragraph that a direct phone call is being considered as a</p>



formal notification. A phone call would neither allow for a factual information gathering and decision making nor traceability. The procedure involving a “direct phone call” shall be clearly established and the means for it to work shall be in place.

response

Partially accepted

Firstly, the quarterly notification period is not mandatory; it is simply an example. There is no contradiction because (3) specifically states that short lead time notifications should be the exception not the norm. The frequency of short lead time notifications is related to the rate of changes needed by a service provider, which should not correlate with the notification period referred to in (2). If it does then this could be a concern to a CA because the rate of change of the service is likely to correlate with ill-considered changes.

A phone call is not an appropriate notification. However, it could be used as an alert so that the CA is aware of the problem and will respond optimally to the notification when it arrives.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — AMC3 ATM/ANS.OR.A.045(a) Changes to the functional system p. 106

comment

452

comment by: UK CAA

Page No: 106**Paragraph No:** AMC3 ATM/ANS.OR.A.045(a) Changes to the functional system**Comment:** The numbering of this section is inconsistent**Justification:** The section contains two sub paragraph (a) and two subparagraphs (b).**Proposed Text:** Renumber subparagraphs (a) to (e).

response

Accepted

The paragraphs have been renumbered.

comment

500

comment by: UK CAA

Page No: 106**Paragraph No:** AMC3 ATM/ANS.OR.A.045(a) Changes to the functional system**Comment:** The service provider should keep a single centralised register. The word single is not necessary and should be removed.**Justification:** Clarity.**Proposed Text:** The service provider should keep a centralised register

response

Accepted



The word has been removed.

comment

501

comment by: UK CAA

age No: 106

Paragraph No: AMC3 ATM/ANS.OR.A.045(a) Changes to the functional system

Comment: This requires the ANSP to maintain a Register of Notified Changes NPA 2013-08 and the Aerodrome Legislation 139/2014 both require a common management system where the ANSP and Aerodrome Certificate holder are same entity Aerodrome Legislation 139/2014 does not require the use of a Register of Notified Changes

Justification: Confusion where there is a common management system.

Proposed Text: The process for the recording of Notified Changes should be the same in ATM/ANS and Aerodrome legislation

response

Not accepted

There is no requirement for a common management system for both services (aerodrome and ATS), but there are requirements for a single management system to cover all activities (ADR.OR.D.005(e) of Regulation (EU) 139/2014 and ATM/ANS.OR.B.005(g)).

We believe that ADR.OR.D.035(a) covers record-keeping for notified changes as they are activities under the scope of Regulation (EC) No 216/2008.

comment

1071

comment by: LVNL

AMC **3** **ATM.ANS.OR.045** **(a)**

The issue of registering all changes is a matter of business administration and is more appropriate as part of the change management system than the individual changes. Therefore the subject of this AMC would better be related to ATM.ANS.OR.B.010, although the wording needs to be changed to make it fit to a process rather than each change individually. Furthermore there seems to be a requirement missing at IR level on which this AMC can be based.

response

Partially accepted

The AMC has been moved to become an AMC to ATM/ANS.OR.B.010(a).

The point about there being no IR to associate it with is not correct. ATM/ANS.OR.B.045(a) has the term 'manage' in it. In this sense, it is a management procedure.

comment

1232

comment by: CAA-NL



AMC 3 ATM/ANS.OR.045 (a)

The issue of registering all changes is a matter of business administration and is more appropriate as part of the change management system than the individual changes. Therefore the subject of this AMC would better be related to ATM.ANS.OR.B.010, although the wording needs to be changed to make it fit to a process rather than each change individually. Furthermore there seems to be a requirement missing at IR level on which this AMC can be based.

response [Partially accepted](#)

[The AMC has been moved to become an AMC to ATM/ANS.OR.B.010\(a\)](#)

[The point about there being no IR to associate it with is not correct. ATM/ANS.OR.B.045\(a\) has the term 'manage' in it. In this sense, it is a management procedure.](#)

comment [1294](#)

comment by: *EUROCONTROL*

AMC3 ATM/ANS.OR.A.045(a) Changes to the functional system - Page 106

The use of a register of notified changes is a good practice. However, this would depend on how ATSP's change management process. The SMS needs to identify who is responsible for maintaining this register.

response [Not accepted](#)

[The management of the changes is covered in ATM/ANS.OR.B.010\(a\) and is therefore part of both MS and SMS. There is no need to identify who is responsible as it is clearly a management system task of the service provider.](#)

[However, note that the AMC has been moved to become and AMC related to ATM.ANS.OR.B.010\(a\). This may help in clarifying the ownership issue.](#)

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM5 ATM/ANS.OR.A.045(a) Management of change to a functional system

p. 106-107

comment [911](#)

comment by: *DGAC/DSAC - french NSA*

- The proposed template does not include the items listed in the AMC2 ATM/ANS.OR.A.045 (a) Changes to the functional system.



- What is the purpose of the parenthesis ("and responsible ...") in the left box under 2. CHANGE SUMMARY ? Do you mean the name of the responsible or it is only a reminder about the responsibility for the entity ? Please clarify.

response

Accepted

The form has been changed.

The parenthesis is there to satisfy AMC2 ATM/ANS.OR.A.045(a)(i)

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — AMC1 ATM/ANS.OR.A.045(a)(3) Changes to the functional system p. 107-108

comment

114

comment by: EUROCONTROL Safety Team

AMC1 ATM/ ANS.OR.A.045(a)(3) Page 108

Another theoretically correct but infeasible requirement in the real life. According to this AMC a number of changes would require a significant number of **individual** notifications. In such a case the notification could easily be promulgated through a generic publication. It is in the interest of other SPs and aviation undertakings to refer to the generic publication(s). Additionally there may be changes that have no impact on other SPs and/or aviation undertakings yet this AMC would require that notifications are issued but no one would be interested in such a change.

response

Partially accepted

The AMC has been changed to allow notification of changes to aviation undertakings to be done either individually or via a representative body or via a dedicated publication. Individual notification of service providers is still required; however, unless it is an extremely large change, there should not be too many of these.

Only service providers and aviation undertakings potentially affected by the change need to be notified; so all those notified should be interested.

comment

166

comment by: NATS National Air Traffic Services Limited

Even where known it is not feasible to **individually** notify all known service providers and aviation undertakings. For certain changes this could run into hundreds if not thousands of notifications. There are generic publications that are currently used to promulgate the change and its impact. The onus should be on the other service providers and aviation



	<p>undertakings to read these publications.</p> <p>There will be a significant number of changes that has no effect on any other service provider or aviation undertaking yet (b) would require that they are published - with no-one interested.</p>
response	<p>Partially accepted</p> <p>Please see the response to comment No 114.</p>

comment	<p>300 comment by: <i>DSNA</i></p> <p>Even where known it is <u>not feasible to individually notify all known service providers and aviation undertakings</u>. For certain changes this could run into hundreds if not thousands of notifications. There are generic publications that are currently used to promulgate the change and its impact. The onus should be on the other service providers and aviation undertakings to read these publications.</p> <p>There will be a significant number of changes that has no effect on any other service provider or aviation undertaking yet (b) would require that they are published - with no-one interested.</p> <p>DSNA proposes:</p> <ol style="list-style-type: none"> 1. to replace (a) with : inform all <u>relevant</u> service providers and aviation undertakings of the planned change. 2. <u>to delete (b).</u>
response	<p>Partially accepted</p> <p>Please see the response to comment No 114.</p> <p>The AMC only requires potentially affected service providers and aviation undertakings to be notified. The purpose of notification is to alert people to the potential of a change so that they may become involved in it if need be. It is not to inform them that a change is about to take place.</p> <p>The proposed formulation is not accepted.</p>

comment	<p>488 comment by: <i>skyguide Corporate Regulation Management</i></p> <p>Even where known it is not feasible to <u>individually</u> notify all known service providers and aviation undertakings. For certain changes this could run into hundreds if not thousands of notifications. There are generic publications that are currently used to promulgate the change and its impact. The onus should be on the other service providers and aviation undertakings to read these publications.</p>
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response	<p>There will be a significant number of changes that has no effect on any other service provider or aviation undertaking yet (b) would require that they are published - with no-one interested.</p> <p>Partially accepted</p> <p>Please see the response to comment No 114.</p>
comment	<p>502 comment by: UK CAA</p> <p>Page No: 107 Paragraph No: AMC1 ATM/ANS.OR.A.045(a)(3) Changes to the functional system Comment: Subparagraph (a) requires the service provider to address the notification individually to all <u>known</u> service providers and aviation undertakings. The word KNOWN is superfluous and should be changed to affected Justification: It is not possible to address a notification individually to an Unknown Service Provider Proposed Text: (a) address the notification individually to all service providers and aviation Undertakings known to be affected; and</p>
response	<p>Partially accepted</p> <p>'known' is scoped to the affected service providers/undertakings by the first paragraph of the AMC.</p> <p>Only those service providers and aviation undertakings 'known' to the service provider need to be informed. The AMC is not seeking an unconstrained search for all possible service provides and aviation undertakings. The text has been redrafted.</p>
comment	<p>503 comment by: UK CAA</p> <p>Page No: 107 Paragraph No: AMC1 ATM/ANS.OR.A.045(a)(3) Changes to the functional system Comment: Delete subparagraph (b) this is an unnecessary duplication of notification processes. Described in subparagraph (a) Justification: There is no requirement for ANSPs to have dedicated publications. Proposing such a requirement would place an unnecessary finical burden on ANSPs. Proposed Text: Delete subparagraph (b)</p>
response	<p>Accepted</p> <p>(b) was intended to be an alternative means of notification, not an additional one. The AMC</p>



[has been changed.](#)

comment

715

comment by: *DFS Deutsche Flugsicherung GmbH*

“(a) address the notification individually to all known service providers and aviation undertakings“

There are generic publications that are currently used to promulgate the change and its impact. The onus should be on the other service providers and aviation undertakings to read these publications. There will be a significant number of changes that has no effect on any other service provider or aviation undertaking yet (b) would require that they are published - with no-one interested. It seems not practicable to inform all aviation undertakings e.g. airlines **individually**. The notification should be done by dedicated publications e.g. AIC. Therefore we propose to delete item (a) above or at least the word "individually".
Reference to high level comment "c.ii"

response

[Partially accepted](#)

[‘Known’ is scoped by the first paragraph of the AMC.](#)

[The AMC has been altered to allow generic notifications to aviation undertakings. However, individual notifications are needed for service providers, of which there should be relatively few of them affected for most changes.](#)

comment

1064

comment by: *LVNL*

Even where known it is not feasible to individually notify all known service providers and aviation undertakings. For certain changes this could run into hundreds if not thousands of notifications. There are generic publications that are currently used to promulgate the change and its impact. The onus should be on the other service providers and aviation undertakings to read these publications. There will be a significant number of changes that has no effect on any other service provider or aviation undertaking yet (b) would require that they are published - with no-one interested.

Propose to delete this AMC.

response

[Partially accepted](#)

[Please see the response to comment No 114.](#)

comment

1233

comment by: *CAA-NL*



AMC1 ATM/ANS.OR.A.045(a)(3)

The Netherlands doesn't see the need for an AMC on this para of the rule, since the rule is clear and the proposed AMC states the obvious. Furthermore the rule does not require to inform all known service providers and aviation undertakings, but the affected ones. Only changes that potentially affect others should be published, normally shortly before the introduction. Please delete.

response

Partially accepted

The AMC has been changed to allow notification of aviation undertakings to be performed via representative bodies or publications as well as individually. This is not specifically stated in the rule.

The AMC only requires potentially affected service providers and aviation undertakings to be notified. It has the same scope as the rule.

The purpose of notification is to alert people to the potential of a change so that they may become involved in it if need be. It is not to inform them that a change is about to take place.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM1 ATM/ANS.OR.A.045(a)(3) Changes to the functional system

p. 108

comment

505

comment by: UK CAA

Page No: 108**Paragraph No:** GM1 ATM/ANS.OR.A.045(a)(3) Changes to the functional system DEDICATED PUBLICATION FOR PROPOSED CHANGES**Comment:** UK CAA suggest that it is not reasonable to require all service providers to make publications, or that they should publish websites.

Information the needs to be publicly available must already exist in the public domain, and those arrangements should continue.

Justification: Unreasonable expectation within guidance.

response

Not accepted

The IR (ATM/ANS.OR.A.045(a)(3)) does not require all aviation undertakings to be notified of a change. Consequently, this guidance demonstrates a feasible approach for notifying those aviation undertakings where it would be difficult to do so directly. It therefore allows for more aviation undertakings to be notified.

It is considered that all service providers ought to be notified directly.



comment	651	comment by: <i>CANSO</i>
	<p>AMC1 ATM/ANS.OR.A.045(a)(3)</p> <p>Even where known it is not feasible to individually notify all known service providers and aviation undertakings. For certain changes this could run into hundreds if not thousands of notifications. There are generic publications that are currently used to promulgate the change and its impact. The onus should be on the other service providers and aviation undertakings to read these publications.</p> <p>There will be a significant number of changes that has no effect on any other service provider or aviation undertaking yet (b) would require that they are published - with no-one interested.</p>	
response	<p>Partially accepted</p> <p>The AMC now allows the service provider to inform aviation undertakings via either a representative body or by publishing details in a dedicated publication.</p> <p>However, notifying all service providers individually is feasible and it is still a requirement. This should not pose an insurmountable problem for any change.</p>	

<p>3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — AMC1 ATM/ANS.OR.A.045(b) Changes to the functional system</p>	<p>p. 108</p>
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comment	781	comment by: <i>DGAC/DSAC - french NSA</i>
	<p>The french NSA has one comment related to AMC1 ATM/ANS.OR.A.045(b) :</p> <p>We suggest to write "notified" instead of "informed" in the sentences "that were initially informed" at the end of paragraphs (a) and (b).</p>	
response	<p>Accepted</p> <p>The text has been amended as suggested.</p>	
comment	1133	comment by: <i>EUROCONTROL</i>
	<p>AMC1 ATM/ANS.OR.A.045 (b) Changes to the functional system – Page 108</p> <p>Concerning Article (a), EUROCONTROL notices an evolution in the use of the ‘notification’ definition that needs to be checked.</p> <p>Notification of the change has so far (EC1034/2011) been defined as the way for the ANSP to inform the NSA of a given change. However, in the present NPA, there are instances where</p>	



the word notification is used to inform stakeholders (users, other service providers, etc.) of the changes.

EUROCONTROL therefore proposes to adopt the use of "notification" for relations between ANSPs and NSAs and to use instead "notification" or "information" or "declaration" for the relations between an ANSP and other stakeholders.

response **Not accepted**

Notification is a process of alerting someone to something. It encompasses the notion of some accompanying description of what is being notified. This is relevant regardless of a CA or some other stakeholder being notified. The means of notifying and the information carried with it may be different for individual stakeholders and this will be defined separately. It serves no purpose to complicate the notion by using different terms.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — AMC1 ATM/ANS.OR.A.045(d) Changes to the functional system p. 108

comment 167

comment by: *NATS National Air Traffic Services Limited*

This AMC is very similar to the related IR, however the IR does not allow any parts of the change to enter operational service until approved if subject to CA review; whereas the AMC is limited to part of the change that has the potential to affect functionality or performance. Thus the IR and AMC contradict each other and the AMC is superfluous.

There should be an obligation on the CA to respond to the submitted argument within a reasonable timescale.

We suggest that in order for the CA to respond in a timely manner add "within 30 days of receipt of the argument" to both ATM/ANS.AR.C.040(c)(1) and (2).

response **Not accepted**

There is no contradiction. Implementation is what is meant in the AMC. The implementation of any part of the change may begin before the transition of the change into operational service and continues during this transition. That means that parts of the change can be implemented as long as there is no change in the behaviour of the service. However, no implementation of some behaviour that could affect the operation of the current (unchanged) service will be allowed before an adequate safety case exists and, if applicable, before the CA has approved the change. The safety case will argue about implementation transitions and would not be considered valid if it neglected to argue about the safety of parts of the implementation that could affect the behaviour of current service.

The AMC has been altered to clarify this distinction.



GM will be added to ATM/ANS.OR.A.045(d) to explain this and point to Section 3.2 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities where a fuller explanation may be found specifically relating to this point.

Given the extensive range of changes that will be reviewed, it is not feasible to set a strict time limit on the CA's review of the assurance case.

comment 301

comment by: DSNA

There is a difference between "enter operational service" and "implementation of a change"
The requirement explanation is much more constrained than the ATM/ANS.OR.A45 (d)
DSNA proposes to replace with : "where CA has decided to review the assurance case of a proposed change, the service provider should not **entry into service any part of the change until the related safety assessment has been approved by CA**".

response Partially accepted

The implementation of any part of the change may begin before the transition of the change into operational service and continues during this transition. That means that parts of the change can be implemented without changing the behaviour of the service, which only occurs when the change enters into service. No implementation of some behaviour that could affect the operation of the current (unchanged) service will be allowed before an adequate safety case exists and, if applicable, before the CA has approved the change. The safety case will argue about implementation transitions and would not be considered valid if it neglected to argue about the safety of parts of the implementation that could affect the behaviour of the current service.

The AMC has been altered to clarify this distinction.

comment 506

comment by: UK CAA

Page No: 108**Paragraph No:** AMC1 ATM/ANS.OR.A.045(d) Changes to the functional system**Comment:** This section is entitled ENTER OPERATIONAL SERVICE OF A CHANGE SELECTED FOR REVIEW. This does not reflect the tense of the action.**Justification:** The title should be changed to reflect the tense of the action.**Proposed Text:****'ENTRY INTO OPERATIONAL SERVICE OF A CHANGE SELECTED FOR REVIEW.'**

response Accepted

The title has been changed.



comment	716	comment by: <i>DFS Deutsche Flugsicherung GmbH</i>
	This AMC does not contain valuable information that details the IR. It is a duplication of the requirement of the IR and can therefore be deleted. Reference to high level comment "a"	
response	Not accepted Please see the response to comment No 301.	

comment	1234	comment by: <i>CAA-NL</i>
	AMC1 ATM/ANS.OR.A.045(d) This AMC states the obvious and could be removed.	
response	Not accepted Please see the response to comment No 301.	

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM1 ATM/ANS.OR.A.045(c); (d) Changes to the functional system	p. 108
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comment	928	comment by: <i>DGAC/DSAC - french NSA</i>
	Why not adding "safety" after "to affect the functionality or performance" ?	
response	Noted Because until the assurance case has been produced, it is not known whether a change in behaviour will or will not affect safety.	

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM2 ATM/ANS.OR.A.045(c); (d) Changes to the functional system	p. 108-109
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comment	115	comment by: <i>EUROCONTROL Safety Team</i>
	GM2 ATM/ ANS.OR.A.045(c); (d) Page 108 The use of 'volcanic ash' as an example is wrong because 'volcanic ash' is not a change to the	



functional system but an environmental event for which contingency procedures (defined, reviewed and overseen) should be in place.

response **Not accepted**

The commentator has misread the guidance. The change to the functional system is as a result of the change to the environment — in this case volcanic ash — which was unforeseen in the contingency procedures.

comment 507 comment by: UK CAA

Page No: 108/9
Paragraph No: GM2 ATM/ANS.OR.A.045(c); (d) Changes to the functional system CHANGES IMPLEMENTED PRIOR TO RECEIVING APPROVAL
Comment: The guidance provided is not sufficient to rule out abuse of this clause. Moreover the example given in footnote 112 is confusing because it discusses a situation that is not applicable, rather than one where it is applicable.
Justification: Clarity.

response **Partially accepted**

Since the guidance is dealing with the unforeseen, it cannot be complete. It is, however, thought to be sufficient since the criterion it describes is ‘urgent unforeseen circumstances that would, if uncorrected, lead to an unsafe condition’. However, ‘immediate’ has been added to strengthen the criterion.

The footnote was intended to provide a contrast. It has been amended to make this clear.

comment 943 comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX III COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR) GM2 ATM/ANS.OR.A.045(c)	It does not seem appropriate that an option for the ANSP to implement changes without having received an answer from the CA for urgency reasons is included in a GM , when in fact a GM does <u>neither imply nor ensure that its application is mandatory.</u>	In the requirements there is no reference to this exception to the general requirement about receiving an answer by the CA. This is only commented once in letter (k) of <i>GM1 Annex I Definitions (35) & ATM/ANS.OR.A.045 & ATM/ANS.OR.C.005 & ATS.OR.205 General.</i> If this has to do with <i>Article 14.1 of</i>



& (d)		<i>regulation (EC) No 216/2008</i> it should be made perfectly clear and an explicit reference to that article should be included.
response	<p>Partially accepted</p> <p>It is true that neither the IR or the associated AMC give the service provider the right to implement a change without approval if the change has been selected for review. However, the GM does not encourage this practice, it simply accepts that there may be immediate conditions that require an urgent response. It points out that if this is the case, the service provider is to remember that it is still responsible for safety.</p>	

comment	1164	comment by: <i>EUROCONTROL</i>
response	<p>GM2 ATM/ANS.OR.A.045 (c); (d) Changes to the functional system – Page 108 CHANGES IMPLEMENTED PRIOR TO RECEIVING APPROVAL EUROCONTROL makes two comments. There is no definition of what a change is and the examples provided cannot be considered as a sufficient substitute. Concerning the “volcanic ash” example: it cannot be considered as a change to the functional system but as an environmental event for which contingency procedures (defined, reviewed and overseen) shall be in place.</p> <p>Not accepted</p> <p>1. Although not defined (because it was thought impossible to provide an unambiguous and complete definition of change), change is dealt with thoroughly in the new Section 2.2 Section 1 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities. This section of GM is considered adequate.</p> <p>2. Please see the response to comment No 115.</p>	

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM1 ATM/ANS.OR.A.045(e) Changes to the functional system p. 109-110

comment	116	comment by: <i>EUROCONTROL Safety Team</i>
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GM1 ATM/ ANS.OR.A.045(e) on Page 109

(e)(3) requires *However, no matter how many individual changes to service providers' functional systems are part of the change, they should be coordinated. An overarching safety argument, coherent with the arguments of the individual changes, that claims the complete change is safe should be provided"*

The concept of over-arching safety case is a good practice. However, the practicalities of who develops it and when is unclear in this NPA while it is infeasible.

This requirement introduces the notion of a 'lead' service provider which is not mentioned anywhere in the IR where requirements are at the level of the individual service provider except for interactions between them (e.g. notification and dependencies). Each SP would have argued the safety acceptability of the changes to their functional system according to prescribed safety criteria (which could be different across SPs) and obtained CA approval.

Additionally the situation gives rise to the following two questions:

1. If the SPs were from more than one state how would this be managed by the competent authority(ies)?
2. If the overarching argument were found to be unsound how would that impact the individual service providers (whose individual changes would be approved)?

Coordination between ANSPs is already covered in the FAB IR and set up by provisions in the ANSP (and NSA) arrangements at FAB level; it does not seem necessary to address this again in this NPA.

Recommend to delete AMC1 ATM/ANS.OR.A.045(e)(3).

response

Not accepted

The Agency concurs with the analysis that the use of the overarching safety case is a good practice. The practicalities of who develops it have been left open, as this may be organised in very different ways, all of them being equally valid. This is a decision that the service providers should make.

Whilst each service provider must argue the safety consequences (for ATS providers) or the trustworthiness of the change he makes (for providers others than ATS), this will depend fundamentally on the way the change is introduced into service and the way his changed service interacts with all other services within the system of interest, whether changed or not. This safe transition of all services being changed cannot be the responsibility of each service provider; it must be co-ordinated. Equally, the overall safety of the system cannot be argued by each service provider individually. This is the purpose of the overarching safety case. So, even if the acceptability of each individual change is evaluated against prescriptive safety criteria, those safety criteria may well be dependent on the way the change is introduced, and thus they are not independent.

Please see comment No 510 for the response to the comment on 'lead' service provider.

The management of multi-actor changes across state boundaries, and in the case where not all assurance cases are acceptable to the relevant CA, is dealt with specifically in



GM1 ATM/ANS.OR.A.045(f)(2). There is a requirement to set coordination arrangements between CAs in ATM/ANS.AR.A.005(c) to deal with these multi-actor changes. The CAs must agree on the way to review and approve the safety assessments, including the overarching safety case.

Multi-actor changes can exist outside a FAB and so would not be covered by the FAB IR. The scope of this IR is all multi-actor changes, of which FAB is only one subset. Service providers may be in States that are not part of the same FAB. The Agency believes that there is nothing in this NPA that goes against the FAB approach; on the contrary, it is complementary.

comment 1295

comment by: EUROCONTROL

GM1 ATM/ANS.OR.A.045(e) Changes to the functional system - Page 109

The concept of over-arching safety case is a good practice. However, the practicalities of who develops it and when is unclear in this NPA.

As this is already covered in the FAB IR and set up by provisions in the ANSP (and NSA) arrangements at FAB level, it does not seem necessary to address this again in this NPA.

response Not accepted

Multi-actor changes can exist outside a FAB and so would not be covered by the FAB IR. The scope of this IR is all multi-actor changes, of which FAB is only one subset. Service providers may be in States that are not part of the same FAB. The Agency believes that there is nothing in this NPA that goes against the FAB approach; on the contrary, it is complementary.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM2 ATM/ANS.OR.A.045(e) Changes to the functional system p. 110-111

comment 117

comment by: EUROCONTROL Safety Team

GM2 ATM/ ANS.OR.A.045(e) Affected stakeholders (b) Page 110

Normally an ATSP has contact only with the national regulatory bodies. The inclusion of the European Commission and EASA as examples of 'aviation undertakings' affected by a change of ATSP is seen as out of context. If it is felt necessary that such bodies are included then it would also be necessary to include global regulators such as ICAO. The chance that a change introduced by an individual provider would impact such regional and global stakeholders is considered to be extremely remote.

response Not accepted

An ATSP should be aware of forthcoming changes to regulation. It certainly observes the



developments and can therefore be considered to be in contact with the regulating body issuing them. It is unlikely that an ATSP will have no contact with the Agency or the EC, even if only via national representatives.

If a change may have an impact on service that is known to be the subject of a forthcoming regulation, then it would be sensible for the ATSP to contact the relevant regulatory body to ensure that the planned change falls within the constraints being proposed.

comment 168 comment by: *NATS National Air Traffic Services Limited*

Point (a) – if “service providers” encompasses those organisations that are regulated in accordance with 216/2009 (sic) and its IR then the definition of service provider in CRD 2013-08 is insufficient

response Partially accepted

The date of the Basic Regulation has been corrected.

Those service providers within the scope of the Basic Regulation are covered by (a) except the one who is proposing the change. This is correct.

comment 169 comment by: *NATS National Air Traffic Services Limited*

Point (b)(1) – if non-European then the “service provider” will not be subject to this Regulation so it is misleading to use the term “service provider” in this context given its definition.

response Partially accepted

‘Service providers’ are defined as providers of ATM/ANS services and other ATM network functions. When the service is provided within the territory of the Treaty on the Functioning of the European Union, then they are subject to this Regulation. The fact that the service is provided within or outside of the territory of the Treaty is not included in the definition. The example has been changed to avoid confusion.

comment 462 comment by: *APROCTA*

Proposed text for paragraph B:

Aviation undertakings affected by the change included in AMT/ANS.OR.A.045(e) can be understood as the stakeholders **and/or professional associations** with dependencies with the changed service, and may include the following



response [Not accepted](#)

[There is no need and it is not appropriate to highlight one stakeholder in particular.](#)

comment **463** comment by: *APROCTA*

Proposed text for paragraph B, subparagraph 8:

other bodies not regulated by Regulation (EC) No 216/2008 and its Implementing Rules, e.g. power supplier organisation, ~~staff~~ **professional** associations, or passenger associations

response [Accepted](#)

[The text has been amended.](#)

comment **940** comment by: *DGAC/DSAC - french NSA*

In paragraph (b) (7), it should not be limited to "European regulatory bodies". We suggest "regulatory bodies" instead. National civil aviation authorities or other regulatory bodies should not be forgotten.

response [Accepted](#)

[The text has been amended.](#)

comment **1296** comment by: *EUROCONTROL*

GM2 ATM/ANS.OR.A.045(e) Changes to the functional system - Page 110

EUROCONTROL makes a comment on Article (b):

Normally an ATSP only has contact with the national regulatory bodies. The inclusion of the European Commission and EASA as examples of 'aviation undertakings' affected by a change of ATSP is seen out of context. If it is felt necessary that such bodies are included then it would also be necessary to include global regulators/organisations including ICAO.

response [Not accepted](#)

[An ATSP should be aware of forthcoming changes to regulation. It certainly observes the developments and can therefore be considered to be in contact with the regulating body issuing them. It is unlikely an ATSP will have no contact with the Agency or the EC, even if only via national representatives.](#)

[If a change may have an impact on service that is known to be the subject of a forthcoming regulation, then it would be sensible for the ATSP to contact the relevant regulatory body to](#)



ensure that the planned change falls within the constraints being proposed.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM1 ATM/ANS.OR.A.045(e)(1) p. 111-114
Changes to the functional system

comment 141 comment by: ENAIRE

There is not mandatory requirements for the relations among different providers ATS, CNS, etc.

Page 113: ...*however, whilst recommended, this is not required by this Regulation...*

GM shall be provided, based on an agreement to be reached among them.

response Noted

It is unclear what the commentator suggests to be included. This NPA does not introduce a requirement to perform a coordinated assessment, but it requires certain coordination in relation to hazards identification, assumptions and risk mitigations that are common to several service providers and stakeholders. There is already GM provided about this coordination.

comment 170 comment by: NATS National Air Traffic Services Limited

Para (g) “this is best accomplished by a coordinated assessment involving all those parties”. However, whilst recommended, this is not required by the regulation and therefore this is not an appropriate statement.

Please delete the text in GM1 ATM/ANS.AR.A.045 (e) (1)(g)

response Accepted

A coordinated assessment is one way to achieve that coordination. But it is acknowledged that other ways of coordination may achieve the same purpose. The text has been removed.

comment 508 comment by: UK CAA

Page No: 113

Paragraph No: GM1 ATM/ANS.OR.A.045(e)(1) Changes to the functional system CHANGE AFFECTING MULTIPLE SERVICE PROVIDERS AND AVIATION UNDERTAKINGS – FORMS OF DEPENDENCIES (g)

Comment: In this paragraph, and in AMC1 ATM/ANS.OR.A.045(e)(3) on page 114, it is not



	<p>clear what the responsibilities of the CA are, if an overarching assessment and/or safety argument are not produced. Justification: Clarity.</p>
response	<p>Noted</p> <p>The responsibilities of CA are not detailed in this section, as this Annex deals with service providers. The requirement for the CA is to have coordination arrangements (ATM/ANS.AR.A.005(c)) to effectively select and review notified changes. When this is a multi-actor change, the CA should consider that the service providers comply with requirements related to multi-actor changes. In particular, in relation to agreed assumptions and risk mitigations related to more than one service provider, and the overarching safety case, if applicable.</p> <p>Additional GM will be developed in the 2nd NPA.</p>

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — AMC1 ATM/ANS.OR.A.045(e)(3) Changes to the functional system

p. 114

comment	<p>171 comment by: NATS National Air Traffic Services Limited</p> <p>“However, no matter how many individual changes to service providers’ functional systems are part of the change, they should be coordinated. An overarching safety argument, coherent with the arguments of the individual changes, that claims the complete change is safe should be provided.”</p> <p>This is not feasible given that each service provider will have argued the safety acceptability of their changes to their functional system against prescribed safety criteria (which may well differ across service providers for any given change) and obtained CA approval. Within this rule requirements are leveled at the individual service provider except for interactions between them (e.g. notification and dependencies). Nowhere in the rule is there a notion of a “lead” service provider that could (try) and fulfill the notion of an overarching safety argument. To do so would require the release of propriety information possibly including intellectual property between service providers that would normally be commercial competitors. If such a proposal were feasible and the service providers concerned were from more than one state how would this be managed by the competent authority(ies)? If the overarching argument were found to be unsound how would that impact the individual service providers (whose individual changes would be approved)?</p>
response	<p>Not accepted:</p> <p>Whilst each service provider must argue the safety consequences or the trustworthiness of the change he makes, this will depend fundamentally on the way the change is introduced</p>



into service and the way his changed service interacts with all other services within the system of interest, whether changed or not. This safe transition of all services being changed cannot be the responsibility of each service provider; it must be co-ordinated. Equally, the overall safety of the system cannot be argued by each service provider individually. This is the purpose of the overarching safety case. So, even if the acceptability of each individual change is evaluated against prescriptive safety criteria, those safety criteria may well be dependent on the way the change is introduced.

Please see comments Nos 116 and 510 for a response to the comment on 'lead' service provider.

The management of multi-actor changes across state boundaries, and in the case where not all assurance cases are acceptable to the relevant CA, is dealt with specifically in GM1 ATM/ANS.OR.A.045(f)(2). GM for ATM/ANS.OR.A.045 (e) & (f) provides an overview of all aspects of multi-actor changes. There is a requirement to set coordination arrangements between CAs in ATM/ANS.AR.A.005 (c) to deal with these multi-actor changes.

comment

302

comment by: DSNA

what is the meaning of a "complete change" ?

It is infeasible in real life because a multi ANSP change may enter into operational service step by step and at different moment by different ANSP.

Each service provider will have argued the safety acceptability of their changes to their functional system against prescribed safety criteria (which may well differ across service providers for any given change) and obtained CA approval. Within this rule requirements are leveled at the individual service provider except for interactions between them (e.g. notification and dependencies). Nowhere in the rule is there a notion of a "lead" service provider that could (try) and fulfill the notion of an overarching safety argument. To do so would require the release of propriety information possibly including intellectual property between service providers that would normally be commercial competitors. If such a proposal were feasible and the service providers concerned were from more than one state how would this be managed by the competent authority(ies)? If the overarching argument were found to be unsound how would that impact the individual service providers (whose individual changes would be approved)?

The requirement explanation is much more constraint than the ATM/ANS.OR.A45 (e).

DSNA proposes to delete the AMC1 ATM/ANS.OR.A.045(e)(3) and the related GM.

response

Not accepted

A complete change is the set of changes being assured by the overarching safety case.



Please see the response to comment No 171.

The GM related is kept, but it has been integrated into Section 2.4.5 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities.

comment

492

comment by: skyguide Corporate Regulation Management

(e)(3) requires “However, no matter how many individual changes to service providers’ functional systems are part of the change, they should be coordinated. An overarching safety argument, coherent with the arguments of the individual changes, that claims the complete change is safe should be provided.”

This is not feasible given that each service provider will have argued the safety acceptability of their changes to their functional system against prescribed safety criteria (which may well differ across service providers for any given change) and obtained CA approval. Within this rule requirements are leveled at the individual service provider except for interactions between them (e.g. notification and dependencies). Nowhere in the rule is there a notion of a “lead” service provider that could (try) and fulfill the notion of an overarching safety argument. To do so would require the release of propriety information possibly including intellectual property between service providers that would normally be commercial competitors. If such a proposal were feasible and the service providers concerned were from more than one state how would this be managed by the competent authority(ies)? If the overarching argument were found to be unsound how would that impact the individual service providers (whose individual changes would be approved)?

We suggest that the text in AMC1 ATM/ANS.OR.A.045(e)(3) should be deleted.

response

Not accepted

Please see the response to comment No 171.

comment

509

comment by: UK CAA

Page No: 114

Paragraph No: AMC1 ATM/ANS.OR.A.045(e)(3) Changes to the functional system

Comment: AMT/ANS - should be ATM/ANS

Justification: Incorrect abbreviation (please note this occurs on several occasions throughout the document)

Proposed Text: ‘A change as defined in ATM/ANS.OR.A.045 (e) may...’

response

Accepted

The acronym has been corrected.



comment

510

comment by: UK CAA

Page No: 114**Paragraph No:** AMC1 ATM/ANS.OR.A.045(e)(3) Changes to the functional system**Comment:** Where the changes are changes affecting multiple service providers —an overarching safety argument is required. It has not been made clear which of the service providers concerned is to take ownership of the safety argument**Justification:** The current text does not specify who is responsible for the final development and

Coordination of the overarching safety argument.

Proposed Text: Suggest amend from third sentence to read:‘However, no matter how many individual changes to service providers’ functional systems are part of the change, they should be **Coordinated by the Service Provider proposing the Initial change**. An overarching safety argument, coherent with the arguments of the individual changes that claim the complete change is safe, should be provided.’

response

Not accepted

Who co-ordinates the overarching safety case is not of concern. Certainly, it would not necessarily be appropriate for the initiator to co-ordinate. The change could have initially been a small one proposed by a remote service provider, which, while found to be useful, has far-reaching consequences. It would probably be more appropriate for the service provider close to the ‘sharp end’ to co-ordinate the overarching safety case in these circumstances.

The responsibility for the overarching safety case is not considered to be a regulatory matter. It is for those performing the change to agree amongst themselves.

comment

652

comment by: CANSO

(e)(3) requires “However, no matter how many individual changes to service providers’ functional systems are part of the change, they should be coordinated. An overarching safety argument, coherent with the arguments of the individual changes, that claims the complete change is safe should be provided.”

This is not feasible given that each service provider will have argued the safety acceptability of their changes to their functional system against prescribed safety criteria (which may well differ across service providers for any given change) and obtained CA approval. Within this rule requirements are leveled at the individual service provider except for interactions between them (e.g. notification and dependencies). Nowhere in the rule is there a notion of a “lead” service provider that could (try) and fulfill the notion of an overarching safety argument. To do so would require the release of propriety information possibly including intellectual property between service providers that would normally be commercial competitors. If such a proposal were feasible and the service providers concerned were from



more than one state how would this be managed by the competent authority(ies)? If the overarching argument were found to be unsound how would that impact the individual service providers (whose individual changes would be approved)?
CANSO suggests that the text in AMC1 ATM/ANS.OR.A.045(e)(3) should be deleted.

response [Not accepted](#)

[Please see the response to comment No 171.](#)

comment **697** comment by: *ROMATSA*

(e)(3) requires “However, no matter how many individual changes to service providers’ functional systems are part of the change, they should be coordinated. An overarching safety argument, coherent with the arguments of the individual changes, that claims the complete change is safe should be provided.”

This is not feasible given that each service provider will have argued the safety acceptability of their changes to their functional system against prescribed safety criteria (which may well differ across service providers for any given change) and obtained CA approval. Within this rule requirements are leveled at the individual service provider except for interactions between them (e.g. notification and dependencies). Nowhere in the rule is there a notion of a “lead” service provider that could (try) and fulfill the notion of an overarching safety argument. To do so would require the release of propriety information possibly including intellectual property between service providers that would normally be commercial competitors. If such a proposal were feasible and the service providers concerned were from more than one state how would this be managed by the competent authority(ies)? If the overarching argument were found to be unsound how would that impact the individual service providers (whose individual changes would be approved)?

ROMATSA supports CANSO suggestion to delete the text in AMC1 ATM/ANS.OR.A.045(e)(3).

Supporting comment to summary issue: Unfeasible requirement.

response [Not accepted](#)

[Please see the response to comment No 171.](#)

comment **717** comment by: *DFS Deutsche Flugsicherung GmbH*

(e)(3) requires “However, no matter how many individual changes to service providers’ functional systems are part of the change, they should be coordinated. An overarching safety argument, coherent with the arguments of the individual changes, that claims the complete change is safe should be provided.”

This is not feasible given that each service provider will have argued the safety acceptability



of their changes to their functional system against prescribed safety criteria (which may well differ across service providers for any given change) and obtained CA approval. Within this rule requirements are leveled at the individual service provider except for interactions between them (e.g. notification and dependencies). Nowhere in the rule is there a notion of a “lead” service provider that could (try) and fulfill the notion of an overarching safety argument. To do so would require the release of propriety information possibly including intellectual property between service providers that would normally be commercial competitors. If such a proposal was feasible and the service providers concerned were from more than one state how would this be managed by the competent authority(ies)? If the overarching argument was found to be unsound how would that impact the individual service providers (whose individual changes would be approved)?

In lack of a feasible solution, we suggest that the text in AMC1 ATM/ANS.OR.A.045(e)(3) should be deleted.

Reference to high level comment "c.ii"

response

[Not accepted](#)

[Please see the response to comment No 171.](#)

comment

785

comment by: *DGAC/DSAC - french NSA*

The french NSA has one comment related to AMC1 ATM/ANS.OR.A.045 (e) (3) :

There is no equivalent AMC for CAs involved in the review of such overarching argument (foreseen as mentionned in appendix 6.3 p230). See also french NSA answer to question 4.

response

[Partially accepted](#)

[The answer to question 4 suggests adding GM on this issue. This is accepted and it is believed that this should be sufficient. This GM will be developed in the 2nd NPA. Other comments made against Question 4 suggested that going into many details in IR and AMC may be against the subsidiarity principle and so no AMC will be provided at this stage.](#)

comment

838

comment by: *EUROCONTROL*

AMC1 ATM/ANS.OR.A.045 (e) (3) – Changes to the functional system – Page 114

Although the concept of overarching safety case is clear, the practicalities on who will develop it, and when, is unclear.

As it is already covered in the FAB IR and set up by provisions in the ANSP (and NSA) arrangements at FAB level, it does not seem necessary to address it in this NPA.



response Partially accepted:

The practicalities mentioned are not of regulatory concern. However, guidance is provided in the GM for ATM/ANS.OR.A.045 (e) & (f).

Multi-actor changes can exist outside a FAB and so would not be covered by the FAB IR. The scope of this IR is all multi-actor changes, of which FAB is only one subset.

Who develops the overarching safety case is not of regulatory concern. Please see the response to comment No 510.

Additional GM will be provided to give more information about the overarching safety case in the 2nd NPA.

Not all multi-actor changes will be performed in a FAB environment and so the FAB IR is not applicable in these circumstances.

comment 1065 comment by: LVNL

(e)(3) requires "However, no matter how many individual changes to service providers' functional systems are part of the change, they should be coordinated. An overarching safety argument, coherent with the arguments of the individual changes, that claims the complete change is safe should be provided." This is not feasible given that each service provider will have argued the safety acceptability of their changes to their functional system against prescribed safety criteria (which may well differ across service providers for any given change) and obtained CA approval. Within this rule requirements are leveled at the individual service provider except for interactions between them (e.g. notification and dependencies). Nowhere in the rule is there a notion of a "lead" service provider that could (try) and fulfill the notion of an overarching safety argument. To do so would require the release of propriety information possibly including intellectual property between service providers that would normally be commercial competitors. If such a proposal were feasible and the service providers concerned were from more than one state how would this be managed by the competent authority(ies)? If the overarching argument were found to be unsound how would that impact the individual service providers (whose individual changes would be approved)? It is suggested that the text in AMC1 ATM/ANS.OR.A.045(e)(3) is deleted.

response Not accepted

Please see the response to comment No 171.



Changes to the functional system

comment	876	comment by: EUROCONTROL
	<p>GM1 ATM/ANS.OR.A.045(e)(3) – Changes to the functional system - Page 116</p> <p>EUROCONTROL thinks that mitigation strategies depend on the local reality independently of any other involved ANSP, meaning that agreement on the assessment of the change shall not be given by others.</p>	
response	<p>Partially accepted</p> <p>The risk mitigations that are subject to agreement are only those that relate to more than one service provider and aviation undertaking. In general, the commentator is right that mitigation strategies are applied individually by service providers without the need of agreements. However, there are situations where the mitigation strategies applied by two service providers must be compatible to be effective, or have to be applied jointly, and those are the cases this part of the Regulation is dealing with. The text has been amended to clearly express this intent and limit clearly the agreement to those mitigations that are related to more than one service provider.</p>	
comment	1060	comment by: Frasier Loredana
	<p>b)</p> <p>Delete the expression: <i>e.g. setting up a coordination team</i> and ammend the graphical representation accordingly or insert <i>if possible</i> Justification</p> <ol style="list-style-type: none"> 1. For the States at the EU border, this might not be possible due to numerous reasons (eg. Ukraine situation). 2. From the graphical representation, setting up a coordination team seems to become the rule. 3. We strongly agree with the need for coordination, but the arrangements needs to be left at the ATM/ANS provider level. 	
response	<p>Partially accepted</p> <p>This GM is about a specific example, and it suggests that setting up a coordination team is a possible approach. However, setting a coordination team is just one option in the multi-actor change. There is no requirement in the rule that requires setting up this team. In order to avoid misinterpretations, the text has been modified.</p>	



3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM1 ATM/ANS.OR.A.045(e)(3) Changes to the functional system	p. 116-117
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comment	<p>118</p> <p style="text-align: right;">comment by: <i>EUROCONTROL Safety Team</i></p> <p>GM1 ATM/ ANS.OR.A.045(e)(3) on page 116 Mitigation strategies depend on the local reality independent of any other involved ANSP. Therefore; no agreement can be given by others.</p>
response	<p>Partially accepted</p> <p>The risk mitigations that are subject to agreement are only those that relate to more than one service provider and aviation undertaking. In general, the commentator is right that mitigation strategies are applied individually by service providers without the need of agreements. However, there are situations where the mitigation strategies applied by two service providers must be compatible to be effective, and those are the cases this part of the Regulation is dealing with. The text has been amended to clearly express this intent and limit clearly the agreement to those mitigations that are related to more than one service provider.</p>
comment	<p>566</p> <p style="text-align: right;">comment by: <i>Frasie Loredana</i></p> <p>Include information and guidance (generalities) about the correlation of the procedures used by ATS providers and service providers, other than ATS providers to perform <i>coordinated (safety) assessment</i>. Justification From experience, we appreciate that lack of guidance on the correlation of the procedures for safety assessment for ATS providers (in an SMS context) and safety support assessment for the service providers, other than ATS providers (outside the SMS context), will be a barrier in coordinating the assessments referred in ATMANS.OR.A045 (e) (3). GM1 ATM/ANS.OR.B.010(a) Change management procedures GENERAL does not contain any indication on the change management procedures for the correlation of the safety assessment for ATS providers and safety support assessment for the service providers, other than ATS providers.</p>
response	<p>Partially accepted</p> <p>The GM has been restructured to describe more clearly the relationship of the safety assessment and the safety support assessment.</p>



comment

946

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX III COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR) GM1 ATM/ANS.OR.A.045(e)(3)	This GM1 ATM/ANS.OR.A.045(e)(3) should be promoted to the level of AMC.	Compliance with this section (provided more detail is given) would directly demonstrate compliance with the related regulatory requirement.

response

Not accepted

The IR text has been amended in a way that coordination is required, but performing an explicit coordination assessment is not. This GM provides explanatory elements of what the coordination implies, but it does not provide a means to achieve the coordination, but the content of the coordination itself.

comment

947

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX III COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR) GM1 ATM/ANS.OR.A.045(e)(3)	(f): First of all, a common basis for the safety management processes should be established between both service providers.	This is specially relevant if the service providers use different severity classification schemes and different safety assessment methodologies.



response

Accepted

This is already recognised in the GM. No proposal is provided by the commentator, and thus no change has been made.

comment

1297

comment by: EUROCONTROL

GM1 ATM/ANS.OR.A.045(e)(3) Changes to the functional system - Page 116

Mitigation strategies depend on the local reality independent of any other involved ANSP. Therefore; no agreement can be given by others.

response

Partially accepted

The risk mitigations that are subject to agreement are only those that relate to more than one service provider and aviation undertaking. In general, the commentator is right that mitigation strategies are applied individually by service providers without the need of agreements. However, there are situations where the mitigation strategies applied by two service providers must be compatible to be effective, and those are the cases this part of the Regulation is dealing with. The text has been amended to clearly express this intent and limit clearly the agreement to those mitigations that are related to more than one service provider.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM1 ATM/ANS.OR.A.045(f)(2) Changes to the functional system

p. 117-118

comment

172

comment by: NATS National Air Traffic Services Limited

Point (a) refers to GM1 ATM/ANS.OR.A.045(f)(2) which is this GM?

response

Accepted

The reference is incorrect. Since the IR has changed, the GM has been adapted to the changed structure.

comment

173

comment by: NATS National Air Traffic Services Limited

Point (c) – ATM/ANS.OR.A.045(f)(2) does not, and cannot, require that aviation undertakings



	participate as the action is on the service provider.
response	<p>Noted</p> <p>The IR does not actually impose a requirement on the aviation undertaking, but on the service provider. The GM acknowledges the point made by the commentator, and it proposes several ways to move forward. It is uncertain what the commentator wishes to change.</p>
comment	<p>962 comment by: DGAC/DSAC - french NSA</p> <ul style="list-style-type: none"> • paragraph (a) : <p>There is a circular reference to the GM1 ATM/ANS.OR.045 (f) (2).</p> <ul style="list-style-type: none"> • paragraph (b) : <p>The sentence starting by "This because, were it not so, " should be simplified. It is very difficult to understand it.</p>
response	<p>Accepted</p> <p>The reference is incorrect. Since the IR has changed, the GM has been adapted to the changed structure.</p> <p>Paragraph (b) has been amended.</p>

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM1 ATM/ANS.OR.B005(a)(5)

p. 118-119

comment	<p>121 comment by: EUROCONTROL Safety Team</p> <p>GM1 ATM/ ANS.OR.B005(a)(5) Identification of changes (a) Para 2 on Page 118</p> <ol style="list-style-type: none"> 1. RVSM is not a very good example because it is now well and truly established. Perhaps Free Routing, Free Flight and other modern concepts could be better examples. 2. Recommend to include safety monitoring and safety surveys in the list of processes that identify changes.
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response [Accepted](#)

The RVSM example has been changed and the safety monitoring/safety surveys have been added.

comment 174 comment by: NATS National Air Traffic Services Limited

GM1 ATM/ANS.OR.B.005(a)(5)
 This GM seems to have very little in common with its related IR. It appears to be possible triggers that could arise such that a change to the functional system may be desirable. This is no different to any other source of change driver.
 Please delete GM1 ATM/ANS.OR.B.005(a)(5)

response [Partially accepted](#)

The reference is now wrong due to changes in the IR; it has been changed. However, this is GM for the change drivers that affect the functional system and so is relevant to the process described in ATM/ANS.OR.B.005(a)(4).

comment 194 comment by: NATS National Air Traffic Services Limited

GM1 ATM/ANS.OR.B.005(a)(5)
Page 119

Point (b) – ATM/ANS.OR.B.015(f) does not exist (in CRD 2013-08).

response [Accepted](#)

The reference has been corrected.

comment 568 comment by: Frasier Loredana

(a) (5)
 After the text:
excluding changes during maintenance, repair and alternative operations
 add the following text:
 already contained in the accepted operating envelope.
 Justification
 To clarify the text.

response [Partially accepted](#)



The suggested words have been slightly altered.

comment

663

comment by: EUROCONTROL

GM1 ATM/ANS.OR.B005(a)(5) Management system – Page 118

(a) (3) and (a) (8)

EUROCONTROL suggests adding a definition of operational personnel and key personnel. In addition, RVSM is not a very good example (in (5)) because it is today well and truly established. Perhaps Free Routing, Free Flight and other recent concepts could be better examples.

Include safety monitoring and safety surveys in the list of processes that identify changes.

response

Partially accepted

It is not felt that a definition of operational and key personnel is needed. The GM provides sufficient context for them to be identified. It is unlikely that an appropriate complete definition could be found.

The RVSM example has been changed and the safety monitoring/safety surveys have been added.

comment

948

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX III COMMON REQUIREMENTS FOR SERVICE PROVIDERS <i>(Part-ATM/ANS.OR)</i> GM1 ATM/ANS.OR.B.005(a)(5)	Some more specific GM should be provided.	It seems to be quite difficult for the service provider to comply with this requirement, which would imply a high level coordination through the whole organisation.

response

Not accepted

ATM/ANS.OR.B.005(a)(4) is a requirement that is a consolidation and clarification of many requirements in Regulation (EU) No 1035/2011. This GM relates that requirement to the



change drivers for the functional system. As such, it can be no more onerous than satisfying Regulation (EU) No 1035/2011 and should be simpler in that it is clearer.

comment 949

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX III COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR) GM1 ATM/ANS.OR.B.005(a)(5)</p>	<p>(b): an important reference to <i>ATM/ANS.OR.B.015(f)</i> is mentioned, but in fact, this should be to <i>ATM/ANS.OR.B.005(g)</i>.</p>	<p>This reference changed from the NPA 2013-08 (where it was, in fact, <i>ATM/ANS.OR.B.015(f)</i>) to the CRD 2013-08.</p>

response Partially accepted

The reference is wrong but the suggested reference is also wrong. The reference has been corrected.

comment 971

comment by: DGAC/DSAC - french NSA

- paragraph (a) (5) :

The sentence "excluding changes during maintenance, repair and alternative operations" is not precise enough and could cover many things. A note should be added in line with the material of interpretation provided in GM1 Annex I Definitions (35) & ATM/ANS.OR.A.045 & ATM/ANS.OR.C.005 & ATS.OR.205 General p60 (idem p166).

- paragraph (b) :



ATM/ANS.OR.B.015 (f) referenced to doesn't exist.

response [Partially accepted](#)

[\(a\)\(5\)](#) has been clarified but not in the way suggested – see the [response to comment No 568](#).

The reference has been corrected.

comment **1122** comment by: *Belgocontrol*

GM1 ATM/ ANS.OR.B005(a)(5) Identification of changes (a) Para 2 on Page 118
Recommend to include safety monitoring and safety surveys in the list of processes used to identify changes.

response [Accepted](#)

The safety monitoring/safety surveys have been added.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — AMC1 ATM/ANS.OR.B.010(a) Change management procedures p. 119

comment **195** comment by: *NATS National Air Traffic Services Limited*

AMC1 ATM/ANS.OR.B.010(a)
Page 119

Given the general nature of the text it is considered that this text would be more appropriate as GM. It is singling out change management procedures as if they are in need of special attention as opposed to being a part of the service providers MS/SMS and subject to the same rules as any other procedures.

Proposal: Redraft as specific GM for change management procedures and incorporate into GM for ATM/ANS.OR.A.040

response [Not accepted](#)

[Change management procedures](#) have been singled out, primarily to provide flexibility so they can be approved separately from the rest of the MS/SMS procedures at the certification



time. See additional supporting justification on the comments against ATM/ANS.OR.B.010.

There are specific criteria described in the AMC that would not be appropriate in GM, e.g. the use of a compliance matrix, the change identification procedure, the notification procedure.

comment 196

comment by: *NATS National Air Traffic Services Limited*

AMC1 ATM/ANS.OR.B.010(a)

Page 119

Point (b) – compliance with the requirements is “as appropriate” depending upon what type of service provider you are (no service provider would have to comply with all of them simultaneously).

Proposal: Add “as appropriate” at the end of the first sentence.

response

Accepted

The text has been added.

comment 303

comment by: *DSNA*

(f):The change management procedure doesn't deserve a specific procedure.

(f): Moreover a change identification procedure will induce a new administrative burden without improving safety.

DSNA proposes to delete ALL (f).

response

Not accepted

(f) is not about the change management procedure but about a change identification procedure. This is necessary as it supports and integrates the change driver principles which are present in other places in the IR, e.g. ATM/ANS.OR.C.005, ATS.OR.205, ATM/ANS.OR.B.005(a), ATM/ANS.B.005(d).

comment 511

comment by: *UK CAA*

Page No: 119

Paragraph No: AMC1 ATM/ANS.OR.B.010(a) Change management procedures



Comment: subparagraph (b) states ‘The service provider should show that the procedures address all the actions and all the evidence needed in order to comply with the requirements laid down in ATM/ANS.OR.A.045, ATS.OR.205, ATS.OR.210, and ATM/ANS.OR.C.005. For that purpose, the service provider should use a compliance matrix.’

NPA 2013-08 and Regulation 139/2014 (the Aerodrome regulation) both require a common management system where the ANSP and Aerodrome Certificate holder are the same entity Regulation 139/2014 does not require the use of a compliance matrix

Justification: Confusion may be caused where there is a common management system.

Proposed Text: Suggest amend paragraph ‘(b)The same process for the recording of the currency and modification state of procedures for management of change should be the same in ATM/ANS and Aerodrome legislation’

response **Not accepted**

There is no requirement for a common management system for both services (aerodrome and ATS), but there are requirements for a single management system to cover all activities (ADR.OR.D.005(e) and ATM/ANS.OR.B.005(g)).

ADR.OR.D.035(a) covers record-keeping for notified changes as they are activities under Regulation (EC) No 216/2008.

comment 805

comment by: DGAC/DSAC - french NSA

The french NSA has one comment related to AMC1 ATM/ANS.OR.B.010 (a) :

The sentence "..., confirm that there is a real intent" should be replaced by "..., confirm that there is an intent". If not, this could lead to late notification.

response **Not accepted**

Whilst it is true that it might delay some notifications, it also prevents false notifications.

comment 950

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX III COMMON REQUIREMENTS FOR	(b): According to section (f) in this AMC1 ATM/ANS.OR.B.010(a), requirements laid down in ATM/ANS.OR.B.005(a) and (d) should also be addressed by the change management procedures of the service providers.	These requirements already include some regulation related to change identification and compliance with them should be shown



<p>SERVICE PROVIDERS (Part-ATM/ANS.OR) AMC1 ATM/ANS.OR.B.010(a)</p>	<p>The difference between the 'change identification procedure' mentioned in (f) and the 'process to identify circumstances that may affect the provision of the service and to plan changes to the functional system' mentioned in ATM/ANS.OR.B.005(a)(5) is not clear.</p>	<p>by service providers.</p>
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response [Accepted](#)

The change identification procedure is needed as it supports and integrates the change driver principles which are present in other places in the IR, e.g. ATM/ANS.OR.B.005(a)(4), ATM/ANS.B.005(d), as identified in this comment and also ATM/ANS.OR.C.005, ATS.OR.205.

GM to ATM/ANS.OR.B.005(a)(5) is developed to explain this relationship.

comment 1243

comment by: *Icetra*

Minor changes in wording suggested:

(b) (b) The service provider should ~~show~~ demonstrate that the procedures address all the actions and all the evidence needed in order to comply with the requirements laid down in ATM/ANS.OR.A.045, ATS.OR.205, ATS.OR.210, and ATM/ANS.OR.C.005. For that purpose, the service provider should use a compliance matrix, , which ~~shows~~ demonstrates:

response [Not accepted](#)

'Show' is a more appropriate word than 'demonstrate' in this context.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM1 ATM/ANS.OR.B.010(a) Change management procedures p. 119-120

comment 512

comment by: *UK CAA*

Page No: 120

Paragraph No: GM1 ATM/ANS.OR.B.010(a) Change management procedures GENERAL (c)

Comment: There is no indication of a valid method for determining when modifications of an



	<p>already approved procedure are not considered material and do not require a new notification and/or approval. Guidance is required on acceptable criteria for each category, to ensure consistency.</p> <p>Justification: Harmonisation.</p>
response	<p>Partially accepted</p> <p>The word 'material' has its normal English meaning: significant, important — significant or relevant, especially to the extent of determining a cause or affecting a judgement (e.g. 'information that could be material to a murder inquiry').</p> <p>The determination of whether a modification is material is a judgement as to whether it changes the meaning of the text describing the procedure. As such, there is no need for a method, and guidance could not cover all conceivable cases. It is felt that the guidance provided is sufficient.</p> <p>However, (c) does not add anything to the IR and in any case contradicts it. Furthermore, it implies that all material and immaterial modifications can be predicted, which is not the case. It has been removed.</p>
comment	<p>973 comment by: DGAC/DSAC - french NSA</p> <p>In paragraph (i), mitigation methods are often studied for a specific case. It could be difficult to define them at the level of this procedure.</p>
response	<p>Noted</p> <p>It is agreed that it would be difficult to describe all conceivable means of mitigation. However, this guidance is seeking a method for identifying mitigations. As such, it does seem feasible to describe such a method.</p>
comment	<p>1057 comment by: Frasier Loredana</p> <p>Include information and guidance (generalities) about the correlation of the procedures used by ATS providers and service providers, other than ATS providers to perform <i>coordinated (safety) assessment</i>.</p> <p>Justification</p> <p>From experience, we appreciate that lack of guidance on the correlation of the procedures for safety assessment for ATS providers (in an SMS context) and safety support assessment for the service providers, other than ATS providers (outside the SMS context), will be a barrier in coordinating the assessments referred in ATMANS.OR.A045 (e) (3).</p> <p>GM1 ATM/ANS.OR.B.010(a) Change management procedures GENERAL does not contain any indication on the change management procedures for the correlation of the safety</p>



assessment for ATS providers and safety support assessment for the service providers, other than ATS providers.	
response	<p>Partially accepted</p> <p>The point made is valid; however, the solution has been incorporated into the multi-actor changes guidance since it is more relevant there.</p> <p>It is unlikely that the solution proposed here could work as the stakeholders involved in all multi-actor changes cannot be predicted. All that can be said is that during a multi-actor change there may be some overhead incurred because the procedures of the stakeholders are incompatible and consequently need to be made compatible as part of the change. This should be borne in mind at the beginning of a multi-actor project and may extend the time and incur additional cost.</p>

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — AMC2 ATM/ANS.OR.B.010(a);(b) Change management procedures	p. 122
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comment	<p>513</p> <p style="text-align: right;">comment by: UK CAA</p> <p>Page No: 122</p> <p>Paragraph No: AMC2 ATM/ANS.OR.B.010(a);(b) Change management procedures MODIFICATION OF PROCEDURES AND DEVIATIONS FROM PROCEDURES</p> <p>Comment: The arrangements appear to inadvertently prohibit the service provider from having alternative procedures concurrently approved. (This may be a misreading of the intent of the clause).</p> <p>There does not seem to be any reason why more than one set of procedures couldn't be valid, for example specific change procedures could be approved for one specific asset, and used on an ongoing basis, whereas more generally applicable procedures could be approved for the majority of the service provider's changes.</p> <p>At the highest level, a larger service provider may need change procedures for the production of both safety cases and safety support cases.</p> <p>Justification: Clarity and recognition of reality.</p>
response	<p>Not accepted</p> <p>The (unwritten) premise for argument appears flawed: that the set of procedures cannot include alternates.</p> <p>There is no bar to alternate procedures. However, if they are to be present then there must be a procedure that defines the criteria for the use of a particular subset and which subsets form a complete set of appropriate procedures. For each particular subset:</p>



- it must comply with the applicable requirement;
 - a modification to a part of a subset must comply with the applicable requirement; and
 - a modification to a part of a subset may require a modification to the use criteria, which must also define an appropriate set of subsets that form a complete set of appropriate procedures, i.e. one that complies with ATM/ANS.OR.B.010(a).
- GM will be provided to make it clear that alternate procedures are acceptable.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM1 ATM/ANS.OR.C.005(a)(2) & ATS.OR.205(a)(2) General p. 122-126

comment 128

comment by: EUROCONTROL Safety Team

This GM and related footnotes are confusing because:

- Title is SAFETY SUPPORT CASE AND SAFETY CASE.
- In (a) it then refers to safety and safety support assurance.
- In footnote 125 there is now reference to an assurance case with footnote 126 effectively repeating the latter part of footnote 125.
- Footnote 127 refers to the safety support case however it associated with safety support assurance in the table
- What is the difference between *as specified in the specified context* (for safety support assurance) and *as specified in a given context* (for a safety support case)?
- What is the difference between a safety support case needing *evidence* and a safety case which needs *a body of evidence*?
- Both safety support case and safety case use the word system but do not refer to functional system or service. Is this the same system as in GM2 Annex I Definition (35) Figure 1?
- What is *regulator CA* mentioned in both safety support case report and safety case report?

response Accepted

The title has been changed to 'safety assurance and safety support assurance', and the GM has been restructured to give more clarity and improve readability.

Footnotes 125 and 126 have been deleted.

The wording of footnote 127 was updated. Instead of 'as specified in a given context', it now reads 'as specified in the specified context'. No difference was implied.



No difference is implied by the use of ‘body of evidence’, so the words are aligned now.

The word ‘system’ used in safety case and safety support case implies ‘functional system’. It has been amended.

‘Regulator’ has been removed from the definitions.

comment

197

comment by: NATS National Air Traffic Services Limited

GM1 ATM/ANS.OR.C.005(a)(2) & ATS.OR.205(a)(2)

Page 122

The text of this GM and related footnotes is confusing. It is titled “SAFETY SUPPORT CASE AND SAFETY CASE”, the text in (a) refers to “safety and safety support assurance” and footnote 125 refers to “an assurance case” with footnote 126 effectively repeating the latter part of footnote 125.

Footnote 127 refers to the safety support case however it associated with safety support assurance in the table.

For safety support assurance it is “as specified in the specified context” whereas for a safety support case it is “as specified in a given context”. If both are correct then what is the difference?

A safety support case needs “evidence” whereas a safety case needs “a body of evidence”. What is the difference?

Both safety support case and safety case use the term “system” (albeit one is the system and the other a system) as opposed to functional system or service. Is this the same system as in GM2 Annex I Definition (35) Figure 1? (Although see previous comment of Figure 1)

The term “regulator CA” in safety support case report and safety case report appears to mix regulator with competent authority – is this intentional?

Footnote 131 mentions “as low as is reasonably practical” (ALARP). This notion does not appear to be in the IR/AMC and this concept may well not be equally (if at all) understood across Europe. ALARP is subjective and it would not be appropriate to enshrine it in a regulation.

response

Accepted

The text has been updated and section a) moved to a dedicated section for definitions (Section 1 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities).



Footnotes 125 and 126 has been deleted.

The wording of footnote 127 was updated. Instead of ‘as specified in a given context’, it now reads ‘as specified in the specified context’. No difference was implied.

No difference is implied by the use of ‘body of evidence’, so the words are aligned now.

The word ‘system’ is meant to be functional system. The words are amended to resolve it.

‘Regulator’ is removed from the definitions.

Regarding the ALARP principle, the concept is already in ATS.OR.210, but has also been introduced in the SMS (see new provision ATS.OR.200(2)(iii)).

comment 304

comment by: DSNA

The text of this GM and related footnotes is confusing. It is titled “SAFETY SUPPORT CASE AND SAFETY CASE”, the text in (a) refers to “safety and safety support assurance” and footnote 125 refers to “an assurance case” with footnote 126 effectively repeating the latter part of footnote 125.

Footnote 127 refers to the safety support case however it is associated with safety support assurance in the table.

For safety support assurance it is “as specified in the specified context” whereas for a safety support case it is “as specified in a given context”. If both are correct then what is the difference?

A safety support case needs “evidence” whereas a safety case needs “a body of evidence”. What is the difference?

Both safety support case and safety case use the term “system” (albeit one is the system and the other a system) as opposed to functional system or service.

The term “regulator CA” in safety support case report and safety case report appears to mix regulator with competent authority – is this intentional?

So the text is over confusing and causes more question than answer.

DSNA proposes to rewrite it or to delete it.

response Accepted

See also response to comment No 197.



comment	<p data-bbox="359 235 406 280">515</p> <p data-bbox="1220 235 1484 280">comment by: UK CAA</p> <p data-bbox="359 324 550 358">Page No: 122-6</p> <p data-bbox="359 369 1484 436">Paragraph No: GM1 ATM/ANS.OR.C.005(a)(2) & ATS.OR.205(a)(2) General SAFETY SUPPORT CASE AND SAFETY CASE (e)</p> <p data-bbox="359 448 1484 560">Comment: The proper structure of arguments is explained, but service providers should be specifically instructed to present arguments that can be seen to be structured in this manner in their assurance cases, otherwise they will revert to unstructured narrative.</p> <p data-bbox="359 571 798 604">Justification: Clarity of requirement.</p>
response	<p data-bbox="359 638 582 672">Partially accepted</p> <p data-bbox="359 705 1484 817">Text has been added to encourage service providers to structure their arguments following the GM, but no prescriptive instruction on how to write them is given. Some text has been added about the type of arguments (inductive/deductive) to give additional guidance.</p>
comment	<p data-bbox="359 907 406 952">516</p> <p data-bbox="1220 907 1484 952">comment by: UK CAA</p> <p data-bbox="359 996 526 1030">Page No: 125</p> <p data-bbox="359 1041 1484 1108">Paragraph No: GM1 ATM/ANS.OR.C.005(a)(2) & ATS.OR.205(a)(2) General SAFETY SUPPORT CASE AND SAFETY CASE (e)</p> <p data-bbox="359 1120 1484 1232">Comment: The footnote states that the top-most claim “is that the system is acceptably safe and its risk is as low as is reasonably practicable.” And similarly for a safety support case. In both cases the present tense is used.</p> <p data-bbox="359 1243 1484 1321">1) As assurance cases are produced before the change is implemented, the claims should be in the future tense.</p> <p data-bbox="359 1332 1141 1366">2) The claims should address all transitional stages of the service.</p> <p data-bbox="359 1377 1484 1444">3) It is debatable whether the safety case should refer to the system being safe or the service.</p> <p data-bbox="359 1456 638 1489">Justification: Accuracy.</p>
response	<p data-bbox="359 1523 582 1556">Partially accepted</p> <p data-bbox="359 1590 1484 1657">1) While this is true, there is no need to state the claim in future tense, as it is implied that the ‘system is safe’ after the implementation of the change.</p> <p data-bbox="359 1691 1484 1769">2) The scope, as per ATM/ANS.OR.C005(a)(1)(iv) and ATS.OR.205(a)(1)(iv), includes transitions.</p> <p data-bbox="359 1803 1484 1960">3) There is no difference between the system and the service provided being safe. The system refers here to the complete ATM system, with the ATS functional system being only a part of it. If the change to the ATS functional system results in the service provided being safe, that means that the total system is safe (as nothing else has been changed).</p>



comment	<p data-bbox="359 235 414 280">718</p> <p data-bbox="893 235 1498 280">comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <div data-bbox="359 324 1498 1086" style="border: 1px solid black; padding: 10px;"> <p data-bbox="359 324 1498 459">It looks like the safety support case report is an excerpt/summary of the safety support case. Producing this report by downsizing the safety case is therefore additional and unnecessary effort.</p> <p data-bbox="359 492 1498 537">We propose to delete this report throughout the AMC/GM.</p> <p data-bbox="359 571 1498 616">In general, is the text of this GM and its related footnotes confusing.</p> <p data-bbox="359 649 1498 1086">It is titled "SAFETY SUPPORT CASE AND SAFETY CASE", the text in (a) refers to "safety and safety support assurance" and footnote 125 refers to "an assurance case" with footnote 126 effectively repeating the latter part of footnote 125. Footnote 127 refers to the safety support case however it associated with safety support assurance in the table. For safety support assurance it is "as specified in the specified context" whereas for a safety support case it is "as specified in a given context". If both are correct then what is the difference? A safety support case needs "evidence" whereas a safety case needs "a body of evidence". What is the difference? Both safety support case and safety case use the term "system" (albeit one is the system and the other a system) as opposed to functional system or service. Is this the same system as in GM2 Annex I Definition (page 35) Figure 1?</p> <p data-bbox="359 1075 1498 1120">Reference to high level comment "c.v"</p> </div>
response	<p data-bbox="359 1198 582 1243">Partially accepted</p> <p data-bbox="359 1265 1498 1512">The report does provide a summary of the assurance case and so, for practical reasons, it will not contain all the evidence. It does not downsize the case. Together with the rest of the evidence it presents the full assurance case. This is a more practical way of providing the assurance case as it avoids the unnecessary effort of having to put all of the evidence in a single document, which, in the cases where a report is used, will be very large and probably held in many places.</p> <p data-bbox="359 1534 1498 1579">For the rest of the comment, please see also the response to comment No 128.</p>
comment	<p data-bbox="359 1713 422 1758">1209</p> <p data-bbox="1117 1713 1498 1758">comment by: <i>Frasie Loredana</i></p> <p data-bbox="359 1803 630 1848">Review the definition.</p> <p data-bbox="359 1848 510 1892">Justification</p> <p data-bbox="359 1892 1498 1971">The definition states<i>that a <u>system</u> is acceptably safe for a given application in a given operating context.</i></p> <p data-bbox="359 1971 1498 2016">The term <i>system</i> it seems to limit the content of the safety case only to the changes which</p>



	are induced by technical factors. The term system is used also in the Safety Support Case definition.
response	<p>Not accepted</p> <p>The word ‘system’ refers to the system in question, which in the case of this Regulation is the ATM system in which the functional system (equipment, humans and procedures) operates — see section 2.1.1 Functional system model of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities.</p> <p>The definition is general as it is not exclusive to this context.</p>

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — AMC1 ATM/ANS.OR.C.005 Safety support assessment and assurance of changes to the functional system	p. 126-127
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comment	<p>198 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>AMC1 ATM/ANS.OR.C.005 Page 126</p> <p>The intent behind this AMC (trained and competent) is already addressed in the MS provisions – ATM/ANS.OR.B.005(a)(8).</p> <p>Proposal: Delete AMC1 ATM/ANS.OR.C.005</p>
response	<p>Accepted</p> <p>The AMC has been deleted.</p>
comment	<p>894 comment by: <i>EUROCONTROL</i></p> <p>AMC1 ATM/ANS.OR.C.005 – Safety support assessment and assurance of changes to the functional system – Page 126</p> <p>The definition of what an ATS provider is should deserve more visibility than that provided through footnote 132 on page 127.</p>
response	<p>Not accepted</p> <p>The comment applies to GM1 ATM/ANS.OR.C.005, not AMC1 ATM/ANS.OR.C.005.</p> <p>The footnote only indicates that the term is being used in a specific way in this GM (note — not AMC). The note has been removed and the paragraph redrafted (and moved to section 2.4.4 in Appendix 1 to GM1 to Article 5 Service Providers and Article 6(2) Oversight</p>



capabilities) as the discussion on how the service providers other than ATS can affect safety of the flight is addressed in Section 2.3 in that Appendix 1.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM1 ATM/ANS.OR.C.005 Safety support assessment and assurance of changes to the functional system p. 127-134

comment 199

comment by: *NATS National Air Traffic Services Limited*

GM1 ATM/ANS.OR.C.005

Page 127

This GM is very difficult to understand and comprehend with a mixture of cases and examples (what is the difference?).

By way of examples (not complete) please see the detailed comments below.

The GM, if retained, should be simplified and made consistent.

(a) states (use of i.e.) who the service providers other than ATS providers are, whereas (b) suggests (use of e.g.) who are service providers other than ATS providers and the list is different. Presumably this is because ASM is not considered to be a service direct to the aircraft albeit (a) does suggest that it could be.

(b) states that the end user of the service (i.e. the pilot or the operator) should undertake a safety assessments. Pilots or the operator are not subject to this rule (they are not service providers) so why would they produce a safety assessment? They would not even be aware of the rule. What is the purpose of service providers, other than ATS providers, producing a safety support assessment that will go unread, and unknown, in these circumstances? The safety support assessment may well argue that the service only behaves as specified but unless that specification is made available and used it is meaningless. Granted the CA may review the change to a functional system and approve the change but they are in no better a position to know if the service is fit for purpose.

(c) and Footnote 133 refers to the safety support assurance argument and suggests GM that provides guidance on this. There is no such guidance and the term safety support assurance argument is only found in (c) and Footnote 133.

(c) states “The specification of the changed service and the context specification should be made available to **any** service provider or other body or person that wishes to use the changed service.” Surely such information would be parted with on a commercial basis and the service provider can reserve the right to not release such information?

(j)(1) and Footnote 136 – the footnote explains that Step 2 in Figure 3 relates to (k)(2).



	<p>However in (k) there are only 4 “steps” whereas Figure 3 has 5 steps. Is it really (k) or should it be (j)?</p>
response	<p>Partially accepted</p> <p>(a) The interpretation is correct. However, in order to simplify the text, the list of service providers other than ATS, is listed just once.</p> <p>(b) The aim is not to impose a requirement on the aircraft operator or the pilot to produce a safety assessment, but to highlight that they have the responsibility to ensure the service can be used safely. The wording has been changed to reflect more precisely this intent. The main purpose of the safety support assessment is to provide assurance of the trustworthiness of the specification in the context of its use, and that is for the benefit of the service provider. The specifications have also to be made available to the ATS provider or the end users for them to assess the impact on their services. The CA has to assess if the service is trustworthy using the safety support assurance case. In the case of a responsive change to an ATS, the CA, when it chooses to do so, has to assess the validity of the safety case by reviewing it in combination with the safety assurance case.</p> <p>(c) To avoid the use of a technical term, the wording is changed.</p> <p>(d) It is understood that the specification is made available to those who will use it (either because they will have a contractual agreement or because the service is provided freely). If the service provider does not share the specification, then the service will not be used (who would use a service that has no specifications available?). The intent here is to explain that in addition to the SSA (for the CA), the specification will also be made available to the users.</p> <p>(j) It refers to section (k) but there is a missing step in the description. The text has been amended accordingly.</p>
comment	<p>305 comment by: <i>DSNA</i></p> <p>The figures are over complicated.</p> <p>The figures are incomprehensible and explanations do not help understanding.</p> <p>The figure’s number is 4 rather than 2.</p> <p><u>DSNA proposes to rewrite and redraw this part.</u></p>
response	<p>Partially accepted</p> <p>The figures are moved to a different GM to describe specific cases of multi-actor changes from a process perspective. The drawings are simplified and descriptions are amended to</p>



[ease the reading.](#)

comment

335

comment by: *BAF-M.Jancokova*

Subparagraph b):

This is clearly a shift of responsibility which cannot be easily accepted without further elaboration of the issue. In the current regulation, a CNS provider is supposed to provide a safety argument for any change. This NPA proposes, in certain cases, to put this burden on the user of the service. It should be taken into consideration, that the end users do not fall under the supervision of NSAs. It has to be laid down, that also under the new regulation, safety assessments for those changes are actually done and reviewed if necessary.

response

[Not accepted](#)

This Regulation does not impose requirements on end users to perform a safety assessment when there is no ATS involved, but it only states that the responsibility of the safe use of services is on the end user's side. The change is, as highlighted by the commentator, based on the fact that CNS providers do not have to provide a safety argument, because it is considered disproportionate to require them to assess the safety risks of the use of their services. These services are used by others (ATS or directly by the aircraft) to ensure separation. The goal of a safety support assessment is to assess the performance of the service (e.g. timeliness, accuracy, integrity, reliability) in the intended context of use. Additionally, assurance has to be provided that the changed service will behave only as specified (i.e. it does what it is said to do and nothing more) in the specified operational environment. The non-ATS providers (including CNS providers) will remain subject to certification and will be required to have in place a management system to manage the performance of the services they provide to the user.

comment

519

comment by: *UK CAA*

Page No: 129

Paragraph No: GM1 ATM/ANS.OR.C.005 Safety support assessment and assurance of changes to the functional system GENERAL (j) to end of section

Comment: Even though the cases presented are quite lengthy, when discussing how safety cases and safety support cases are developed and adjusted according to developments, the text does not relate these activities to the gaining of necessary approvals and the coordinated deployment of the changes. Clarification is required as to how the activities presented in the cases relate to the granting of the necessary approvals and the subsequent deployment of change.

Justification: Completeness, plus clarification on the requirements.

response

[Partially accepted](#)



It was considered too prescriptive to indicate how the assurances should be approved by the CAs. The manner in which the safety case and associated safety support cases are approved is a matter for the agreement of the CAs. The myriad situations that are possible prevented the Agency from proposing a single approach. It is understood that no safety case can be approved if the associated safety support cases are not approved (assuming they have been selected for review). Text has been added to clarify the dependencies of the necessary approvals.

The interactions that occur during the development of a change, which includes the development of the associated assurance cases and the deployment to the change can be found in the new Section 3.3 'Multi-actor view' of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities.

comment 979

comment by: DGAC/DSAC - french NSA

We strongly disagree with the opinion expressed in the paragraph (b). If a service provider provides service directly to an a/c, the it should undertake a safety assesment and not a safety support assessment. There is no rule requiring a pilot or an operator to assess the safety following a change in the functional system of a service provider other than a ATS, and no rule asking him to base his assessment of the safety support assessment. We fear that, in this case, there is no safety assessment at all, even if the aviation undertaking have been informed by the service provider. Please refer to our previous comment to ATM/ANS.OR.C.005 and the associated proposal.

In addition, taking the assumption in this guidance that a pilot of an a/c is able to undertake a safety assessment (and consequentky takes on his own the responsibility of the safety of the navigation services he uses) is greatly questionnable. As it is mentioned in AMC1 ATS.OR.205 (b), only trained and competent personnel should perform safety assessment.

response Not accepted

Please see the response to comment No 335.

comment 1068

comment by: EUROCONTROL

GM1 ATM/ANS.OR.C.005 – Safety support assessment and assurance of changes to the functional system – page 127

EUROCONTROL concurs with the guidance material under the present heading since it formalizes the obligation for external services and suppliers to provide the required data feeding the Safety Case. Why not, therefore, make use of wordings such as “external services”, “suppliers”, etc.?

However, EUROCONTROL raises a point and makes a proposal: a safety support assessment



	<p>would only deal with quality, performance, requirement identification and verification, and, to a limited extent, validation. There are no safety elements in this. The wording of Safety Support Assessment could therefore be limited to Support Assessment.</p>
response	<p>Not accepted</p> <p>The use of ‘safety support assessment’ conveys the notion that the main purpose of that assessment is to support the evaluation of safety of ATS service or of the use of that service. The Agency considers appropriate to continue using this term, even though the main subject of the assessment is to assess the performance of the service, and argue about its trustworthiness, and not safety per se.</p>

<p>3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM2 ATM/ANS.OR.C.005(a) Safety support assessment and assurance of changes to the functional system p. 134-135</p>
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comment	<p>698 comment by: ROMATSA</p> <p>The text of this GM and related footnotes is confusing. It is titled “SAFETY SUPPORT CASE AND SAFETY CASE”, the text in (a) refers to “safety and safety support assurance” and footnote 125 refers to “an assurance case” with footnote 126 effectively repeating the latter part of footnote 125.</p> <p>Footnote 127 refers to the safety support case however it associated with safety support assurance in the table.</p> <p>For safety support assurance it is “as specified in the specified context” whereas for a safety support case it is “as specified in a given context”. If both are correct then what is the difference?</p> <p>A safety support case needs “evidence” whereas a safety case needs “a body of evidence”. What is the difference?</p> <p>Both safety support case and safety case use the term “system” (albeit one is the system and the other a system) as opposed to functional system or service. Is this the same system as in GM2 Annex I Definition (35) Figure 1? (Although see previous comment of Figure 1)</p> <p>The term “regulator CA” in safety support case report and safety case report appears to mix regulator with competent authority.</p> <p>Supporting comment to summary issue: Missing, Incorrect and more focused Guidance Material</p>
response	<p>Accepted</p> <p>The text has been changed and now aligns with the comments. Please see the response to comment No 197.</p>



comment

951

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX III COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR) GM2 ATM/ANS.OR.C.005(a)</p>	<p>(c) and (d): the reason why the situation of a compound provider is dealt in a different way is not justified enough.</p> <p>Assurance about the way the system behaves (even internally) should be provided.</p>	<p>We should think that, in this kind of organisation, the safety support assessment will be normally carried out by people different than those who undertake the safety assessment (ATS).</p> <p>Maybe a deep knowledge about the technical aspects of the system will be necessary for the first set of people. People undertaking the safety assessment (ATS) will require some information about the way the specification of other systems changes and the best way to do this is through the safety support case report.</p> <p>Also, any proposed requirement in this NPA allows a service provider other than an ATS provider not to develop a safety support assessment once the change to its functional system has been notified.</p> <p>Maybe a GM is not the most suitable way to allow this option.</p>

response

Not accepted

The situation of a compound provider is not dealt with in a different way. This GM simply points out that an ATS provider has two options for dealing with a change. He can separate his organisation such that it consists of ATS and Non ATS parts. If he does this, and provided the non ATS services are not delivered separately to the ATS services, he does not need to produce a separate safety support case when he makes a change to what is internally regarded as a non ATS service.

Neither the rule nor the GM provide constraints on who should or who should not undertake the assessment and assurance activities; it is up to the service provider to use the right people. The objective is to produce a valid assurance case. It is unlikely to be valid if the



wrong people are used.

Neither the IR, nor the AMC and the GM allow a change to be made without the necessity to produce a valid assurance case. An ATS provider may simply choose to produce a safety case rather than a safety support case and a safety case, even though the change may be considered to be a non ATS change. On the other hand, he may choose to produce both.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM3 ATM/ANS.OR.C.005(a)(1) Safety p. 135-137 support assessment and assurance of changes to the functional system

comment 306 comment by: DSNA

What do VoR, SoL, SIS mean?

response Accepted

The acronyms have been replaced by full terms.

comment 983 comment by: DGAC/DSAC - french NSA

This table is a major material supporting the concept of SSA and SA. However, we have some difficulties to understand the logic behind. For example, in the case of replacement of the radar tracking and monitoring software system, even if the ATCO IHM and the way the tracking system behaves are not impacted, the effect of a potential bug of the new software should be seen at the level of ATS, so a SA should be carried out.

response Partially accepted

There are actually two tables: one in GM1 Annex I Definitions (35) & ATM/ANS.OR.A.045 & ATM/ANS.OR.C.005 & ATS.OR.205 and the other, referred to here in GM3 ATM/ANS.OR.C.005(a)(1). They have now been combined into a single table.

If the safety support assessment confirms that the behaviour of the service has not changed, then there is no need for a user to carry out an assessment. The possible behaviour of the software under fault conditions is part of the assessment — see ATM/ANS.OR.C.005(a)(v) and GM on Degraded modes of operation. Consequently, any change in behaviour as a result of faults in the software will change the specification and, in this case, a safety assessment would be performed.



3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — AMC1 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system	p. 138
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comment 200

comment by: NATS National Air Traffic Services Limited

AMC1 ATM/ANS.OR.C.005(a)(2)**Page 138**

Point (b) – “A safety support case shall be an argument that provides a compelling, comprehensible and valid justification that the system behaves only as specified in a given context. The argument shall consist of claims that are supported via inferences by a body of evidence.”

The text underlined appears to preclude the use of COTS equipment for support systems.

These are statements and contain “shall” which is not appropriate in AMC. That said this is mostly a repeat of what a safety support case is as documented in the table at GM1 ATM/ANS.OR.C.005(a)(2) & ATS.OR.205(a)(2) and as such should be deleted.

Additionally this text refers to “behaves only as specified in a given context” whereas the related IR refers to “behave only as specified in the specified context”. Which is correct? If both then what is the difference?

Proposal: Revise the wording in AMC1 ATM/ANS.OR.C.005(a)(2) (b) to read:

Redraft as “A safety support case shall be an argument that provides a compelling, comprehensible and valid justification that the system meets its specification. The argument shall consist of claims that are supported via inferences by a body of evidence.”

Or delete as already covered by other text.

response

Partially accepted

The claim that this appears to preclude the use of COTS is incorrect. It is not clear how this assumption was made. It does not appear to be supported by the IR or AMC or GM.

‘Shall be’ has been replaced by ‘is’ and ‘Shall consist’ has been replaced by ‘consists’.

‘In a given context’ has been changed to ‘in the specified context’.

However, this is a definition of what a safety support assessment is and it is not appropriate to be at AMC level. The AMC has been deleted. There is already a GM that includes this as definition using the verb ‘to be’ in present tense. Please see Section 1.1 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities.

comment 307

comment by: DSNA



(b) : DSNA proposes to replace the text with “A safety support case **should** be an argument that provides a compelling, comprehensible and valid justification that the system behaves as specified in a given context. The argument **should** consist of claims that are supported via inferences by a body of evidence.”

response

Partially accepted

It is acknowledged that an AMC or GM cannot use any language that expresses an obligation (neither ‘shall’ nor ‘must’), as they only provide one means to comply with the IR, so the proposal by the commentator is appropriate. However, this is a definition of what a safety support assessment is and it is not appropriate to be at AMC level. The AMC has been deleted. There is already a GM that includes this as definition using the verb ‘to be’ in present tense. Please see Section 1.1 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities.

comment

495

comment by: skyguide Corporate Regulation Management

The text of this GM and related footnotes is confusing. It is titled “SAFETY SUPPORT CASE AND SAFETY CASE”, the text in (a) refers to “safety and safety support assurance” and footnote 125 refers to “an assurance case” with footnote 126 effectively repeating the latter part of footnote 125.

Footnote 127 refers to the safety support case however it associated with safety support assurance in the table.

For safety support assurance it is “as specified in the specified context” whereas for a safety support case it is “as specified in a given context”. If both are correct then what is the difference?

A safety support case needs “evidence” whereas a safety case needs “a body of evidence”. What is the difference?

Both safety support case and safety case use the term “system” (albeit one is the system and the other a system) as opposed to functional system or service. Is this the same system as in GM2 Annex I Definition (35) Figure 1? (Although see previous comment of Figure 1)

The term “regulator CA” in safety support case report and safety case report appears to mix regulator with competent authority – is this intentional?

response

Accepted

The text has been changed and now aligns with the comments. Please see the response to comment No 197.

comment

520

comment by: UK CAA

Page No: 138**Paragraph No:** AMC1 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of

changes to the functional system FORM OF ASSURANCE (b)

Comment: The last sentence uses the phrase “via inferences”, which is stylistically questionable. The form used on page 27 is preferable “argument is a collection of claims, evidence and inferences that link the evidence to the claims.”

Justification: Readability.

Proposed Text: Suggest replacing final sentence of (b) with “The argument shall consist of a collection of claims, evidence and inferences that link the evidence to the claims.”

response [Partially accepted](#)

[It is not clearly supported why it is stylistically questionable. The punctuation is questionable \(missing commas\) and has been corrected. In any case, the AMC text has been removed.](#)

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM1 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system p. 138

comment 521

comment by: UK CAA

Page No: 138

Paragraph No: GM1 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system SPECIFICATION

Comment: The UK CAA is of the view that the guidance as stated could be improved through simplification.

Justification: Improved text.

Proposed Text:

‘Continues to be behave only as specified in the specified context’ means that assurance needs to be provided that the monitoring requirements of TM/ANS.OR.C.005(b)(3) are suitable for demonstrating that the service behaves only as specified in the specified context during operation.

response [Accepted](#)

[The text has been amended as suggested.](#)

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM2 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system p. 138

comment 134

comment by: EUROCONTROL Safety Team



response	<p>AMC2 ATM/ ANS.OR.C.005(a)(2) Completeness of the argument (b) No definition of “safety support requirement”.</p> <p>Accepted</p> <p>The definition has been added in paragraph (b) of the new GM3 ATM/ANS.OR.C.005(a)(2).</p>
comment	<p>201 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>GM2 ATM/ANS.OR.C.005(a)(2) Page 138</p> <p>This GM is not helpful as it appears to advocate assurance levels and yet there are “might” and “maybe” which is not encouraging their use. PAL and HAL are not sufficiently mature concepts to be advocated at this time.</p> <p>Proposal: Delete the GM</p>
response	<p>Partially accepted</p> <p>Please see the response to comment No 207.</p>
comment	<p>499 comment by: <i>skyguide Corporate Regulation Management</i></p> <p>NPA covers more than EC482/2008 especially by extending it to every part of the functional system, introducing however scope unclarity. As an example, assurance level is extended to Human through Human Assurance Level, but in EC1035/2011 Annex II point 3.3 the competence of the technical personnel is not commensurate to the safety criticality of task to be executed. Does this apply to technical personnel as well or is it limited to Operations Room staff only (Controllers, Assistants and Supervisors) as proposed in the EUROCONTROL paper entitled "Assurance Levels for ATM elements: Human (HAL), Operational Procedure (PAL), and Software (SWAL)" by P. Mana, J-M Rede, and D. Fowler. Same question is raised for procedures. -Missing guidelines to implement assurance level for human, procedure, and hardware. The current document does not provide enough clear guidelines on the number of assurance level and their associated respective objectives to be met</p>
response	<p>Accepted</p> <p>HAL is limited to the human element of the functional system, thus it is limited to the operations room staff, in the case of ATS. It has been removed (see the response to comment No 207)</p> <p>It is recognised that there is work still to be done on the AMC/GM to address how the rules</p>



may be applied in the other disciplines (i.e. software, hardware, people and procedures) and also potential elements of Regulation (EC) No 482/2005 to be included here. This will be subject of future work of the Agency.

comment 525 comment by: UK CAA

Page No: 138

Paragraph No: GM2 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system ASSURANCE LEVELS

Comment: This topic seems to not be introduced, and provides too little information to be useful by itself. In particular, there is no discussion of how the ‘helpfulness’ of assurance level concepts can be established, how it can be ascertained that the body of evidence is appropriate, how it can be ascertained that the body of evidence is sufficient, and how it can be ascertained that the required confidence has been established.

Justification: Utility.

response Partially accepted

The guidance simply states that the concept of assurance levels may be helpful in assembling an appropriate and sufficient body of evidence. The appropriateness and sufficiency of the evidence is dealt with in other GM, as is how adequate confidence has been established.

It is recognised that there is work still to be done on the AMC/GM to address how the rules may be applied to all the disciplines (i.e. software, hardware, people and procedures) and also how elements of Regulation (EC) No 482/2005 may be included and broadened to cover the other disciplines. This will be subject of future work of the Agency.

comment 1123 comment by: Belgocontrol

AMC2 ATM/ ANS.OR.C.005(a)(2) Completeness of the argument (b)
What are “safety support requirements”.

response Accepted

The definition has been added in paragraph (b) of the new GM3 ATM/ANS.OR.C.005(a)(2).

comment 1165 comment by: EUROCONTROL

GM2 ATM/ANS.OR.C.005 (a) (2) Safety support assessment and assurance of changes to the functional system – Page 138

ASSURANCE LEVELS



	<p>EUROCONTROL notices that reference is made multiple times to SWAL, HAL, DAL, HWAL and PAL but without making reference to any guidance material.</p> <p>It is therefore suggested to add a reference to documents such as ED153, SAAP (Guidelines for the Safety Assessment of ATM Procedures - SAF.ET1.ST03.1000-SAAP-01-00).</p>
response	<p>Not accepted</p> <p>It is recognised that some references could be added to provide additional information. However, there is work still to be done on the AMC/GM to address the elements of Regulation (EC) No 482/2008 that may need to be included. There is also work to be done on the AMC/GM to address how the rules may be applied to the other disciplines (i.e. software, hardware, people and procedures). A more thorough analysis of what standards need to be referenced in the material (other standards may be appropriate as well, e.g. ED-109) will be undertaken by the Agency at that time. The GM is left as is, as a placeholder for the future work.</p>

<p>3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — AMC2 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system</p>	<p>p. 138-139</p>
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comment	<p>202</p> <p>comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>AMC2 ATM/ANS.OR.C.005(a)(2) Page 138</p> <p>“(a)(4) the specification encompasses <u>all</u> interaction with the environment.”</p> <p>It is difficult to foresee the possibility whereby “all” interactions with the environment can be identified all of the time</p> <p>As this is AMC the use of the term “shall” is not appropriate; replace with should.</p> <p>Proposal: Revise the wording in AMC2 ATM/ANS.OR.C.005(a)(2)(a)(4) to read: “the specification encompasses <u>all foreseen</u> interaction with the environment.”</p>
response	<p>Partially accepted</p> <p>‘All’ will usually be interpreted as ‘all given the state of the art’</p> <p>‘Foreseen’ does not appear to add anything to constrain the scope. Moreover, it can be argued that ‘foreseen’ implies ‘given the competence and alertness of the service provider’ rather than the intended meaning: ‘given the state of the art’.</p> <p>Nevertheless, ‘all’ will be replaced by ‘the’ in order to make the intent clearer.</p>



comment	<p data-bbox="359 235 406 280">526</p> <p data-bbox="1220 235 1498 280" style="text-align: right;">comment by: UK CAA</p> <p data-bbox="359 324 526 369">Page No: 138</p> <p data-bbox="359 369 1498 448">Paragraph No: AMC2 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system</p> <p data-bbox="359 448 1498 571">Comment: The statement in subparagraph (c) that ‘The behaviour necessitated by the safety support requirements is the complete behaviour expressed by the service specification;’ is not easily understood and needs to be clarified.</p> <p data-bbox="359 571 1252 616">Justification: The meaning of the statement in subparagraph (c) is unclear.</p> <p data-bbox="359 616 550 660">Proposed Text:</p> <p data-bbox="359 660 1498 739">‘(c)The service specifications determined in (a) are still valid after the safety support requirements have been implemented’</p>
response	<p data-bbox="359 761 526 795">Not accepted</p> <p data-bbox="359 828 1498 907">The proposed text does not cover the concept of completeness that was covered in the original text.</p> <p data-bbox="359 940 1498 1064">It is noted that the commentator feels the text is unclear. It is written in this way because the model proposed assumes that given the implementation satisfies its requirements and only these requirements; then the requirements become the specification.</p> <p data-bbox="359 1086 726 1131">This concept is clarified in GM.</p>
comment	<p data-bbox="359 1209 406 1243">530</p> <p data-bbox="1220 1209 1498 1254" style="text-align: right;">comment by: UK CAA</p> <p data-bbox="359 1299 526 1344">Page No: 138</p> <p data-bbox="359 1344 1498 1422">Paragraph No: AMC2 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system COMPLETENESS OF THE ARGUMENT</p> <p data-bbox="359 1422 1498 1500">Comment: It seems strange to address ‘completeness’ in isolation. Perhaps the section should also address correctness?</p> <p data-bbox="359 1500 893 1545">Justification: Completeness of requirement.</p>
response	<p data-bbox="359 1568 526 1601">Not accepted</p> <p data-bbox="359 1635 1498 1803">The AMC only covers the completeness requirement in the IR, hence its title. This is because it is assumed that ‘correctness’ of requirements is part of the completeness of the argument. Furthermore, it can be seen from the AMC that correctness is neither specifically considered nor is it mentioned in the IR.</p> <p data-bbox="359 1825 1498 1960">Moreover, it is assumed that documented is self-evident and that validity is the validity of the argument (logically). Whilst validity is not covered in this AMC, it is clearly not self-evident and may require some GM to explain its use here.</p>



comment	<p>591 comment by: <i>Federal Office of Civil Aviation FOCA</i></p> <p>AMC2 ATM/ANS.OR.C.005 (a) (2) par. (b)-(e): We do not understand the requirements and where they stem from.</p> <p>If the term safety applies there should be a clear link indicating that in order to define these requirements a safety assessment has to be initially performed (before any design work starts).</p>
response	<p>Not accepted</p> <p>The requirements come from a necessary decomposition of the IR, i.e. they show what is necessary to provide a complete argument.</p> <p>The term ‘safety support requirement’ has been introduced to differentiate the requirements for changes to functional systems that are not part of an ATS provider’s functional system from those that are. The term does not imply any necessary relationship to safety requirements, even though they may be derived from them. GM1 ATM/ANS.OR.C.005 describes the relationship between safety requirements and safety support requirements.</p>
comment	<p>1109 comment by: <i>EUROCONTROL</i></p> <p>AMC2 ATM/ANS.OR.C.005 (a)(2) Safety support assessment and assurance of changes to the functional system – Page 138 and 139</p> <p>Articles (b), (c), (d) and (e) are about safety support requirement. EUROCONTROL recommends adding a definition for this notion.</p>
response	<p>Noted</p> <p>Safety and safety support are used as adjectives. Their use is shown in Section 1.1 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities.</p> <p>The term ‘safety support requirement’ has been introduced to differentiate the requirements for changes to functional systems that are not part of an ATS provider’s functional system from those that are.</p> <p>The derivation and use of safety support requirements is explained in GM3 ATM/ANS.OR.C.005(a)(2).</p>

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM3 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system p. 139-142



comment	<p data-bbox="359 235 406 280">203</p> <p data-bbox="821 235 1484 280" style="text-align: right;">comment by: <i>NATS National Air Traffic Services Limited</i></p> <p data-bbox="359 324 742 414">GM3 ATM/ANS.OR.C.005(a)(2) Page 140</p> <p data-bbox="359 448 1484 649">Point (b)(1) - Safety support requirements – the text says that if it is hard to argue that a valid requirement is not a safety support requirement it should be treated as a safety support requirement. This may lead to the unintended consequence of all requirements being treated as safety support requirements and significantly increasing the cost of the assessment.</p>
response	<p data-bbox="359 672 438 716">Noted</p> <p data-bbox="359 739 1484 828">Indeed, that is a consequence. To mitigate this cost, the architecture should seek to minimise the number of such requirements.</p>
comment	<p data-bbox="359 907 406 952">531</p> <p data-bbox="1220 907 1484 952" style="text-align: right;">comment by: <i>UK CAA</i></p> <p data-bbox="359 996 526 1041">Page No: 139</p> <p data-bbox="359 1041 1484 1131">Paragraph No: GM3 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system COMPLETENESS OF THE ARGUMENT</p> <p data-bbox="359 1131 1404 1176">Comment: The introductory sentence is strange and could be misleading. In particular:</p> <ol data-bbox="359 1176 1484 1332" style="list-style-type: none"> 1) 'Besides completeness' implies that the section exceeds its scope, when it doesn't 2) 'the change is sufficiently trustworthy' seems to be the wrong subject for 'confidence'. It is unclear what is being said about items (a) to (f). Perhaps these are a complete or typical set of things that arguments concerning something must address? <p data-bbox="359 1332 1484 1422">A better introduction to this section would seem beneficial, or else failing that, delete the sentence and let the reader connect it to the topics in the equivalent section of the AMC.</p> <p data-bbox="359 1422 758 1467">Justification: Improved guidance</p>
response	<p data-bbox="359 1467 582 1512">Partially accepted</p> <p data-bbox="359 1545 1484 1713">1. The interpretation seems incorrect. This section of the GM deals with completeness. The reader is reminded that the IR deals not only with the completeness of the argument but also with the confidence one has in the argument, i.e. the GM is not intended to be complete.</p> <p data-bbox="359 1736 1484 1825">However, since the meaning is not clear, the sentence has been changed. GM3 ATS.205(a)(2) has been altered in the same way.</p> <p data-bbox="359 1848 1484 1937">2. In terms of a specification, the measure of trustworthiness is confidence in the specification.</p>



comment	<p>533</p> <p>Page No: 139 Paragraph No: GM3 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system COMPLETENESS OF THE ARGUMENT (a) Comment: The introductory paragraph is strange and unhelpful. In particular: 1) It is unclear whether it is saying that including a description of the derivation of the service specification has any value 2) It is unclear whether (a)(1) and (a)(2) are an expansion of derivation of the service specification or alternative, more valuable information 3) It is unclear what is being said about items (1) & (2) Justification: Clarity.</p>	comment by: UK CAA
response	<p>Accepted</p> <p>Including a description of the derivation of the specification would not be helpful.</p> <p>(a)(1) & (2) are necessary conditions for the specification to be considered sufficient.</p>	
comment	<p>534</p> <p>Page No: 139 Paragraph No: GM3 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system COMPLETENESS OF THE ARGUMENT (a)(1) Comment: This paragraph is unclear. In particular: 1) When is the 'Assessment of failure conditions' performed? It is unclear By who? 2) It appears that this is implying that a specification is incomplete without an analysis to identify all possible deviations from intent, and characterising how often they may occur. If so, this should be stated explicitly, rather than left to supposition. Justification: Clarity.</p>	comment by: UK CAA
response	<p>Partially accepted</p> <p>1. When and by whom the assessment is performed is not relevant to the argument and so no additional guidance is given.</p> <p>2. The assumption is correct. It has been stated explicitly in the text.</p>	
comment	<p>535</p> <p>Page No: 140 Paragraph No: GM3 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system COMPLETENESS OF THE ARGUMENT (b)(4)</p>	comment by: UK CAA



	<p>Comment: UK CAA suggests that discussing the ‘way safety support requirements are arrived at’ should be part of the argument that the specification is complete. For example, if the potential deviations in (a)(1)(i) are not systematically considered, it is difficult to see how their absence or frequency can be verified.</p> <p>Justification: Clarity.</p>
response	<p>Not accepted</p> <p>The requirement is for the specification to be sufficiently trustworthy, not for the requirements to be derived in any particular way. It may be the case that the service provider does use a process argument in support of the product argument, but that is his choice and not a regulatory matter.</p>
comment	<p>537 comment by: UK CAA</p> <p>Page No: 140 Paragraph No: GM3 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system COMPLETENESS OF THE ARGUMENT (c) Comment: It is unclear whether this section is discussing safety support requirements (and their allocation down to elements) or to all requirements (i.e. including non-safety-related requirements). Justification: Clarity.</p>
response	<p>Noted</p> <p>Agreed the word ‘requirement’ is overloaded. However, section (c)(2) should provide sufficiently clear guidance on the scope of the requirements being dealt with.</p>
comment	<p>538 comment by: UK CAA</p> <p>Page No: 140 Paragraph No: GM3 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system COMPLETENESS OF THE ARGUMENT (c)(2)(i) Comment: This is strangely phrased, and may be incorrect. Is the issue more that the set of requirements allocated to each sub-element are a complete and correct decomposition of the set of the requirements for their assembly, within the defined architecture? The Agency is requested to provide clarity on the meaning of the text and to consider providing more clearly written text. Justification: Clarity, possibly accuracy.</p>
response	<p>Not accepted</p> <p>Traceability of decomposition is dealt with in (d)(1). Any requirements that did not trace to a</p>



higher-level requirement would have to be justified. Such requirements are usually related to architectural constraints or other non-behavioural requirements such as coding language. Please see paragraph (c)(3)(ii).

comment 540

comment by: UK CAA

Page No: 141**Paragraph No:** GM3 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system COMPLETENESS OF THE ARGUMENT (c)(3)**Comment:** This section seems to deviate from the scope of the safety support requirements, specification, etc, i.e. there are considerations here that seem apply to the safety arguments, not the safety support arguments. For example setting additional requirements in the last sentence of (3)(i).

The Agency is requested to provide clarity on the meaning and context of the text and to consider providing more clearly written text.

Justification: Clarity, perhaps correctness.

response Not accepted

It is hard to see how the commentator comes to this conclusion. Safety is not mentioned in the text and is not in fact relevant in this GM. The requirements being discussed are those necessary to prevent unwanted behaviour which may be caused by the reuse of components.

comment 541

comment by: UK CAA

Page No: 141**Paragraph No:** GM3 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system COMPLETENESS OF THE ARGUMENT (d)(1)**Comment:** Given the importance of the context, the UK CAA suggests that this paragraph needs to make reference to the requirement for the 'verification in isolation' to be conducted in a context that matches the one that the element will experience during operation. We suggest that this should be addressed in a new (d)(2), or a new subparagraph (e), 'Traceability of context'.**Justification:** Clarity, perhaps correctness.

response Partially accepted

The verification in isolation is necessary in order to make the system verifiable. GM pointing this out has been added to point (b).

The change proposed here has, in a slightly different form, been added to



GM3 ATS.OR.205(a)(2) as the comment is also relevant to that GM.

The need for contextual equivalence is a fundamental part of the verification argument and has now been added in (e)(3).

comment

542

comment by: UK CAA

Page No: 141

Paragraph No: GM3 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system COMPLETENESS OF THE ARGUMENT (e)(1)

Comment: This paragraph is unclear. It, and paragraph (2), use the term 'component', whereas previous sections use 'element'. It also refers to paragraph (b), which does not seem to be particularly relevant, or at least does not seem to expand or illuminate the guidance given here.

Justification: Clarity, perhaps correctness.

response

Partially accepted

The terminology is used consistently and is defined in GM1 ATM/ANS.OR.C.005(b)(1)(i).

The reference to (b) remains but its relevance has been improved in response to comment No 541.

comment

543

comment by: UK CAA

Page No: 141

Paragraph No: GM3 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system COMPLETENESS OF THE ARGUMENT (f)(2)

Comment: The tone in this section is strangely weak compared to others e.g. 'should probably not'. Surely the validity of verification evidence fundamentally depends on it being collected in a context that matches the operational content?

Justification: Rigour.

response

Not accepted

The contexts could be the same and so 'should probably not' is appropriate.

comment

544

comment by: UK CAA

Page No: 141

Paragraph No: GM3 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system COMPLETENESS OF THE ARGUMENT (f)(2)



	<p>Comment: This section refers only to ‘testing’, rather than ‘verification’, which is used elsewhere. The Agency is request to confirm which word is appropriate and amend the text if necessary.</p> <p>Justification: Clarity, perhaps correctness.</p>
response	<p>Noted</p> <p>‘Testing’ is meant and it is the text used. No additional change is considered necessary.</p>
comment	<p>719 comment by: DFS Deutsche Flugsicherung GmbH</p> <p>On page 141 in (e)(1) the term "must" is used, which is not suitable for GM.</p> <p>This also applies for page 157 GM3 ATS.OR.205(a)(2) - (e) (1) and (f) (1) (there is a "must" and a "have to")</p> <p>Reference to high level comment "c.v"</p>
response	<p>Not accepted</p> <p>It is imperative that the component view support verification, and this is exactly what has been included in the GM. It has nothing to do with the fact that this is GM. There is no imposed obligation in the guidance material.</p>

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM4 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system p. 142

comment	<p>546 comment by: UK CAA</p> <p>Page No: 142</p> <p>Paragraph No: GM4 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system SUFFICIENCY OF SAFETY SUPPORT REQUIREMENTS</p> <p>Comment: This section refers to ‘confidence’ twice. This is not a standard term, i.e. it will suggest different things to different readers, and we recommend that it is defined.</p> <p>Justification: Clarity, perhaps correctness.</p>
response	<p>Not accepted</p> <p>The word ‘confidence’ is used in general English sense: The feeling or belief that one can have faith in or rely on someone or something.</p>



comment	547	comment by: UK CAA
	<p>Page No: 142</p> <p>Paragraph No: GM4 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system SUFFICIENCY OF SAFETY SUPPORT REQUIREMENTS (a)</p> <p>Comment: This section refers to 'integrity'. This is not a standard term, i.e. it will suggest different things to different readers, and we recommend that it is defined.</p> <p>Justification: Clarity, perhaps correctness.</p>	
response	<p>Not accepted</p> <p>The word 'integrity' is used in general English sense: The condition of being unified or sound in construction.</p>	
comment	548	comment by: UK CAA
	<p>Page No: 142</p> <p>Paragraph No: GM4 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system SUFFICIENCY OF SAFETY SUPPORT REQUIREMENTS (b)</p> <p>Comment: This section does not refer to 'integrity' or 'order', which are referred to in (a). We would suggest that these properties are also applicable to 'people'.</p> <p>Justification: Consistency.</p>	
response	<p>Not accepted</p> <p>The word 'integrity' is not generally used for people. Order for people is encapsulated in the requirement to follow a procedure and so it is unnecessary to repeat it.</p>	
comment	554	comment by: UK CAA
	<p>Page No: 142</p> <p>Paragraph No: GM4 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system SUFFICIENCY OF SAFETY SUPPORT REQUIREMENTS (b)</p> <p>Comment: This section refers to 'reliability', as does section (a). However, the 'reliability' of a piece of equipment is usually a 'simple' matter of a (lengthy) MTBF, whereas the 'reliability' of a person is more complex, more related to errors in required tasks and likely to have to account for workload, fatigue, shifts and rostering, (etc) and may overlap with 'integrity'. Hence to refer to both 'equipment' and 'people' reliability in the same manner is misleading.</p> <p>Justification: Clarity.</p>	
response	<p>Not accepted</p> <p>Reliability is the same concept for both people and equipment. When applied to people, it is</p>	



related to a person's failure to behave as required. It is agreed that many factors affect that, and the assessment may not cover all of them. The word 'integrity' is not generally used for people.

(HRA is a technique that is well known and established, even though with limitations).

comment 556

comment by: UK CAA

Page No: 142

Paragraph No: GM4 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system SUFFICIENCY OF SAFETY SUPPORT REQUIREMENTS (c)

Comment: The UK CAA recommend that the attributes of procedures discussed in this section are considered again. A procedure is effectively a requirement document, and does not do anything other than make requirements:

- 1) 'the circumstances for their enactment' are external to the procedure, and so not a requirement on the procedure, but the context in which the procedure must be valid
- 2) 'the resources needed' should be 'the maximum (and minimum?) resources that the procedure may assume are available for consumption during execution of the procedure'
- 3) 'the sequence of actions to be performed' should be 'the sequence of actions the procedure must require'
- 4) the list seems rather short, and validation with an authoritative source is recommended.

Justification: Correctness.

response Not accepted

Only examples are given.

1) In the same way as the requirements for the hardware are 'external' to the performance requirements of the software but are nonetheless requirements, the requirements for the circumstances for the enactment of the procedure, while being 'external' are still necessary at the level of the interactions that happen within the system 'people/procedure/equipment'.

2) It is accepted that resources should be maximum and minimum but so too should accuracy, timing, capacity, availability and reliability. However, at this level of GM, this is implied.

3) Not accepted — there is no change in meaning.

4) Validation is not a procedural property. Validation is needed for all parts of the system and is dealt with separately.

comment 570

comment by: Frasier Loredana



	<p>b) Delete the text: <i>personal characteristics</i> Justification 1. This is subjective and not relevant to be introduced in a safety support assessment. 2. The personal characteristics are evaluated during the employment processes and included in the job description.</p>
response	<p>Accepted</p> <p>The elements included in the description under personal characteristics have been removed.</p>
comment	<p>783 comment by: UK CAA</p> <p>Page No: 142 Paragraph No: GM4 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system SUFFICIENCY OF SAFETY SUPPORT REQUIREMENTS (a) to (c) Comment: Paragraphs (a) to (c) discuss elements of different types, but do not address all the elements in the figure on page 46. Justification: Completeness.</p>
response	<p>Partially accepted</p> <p>Paragraphs (a) to (c) discuss elements at the highest level in the diagram and are complete. There is no need at this level of GM to go deeper.</p> <p>The diagram has been removed and so the elements are those defined in Annex I.</p>
comment	<p>784 comment by: UK CAA</p> <p>Page No: 142 Paragraph No: GM4 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system SUFFICIENCY OF SAFETY SUPPORT REQUIREMENTS (a) to (c) Comment: Paragraphs (a) to (c) discuss elements of different types, but do not address the properties of assemblies of the types of elements (which are systems or subsystems, according to GM1 ATM/ANS.OR.C.005(b)(1)(i)(f) on page 144). Justification: Completeness.</p>
response	<p>Not accepted</p> <p>This is not the purpose of this guidance.</p>



comment	786	comment by: UK CAA
	<p>Page No: 142</p> <p>Paragraph No: GM5 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system SUFFICIENCY OF SAFETY SUPPORT REQUIREMENTS</p> <p>Comment: Paragraphs (a) to (c) seem to address totally different aspects of Equipment, People and Procedures. This seems inconsistent. The UK CAA suggests the material be organised according to discussions of one concept across the three element types. Currently (a) discusses Isolation, (b) discusses just 4 of the properties in GM4 ATM/ANS.OR.C.005(a)(2)(b), and (c) just one property from GM4 ATM/ANS.OR.C.005(a)(2)(c).</p> <p>Justification: Consistency and comprehensive coverage.</p>	
response	<p>Partially accepted</p> <p>As can be seen from the GM, while there is some measure of commonality across the different types there are also some differences. Therefore, it is not appropriate to try to force the aspects into the same mould.</p> <p>However, to aid clarity, the GM has been redrafted and simplified.</p>	

comment	787	comment by: UK CAA
	<p>Page No: 142</p> <p>Paragraph No: GM4 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system SUFFICIENCY OF SAFETY SUPPORT REQUIREMENTS (d)</p> <p>Comment: The rationale for this is not obvious. It is also unclear what is meant here by 'parts of' and 'the system'. It is possible that this is seeking an interface specification for whichever type of element is being considered (a to c). Clarification is requested.</p> <p>Justification: Need for clarity.</p>	
response	<p>Not accepted</p> <p>Since a system is characterised not only by its parts but also by the interactions of the parts, then it seems obvious that these interactions would need to be specified. Furthermore, interaction between some parts of the system would leave the requirements incomplete.</p>	

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM5 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system p. 142-143

comment	204	comment by: NATS National Air Traffic Services Limited
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GM5 ATM/ANS.OR.C.005(a)(2)**Page 142**

Point (b)(3) - it is not appropriate to define the personal characteristics required in a functional change IR. At best it is subjective and if documented could lead to legal argument at the personal level. Relevant staff are already deemed competent and licensed if necessary and this type of requirement could discriminate against individuals going against employment law.

Proposal: Please delete the text in GM5 ATM/ANS.OR.C.005(a)(2)(b)(3) on personal characteristics.

response

Accepted

The elements included in the description under personal characteristics have been removed.

comment

575

comment by: *Frasie Loredana*

b) People

Remove the following text:

The personal characteristics are those required of anyone who is expected to perform the defined task, i.e. those who have the required skills and knowledge, and do so within the bounds of the defined accuracy, response times and reliability. These personal characteristics are:

(i) resilience to distraction;

(ii) self-awareness — the ability to know when they are out of their depth and need help;

(iii) team 'playerness' — the ability to work together with other members of a team to best resolve abnormal situations (CRM – Behavioural Markers);

(iv) adaptability — the ability to synthesise/innovate when unforeseen things happen.

Justification

1.This is subjective and not relevant to be introduced in a safety support assessment.

2. The personal characteristics are evaluated during the employment processes and included in the job description.

response

Accepted

The elements included in the description under personal characteristics have been removed.

comment

788

comment by: *UK CAA*

Page No: 142

Paragraph No: GM4 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of



changes to the functional system SUFFICIENCY OF SAFETY SUPPORT REQUIREMENTS (b)
Comment: This section refers to ‘workload’ which seems to be a demand from the context of the person, rather than a property of a person. We suggest that this should be replaced with something like ‘capacity’, or specifications of workload maxima and minima (bored controllers make mistakes)?

Justification: Consistency.

response

Not accepted

In the same way as the requirements for the hardware are ‘external’ to the performance requirements of the software but are nonetheless requirements, the requirements for the workload of the person, while being ‘external’, are still necessary at the level of the interactions that happen within the system ‘people/procedure/equipment’.

It is accepted that workload should be between maximum and minimum levels, and it may have unwanted consequences when it is low or high, but it is rather impossible to specify absolute values for maximum and minimum workload, even though there are some techniques to estimate it (e.g. NASA TLX). At this level of GM description, it is not considered necessary to add additional details until the guidance is further developed, but so too should accuracy, timing, capacity, availability and reliability. However, at this level of GM, this is implied.

The mistakes bored controllers make would be causes of failures to meet requirements for accuracy, response time and reliability and so are already included.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM1 ATM/ANS.OR.C.005(b) Safety support assessment and assurance of changes to the functional system

p. 143

comment

789

comment by: UK CAA

Page No: 143

Paragraph No: GM1 ATM/ANS.OR.C.005(b) Safety support assessment and assurance of changes to the functional system PROCEDURE DEVELOPMENT

Comment: Effectively, this appears to say that changing a procedure that a person must follow impacts the ‘person’, so that the person’s requirements have changed, and the person’s changed role and performance need analysis. This is not clearly stated.

Justification: Completeness and clarity.

response

Partially accepted

The supposition is true but seems incomplete. Certainly, changing a procedure or the interface between a person and the rest of the system is included in the scope of the change



(ATM/ANS.OR.C.005(a)(1)) and so must be assessed. The GM relates this change to training. However, and perhaps more importantly, guidance is provided on two types of training: initial and refreshment.

A paragraph has been added to clarify the training aspects.

comment 790

comment by: UK CAA

Page No: 143

Paragraph No: GM1 ATM/ANS.OR.C.005(b) Safety support assessment and assurance of changes to the functional system PROCEDURE DEVELOPMENT

Comment: The guidance does not mention procedures. It is not clear why this should be so.

Justification: Potential deviation from topic, potentially incomplete text or incorrect topic name.

response Accepted

The title of the GM has been changed to 'Training'.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — AMC1 ATM/ANS.OR.C.005(b)(1) Safety support assessment and assurance of changes to the functional system p. 143

comment 1063

comment by: Frasier Loredana

Rephrase the following text:

all operational transitions that are part of the change.

Propose to add the text: *all identified operational transitions*

Justification

1. In our opinion all the operational transitions that are part of the change might be unknown to the service provider, other than an ATS provider, or ATS provider and therefore cannot be included in the safety (support) assessment.

response Partially accepted

Having removed 'all', the AMC looks similar to the IR so it has been removed.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM1 ATM/ANS.OR.C.005(b)(1) Safety support assessment and assurance of changes to the functional system p. 143-144



comment	<p>308</p> <p>comment by: <i>DSNA</i></p> <p>What is the meaning of “Identify indirectly impacted components by identifying directly impacted components”?</p>
response	<p>Noted</p> <p>The comment has not used the sentence as written in the GM. The meaning should be clear if the whole paragraph is read.</p>
comment	<p>792</p> <p>comment by: <i>UK CAA</i></p> <p>Page No: 144 Paragraph No: GM1 ATM/ANS.OR.C.005(b)(1) Safety support assessment and assurance of changes to the functional system COMPLETENESS OF THE SCOPE OF THE SAFETY SUPPORT ASSESSMENT (c) Comment: In (2), the adjective ‘directly’ is used with ‘affected’ and ‘impacted’, but the means of affect or impact is not defined. Consequently it is difficult to distinguish this from ‘indirectly’ impacting as discussed in (3). The terms need to be defined, if the distinction is important, but there does not seem to be any advantage in this distinction, such that this section could be simplified by only using one term. Justification: Clarity/rationalisation.</p>
response	<p>Accepted</p> <p>The word ‘affected’ has been used throughout the AMC/GM, instead of the original combination of words.</p>
comment	<p>794</p> <p>comment by: <i>UK CAA</i></p> <p>Page No: 144 Paragraph No: GM1 ATM/ANS.OR.C.005(b)(1) Safety support assessment and assurance of changes to the functional system COMPLETENESS OF THE SCOPE OF THE SAFETY SUPPORT ASSESSMENT (d) Comment: It is not clear to what ‘the interface’ refers. The service is specified at the point of delivery, the ‘using’ system connects to this. An ‘interface through which the service will be delivered’ would be an intervening system. Justification: Clarity.</p>
response	<p>Not accepted</p> <p>The interface through which the service is delivered is not an intervening system but the</p>



means of communicating the service to its users, e.g. the interface between the transmitting area and the environment in the case of a radio communications service, or the connection to a broadband cable for an internet service that does not use Wi Fi.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM1 ATM/ANS.OR.C.005(b)(1)(i) Safety support assessment and assurance of changes to the functional system p. 144-145

comment 576

comment by: *Frasie Loredana*

Review the text:.... "*elements being changed*" to include new equipment, procedures and human elements

Justification

In the context of the change some equipment, procedures and human elements might be new.

response **Noted**

This text does not appear in this GM. It cannot be traced to what text is referring to.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM1 ATM/ANS.OR.C.005(b)(1)(iv) & ATS.OR.205 (b)(1)(iv) General p. 145

comment 571

comment by: *Frasie Loredana*

Review all the text to specify the change phases from the service provider, other than an ATS provider, perspective.

Justification

The phases of the change are not clear. Moreover, the service provider, other than an ATS provider, responsibilities are put together with the manufacturer responsibilities, without differentiating between them.

response **Not accepted**

It is not clear what is meant by the first part of the comment. The review of the change is covered in (b), (c) & (d) and is a result of reviewing the claims, inferences and evidence gathered during the development and implementation phases of the change. The review of change transitions is covered in the GM on the interactions between the service provider and CA during a change. Please see Section 3.2.1 of Appendix I to GM1 to Article 5 Service



Providers and Article 6(2) Oversight capabilities.

The NPA does not deal with the responsibilities of the manufacturer unless it is a regulated service provider in the terms of the ATM IR. These responsibilities are assumed by the service provider using the products.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM1 ATM/ANS.OR.C.005(b)(1) & (2) p. 146-149 Safety support assessment and assurance of changes to the functional system

comment

796

comment by: UK CAA

Page No: 146

Paragraph No: GM1 ATM/ANS.OR.C.005(b)(1) & (2) Safety support assessment and assurance of changes to the functional system DEGRADED MODES OF OPERATION (a)

Comment: The UK CAA considers the meaning and purpose of the first sentence to be unclear.

1) We are unclear why ‘training for personnel’ gets a special mention here. We would suggest that it is just a means for modifying a person element, analogous to changing a resistor on a production line.

2) The sentence seems to contain an element of tautology: “The following guidance deals with the safety support assessment associated with degraded modes of operation, it, therefore, ... includes ... the degraded modes of operation of the services delivered by the functional system.”

Justification: Clarity.

response

Partially accepted

1). The training is for the degraded modes of operation and also for first line maintenance activities, i.e. the removal from service and reintroduction to service. It is dealt with in detail later — see (h).

2) Tautology was unintentional and is removed. The second occurrence of degraded modes should have been the specification of the degraded modes of operation delivered by functional systems. A third occurrence has also been added, that of the degraded modes of services delivered to functional systems.

comment

798

comment by: UK CAA

Page No: 146

Paragraph No: GM1 ATM/ANS.OR.C.005(b)(1) & (2) Safety support assessment and



	<p>assurance of changes to the functional system DEGRADED MODES OF OPERATION (c) and (d)</p> <p>Comment: The issue in (c)(2) and in the sentence spanning the page break gets a bit lost in these sections. We suggest that it is important to emphasise that all potential behaviour should appear in the specifications, not just desired behaviour. This includes the behaviour when there is a malfunction, when there is a planned degraded mode, and when a planned mitigation fails to mitigate some unacceptable behaviour, (unless this is not possible). Clause (d) in particular seems to lose this point amongst some lengthy text (d)(1) to (5), that seems to be intended to encourage the safety support service provider to analyse potential failures and mitigate their effect.</p> <p>Justification: Clarity.</p> <p>Proposed Text: Suggest a new clause between (b) and (c) to highlight the need for all the behaviour to be specified, including that associated with degraded modes.</p>
response	<p>Partially accepted</p> <p>The commentator's difficulty appears to be in differentiating between the desired modes of operation, those behaviours that result temporarily from a malfunction (temporarily because the malfunction is unlikely to be detected and isolated immediately — see diagram) and the behaviour of the service once the malfunction has been detected and its cause isolated. In the latter case, the behaviour is not as desired but is acceptable, at least for the time it takes to repair the system. It was felt that this was adequately explained. The text has been clarified.</p>
comment	<p>800 comment by: UK CAA</p> <p>Page No: 146</p> <p>Paragraph No: GM1 ATM/ANS.OR.C.005(b)(1) & (2) Safety support assessment and assurance of changes to the functional system DEGRADED MODES OF OPERATION (d)</p> <p>Comment: UK CAA suggests that this section should mention that Responses will often include the introduction of requirements to monitor certain system properties to detect malfunctions (especially when manifest as corruption) and instigate repair.</p> <p>Justification: Clarity of scope.</p>
response	<p>Partially accepted</p> <p>This is covered in (d)(3). Please note that the section does not describe requirements but what constitutes a degraded mode and what responses to it might be appropriate. The text has been slightly modified to improve clarity.</p>
comment	<p>802 comment by: UK CAA</p> <p>Page No: 147</p> <p>Paragraph No: GM1 ATM/ANS.OR.C.005(b)(1) & (2) Safety support assessment and</p>



assurance of changes to the functional system DEGRADED MODES OF OPERATION (f)(2)
Comment: In the phrase “the malfunction is detected and isolated”, the word ‘isolated’ is ambiguous. It initially seems most likely to mean that the cause of the malfunction has been identified, but later text suggests it is intended to mean that the element which is causing the malfunction has been removed (or similar) such that it no longer contributes to the functional system. The end of the sentence “the functional system, now available, is incomplete” suggests that the latter interpretation is intended.
 Whichever meaning is intended, the text needs revision for clarity.
Justification: Clarity.

response

Accepted

The text has been redrafted for clarity.

comment

806

comment by: UK CAA

Page No: 149**Paragraph No:** GM1 ATM/ANS.OR.C.005(b)(1) & (2) Safety support assessment and assurance of changes to the functional system DEGRADED MODES OF OPERATION (f)(2)**Comment:** The diagram includes a note “This variation [of the service] is unacceptable because it is inappropriate and unspecified”.

1) The reference to ‘unspecified’ is not necessarily true, and in fact should not be true, as specifications should define ALL potential behaviour. The service may be in an undesirable state, but that state should have been anticipated and predicted to occur acceptably rarely.

2) Without the reference to ‘unspecified’, the note becomes more or less a tautology: “unacceptable because it is inappropriate”.

UK CAA recommends careful reconsideration to determine what should be said about this service variation.

Justification: Clarity.

response

Partially accepted

1) While it is true that the undesirable state should have been anticipated, it is not true that its behaviour can be specified. It is more likely that understanding the possible range of behaviours will lead to an understanding of what is necessary to detect and how soon after the malfunction occurs it should be detected. Thus, while it is known that the behaviour will be unacceptable the exact nature of the behaviour may not be known in all circumstances. This will be explained in more detail in (d)(3) and the diagram will be modified accordingly.

2) Agreed. The figure has been modified.

comment

808

comment by: UK CAA



Page No: 149

Paragraph No: GM1 ATM/ANS.OR.C.005(b)(1) & (2) Safety support assessment and assurance of changes to the functional system DEGRADED MODES OF OPERATION (f)(2) and (3)

Comment: The diagram and supporting text are unclear.

The service must be fully specified, including all potential behaviour, and predicted to be acceptably safe even accounting for the effect of malfunctions. Therefore the assurance case must address the service provided during all parts of this diagram. The concept of the malfunction making the service variation unacceptable does not seem correct therefore.

However, the malfunctioning state may indeed be very high risk, and the assurance argument may depend on the rapid detection and rectification of this particular malfunction. So the unacceptable thing is for the functional system to be in this malfunctioning state for longer than a certain time.

We suggest therefore that this section should talk about deviation of the functional system from its design intent.

Justification: Clarity and correctness.

response

Partially accepted

The commentator's analysis in the second part is correct and is covered in (d). However, the conclusion does not follow from the first premise — see the response to comment No 802.

The text in (d) has changed so that it is clear that what is unacceptable is the risk, which includes the time for which the consequences may be applicable.

comment

810

comment by: UK CAA

Page No: 148

Paragraph No: GM1 ATM/ANS.OR.C.005(b)(1) & (2) Safety support assessment and assurance of changes to the functional system DEGRADED MODES OF OPERATION (f)(4)

Comment: This clause repeats the erroneous concept that “Clearly the way the service behaves does not meet its specification (possibly by a considerable margin) during the time the malfunction is undetected”.

The behaviour during malfunction must form part of the specification.

Justification: Clarity and correctness.

Proposed Text: “Clearly the way the service behaves is not as desired (possibly by a considerable margin) during the time the malfunction is undetected.”

response

Not accepted

Please see the response to comment No 806.

comment

813

comment by: UK CAA



	<p>Page No: 149</p> <p>Paragraph No: GM1 ATM/ANS.OR.C.005(b)(1) & (2) Safety support assessment and assurance of changes to the functional system DEGRADED MODES OF OPERATION (i)(3)</p> <p>Comment: Undefined and unintroduced abbreviation 'MS' used twice.</p> <p>Justification: Clarity.</p>
response	<p>Accepted</p> <p>Full text has been added.</p>

comment	<p>815 comment by: UK CAA</p> <p>Page No: 149</p> <p>Paragraph No: GM1 ATM/ANS.OR.C.005(b)(1) & (2) Safety support assessment and assurance of changes to the functional system DEGRADED MODES OF OPERATION (i)(3)</p> <p>Comment: We suggest that it is appropriate for the detection of unauthorised changes to be addressed in this clause regarding Maintenance of configuration:</p> <ol style="list-style-type: none"> 1) Unauthorised changes/adjustments/modifications/patches introduced (perhaps with good intent) by errant personnel, including software updates and configuration/parameter changes 2) Malicious modifications – vandalism, introduction of malware, etc. <p>Justification: Clarity of scope.</p>
response	<p>Partially accepted</p> <p>Changes to the configuration, whether authorised or not, are dealt with in the second paragraph of (1). The means of detecting such changes is dealt with in (2) and when that fails, is covered by ATM/ANS.OR.B.005 (a)(4) & (d).</p> <p>The list given by the commentator contains all changes to the configuration except that some adjustments/parameter changes may be allowed. These must be covered in the safety case and so adjustments/parameter changes beyond this are considered to be changes in configuration.</p> <p>An examples list has been provided in (i)(3) to clarify the meaning of changes in configuration.</p>

<p>3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — AMC3 ATM/ANS.OR.C.005(a)(2) p. 149-150</p> <p>Safety support assessment and assurance of changes to the functional system</p>

comment	<p>824 comment by: UK CAA</p>
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Page No: 149

Paragraph No: AMC3 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system DETERMINATION OF THE SPECIFICATION OF THE CHANGED SERVICE

Comment: (a) addresses the verifiability of specified properties of the service. (b) requires that “the specification must cover everything that has changed in the service provided”.

1) It would be clearer if (b) started “the specification of the changed service must cover ...”

2) The use of the term ‘everything’ is ambiguous, as it is unclear whether this refers to service behaviour that has changed, or to all the behaviour of the changed parts of the functional system

3) UK CAA recommends that there must be a complete specification of the service, not just the changed parts. Things that have not changed may have had to be re-verified in the changed environment of the functional system. Things that have not changed may have been truly unaffected, but still need to be specified. Without a complete specification of the service it is not credible that the service provider has understood the complete impact of the change (e.g. unspecified behaviour would not be noted during verification).

Note that the title of the clause is “DETERMINATION OF THE SPECIFICATION OF THE CHANGED SERVICE” not ‘determination of the change parts of the service specification’

GM6 ATM/ANS.OR.C.005(a)(2) notes the difference between the specification of the change and of the service, so the difference is recognised in the NPA, but the AMC should ensure that the whole service is specified.

Justification: Completeness.

response

Partially accepted

1) The text has been amended as suggested.

2) The scope of the change as defined in ATM/ANS.OR.C.005(b)(1) (now ATM/ANS.OR.C.005(a)(1)) includes the effects of the changed parts on the rest of the system and its context and so are considered to be part of the ‘change’. So (b) is not ambiguous in the way described by the commentator because the two explanations are actually the same.

3) It is expected that there will be a complete specification of the system although, for pragmatic reasons, it is not a requirement. The system before the change has been certified and it can be assumed that an adequate specification of the system and its context exists. The change is considered to affect only part of the system, consequently the full system specification is the specification before the change as amended by the specification after the change. Establishing the scope of the change ensures that any assumptions about the extent of the effects of the change will have to be assured. Consequently, given that assurance, no re-verification of unchanged parts is required. It may be that a service provider chooses to re-verify parts of the unchanged system in order to provide the necessary level of assurance. However, this is his choice and there may be other ways of providing such assurance. Therefore, it is not a regulatory matter.



comment 952

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX III COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR) AMC3 & AMC4 ATM/ANS.OR.C.005(a)(2)</p>	<p>Too many ambiguous terms have been used in the following paragraph: "<u>...with a degree of certainty commensurate with the level of confidence sought from assurance</u>".</p> <p>Further to this, we wonder what is understood by the expression 'level of confidence sought'. Would this be directly linked to the concept of 'Assurance Levels' (SWAL, HAL,...)?</p> <p>More explanation should be provided.</p>	<p>This NPA is quite important for the functioning of the whole system and it should be as clear as possible in order to avoid present and future misunderstandings.</p>

response Partially accepted

This is a valid request and will be satisfied. However, it is not clear that a change to the AMC would be necessary.

GM will be provided when the material about confidence is finished in the future 2nd NPA. Note that the degree of uncertainty is related to the measurement of individual properties and the level of confidence is related to the complete assurance argument.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — AMC4 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system p. 150

comment 827

comment by: UK CAA

Page No: 150



	<p>Paragraph No: AMC4 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system</p> <p>Comment: Typo. (b) (b)</p> <p>Proposed Text: Remove additional (b)</p>
response	<p>Accepted</p>
	<p>829 comment by: UK CAA</p> <p>Page No: 150</p> <p>Paragraph No: AMC4 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system DETERMINATION OF THE OPERATIONAL CONTEXT FOR THE CHANGE (a)(1)</p> <p>Comment: It is unclear which specification is meant. It appears that this is intended to require that there is a verified specification for the operational context of the service.</p> <p>Justification: Clarity.</p> <p>Proposed Text: Change “(1) the specification can ...” to “(1) the specification of the operational context of the service can ...”</p>
response	<p>Accepted</p>
	<p>The text has been updated.</p>
	<p>832 comment by: UK CAA</p> <p>Page No: 150</p> <p>Paragraph No: AMC4 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system DETERMINATION OF THE OPERATIONAL CONTEXT FOR THE CHANGE (a)(2)</p> <p>Comment: The clause requires “the operational context ... is internally consistent”. This appears to be a typographic error.</p> <p>Justification: Correctness/clarity.</p> <p>Proposed Text: Change (a)(2) to read “the specification of the operational context of the service is complete and coherent, and is internally consistent.” (However, consider also whether the clause requires both ‘coherent’ and ‘consistent’.)</p>
response	<p>Partially accepted</p>
	<p>It is true that there is an inconsistency between the first and last parts of the sentence. The first deals with the context itself while the last deals with the consistency of the specification.</p>



It is difficult to get these into a single sentence and so a third clause has been added.

comment 952 ❖

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX III COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR) AMC3 & AMC4 ATM/ANS.OR.C.005(a)(2)</p>	<p>Too many ambiguous terms have been used in the following paragraph: "...with <u>a degree of certainty commensurate with the level of confidence sought from assurance</u>".</p> <p>Further to this, we wonder what is understood by the expression 'level of confidence sought'. Would this be directly linked to the concept of 'Assurance Levels' (SWAL, HAL,...)?</p> <p>More explanation should be provided.</p>	<p>This NPA is quite important for the functioning of the whole system and it should be as clear as possible in order to avoid present and future misunderstandings.</p>

response Partially accepted

This is a valid request and will be satisfied. However, it is not clear that a change to the AMC would be necessary.

GM will be provided when the material about confidence is finished in the future 2nd NPA. Note that the degree of uncertainty is related to the measurement of individual properties and the level of confidence is related to the complete assurance argument

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — GM6 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system p. 150



comment

854

comment by: UK CAA

Page No: 150**Paragraph No:** GM6 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system SPECIFICATION OF THE CHANGED SERVICE**Comment:** UK CAA recommends that this section is changed to reflect the comment made regarding AMC3 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system DETERMINATION OF THE SPECIFICATION OF THE CHANGED SERVICE

(a) addresses the verifiability of specified properties of the service. (b) requires that “the specification must cover everything that has changed in the service provided”.

1) It would be clearer if (b) started “the specification of the changed service must cover ...”

2) The use of the term ‘everything’ is ambiguous, as it is unclear whether this refers to service behaviour that has changed, or to all the behaviour of the changed parts of the functional system

3) There must be a complete specification of the service, not just the changed parts. Things that have not changed may have had to be re-verified in the changed environment of the functional system. Things that have not changed may have been truly unaffected, but still need to be specified. Without a complete specification of the service it is not credible that the service provider has understood the complete impact of the change (e.g. unspecified behaviour would not be noted during verification).

Note that the title of the clause is “DETERMINATION OF THE SPECIFICATION OF THE CHANGED SERVICE” not ‘determination of the change parts of the service specification’

GM6 ATM/ANS.OR.C.005(a)(2) notes the difference between the specification of the change and of the service, so the difference is recognised in the NPA, but the AMC should ensure that the whole service is specified.

Justification: Completeness.

response

Partially accepted

This guidance material has been moved to a more generic part of the AMC/GM in Section 1 in Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities. Please see the response to comment No 824.

comment

856

comment by: UK CAA

Page No: 150**Paragraph No:** GM6 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system SPECIFICATION OF THE CHANGED SERVICE**Comment:** This section fails to address how the specification addresses the confidence requirement made in AMC3 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system DETERMINATION OF THE SPECIFICATION OF THE CHANGED SERVICE: “observed and measured either directly or indirectly with a degree

of certainty commensurate with the level of confidence sought from assurance”

Justification: Completeness.

response **Noted**

This is a valid request and will be satisfied. GM should be provided when the material about confidence is finished in the 2nd NPA.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — AMC1 ATM/ANS.OR.C.005(b)(2) Safety support assessment and assurance of changes to the functional system p. 151

comment 309

comment by: *DSNA*

(f) : DSNA proposes to replace the text with “verification, to the intended degree of confidence, that the implementation behaves as specified in the given operational context; and ...”

response **Not accepted**

This would allow unspecified behaviour to exist even within the given context. This is unacceptable because any user would not know of this behaviour and therefore could not assess if it had a detrimental effect on his service.

comment 721

comment by: *DFS Deutsche Flugsicherung GmbH*

The following is required:

- „verification that: (i) the change conforms to the scope that was subject to safety support assessment“ [ATM/ANS.OR.C.005 (b) (2) (i)]
- “verification that the change: (i) conforms to the scope that was subject to safety assessment” [ATS.OR.205 (6)]
- “verification that the specification was for the service analyzed in the context specified by the operational context” [AMC1 ATM/ANS.OR.C.005 (b) (2) (e)]

Please define the term "verification".

In the German translation of CR (EU) 1035/2011 for "verification" the German term "Bestätigung" was used, which can be fulfilled with a signature e.g.. Other possible translations could include much more effort, because evidence is necessary that forms a complete argument. Especially in the above mentioned requirements, proof would be not feasible to bring.

This also applies for the term "verifiable" on page 157 GM3 ATS.OR.205(a)(2) - (e) (1).



Reference to high level comment "c.i"

response

Not accepted

The first two proposals are covered by (a). The third proposal is covered by (e).

Verification is used in its normal English sense, i.e.: ‘The process of establishing the truth, accuracy, or validity of something’, ‘The establishment by empirical means of the validity of a proposition’.

This seems a strange request since it has been used for many years in the forerunners to this IR and in the IRs in other domains.

Verifiable means something for which verification is feasible — this is explained in the GM.

comment

858

comment by: UK CAA

Page No: 151

Paragraph No: AMC1 ATM/ANS.OR.C.005(b)(2) Safety support assessment and assurance of changes to the functional system VERIFICATION (f) & (g)

Comment: These clauses fail to recognise the obligation on the service provider to ensure that the service provider’s specification is complete and correct, and supported by objective evidence.

Clause (f) should already be addressed, as any behaviour observed but not specified in the specification must be added to the specification.

Clause (g) already notes that the specification should be changed, and so the verification would now have been performed to the confidence stated in the specification.

Perhaps (g) should be changed to more directly address the revision of the specification in the light of the complete findings of verification.

Justification: Clarity.

response

Partially accepted

The statement is a post condition, it implies neither preconditions nor a process.

While it is true that during implementation the process of verification may find unspecified behaviour, it is not true that the only way of going forward is to include this behaviour in the specification. It may be decided to eliminate the behaviour.

(f) is the objective for verification of the implementation. Other verifications required can be satisfied by design analysis and therefore do not give confidence that the implementation is correct.



The statement about (g) is a non sequitur. The analysis of the results of the verification leads to a conclusion about the confidence which must be recorded in the specification. There is no necessity to repeat anything. It is conceivable that the service provider does indeed wish to achieve the intended level of confidence. If so, he would have to perform more verification, at least. In some circumstances, he may also need to alter the system such that it is feasible to assure the service to the desired level of confidence with reasonable effort.

However, since (g) is actually not a requirement but a statement of what might be, it has been removed.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX III — Common requirements for service providers (Part-ATM/ANS.OR) — AMC1 ATM/ANS.OR.C.005(b)(3) Safety support assessment and assurance of changes to the functional system p. 151

comment 860

comment by: UK CAA

Page No: 151

Paragraph No: AMC1 ATM/ANS.OR.C.005(b)(3) Safety support assessment and assurance of changes to the functional system MONITORING (b)

Comment: Clause (b) starts with the pronoun “they”, which logically refers to “These criteria”. However, the criteria don’t “remain within the bounds”, but some aspect of the system does.

Justification: Accuracy/clarity.

Proposed Text: Change “(b) they” to “(b) specified performance parameters”

response Partially accepted

It is true that the pronoun ‘they’ refers to the monitoring criteria. It is also true that (b) does not appear to be a valid requirement. However, it does not appear to be the case that the proposal is valid.

What is meant is that if the properties being monitored remain within the bounds set by these criteria, the service will be behaving as specified and so the safety support case will remain valid, i.e. the service is behaving as predicted by the safety support case. The text has been updated to reflect this intent.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM1 Annex I Definitions(35) & ATM/ANS.OR.C.005 & ATS.OR.205 General p. 154



comment	1285	comment by: <i>Per Ove Torsteinsson</i>
	Does this GM contain any information which explains how a safety support assessment (produced by a non-ATS provider) could be used as argument/evidence in a safety assessment produced by an ATS provider (e.g. in a multi actor change)?	
response	Noted	
	There is no explicit way explaining this point in the GM. This may be added in the 2nd NPA.	

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM1 ATM/ANS.OR.C.005(a)(2) & ATS.OR.205(a)(2) General p. 154

comment	653	comment by: <i>CANSO</i>
	<p>The text of this GM and related footnotes is confusing. It is titled “SAFETY SUPPORT CASE AND SAFETY CASE”, the text in (a) refers to “safety and safety support assurance” and footnote 125 refers to “an assurance case” with footnote 126 effectively repeating the latter part of footnote 125.</p> <p>Footnote 127 refers to the safety support case however it associated with safety support assurance in the table.</p> <p>For safety support assurance it is “as specified in the specified context” whereas for a safety support case it is “as specified in a given context”. If both are correct then what is the difference?</p> <p>A safety support case needs “evidence” whereas a safety case needs “a body of evidence”. What is the difference?</p> <p>Both safety support case and safety case use the term “system” (albeit one is the system and the other a system) as opposed to functional system or service. Is this the same system as in GM2 Annex I Definition (35) Figure 1? (Although see previous comment of Figure 1)</p> <p>The term “regulator CA” in safety support case report and safety case report appears to mix regulator with competent authority – is this intentional?</p>	
response	Accepted	
	Please see also the response to comment No 197.	

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM1 ATS.OR.205(a)(1) Safety assessment and assurance of changes to the functional system p. 154



comment	<p>205 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>GM1 AT.S.OR.205(a)(1) Page 154</p> <p>Point (b) – given that functional system is a defined term then it is not necessary to detail, in parenthesis, what a functional system is, especially where this differs from the definition.</p> <p>Proposal: Delete “(people, procedures, equipment, or the way they are organised or to any combination of these elements)”</p>
response	<p>Accepted</p> <p>The text has been removed.</p>
comment	<p>579 comment by: <i>Frasie Loredana</i></p> <p>(a)</p> <p>Delete the following text:</p> <p><i>It may also be carried out by another organisation, on its behalf, provided that the responsibility for the safety assessment remains with the provider of air traffic services.</i></p> <p>Justification</p> <p>In our opinion, another organisation cannot perform the safety assessment because does not has the knowledge and experience about the environment or the applicable internal rules. For us, as CA, this will be a criteria to review all changes, because the probability that the safety argument to be unsound will be high.</p>
response	<p>Not accepted</p> <p>The ATS provider is free to subcontract other organisations to carry out any activity within the service provider’s scope (ATM/ANS.OR.B.015), but these organisations work under its responsibility and oversight. These contracted organisations are obliged by the same requirements (i.e. this Regulation). In particular, they need to ensure that personnel are trained and competent to perform their duties.</p> <p>It is the prerogative of the CA to consider that the involvement of other organisation performing the safety assessment is a factor that has an influence on the risk of this organisation being unfamiliar with the environment and therefore, it may have negative consequences in the assessment. However, this is not always true, as this other organisation may have more experience, knowledge and resources performing safety assessments, and the integration of ATS’s staff knowing well the environment may suffice to perform a correct safety assessment.</p>



3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — AMC1 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional system	p. 155
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comment 206 comment by: NATS National Air Traffic Services Limited

AMC1 ATS.OR.205(a)(2)
Page 155

Point (b) is a statement and not a requirement (no should) and should therefore be GM. It is also similar to terms used to describe a safety case in GM1 ATM/ANS.OR.C.005(a)(2) & ATS.OR.205(a)(2). Which is correct?

response [Partially accepted](#)

The commentator is correct that (b) is not the definition of a safety case. However, it was provided here to aid readability — the reader does not need to remember what a safety case is.

The definition here is more complete, so it is used to update the GM definition in Section 1.1 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities. The GM will be modified.

comment 864 comment by: UK CAA

Page No: 155

Paragraph No: AMC1 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional system FORM OF ASSURANCE (b)

Comment:

1) The last sentence uses the phrase “via inferences”, which is stylistically strange. The form used on page 27 is preferable “argument is a collection of claims, evidence and inferences that link the evidence to the claims.”

2) Additionally, similar text on page 138 for AMC1 ATM/ATS.OR.C.005(a)(2) uses ‘shall’ in both sentences of (b), ‘justification’ instead of ‘case’ - the proposed text adopts this.

3) The UK CAA suggests that the differences between the versions on p27, p138 and p155 are revisited and rectified as necessary.

Justification: Readability.

Proposed Text: Replace (b) with “A safety case shall be an argument that provides a compelling, comprehensible and valid justification that a system is safe for a given application in a given context. The argument shall consist of a collection of claims, evidence and inferences that link the evidence to the claims.”



response	<p>Partially accepted</p> <p>1) It is not clear why it is stylistically strange. The punctuation is questionable (missing commas) and has been corrected. The proposed text could be ambiguous and seems unnecessarily complex.</p> <p>2) The word 'shall' has been removed in both cases and 'justified' has replaced 'case'.</p> <p>3) The versions in AMC have been aligned</p>
comment	<p>1200 comment by: Avinor ANS</p> <div style="border: 1px solid black; padding: 5px; margin: 10px 0;"> <p>Safety assessment and assurance of changes to the functional system. The text in AMC1 ATS.OR.205(b) is too detailed and prescriptive and of an explanatory nature for AMC and should be moved to GM.</p> </div>
response	<p>Partially accepted</p> <p>Please see the response to comment No 206.</p>
comment	<p>1201 comment by: Avinor ANS</p> <p>Some of the AMC is very long, detailed and prescriptive (for example AMC1 ATS.OR.205(b)). This AMC should be subdivided in to separate AMC, i.e., AMC1, AMC2, AMC3, etc. each dealing with a specific sub-topic This will allow organisations to propose alternative means of compliance for individual means of compliance for small parts rather than the whole of the material</p>
response	<p>Accepted</p> <p>Please see the response to comment No 311.</p>
comment	<p>1215 comment by: Frasier Loredana</p> <p>Review the definition / information on safety case. Justification The definition states<i>that a <u>system</u> is acceptably safe for a given application in a given operating context.</i> The term <i>system</i> it seems to limit the content of the safety case only to the changes which are induced by technical factors (systems).</p>



	The term <i>system</i> is used also in the Safety Support Case definition.
response	<p>Accepted</p> <p>(b) is not the definition of a safety case. It is provided here so that it can be used to aid readability — the reader does not need to remember what a safety case is. In any case, the definition has been moved to GM.</p> <p>The term ‘system’ is used generically and in its normal English sense (see below). It can be taken to mean the system of interest. In this instance it means ‘that part of the functional system that can be treated independently of the rest of the functional system for the purposes of assuring the safety of the change’.</p> <p>System: A set of things working together as parts of a mechanism or an interconnecting network; a complex whole. The ‘things’ in the definition are not limited to technical things, people and procedures are ‘things’.</p> <p>However, ‘system’ has been replaced by ‘service’ in order to avoid the confusion apparently caused by the use of ‘system’.</p>

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM1 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional system	p. 155
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comment	<p>497 comment by: <i>skyguide Corporate Regulation Management</i></p> <p>The text of this GM and related footnotes is confusing. It is titled “SAFETY SUPPORT CASE AND SAFETY CASE”, the text in (a) refers to “safety and safety support assurance” and footnote 125 refers to “an assurance case” with footnote 126 effectively repeating the latter part of footnote 125.</p> <p>Footnote 127 refers to the safety support case however it associated with safety support assurance in the table.</p> <p>For safety support assurance it is “as specified in the specified context” whereas for a safety support case it is “as specified in a given context”. If both are correct then what is the difference?</p> <p>A safety support case needs “evidence” whereas a safety case needs “a body of evidence”. What is the difference?</p> <p>Both safety support case and safety case use the term “system” (albeit one is the system and the other a system) as opposed to functional system or service. Is this the same system as in GM2 Annex I Definition (35) Figure 1? (Although see previous comment of Figure 1)</p> <p>The term “regulator CA” in safety support case report and safety case report appears to mix regulator with competent authority – is this intentional?</p>
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response

[Accepted](#)

[Please see the response to comment No 197.](#)

comment

699

comment by: ROMATSA

The text of this GM and related footnotes is confusing. It is titled “SAFETY SUPPORT CASE AND SAFETY CASE”, the text in (a) refers to “safety and safety support assurance” and footnote 125 refers to “an assurance case” with footnote 126 effectively repeating the latter part of footnote 125.

Footnote 127 refers to the safety support case however it associated with safety support assurance in the table.

For safety support assurance it is “as specified in the specified context” whereas for a safety support case it is “as specified in a given context”. If both are correct then what is the difference?

A safety support case needs “evidence” whereas a safety case needs “a body of evidence”. What is the difference?

Both safety support case and safety case use the term “system” (albeit one is the system and the other a system) as opposed to functional system or service. Is this the same system as in GM2 Annex I Definition (35) Figure 1? (Although see previous comment of Figure 1)

The term “regulator CA” in safety support case report and safety case report appears to mix regulator with competent authority.

Supporting comment to summary issue: Missing, Incorrect and more focused Guidance Material

response

[Accepted](#)

[Please see the response to comment No 197.](#)

comment

955

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX IV SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES	This GM1 ATS.OR.205(a)(2) should be promoted to the level of AMC.	Compliance with this section (provided more detail is given) would directly demonstrate compliance with the related regulatory requirement.



(Part-ATS)	GM1 ATS.OR.205(a)(2)	
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response [Not accepted](#)

The only purpose here is to explain what is meant by the requirement in the IR, and explicitly link this to the requirement for establishing the monitoring criteria. This GM explains the purpose of the monitoring criteria, and does not propose any means to comply with the IR. The text has been redrafted for clarity.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM2 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional system p. 155

comment 207

comment by: *NATS National Air Traffic Services Limited*

GM2 ATS.OR.205(a)(2)
Page 155

This GM is not helpful as it appears to advocate assurance levels and yet there are “might” and “maybe” which is not encouraging their use.
PAL and HAL are not sufficiently mature concepts to be advocated at this time.

Proposal: Delete the GM.

response [Partially accepted](#)

It is accepted that whereas PAL & HAL are immature in their application, the concept is not, as it is simply an extension of the assurance level concept of which DAL/SWAL/HWAL are more mature in their application. The text has been redrafted to more accurately reflect this lack of maturity. While assurance levels may be useful to increase confidence in generating evidence, this GM is not recommending their use. Appropriate arguments can be made without their use. In this context, the use of ‘might’ and ‘may’ is appropriate.

comment 954

comment by: *AESA / DSANA*

PART	COMMENT	JUSTIFICATION



<p>Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX III <i>COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR)</i> GM2 ATM/ANS.OR.C.005(a)(2)</p> <p>ANNEX IV <i>SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS)</i> GM2 ATS.OR.(a)(2)</p>	<p>If the application of this GM is the justification for the removal of <i>regulation (EC) No 482/2008</i>, then the removal of <i>regulation (EC) No 482/2008</i> is not considered justified.</p> <p>We kindly refer EASA to our response to Question 2.</p>	<p>The use of the concept of 'Assurance Levels' should be considered at AMC level for the requirement "<i>provide assurance, with sufficient confidence</i>" and, as an AMC, should be properly developed together with further GM.</p> <p>In this sense, <i>regulation (EC) No 482/2008</i> went much deeper into the concept of 'Assurance Levels' as applied to software (SWAL). The fact that the proposal is made to remove this regulation without including in this NPA an equivalent level of regulation means that all the progress achieved up to now will be in vain.</p> <p>With this regulatory proposal the requirements for Assurance Levels are considerably relaxed which, in turn, directly results in an loss of the level of safety assurance that the system based in the concept of 'Assurance Levels' provides.</p>
<p>response</p>	<p>Partially accepted</p> <p>The Agency takes due consideration of the comment together with answer to question Q2 Please see the Agency’s responses to comments related to the repeal of Regulation (EC) No 482/2008 for additional information on the final position taken by the Agency.</p> <p>The work still to be done on the AMC/GM will address those elements of Regulation (EC) No 482/2008 which are not currently transposed and that contribute to ensuring safety of the software elements of the change. AMC/GM will also be provided in the future on how the rules may be applied in the other disciplines (i.e. hardware, people and procedures).</p>	



assessment and assurance of changes to the functional system

comment	<p>208 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>AMC2 ATS.OR.205(a)(2) Page 155 This AMC is a statement and not a requirement (no should) and should therefore be GM or be deleted.</p>
response	<p>Not accepted</p> <p>It is not a statement. It provides the criteria by which the completeness of the safety argument can be judged, thus provides the elements that should be used to assess compliance with the IR.</p>
comment	<p>720 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>AMC2 ATS.OR.205 (a) (2) - (b) to (g) and AMC2 ATM/ANS.OR.C.005(a)(2) - (b) to (f) were added after the closure of the group and not agreed on in RMT.</p> <p>S. 155 "(b) safety requirements have been placed on <u>all</u> elements affected" S. 138 "(b) safety support requirements have been placed on all elements affected"</p> <p>S. 144: GM1 (c): "(c) An element can comprise only sub-elements of the same type, i.e. equipment, procedure, human resource"</p> <p>Together, the above can create extremely high effort, if it is required to break down elements until they are purely consisting of one "type". It is also <u>unnecessary</u> to require it, since most of the time it is enough to place requirements on "mixed" elements.</p> <p>And how is "safety requirement" defined? Does it only apply to safety-relevant systems?</p> <p>We strongly suggest to remove the paragraph (b) on page 155, since it is definitely not always necessary to place requirements on ALL elements to achieve acceptable risk!!!</p> <p>unnecessary <i>overregulation</i></p> <p>This applies also for page 195, GM1 ATS.OR.20 (b) (1)(i): delete (c) and (d) Reference to high level comment "c.ii"</p>
response	<p>Partially accepted</p>



The statement is true, although inaccurate. The AMC were not agreed by the Rulemaking Group due to lack of time to finish the material. However, the provisions were circulated and reviewed by the Rulemaking Group before the NPA was published.

'all' has been removed from both AMCs. However, this is because 'all' is unnecessary. It does not affect the scope of the requirement.

It is difficult to understand the reason for the comment. A complete suite of situation displays, the signal processing units that drives the displays and the radar that drives the signal processing units can be considered an element of type equipment. If the human operator was added, then the resulting subsystem would not be of one type and therefore would not be an element. These elements could hardly be considered to have been 'broken down' and to create 'extremely high effort' in setting safety requirements for them. Furthermore, such an element ought to have safety requirements placed upon it. The reason for requirements being placed on elements, which, by definition are of one type, is that it is difficult to adequately verify humans and equipment together. Generally, they are verified independently and then an argument is made about their behaviour when integrated as a subsystem. Such an argument does not usually rely on exhaustive testing.

This is now explained in the redrafted GM3 ATS.OR.205(a)(2).

Moreover, as explained in paragraph (d) of GM3 ATS.OR.205(a)(2), the traceability of safety requirements essentially places a stopping condition on the level in the architecture for which safety requirements are necessary. Although, in order to design and implement a change, it may be necessary to deal with elements below this level, the requirements placed on them are not considered to be safety requirements.

Safety requirement is not explicitly defined in the rule, but now a definition is included in GM3 ATS.OR.205(a)(2). They prescribe or proscribe behaviour that is necessary for safety. They are hierarchical and result from the decomposition of the safety criteria. See also paragraphs (a) and (c) of AMC2 ATS.OR.205 that effectively state that safety requirements are those that necessitate the behaviour required to satisfy the safety criteria.

comment

722

comment by: *DFS Deutsche Flugsicherung GmbH*

(d) - (g) was added after the closure of the group and not agreed on in RMT.

“(d) all safety requirements have been traced from the safety criteria to the level of the architecture at which they have been satisfied”

Isn't "architecture" and "versions" technical/software-specific?

(Very short) advice on ALs can only be found in GM2 ATS.OR.205 (a) (2) page 155. (AMC3 on page 149 only speaks of "level of confidence".)



Otherwise, service providers would be obliged now to assign Assurance Levels in all areas, while it used to be only necessary for software.

This guidance takes the traceability of requirements to a whole new level. It requires traceability of requirements not only for software anymore, but all requirements.

- Can this be fulfilled without assigning Assurance Level? ("tracing to the highest level element"). If not, is it intended to require ALs for all system elements?!
- Which IR part justifies this?

We suggest to remove the paragraph (d) on page 155 and give more thoughts to the other parts, especially (g).

Reference to high level comment "c.ii"

response **Not accepted**

The opening statement is true, although inaccurate. The AMC were not agreed by the Rulemaking Group due to lack of time to finish the material. However the provisions were circulated and reviewed by the Rulemaking Group before the NPA was released

With regard to the comment about architecture, the architecture includes people, procedures and the way they relate to one another as well as equipment. 'Version' is certainly an unusual way of referring to people but the notion can also be applicable to humans encompassing their level of knowledge and skill and the training they have undergone.

It is difficult to see what impact this comment has on the AMC. Whilst unwritten before in such a specific way, it is a requirement for any assurance argument, and has been previously required for all parts of the system (Regulation (EU) No 1035/2011 – Annex II – 3.2.3)

The necessity of assigning assurance levels is not regulated in this IR, although they may be useful in arguing for specific levels of confidence, which is required by the IR. It is not clear why the commentator believes there is a relationship between traceability and assurance levels. None is foreseen in Regulation (EC) No 482/2008 from which this text comes.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM3 ATS.OR.205(a)(2) Safety p. 156-158 assessment and assurance of changes to the functional system

comment 142

comment by: EUROCONTROL Safety Team



response	<p>GM3 ATS.OR.205(a)(2) Completeness of the argument (b) There seems to be something missing because point (e) of the same GM refers to guidance on safety requirements in (b) but there is no text in point (b).</p> <p>Noted</p>
comment	<p>209 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>GM3 ATS.OR.205(a)(2) Page 156</p> <p>Point (b) has no content.</p>
response	<p>Accepted</p> <p>Text has been added.</p>
comment	<p>723 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <div style="border: 1px solid black; padding: 10px; margin: 10px 0;"> <p>(a) (2) What does "Optimally," mean?</p> <p>Is really an optimum set required - or just better than a set with overlapping criteria? We do not think that is necessary.</p> <p>We suggest to remove this paragraph, since it is unnecessary overregulation. Reference to high level comment "c.ii"</p> </div>
response	<p>Not accepted</p> <p>This GM does not require using an optimal set of criteria. It says that it is preferable to use other set that overlaps criteria. This is because arguing about the relationship between overlapping criteria and safety risks will be more complex and difficult to establish. The text is amended to explicitly clarify that it is only preferable, but overlapping criteria are not excluded.</p>
comment	<p>724 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p>



(3) (i) Additional requirements for functions producing unnecessary behavior are not always possible, nor always necessary. E.g. if a risk assessment shows no risks even with the unnecessary behavior, additional requirements are *overregulation*.

We suggest to remove the paragraph, since it is covered in the overall intention or risk assessments.

Reference to high level comment "c.i"

response **Partially accepted**

There is no overregulation with this GM. Firstly, this is only guidance material. Secondly, the point in (3)(i) says that the requirements 'may' be needed. As the commentator says, if no risks are foreseen with the unnecessary behaviour, no need for additional requirements. However, this has to be specifically assessed.

comment

725

comment by: *DFS Deutsche Flugsicherung GmbH*

(d) (1) What "level" is meant?

Please add explanation.

Reference to high level comment "c.v"

response

Noted

It is the level of an element in the architecture.

comment

865

comment by: *UK CAA*

Page No: 156

Paragraph No: GM3 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional system COMPLETENESS OF THE ARGUMENT (a)(1)

Comment: The wording in the examples needs correction.

1) Stating that the examples are 'typical' is probably incorrect. Suggest use the simpler text "An example ..." is far preferable. This occurs twice.

2) The second example needs to refer consistently to 'within 5 m', and not also use 'shall be 5 m'.

The UK CAA also suggests that the Agency considers whether the examples are properties at the right general system level expected for safety criteria.

As the examples are trying to be very specific, it is important that they are themselves correct.



response	<p>Justification: Accuracy.</p> <p>Accepted</p> <p>Points 1) and 2) are accepted, and the text has been amended.</p> <p>These are not intended to be examples of safety criteria, but examples of incomplete and incorrect criteria, in general.</p>
comment	<p>867 comment by: UK CAA</p> <p>Page No: 156 Paragraph No: GM3 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional system COMPLETENESS OF THE ARGUMENT (a)(4)(ii) Comment: UK CAA suggests an amendment to the text to ensure clarity Justification: Clarity. Proposed Text: Replace “significant set of overlapping criteria” with “significantly overlapping set of criteria” or “set of significantly overlapping criteria” or “set of criteria with significant overlap”.</p>
response	<p>Accepted</p> <p>The text has been amended as suggested by the commentator.</p>
comment	<p>868 comment by: UK CAA</p> <p>Page No: 156 Paragraph No: GM3 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional system COMPLETENESS OF THE ARGUMENT (b) & (c) Comment: Formatting anomalies 1) Title (b) ‘Safety requirements’ has no body text. NB (e) suggests that this should contain guidance on verifiable components. 2) (c)(1) refers to (4), which does not exist. Justification: Clarity and accuracy.</p>
response	<p>Accepted</p> <p>This reference is the result of ‘copy and paste’ of the same structure from the safety support assessment GM. The reference is deleted. In point (b), a generic notion of safety requirement is added. The reference to (4) is deleted.</p>
comment	<p>869 comment by: UK CAA</p>



	<p>Page No: 156</p> <p>Paragraph No: GM3 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional system COMPLETENESS OF THE ARGUMENT (b) to (e)</p> <p>Comment: It is unclear whether each reference to ‘requirements’ in these sections refers to safety requirements or general functional requirements. This is readily apparent in (c)(1). With this issue in mind, the relationship of (b) and (c) to (e) is unclear, as they seem to address much the same topic.</p> <p>Justification: Clarity, possibly accuracy.</p>
response	<p>Accepted</p> <p>This reference is the result of ‘copy and paste’ of the same structure from the safety support assessment GM. The reference is deleted. In point (b), a generic notion of safety requirement is added. The reference to (4) is deleted.</p> <p>The word ‘safety’ has been added in (c)(1) and elsewhere where necessary. The distinction between safety and functional requirements seems irrelevant here, as the level where the safety requirement is set is not defined (it can be at functional or other level).</p> <p>The difference between safety criteria and safety requirements is merely a hierarchical: both are requirements, but the safety criteria are requirements at higher level, which when decomposed to lower elements of the functional system become safety requirements.</p> <p>The text has been amended to add clarity.</p>
comment	<p>871 comment by: UK CAA</p> <p>Page No: 157</p> <p>Paragraph No: GM3 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional system COMPLETENESS OF THE ARGUMENT (e)</p> <p>Comment: (e) erroneously refers to (b) for guidance on verifiable components. (e)(2) would appear to belong to the lost section.</p> <p>Justification: Accuracy and clarity.</p>
response	<p>Partially accepted</p> <p>The reference to (b) is deleted. (e)(2) (in the resulting version it has become (d)(2)) seems adequate here as it refers to the decomposition of subsystems to allow they are verifiable.</p>
comment	<p>872 comment by: UK CAA</p> <p>Page No: 157</p> <p>Paragraph No: GM3 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the</p>



functional system COMPLETENESS OF THE ARGUMENT (f)(1)
Comment: It is unclear whether the scope of “All interactions of components” should be limited to those components that are changed or affected by the change
Justification: Clarity.

response

Accepted

The text has been amended to clarify that the components referred to are those changed or affected by the change.

comment

956

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.2. Draft <i>Acceptable Means of Compliance and Guidance Material (Draft EASA Decision)</i> GM3 ATS.OR.205(a)(2) <i>Safety assessment and assurance of changes to the functional system</i>	In '(b) safety requirements' something is missing regarding these safety requirements and how to use them in order to provide sufficient confidence that the change is sufficiently safe. We wonder whether this is done intentionally for some particular reason.	This NPA is quite important for the functioning of the whole system and it should be as clear as possible in order to avoid present and future misunderstandings.

response

Accepted

A simple definition has been added an b) and c) have been merged.

comment

1124

comment by: Belgocontrol

GM3 ATS.OR.205(a)(2) Completeness of the argument (b)
 There is no text under (b), however point (e) of the same GM refers to guidance on safety requirements in (b).

response

Accepted

This reference is the result of ‘copy and paste’ of the same structure from the safety support



assessment GM. The reference has been deleted. In point (b), a generic notion of safety requirement is added.

comment 1298

comment by: EUROCONTROL

GM3 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional system - Page 156

There seems to be something missing because point (e) of the same GM refers to guidance on safety requirements in (b) but there is no text in point (b).

response Accepted

This reference is the result of 'copy and paste' of the same structure from the safety support assessment GM. The reference has been deleted. In point (b), a generic notion of safety requirement is added.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM4 ATS.OR.205(a)(2) Safety assessment and assurance of changes to functional systems p. 158

comment 210

comment by: NATS National Air Traffic Services Limited

**GM4 ATS.OR.205(a)(2)
Page 158**

Point (b) – even if it were appropriate to include individual attributes (which it isn't) it would not be possible to specify safety behavior and performance in a way that would be meaningful given the wide range of "people" who would form an element of the functional system given the variability even though they are all deemed trained and competent.

response Partially accepted

The human element has to be covered, but it is acknowledged that until a comprehensive approach is provided, it is too early to give full details. GM4 ATS.OR.205(a)(2) and GM5 ATS.OR.205(a)(2) have been redrafted and combined in one.

comment 874

comment by: UK CAA

Page No: 158

Paragraph No: GM4 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional system SUFFICIENCY OF SAFETY REQUIREMENTS



	<p>Comment: The UK CAA has commented on particular aspects of GM4 ATM/ANS.OR.C.005(a)(2) Safety support assessment and assurance of changes to the functional system SUFFICIENCY OF SAFETY SUPPORT REQUIREMENTS (page 142. These comments apply equally to GM4 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional system SUFFICIENCY OF SAFETY REQUIREMENTS.</p> <p>Justification: Correctness, consistency.</p>
response	<p>Noted</p> <p>The GM for safety support and safety has been combined and so the responses to comments on safety support have been applied to the GM for Safety.</p> <p>Please see the responses to UK CAA comment No 786 on GM4 ATM/ANS.OR.C.005(a)(2).</p>
comment	<p>875 comment by: UK CAA</p> <p>Page No: 158</p> <p>Paragraph No: GM4 ATS.OR.205(a)(2) Safety assessment and assurance of changes to the functional system SUFFICIENCY OF SAFETY REQUIREMENTS</p> <p>Comment: (a) to (c) seem to address totally different aspects of Equipment, People and Procedures. We propose that the material is organised according to discussions of one concept across the three element types, but (a) discusses Isolation, (b) discusses just 4 of the properties in GM4 ATS.OR.205(a)(2)(b), and (c) just one property from GM4 ATS.OR.205(a)(2)(c).</p> <p>Justification: Accuracy, consistency.</p>
response	<p>Partially accepted</p> <p>As can be seen from the GM, while there is some measure of commonality across the different types, there are also some differences. Therefore, it is not appropriate to try to force the aspects into the same mould.</p> <p>However, to aid clarity, the GM has been redrafted and simplified.</p>
comment	<p>1223 comment by: Frasier Loredana</p> <p>Delete the text: personal characteristics</p> <p>Justification</p> <ol style="list-style-type: none"> 1. This is subjective and not relevant to be introduced in a safety support assessment. 2. The personal characteristics are evaluated during the employment processes and included in the job description.
response	<p>Accepted</p>



The elements included in the description under personal characteristics have been removed.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM5 ATS.OR.205(a)(2) Safety p. 158-159 assessment and assurance of changes to functional systems

comment 211 comment by: *NATS National Air Traffic Services Limited*

GM5 ATS.OR.205(a)(2)
Page 158

This has the same sub-heading as GM4 and appears to elaborate similar, but slightly different, guidance as is in GM4.
At point (c) reference is made to AMC3 ATS.OR.210(a)(2)(c) – the reference is not found (ATS.OR.210 has only one GM).

response [Accepted](#)
[GMs are combined. The correct reference is GM4 ATS.OR.210\(a\)\(2\).](#)

comment 212 comment by: *NATS National Air Traffic Services Limited*

GM5 ATS.OR.205(a)(2)
Page 158

Point (b)(3) - it is not appropriate to define the personal characteristics required in a functional change IR. At best it is subjective and if documented could lead to legal argument at the personal level. Relevant staff are already deemed competent and licensed if necessary and this type of requirement could discriminate against individuals going against employment law.

Proposal: Please delete the text in GM5 ATS.OR.205 (a)(2)(b)(3) on personal characteristics.

response [Accepted](#)
[The elements included in the description under personal characteristics have been removed.](#)

comment 347 comment by: *ATCEUC - Air Traffic Controllers European Unions Coordination*



GM5 ATS.OR.205(a)(2) Safety assessment and assurance of changes to functional Systems
ATCEUC is concerned about the use of the term “reasonable workload”. Who determines what is a “reasonable workload”? It is important that in defining this aspect of the change staff affected by the change, and especially those who will need to work with the new equipment/procedure is, at least, consulted.

This is emphasized by

(c) ... and the people that are needed to perform the procedure

Therefore these people should be involved in the safety assessment, also for procedures ATCEUC considers that this safety requirement is important enough to be included in the IR

Text proposal to GM5 ATS.OR.205(a)(2):

(c) When making the safety assessment and assurance of changes to functional systems, the staff affected by the change, including those who will need to work with the new equipment and/or procedures, shall be consulted

response **Not accepted**

The determination of a reasonable workload is provided in the assurance case. It relates to an assurance that the error rate of the tasks performed by the human is low enough to give confidence that the safety is achieved or the specification satisfied. It is claimed by the service provider and assessed by the CA if it chooses to do so. For the assessment to be valid, it is expected that it has to be performed involving the operational staff; otherwise, it is difficult, if not impossible, to gather robust evidence that provide enough confidence to approve a change. Consultation is not needed, but the involvement of the operating staff in the assessment is.

comment **1225**

comment by: *Frasie Loredana*

Delete the text: personal characteristics

Justification

1. This is subjective and not relevant to be introduced in a safety support assessment.
2. The personal characteristics are evaluated during the employment processes and included in the job description.

response **Accepted**

The elements included in the description under personal characteristics have been removed.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — AMC1 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system p. 159-162



comment	<p>143 comment by: <i>EUROCONTROL Safety Team</i></p> <p>Description of a process is GM not AMC. Additionally it too detailed, overly complicated and prescriptive for an AMC. Recommend using part of the text of AMC1 ATS.OR.205(b) as guidance material.</p>
response	<p>Not accepted</p> <p>The AMC provides the criteria against which the safety assessment may be judged and so cannot be considered to be GM. It is no more prescriptive than is necessary. It is complicated; however, the commentator does not offer any suggestions that would assist in its simplification.</p>
comment	<p>213 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>AMC1 ATS.OR.205(b) Page 159</p> <p>Some of the AMC is very long, detailed and prescriptive (for example AMC1 ATS.OR.205(b))and should either be sub-divided or recast into GM. At point (c) reference is made to ATM/ANS functional system which is interpreted as meaning the definition in 216/2008 prevails and therefore not all service providers' functional systems are in scope. Additionally as this AMC is related to safety assessment then it only applies to ATS providers. At point (f)(6) additional explanation is required to understand how "incorporate societal views" is to be considered.</p> <p>Proposal: This AMC should be subdivided in to separate AMC, i.e., AMC1, AMC2, AMC3, etc. each dealing with a specific sub-topic or preferably recast as GM. This will allow organisations to propose alternative means of compliance for individual means of compliance for small parts rather than the whole of the material</p>
response	<p>Accepted</p> <p>An AMC or AltMOC relates to a specific part of an IR. The fact that an AMC exists does not preclude the creation of AltMOC covering all or part of the same scope as the existing AMC. Consequently, the implied relationship drawn here is false and does not, of itself, force the production of small AMCs. However, the AMC has been split to facilitate handling parts of the original AMC, including the identification of what parts of the AMC relate to what parts of the IR, and the introduction of GM more focussed to parts of AMC, improving readability and comprehension of material.</p>



comment	<p>310 comment by: DSNA</p> <p>The text in AMC1 ATS.OR.205 (b) is too detailed and prescriptive and of an explanatory nature for AMC. Move the text in AMC1 ATS.OR.205(b) to GM.</p>
response	<p>Not accepted</p> <p>The AMC provides the criteria against which the safety assessment may be judged and so cannot be considered to be GM. It is no more prescriptive than is necessary.</p>
comment	<p>311 comment by: DSNA</p> <p>This AMC is very long, detailed and prescriptive (for example AMC1 ATS.OR.205(b)). This AMC should be subdivided in to separate AMC, i.e., AMC1, AMC2, AMC3, etc. each dealing with a specific sub-topic . This will allow organisations to propose alternative means of compliance for individual means of compliance for small parts rather than the whole of the material.</p>
response	<p>Accepted</p> <p>An AMC or AltMOC relates to a specific part of an IR. The fact that an AMC exists does not preclude the creation of AltMOC covering all or part of the same scope as the existing AMC. Consequently, the implied relationship drawn here is false and does not, of itself, force the production of small AMCs. However, the AMC has been split to facilitate handling parts of the original AMC, including the identification of what parts of the AMC relate to what parts of the IR, and the introduction of GM more focussed to parts of AMC, improving readability and comprehension of material.</p>
comment	<p>312 comment by: DSNA</p> <p>(d) : points (a), (b) and (c): the relative and absolute concepts need a specific explanatory note. According to DSNA, an absolute approach refers to figures as safety criteria, and a relative approach is about the difference in safety risk of the system before and after the change.</p> <p>(3) : Proxies are real progress because much more understandable by operational people however too many constraints (e.g. points (i) (ii) (iii)) make them unusable. DSNA proposes to replace the text (3) with : “proxies for safety risk, used as safety criteria for those parts of the functional system affected by the change.” and delete points (i), (ii) and (iii).</p>



(e) : Depending on the source, success case or approach definitions are defined differently.
There is a need to more explanations.

(e)(1)(iii) : **proposed text** : “ hazards or proxies introduced due to implementation

Proposed text (after (4)): “**Where relevant**, the risk analysis takes into account the reduction of risk due to the change, i.e. the positive safety contributions of the change are also evaluated (success approach).”

response

Not accepted

The comment on points (A), (B) & (C) is not clear. These sub paragraphs describe the types of risk analysis that can be performed and relates them to relative or absolute objectives. The safety criteria need to support such risk analyses which will be performed in an objective manner, as stated in point (ii). This seems clear enough.

The sub-points of (3) provide the criteria for the use of proxies; their removal would leave proxies effectively undefined.

comment

313

comment by: DSNA

(f) : As written, the text may lead people to understand that the safety assessment shall focus only on accident (e.g. title of chapter). However, the assignment of severity classification to hazard effect seems to imply that we have also to address incidents. The worst credible case as described in EUROCONTROL SAM is used by many service providers for years and removing this from the process would lead to major issues and costs. Reading pages 161 & 176, it's unclear if it remains possible with the new regulation.

response

Not Accepted:

The definition of a hazard is that it induces a ‘harmful’ effect, which limits the scope of a hazard to accidents. While incidents are still useful in the management of safety, they cannot be considered as causing ‘harmful’ effects. (See section 5.1.1 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities)

There is no restriction on arguing that a risk is so small that it can be considered to be zero. Furthermore, (b)(3) allows non-credible hazards to be eliminated from the risk analysis.

comment

314

comment by: DSNA

DSNA proposes to replace the text with “verification that the implementation is that of the design and behaves as specified.”



response [Not accepted](#)

[The proposal is incomplete. It does not allow for the presence of unspecified behaviour.](#)

comment 348

comment by: *ATCEUC - Air Traffic Controllers European Unions Coordination*

AMC1 ATS.OR.205(b) Safety assessment and assurance of changes to the functional System

ATCEUC proposes to move this provision to IR level since, again, it is important that affected personnel takes part in the process

(see previous comment and text proposed as ATS.OR.205(c))

As stated before, it is important that the people that will be affected by the change are involved in the safety assessment because they know better than anyone else the impact that change might have in the safety of their tasks.

(e) The ATS provider ~~should~~ shall ensure that the risk analysis is carried out by personnel trained and competent to perform this task, which will include personnel affected by the proposed change

response [Not accepted](#)

[For the risk assessment to be valid, it is expected that it has to be performed by competent personnel involving the operational staff affected; otherwise it is difficult, if not impossible, to gather robust evidence that provide enough confidence to approve a change. The fact that the personnel affected carry out themselves the assessment is not needed, but the involvement of the operating staff is.](#)

comment 437

comment by: *EUROCONTROL*

AMC1 ATS.OR.205(b)(d)(3) - Page 160

Please refer to EUROCONTROL's recommendation concerning the notion of 'proxy' made when commenting page 170 (GM1 ATS.OR.205(b)(3)).

Please correct indentation of (i) against (ii) and (iii).

response [Accepted](#)

[Footnote has been added and indentation corrected.](#)

comment 456

comment by: *NAV Portugal E.P.E*

AMC1 ATS.OR.205 (b)

The term accident is used where NAV Portugal believes "hazard" is more appropriate. Accident is defined by ICAO and has a specific meaning which seems no to be the one in (f) -



response	<p>Severity classification of accident leading to harmful effects.</p> <p>Not accepted</p> <p>The word 'accident' is used correctly. Please see the response to comment No 313.</p>
comment	<p>496 comment by: <i>skyguide Corporate Regulation Management</i></p> <p>Safety assessment and assurance of changes to the functional system. The text in AMC1 ATS.OR.205(b) is too detailed and prescriptive and of an explanatory nature for AMC and should be moved to GM. Some of the AMC is very long, detailed and prescriptive (for example AMC1 ATS.OR.205(b)). This AMC should be subdivided in to separate AMC, i.e., AMC1, AMC2, AMC3, etc. each dealing with a specific sub-topic This will allow organisations to propose alternative means of compliance for individual means of compliance for small parts rather than the whole of the material</p>
response	<p>Accepted</p> <p>Please see the response to comment No 311.</p>
comment	<p>581 comment by: <i>Frasie Loredana</i></p> <p>Rephrase the following text: <i>all operational transitions that are part of the change.</i> Propose to add the text: <i>all identified operational transitions</i> Justification 1. In our opinion <u>all the operational transitions that are part of the change</u> might be unknown to the service provider, other than an ATS provider, or ATS provider and therefore cannot be included in the safety (support) assessment. (f) Remove the text related to the assignment of an harmful effect to a severity category Justification The assignment of a harmful effect to a severity category is irrelevant in the context of safety assessment of changes to ATM/ANS functional system. The assignment of a harmful effect to a severity category brings no benefit to the ATM system. This is mostly associated with accidents and in this case the ATM system fails, when ATM has direct contribution. The ATS provider cannot plan for an accident which results in injuries only. Furthermore, this is unacceptable. This evaluation could be subjective. We do not agree that the severity of 10 fatalities equals 101 minor injuries. We believe that this cannot be compared.</p>



response	<p>Not accepted</p> <p>Regarding the operational transitions, this AMC is only applicable to ATS providers. It is not included in safety support assessment.</p> <p>With regard to the comment on harmful effect, the comment seems to question the very nature of risk analysis. In such case, the whole of ATS.OR.210 should be deleted and along with it this AMC.</p> <p>Please see GM1 ATS.OR.205.(b)(4) for an explanation of how harmful effects are treated.</p> <p>The reference to 10 fatalities equalling 101 injuries appears to be a reference to the GM, where it is used as an example to explain the concept of multiple-value severity schemes. Consequently, it has no legal value and is not a requirement of this IR or of the related AMC.</p>
comment	<p>654 comment by: <i>CANSO</i></p> <p>Safety assessment and assurance of changes to the functional system. The text in AMC1 ATS.OR.205(b) is too detailed and prescriptive and of an explanatory nature for AMC and should be moved to GM.</p>
response	<p>Not accepted</p> <p>The AMC provides the criteria against which the safety assessment may be judged and so cannot be considered to be GM. It is no more prescriptive than is necessary.</p>
comment	<p>655 comment by: <i>CANSO</i></p> <p>Some of the AMC is very long, detailed and prescriptive (for example AMC1 ATS.OR.205(b)). This AMC should be subdivided in to separate AMC, i.e., AMC1, AMC2, AMC3, etc. each dealing with a specific sub-topic This will allow organisations to propose alternative means of compliance for individual means of compliance for small parts rather than the whole of the material</p>
response	<p>Accepted</p> <p>Please see the response to comment No 311.</p>
comment	<p>700 comment by: <i>ROMATSA</i></p> <p>Safety assessment and assurance of changes to the functional system.</p> <p>Supporting comment to summary issue: Level of detail and split between IR and AMC</p>



The text in AMC1 ATS.OR.205(b) is too detailed and prescriptive and of an explanatory nature for AMC and should be moved to GM.

Supporting comment to summary issue: Move the text in AMC1 ATS.OR.205(b) to GM

Some of the AMC is very long, detailed and prescriptive (for example AMC1 ATS.OR.205(b)). This AMC should be subdivided in to separate AMC, i.e., AMC1, AMC2, AMC3, etc. each dealing with a specific sub-topic This will allow organisations to propose alternative means of compliance for individual means of compliance for small parts rather than the whole of the material

Supporting comment to summary issue: Overly complicated and Missing AMC

response **Partially accepted**

With regard to moving AMC1 ATS.OR.205(b) to GM, the comment is rejected. Please see the response to comment No 310.

As regards splitting AMC1 ATS.OR.205(b), the comment is accepted and the AMC has been split. Please see the response to comment No 311.

comment

726

comment by: *DFS Deutsche Flugsicherung GmbH*

The text in AMC1 ATS.OR.205(b) is too detailed and prescriptive and of an explanatory nature for AMC and should be moved to GM.
Reference to high level comment "b"

response **Not accepted**

The AMC provides the criteria against which the safety assessment may be judged and so cannot be considered to be GM. It is no more prescriptive than is necessary.

comment

727

comment by: *DFS Deutsche Flugsicherung GmbH*

“(2) the safety criteria are measurable to an adequate degree of certainty”

Where is "certainty"/"adequate certainty" defined? Depending on this definition, the effort



for quantification might be increased significantly, not to mention that for some safety criteria, where Human Factors and/or expert judgment are involved, a specific "certainty" might not be achievable at all!

This bears the danger that service providers abandon quantification, which would be a big loss, since a even a very uncertain quantification is still more certain than qualitative assessments.

We suggest to add a definition to avoid over interpretation (e.g. by CAs).
Reference to high level comment "c.ii"

response **Partially accepted**

'Adequate degree of certainty' is not defined. However, the adequacy of the certainty relates to the confidence that is necessary in order to satisfy the service provider (and the CA) that the change is safe enough. This is argued in the safety case.

The relationship between sufficient level of confidence and the validity of an assurance case will be developed during the 2nd NPA.

comment 728

comment by: *DFS Deutsche Flugsicherung GmbH*

"(3) (i) a justifiable causal relationship"

We suggest to add a definition to avoid over interpretation (e.g. by CAs).
Reference to high level comment "c.ii"

response **Partially accepted**

GM will be provided to explain what is expected of the justification.

comment 729

comment by: *DFS Deutsche Flugsicherung GmbH*

"(3) (iii) the proxy is measurable to an adequate degree of certainty"

As in AMC1 ATS.OR.205 (b) - (2) above, the term "certainty" is not defined and we suggest to add a definition.



It might be possible to use one definition for both.
Reference to high level comment "c.ii"

response **Partially accepted**

Certainty of the measure is related to achieve an adequate level of confidence in the safety case. The relationship between sufficient level of confidence and the validity of an assurance case will be developed during the 2nd NPA.

comment 730

comment by: *DFS Deutsche Flugsicherung GmbH*

“(e) (1) a complete list of harmful effects”

We think that this is going beyond what CR (EU) 1035/2011 (and ESARR4) intended to require. E. g SESAR - amongst other methodology, which are in use - is compliant with CR (EU) 1035/2011, but would not be compliant with the above stated requirement.

Therefore, we suggest to remove the term "complete".
Reference to high level comment "c.ii"

response **Not accepted**

The completeness of the list of harmful effects is in relation to those hazards that have been identified in (c), i.e. those related to the change. We cannot see how this contravenes Regulation (EU) No 1035/2011. It seems to be covered in Annex II 3,2,2 (b).

comment 731

comment by: *DFS Deutsche Flugsicherung GmbH*

“(e) [...] risk analysis takes into account [...] positive safety contributions [...] (success approach)”

The conduction of success cases is not part of current regulation. Service providers are not conducting them yet. Though the success approach is without doubt a good development for safety, service providers are not prepared for the additional effort and the methodological implications yet. Risks cannot be simply subtracted or added. As far as we know, no service provider has a method for the "subtraction" of "negative" risks from "positive gains" - although there is significant interest in having it! Obviously, there is also



no harmonized method for this in Europe, although there exists a suggestion from SESAR where percentages of influences on barriers are summed up and subtracted.

Because of additional financial pressures for service providers, this text in an AMC makes the situation increasingly difficult for service providers.

We suggest to move this part to the appropriate GM and add a statement that that is a desired goal for the future, but is not expected to be implemented short term.

Reference to high level comment "c.ii"

response [Not accepted](#)

[Please see the response to comment No 312.](#)

[With respect to the argument about the addition of risks, a risk is represented by a value. Since probability is non-dimensional, the dimensions of risk are the agreed measure for harm to humans — usually the number of lives lost or in some cases the value to the state \(in currency\) of the number of lives lost. On this basis, there is no difficulty in adding or subtracting risks.](#)

comment 732

comment by: *DFS Deutsche Flugsicherung GmbH*

(f) (5): “rules for assigning a harmful effect unambiguously to a severity category”

We do not think that those rules need to be required explicitly.

We suggest to delete the whole paragraph "(f) (5)" (and to not move it to GM).

Reference to high level comment "c.i"

response [Not accepted](#)

[It seems irrational to have a severity scheme where one cannot uniquely place an effect into a category. It makes the scheme meaningless.](#)

comment 733

comment by: *DFS Deutsche Flugsicherung GmbH*

“(f) (6) [...] and can be shown to incorporate societal views of their severity”



We do not think that "societal views" need to be considered in this context.

We suggest to delete the whole paragraph "(f) (6)" (and to not move it to GM).
Reference to high level comment "c.ii"

response **Not accepted**

The aim of the clause is (after (5) which seeks unambiguous categories) to get valid categories. The categories should not be arbitrary, but to reflect the societal views.

comment 734

comment by: *DFS Deutsche Flugsicherung GmbH*

"(g) (2) [...] taking the uncertainty of the risk assessment into account"

There is no definition of "uncertainty".

The notion of "uncertainty" brings with it the problem of (over)interpretation by CAs.

Requiring the service provider to always know and determine the mathematical uncertainty of the results of its risk assessments is nearly **infeasible** - even though the intention does make sense.

We suggest to remove the sentence after "safety criteria".

Reference to high level comment "c.ii"

response **Not accepted**

'Uncertainty' is used in its normal English language sense. If we remove the part of the sentence suggested, it will imply that the comparison has to be made with absolute precision, which is infeasible. Allowing for uncertainty makes it feasible.

comment 735

comment by: *DFS Deutsche Flugsicherung GmbH*

"(g) (3) the identification of the need for risk mitigation or reduction in uncertainty or both"

We do not understand this requirement. Since this might apply also for others, we suggest to apply an explanation - or even better just remove "in uncertainty".

Reference to high level comment "c.ii"



response [Not accepted](#)

The reason why the sentence is not clear is not well understood. There does not seem to be any ambiguity or complexity in the sentence. It means exactly what it reads: the risk evaluation should identify the need of risk mitigation, the reduction of the associated uncertainty of the risk evaluation, or both.

comment [822](#)

comment by: *DGAC/DSAC - french NSA*

The french NSA has one comment related to AMC1 ATS.OR.205 (b) :

We need a clarification about the meaning of "credible" in this sentence : "need only identify hazards that are generally considered as credible". It could be understood as "not highly improbable" and could lead to missing elements in the safety assessment. At least we suggest to explain the word "credible" in the associated GM.

response [Accepted](#)

Clarification has been added in GM that a credible hazard is one that has material effect on the risk assessment.

comment [878](#)

comment by: *UK CAA*

Page No: 159

Paragraph No: AMC1 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system SAFETY ASSESSMENT PROCESS

Comment: There are several references to 'ATS provider' in this section. Should these be 'ATM/ANS provider'?

Justification: Clarification and the need for consistency.

response [Not accepted](#)

The term 'ATM/ANS provider' is not correct since Annex IV only applies to air traffic service providers. However, the use of the term 'ATS provider' (instead of 'air traffic service provider') in the IR has been questioned and there should be consistency between IR and AMC.

comment [879](#)

comment by: *UK CAA*



Page No: 159

Paragraph No: AMC1 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system

Comment: The concept of proportionality of safety assessment is important especially for the smaller less complex ANSPs where it is likely that the impact of any change will be low. It is only referred to in the GM1 OR.205(b)

Justification: The concept of proportionality is an important concept especially where there are multiple ANSPs of varying sizes and complexity and therefore should be included within the AMC part of this regulation rather than the GM

Proposed Text:

NEW PARAGRAPH

(k) PROPORTIONALITY OF SAFETY ASSESSMENT

ATS providers may carry out safety assessment in a way that is commensurate with the type and nature of the change and its impact on safety.

response

Not accepted

While it is agreed that proportionality is necessary, the proportionality is not in respect to the size or competence of the service provider but in proportion to the risk associated with the change. This level of proportionality has already been provided for in ATS.OR.205(a)(2) by the requirement for 'sufficient confidence' in a safety case. The sufficient confidence relates to the level of risk, while the ease of achieving it relates to the difficulties associated with assuring the change, which could be due to the complexity of the change or the novelty of the approach to solving the problem or a combination of both.

comment

880

comment by: UK CAA

Page No: 159

Paragraph No: AMC1 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system SAFETY ASSESSMENT PROCESS(b)

Comment:

1) The UK CAA suggests that in attempting to limit the hazards identified, the text provides too much license to ignore hazards. We recommend use of "identifies all credible hazards".

2) Also please note that the grammar of the lead-in sentence is not compatible with the start of (b)(2) and (b)(3)

Justification: Accuracy.

response

Partially accepted

1) does not limit the hazards identified except in relation to the change. Moreover, 'all' is already implied by the IR and so there would be no point in repeating it in AMC.

Grammar in (b)(3) is fine. Grammar in (b)(2) is OK but the use of 'should' twice makes it look less like English — 'should be' has been replaced by 'has been'.



comment	<p data-bbox="360 275 408 309">881</p> <p data-bbox="1222 275 1484 309" style="text-align: right;">comment by: UK CAA</p> <p data-bbox="360 365 523 398">Page No: 159</p> <p data-bbox="360 409 1484 477">Paragraph No: AMC1 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system SAFETY ASSESSMENT PROCESS(c)(2)</p> <p data-bbox="360 488 1484 555">Comment: The UK CAA is of the opinion that this section contains a number of errors, and suggests the text should be revised to improve clarity.</p> <p data-bbox="360 566 1484 633">1) In (i) the hazards are both “affected by the change” but also “related to the existing parts of the ATM/ANS functional systems which are not changed”</p> <p data-bbox="360 645 1484 757">2) In (ii) the hazards are both “affected by the change” but also “related to hazards outside the ATMS/ANS functional system, for example those inherent to aviation”. This may be possible, but in the present confused section, it is not clear.</p> <p data-bbox="360 768 727 801">Justification: Clarity/Accuracy.</p>
response	<p data-bbox="360 835 475 869">Accepted</p> <p data-bbox="360 902 1244 936">The text has been reviewed and ‘which are not change’ has been deleted.</p>
comment	<p data-bbox="360 1025 408 1059">883</p> <p data-bbox="1222 1025 1484 1059" style="text-align: right;">comment by: UK CAA</p> <p data-bbox="360 1126 523 1160">Page No: 160</p> <p data-bbox="360 1171 1484 1238">Paragraph No: AMC1 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system SAFETY ASSESSMENT PROCESS(d)(1)(i)(B)</p> <p data-bbox="360 1249 1165 1283">Comment: The word ‘and’ has been used in error for the word ‘or’.</p> <p data-bbox="360 1294 606 1328">Justification: Clarity.</p> <p data-bbox="360 1339 1484 1406">Proposed Text: Suggest change “similar system (absolute and relative); and” to “similar system (can be absolute or relative); and”</p>
response	<p data-bbox="360 1429 475 1462">Accepted</p> <p data-bbox="360 1496 845 1529">The text has been amended accordingly.</p>
comment	<p data-bbox="360 1619 408 1653">884</p> <p data-bbox="1222 1619 1484 1653" style="text-align: right;">comment by: UK CAA</p> <p data-bbox="360 1720 523 1753">Page No: 160</p> <p data-bbox="360 1765 1484 1832">Paragraph No: AMC1 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system SAFETY ASSESSMENT PROCESS(d)(2)</p> <p data-bbox="360 1843 1197 1877">Comment: UK CAA suggests amendment to the wording to aid clarity.</p> <p data-bbox="360 1888 606 1921">Justification: Clarity.</p> <p data-bbox="360 1933 1484 2000">Proposed Text: Suggest change to “the safety criteria are measureable” to “the parameters stipulated in the safety criteria are measureable”</p>



response	<p>Not accepted</p> <p>A safety criterion is a parameter: a value of risk, a value of a proxy (another measure related to safety risk).</p>
comment	<p>886 comment by: UK CAA</p> <p>Page No: 160 Paragraph No: AMC1 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system SAFETY ASSESSMENT PROCESS(d)(4) Comment: UK CAA suggests amendment to the wording to aid clarity. Justification: Clarity. Proposed Text: Suggest change to “should cover the complete change” to “should cover all safety-related behaviour relating to the changed and affected elements”</p>
response	<p>Not accepted</p> <p>It is not clear how the proposed wording aids clarity. The use of ‘elements’ is being discussed in comment No 1244, and ‘elements’ are removed now from the AMC.</p>
comment	<p>888 comment by: UK CAA</p> <p>Page No: 160 Paragraph No: AMC1 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system Comment: Paragraph (d) (4) states the set of safety criteria, whether represented totally by proxies or a mixture of proxies and risks, should cover the complete change. The ‘risks’ referred to here are ‘safety risks’ and should be amended to reflect this. Justification: Clarification that the ‘risks’ referred to here and elsewhere are termed ‘safety risks’. Proposed Text: d) (4) states the set of safety criteria, whether represented totally by proxies or a mixture of proxies and <u>safety</u> risks, should cover the complete change</p>
response	<p>Accepted</p> <p>Text has been added as suggested.</p>
comment	<p>889 comment by: UK CAA</p> <p>Page No: 160 Paragraph No: AMC1 ATS.OR.205(b) Safety assessment and assurance of changes to the</p>



response	<p>functional system SAFETY ASSESSMENT PROCESS(d)(6) Comment: Consistency with (5) Justification: Clarity. Proposed Text: Suggest change to “ATS provider’s safety objectives” to “ATS provider’s overall safety objectives”</p> <p>Accepted</p> <p>Text has been amended as suggested.</p>
comment	<p>890 comment by: UK CAA</p> <p>Page No: 162 Paragraph No: AMC1 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system SAFETY ASSESSMENT PROCESS (j) Comment: It may not be practical to monitor the beneficial effect of small changes, or that to do so might introduce a far larger change to the functional system than the intended change itself. The UK CAA recommends that guidance is given on what is considered to be reasonable monitoring for changes. Justification: Practicality.</p>
response	<p>Partially accepted</p> <p>If the small change has no beneficial effect, then the monitoring requirements ensure that the service remains safe using the previous monitoring criteria. This is not precluded by the IR or the AMC.</p> <p>This point will be made clearer in GM.</p>
comment	<p>891 comment by: UK CAA</p> <p>Page No: 162 Paragraph No: AMC1 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system SAFETY ASSESSMENT PROCESS (j)(3) Comment: This appears to be the only reference in the NPA to “safety indicators”. It is not immediately obvious what is intended to be here, as (j)(2) already addresses proxies. Justification: Clarity/accuracy.</p>
response	<p>Noted</p> <p>The intention is to capture properties other than proxies whose value might be affected by the change and to establish monitoring criteria that show whether they remain within the bounds predicted by the safety case.</p>



comment

957

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX IV SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS) AMC1 ATS.OR.205(b)	(a): there are some differences between 'Scope of the change' (what is going to be modified) and 'scope of the assessment of the change' (what is going to be analysed because of the intended modification), and both of them should be clearly defined before the assessment of the change is initiated.	Some components of the functional system (and their inputs or outputs) may not be altered due to the change, but they must be taken into account during the safety assessment because of their relationship with components which do change.

response

Partially accepted

The difference identified here has now been addressed by changing the IR. The wording of this section of the AMC will reflect that change.

comment

958

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX IV SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC	(a): in order to ensure that all the components of the functional system affected by the change have been identified, it is essential that a <i>functional description</i> of the change be included in the safety analysis of that change.	It does not make sense that the need to include a functional description is included in the AMC and then only a fleeting reference is made in the GM when this description is one the keys to ensure the completeness in the identification of hazards.



SERVICES (Part-ATS) AMC1 ATS.OR.205(b)		
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response

Not accepted

There is no mention of a 'functional description' in the AMC. It would not be considered necessary to mention it at this level, but it may be a necessary part of the assurance that the scope has been correctly and completely identified; hence, its inclusion in GM.

comment

959

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX IV SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS) AMC1 AT.S.OR.205(b)	(b)(3): "generally considered as credible" is a very subjective concept.	This NPA is quite important for the functioning of the whole system and it should be as clear as possible in order to avoid present and future misunderstandings.

response

Accepted

Clarification has been added in GM that a credible hazard is one that has material effect on the risk assessment.

comment

960

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.2	(f)(5): We wonder to which rules for assigning a harmful effect	We would welcome clarification on these points



Draft AMC & GM (Draft EASA Decision) ANNEX IV SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS) AMC1 ATS.OR.205(b)	unambiguously to a severity category may this be referring.	in order to better understand and assess this NPA.
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response **Noted**

The comment is unclear. However, it is hoped that the explanation below answers it.

Safety risk is defined as probability times the severity of the harmful effect (accident). It is therefore a two-dimensional property (although probability is usually non-dimensional). It follows from the requirement to perform a risk analysis and evaluation (ATS.OR.205(b)(4) & (5)) that the severity of the accident must be known. In general, the severity is not known exactly and so a severity scheme is used to classify the effects of the accident (the severity of the effects). As explained in the NPA, the Rulemaking Group could not agree on a single severity scheme and so the rules for creating such schemes are included in the AMC associated with ATS.OR.205(b).

comment 961

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.2 Draft AMC & GM (Draft EASA Decision) ANNEX IV SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS) AMC1 ATS.OR.205(b)	(f)(6): We do not quite understand what this provision means.	No ambiguous requirements with which it is not clear how to comply should be introduced in AMCs due to their <i>soft law</i> nature.

response **Noted**



The aim of the clause is (after (5) which seeks unambiguous categories) to get valid categories. The categories should not be arbitrary, but to reflect the societal views.

comment 1066

comment by: LVNL

Safety assessment and assurance of changes to the functional system. The text in AMC1 ATS.OR.205(b) is too detailed and prescriptive and of an explanatory nature for AMC and should be moved to GM.

response Not accepted

The AMC provides the criteria by which the safety assessment may be judged and so cannot be considered to be GM. It is no more prescriptive than is necessary.

comment 1125

comment by: Belgocontrol

Description of a process is GM not AMC. It is also too detailed, complicated and prescriptive for an AMC.

Recommend to use part of the text of AMC1 ATS.OR.205(b) as GM.

response Not accepted

The AMC provides the criteria by which the safety assessment may be judged and so cannot be considered to be GM. It is no more prescriptive than is necessary.

comment 1244

comment by: Icetra

To say that an assessment should include components, elements and transitions does not sound correct, it is suggested that that the wording be revised:

(a) Completeness of the scope

The ATS provider should ensure that the assessment of the change takes the following into account“:

(1) no change suggested

etc.

suggested changes:



	<p>(b) Completeness of hazard identification</p> <p>The ATS provider should ensure that the hazard identification:</p> <p>(1) targets complete coverage of any condition, event, or circumstance related to the change, which could, individually or in combination, induce a harmful effect;</p> <p>(2) should be is done performed by personnel trained and competent for this task; and</p> <p>(3) need only include hazards that are generally considered as credible.</p>
response	<p>Partially accepted</p> <p>(a) This part of the AMC seems to have fewer criteria and is less descriptive than the IR itself. It has been removed, and thus the issue raised by the commentator has been resolved.</p> <p>(b) The suggested changes have been partially accepted.</p>
comment	<p>1280 comment by: <i>European Transport Workers Federation - ETF</i></p> <p>ETF consider of particular importance the contribution provided by the staff affected by the change to functional systems and to fulfil the completeness of risk analysis. We propose to include in the IR ATS.OR.205 the requirements for personnel performing this task to involve staff affected by the change, as it follows:</p> <p><i>“The ATS provider shall ensure that the risk analysis is carried out by personnel trained and competent to perform this task, including consulting personnel affected by the proposed change”</i></p>
response	<p>Not accepted</p> <p>The importance of affected staff in the analysis is acknowledged. For the risk analysis to be valid, it has to be performed with the involvement of the operational staff; otherwise it is difficult, if not impossible, to gather robust evidence that provide enough confidence to approve a change. However, a consultation process with them is not needed.</p>

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM1 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system

p. 162

comment	<p>214 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>GM1 ATS.OR.205(b) Page 162</p> <p>This GM is fully supported, however it is not clear how this can be achieved given that the</p>
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	related AMC is very prescriptive and offers little flexibility. See comment on AMC proposing that it is recast as GM.
response	<p>Noted</p> <p>The proportionality of the safety assessment carried out by the ATS provider should be linked to the confidence needed in the argument; however, to provide additional GM on these aspects, additional work is needed by the Agency, which is foreseen in a future NPA.</p>
comment	<p>892 comment by: UK CAA</p> <p>Page No: 162</p> <p>Paragraph No: GM1 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system PROPORTIONALITY OF SAFETY ASSESSMENT</p> <p>Comment: This guidance on proportionality of safety assessment is not prominent in the NPA overall, or in the guidance, considering the importance of this point to SPs and CAs alike, and its previous presence in Article 9(2) of Regulation (EU) No 1034/2011 (as discussed on page 11 of the NPA).</p> <p>‘Commensurate’ appears very few times in the NPA, and ‘proportion(ate)’ appears a little more frequently, but mainly in relation to the CA’s review of safety cases. Overall there is very little mention of proportionality of assurance, or guidance on what level of assurance is proportionate for different risks.</p> <p>UK CAA recommends that proportionality is more fully discussed and is given greater prominence.</p> <p>Justification: Proportionality.</p>
response	<p>Noted</p> <p>The proportionality of the safety assessment carried out by the ATS provider should be linked to the confidence needed in the argument; however, to provide additional GM on these aspects, additional work is needed by the Agency, which is foreseen in a future NPA.</p>

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM2 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system	p. 162
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comment	<p>144 comment by: EUROCONTROL Safety Team</p> <p>Footnote 151</p> <p>Recommend to remove this footnote as it gives the impression that it is advertising for these proprietary tools. An internet search could easily find the required information.</p>
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response	<p>Not accepted</p> <p>There is no intention to advertise anything. NLR database is publicly accessible, and the SCSC has many papers (but not all) also accessible. The note only points to two trustworthy sources.</p>
comment	<p>215 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>GM2 ATS.OR.205(b) Page 162</p> <p>This GM is fully supported, however it is not clear how this can be achieved given that the related AMC is very prescriptive and offers little flexibility. It is assumed that “safety assessment methods” is synonymous with “safety assessment process”. See comment on AMC proposing that it is recast as GM.</p>
response	<p>Noted</p> <p>A process is a set of steps to achieve something and a method is an established way of doing something. A process can be prescribed, but then different methods can be used to accomplish each step.</p> <p>The Agency does not consider that the safety assessment in this Regulation is very prescriptive. In fact, flexibility has been introduced when compared with Regulation (EU) No 1035/2011.</p>
comment	<p>893 comment by: <i>UK CAA</i></p> <p>Page No: 162 Paragraph No: GM2 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system SAFETY ASSESSMENT METHODS Comment: UK CAA suggests the addition of a sentence to aid clarity. Justification: Clarity. Proposed Text: Add the following sentence to (a): “It is therefore not sufficient for a safety case (or a safety support case) to claim that the assurance provided is adequate due to compliance with a standard or method.”</p>
response	<p>Accepted</p> <p>Text has been added.</p>
comment	<p>1299 comment by: <i>EUROCONTROL</i></p>



GM2 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system - Page 162

Recommend to remove footnote 151 as it gives the impression that it is advertising for these proprietary tools. An internet search could easily find the required information.

response **Not accepted**

There is no intention to advertise anything. NLR database is publicly accessible, and the SCSC has many papers (but not all) also accessible. The note only points to two trustworthy sources.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM3 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system

p. 162

comment 349

comment by: ATCEUC - Air Traffic Controllers European Unions Coordination

GM3 ATS.OR.205(b) Safety assessment and assurance of changes to the functional System

It is essential that part of the FS change includes the training of the staff when the change modifies the way people interact with the rest of the functional system. Therefore we propose to add this provision as point 8 in the IR and use specific GM for clarification.

GM3 ATS.OR.205(b) Safety assessment and assurance of changes to the functional System

(8) Appropriate training before the change becomes operational if such change-if the change modifies the way people interact with the rest of the functional system, then they will require training before the change becomes operational. Also, when needed People may also need periodical refreshment training periodically in order to ensure that their performance does not degrade over time.

GM3 GM1 ATS.OR.205(b)(8)

The training needed before operation forms part of the design of the change, while the refreshment training is part of the maintenance of the functional system after the change is in operation

response **Partially accepted**

Training is included in the scope of change. Training is part of the change of the human element as it modifies its behaviour. GM is kept but the intent has been clarified and moved to link training to the scope of the change.

Training requirements are a result of a risk evaluation, and they are risk mitigations, so they are the output of the safety assessment.



comment	<p>895 comment by: UK CAA</p> <p>Page No: 162 Paragraph No: GM3 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system PROCEDURE DEVELOPMENT Comment: The guidance does not mention procedures, which contradicts the paragraph title. Justification: Potential deviation from topic or incorrect topic name.</p>
response	<p>Accepted</p> <p>The title has been changed to 'training'.</p>
comment	<p>896 comment by: UK CAA</p> <p>Page No: 162 Paragraph No: GM3 ATS.OR.205(b) Safety support assessment and assurance of changes to the functional system PROCEDURE DEVELOPMENT Comment: Effectively, this appears to say that changing a procedure that a person must follow impacts the 'person', so that the person's requirements have changed, and the person's changed role and performance need analysis. This is not clearly stated. Justification: Completeness and clarity.</p>
response	<p>Partially accepted</p> <p>That is not the intent of the guidance. A change in the procedure is a change in the functional system, thus it requires assessment.</p> <p>The intent of the GM is that training may modify the behaviour of the people and thus it is part of the change and needs assessment. GM has been modified and moved to the scope of the change to clarify the intent.</p>
comment	<p>897 comment by: UK CAA</p> <p>Page No: 162 Paragraph No: GM3 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system PROCEDURE DEVELOPMENT Comment: The guidance does not mention that training operational staff may change the existing functional system before any other part of the change is made, and so may have to be treated as a transitional stage of the change. For example, as a result of training, controllers may come to expect information or alerts to be presented differently. Justification: Completeness of guidance.</p>



response

Accepted

The proposed text has been added.

comment

1281

comment by: *European Transport Workers Federation - ETF*

ETF consider competence, training and related assessments as pillars to provide safety, therefore proposes to include in the IR ATS.OR.205 a requirement as follows:

If the change modifies the way people interact with the rest of the functional system, appropriate training shall be provided before the change becomes operational. Refreshment training shall be periodically provided in order to ensure that performance does not degrade over time. The training needed before operation forms part of the design of the change, while the refreshment training is part of the maintenance of the functional system after the change is in operation.

response

Partially accepted

Interaction is included in the scope, and therefore it has to be assessed. It is expected that the risk assessment of a change that modifies the way people interacts with the rest of functional system will identify the need of training. This GM is highlighting this aspect.

This requirement is not necessary at IR level. It fits as parts of the GM. Modifications were introduced to clarify this aspect.

GM is kept but the intent is clarified and moved to link training to the scope of the change.

Training requirements are a result of a risk evaluation, and they are risk mitigations, so they are the output of the safety assessment.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM4 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system p. 163-164

comment

145

comment by: *EUROCONTROL Safety Team*

Figure 1

Figure looks incomplete.

response

Accepted

The figure has been amended and completed.



comment	898	comment by: UK CAA
	<p>Page No: 163</p> <p>Paragraph No: GM4 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system SAFETY ASSESSMENT PROCESS</p> <p>Comment: The figure appears to be truncated (cut off) at the bottom. It is possible that the diagram is considered complete, but if so, the diagram should be modified to make it clear that this is the case. It is accepted that 'operation' just continues, but the unconnected 'no' arrow from 'risk acceptance' is just left hanging (unterminated).</p> <p>Justification: Clarity, completeness.</p>	
response	<p>Accepted</p> <p>The figure has been amended and completed.</p>	
comment	1127	comment by: Belgocontrol
	<p>Figure 1</p> <p>Figure seems to be incomplete</p>	
response	<p>Accepted</p> <p>The figure has been amended and completed.</p>	
comment	1300	comment by: EUROCONTROL
	<p>GM4 ATS.OR.205(b) Safety assessment and assurance of changes to the functional system - Page 163</p> <p>Figure looks incomplete.</p>	
response	<p>Accepted</p> <p>The figure has been amended and completed.</p>	

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM1 ATS.OR.205(b)(1) Safety assessment and assurance of changes to the functional system p. 164-165

comment	580	comment by: Frasier Loredana
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	<p>(b) (2) The meaning of the term system in this sentence should be further explained. We propose the inclusion of NB: System Justification To avoid misinterpretation.</p>
response	<p>Accepted</p> <p>'System' should be read as 'functional system'. The text has been updated. The same change has been introduced in the safety support assessment part.</p>
comment	<p>899 comment by: UK CAA</p>
	<p>Page No: 165 Paragraph No: GM1 ATS.OR.205(b)(1) Safety assessment and assurance of changes to the functional system IDENTIFYING THE SCOPE - GENERAL Comment: The terms 'impacted' and 'affected' are used, but the difference is unclear. Additionally, the modifiers 'directly' and 'indirectly' are used, but the difference is unclear. In (2), the adjective 'directly' is used with 'affected' and 'impacted', but the means of affect or impact is not defined. Consequently it is difficult to distinguish this from 'indirectly' impacting as discussed in (3). The terms need to be defined, if the distinction is important, but there does not seem to be any advantage in this distinction we suggest that this section could be simplified by only using one term. Justification: Clarity.</p>
response	<p>Accepted</p> <p>'Affected' and 'impacted' are synonymous. The text has been amended and aligned using one single term: 'affected'.</p>
comment	<p>900 comment by: UK CAA</p>
	<p>Page No: 165 Paragraph No: GM1 ATS.OR.205(b)(1) Safety support assessment and assurance of changes to the functional system IDENTIFYING THE SCOPE – GENERAL (d) Comment: It is not clear to what 'the interface' refers. The service is specified at the point of delivery, the 'using' system connects to this. An 'interface through which the service will be delivered' would be an intervening system. It is also unclear that the ATS is in fact normally delivered to other service providers, unless the pilot is considered a service provider. Justification: Clarity.</p>



response Partially accepted

The service is delivered through certain interface, which is the point where two systems meet and interact. It is not in itself a separate system, although you could think about it in that sense but it seems not useful here.

The second part of the comment is correct. The service is delivered to the pilot or aircraft. The 'user' is used instead.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM2 ATS.OR.205(b)(1) Safety assessment and assurance of changes to the functional system p. 165

comment 216

comment by: *NATS National Air Traffic Services Limited*

GM2 ATS.OR.205(b)(1)
Page 165

The relationship to SESAR and in particular the SESAR Safety Reference Material is not mentioned in the NPA, however ED-78A is explicitly referenced in GM2 ATS.OR.205(b)(1). The reference to GM1 ATS.OR.205(b)(1)(iii) is not found.

Proposal: Please clarify how this NPA intends to address the methodology in the Safety Reference Material proposed by SESAR

response Noted

The intention of this NPA is not judge to any method to assess safety. The main objective is to propose clear criteria to evaluate the output of a safety assessment. The reference of ED-78A is mentioned here as useful resource to identify interactions in multi-actor changes. This is not a recognition of this or any other method.

The reference to GM is amended to the new structure of guidance.

comment 1286

comment by: *DSNA*

Actual text only refers to ED-78A as a "guidance to cooperatively identify the scope of multi-actor changes"

The Eurocontrol "Safety Assessment Methodology V2", which is framework, a toolbox, containing methods and techniques to address the requirements of initial ESARR4, is also a guidance widely used by ANSPs for safety assessment of their changes thus addressing EC 1035/2011, and taking into account the different components of ATM functional system,



	ground	and	airborn.
	Proposed text : " EUROCAE ED-78A , <i>as well as Eurocontrol Safety Assessment Methodology V2.1</i> may be used as a guidance to cooperatively identify the scope of multi-actor changes"		
response	<p>Not accepted</p> <p>It is not clear that SAM provides guidance on this particular issue (cooperatively identify the scope of multi-actor changes). The commentator does not provide details. As a general method, SAM is included in the list of methods that is maintained by NLR and referred to in the guidance.</p>		
comment	1292	comment by: <i>EUROCONTROL</i>	
	<p>AMC/GM to ANNEX IV SUBPART A GM2 ATS.OR.205(b)(1) - Page 165</p> <p>EUROCONTROL raises a point.</p> <p>EAM 4 / AMC document from the safety Regulation Commission dated 2009 made clear that EUROCAE ED78A did not meet a non-negligible number of ESARR4 mandatory provisions. Considering the limited evolutions over years (succession of transpositions) that ultimately led to the current (EU) No 1035/2011, it is quite certain that ED78A is still not an AMC with current applicable regulatory requirements. It was well acknowledged by EUROCAE WG91 report (dated 2012), where numerous recommendations were made for the evolution of ED78A, thereby acknowledging that massive developments in the areas of safety assessment and oversight would need to be reflected in an evolution of ED78A.</p> <p>Consequently, it is hard to understand how ED78A can be mentioned in GM2 ATS.OR.205(b)(1).</p> <p>It is suggested to remove completely the reference to ED78A.</p>		
response	<p>Not accepted</p> <p>The reference to ED-78A is specific to help in cooperatively identifying the scope in multi-actor changes. This is not recognition of ED-78A as AMC for this Regulation, not even for any provision of the Regulation. In GM2 ATS.OR.205(b), we mention a database of methods that contains many methods and that is not a recognition of any of them as AMC. There is not analysis or judgement on any of them. Some have merits for specific purposes and drawbacks depending on their use. In this particular case, the use is to help in the identification of interactions between multiple actors.</p>		



(4) Safety assessment and assurance of changes to the functional system

comment	11	comment by: AIRBUS
	(d) Planning for degraded modes Fail/safe design Airbus proposes to change the title of the section (d) by "Fail/safe design"	
response	Not accepted Since no reason for the change is given by the commentator, it is difficult to understand the need for the change. The title reflects the terms used in the IR.	
comment	12	comment by: AIRBUS
	(g) Preventive maintenance Airbus proposes to add the following sentence at the end of (g) (1): "The same concept could also be applied to software elements (e.g. performance of a network has to be monitored and redesign is necessary when the performance becomes insufficient). The behaviour would need to be monitored.	
response	Not accepted This does not seem to be preventive maintenance. Monitoring in order to discover inadequacies in performance is covered by ATM/ANS.OR.B.005(d). Were such underperformance to be detected, a change would have to be instigated. This is not the meaning of 'Planned degraded modes' of operation.	
comment	901	comment by: UK CAA
	<p>Page No: 165</p> <p>Paragraph No: GM2 ATS.OR.205(b)(1), (2) & (4) Safety assessment and assurance of changes to the functional system DEGRADED MODES OF OPERATION (a)</p> <p>Comment: The first sentence is unclear.</p> <p>It is not clear to the UK CAA as to why 'training for personnel' is specified here, and asks whether it just a means for modifying a person element, analogous to changing a resistor on a production line?</p> <p>In addition, '(software and hardware)' are also specifically mentioned They are not highlighted in this way in GM1 ATM/ANS.OR.C.005(b)(1) & (2) on page 146.</p> <p>The sentence seems to contain an element of tautology: "The following guidance deals with the safety support assessment associated with degraded modes of operation, it, therefore, ... includes ... the degraded modes of operation of the services delivered by the functional</p>	



	<p>system.”</p> <p>We suggest reconsideration (and amendment as necessary of the text to address these concerns</p> <p>Justification: Clarity.</p>
response	<p>Partially accepted</p> <p>Please see the response to comment No 796.</p>
comment	<p>912 comment by: UK CAA</p>
	<p>Page No: 166</p> <p>Paragraph No: GM2 ATS.OR.205(b)(1), (2) & (4) Safety assessment and assurance of changes to the functional system DEGRADED MODES OF OPERATION (c) & (d).</p> <p>Comment: The issue in (c) (2) and (d) (3) gets a bit lost in these sections. The UK CAA is of the opinion that it is important to emphasise that all potential behaviour should be analysed and shown to be safe (have acceptable associated risk), not just desired behaviour. This includes the behaviour when there is a malfunction, when there is a planned degraded mode, and when a planned mitigation fails to mitigate some unacceptable behaviour, (unless this is not possible).</p> <p>Clause (d) in particular seems to lose this point amongst some lengthy text (d)(1) to (5) that seems to be intended to encourage the safety support service provider to analyse potential failures and mitigate their effect.</p> <p>Justification: Clarity.</p> <p>Proposed Text: Suggest a new clause between (b) and (c) to highlight the need for all the behaviour to be demonstrated to be safe, including that associated with degraded modes.</p>
response	<p>Partially accepted</p> <p>Please see the response to comment No 798.</p>
comment	<p>915 comment by: UK CAA</p>
	<p>Page No: 167</p> <p>Paragraph No: GM2 ATS.OR.205(b)(1), (2) & (4) Safety assessment and assurance of changes to the functional system DEGRADED MODES OF OPERATION (f)(2)</p> <p>Comment: In the phrase “the malfunction is detected and isolated”, the word ‘isolated’ is ambiguous. It initially seems most likely to mean that the cause of the malfunction has been identified, but later text suggests it is intended to mean that the element which is causing the malfunction has been removed (or similar) such that it no longer contributes to the functional system. The end of the sentence “the functional system, now available, is incomplete” suggests that the latter interpretation is intended.</p> <p>Whichever meaning is intended, the text needs revision for clarity.</p>



	<p>Justification: Clarity.</p>
response	<p>Accepted</p> <p>The text has been redrafted to aid clarity.</p>
comment	<p>919 comment by: UK CAA</p> <p>Page No: 169</p> <p>Paragraph No: GM2 ATS.OR.205(b)(1), (2) & (4) Safety assessment and assurance of changes to the functional system DEGRADED MODES OF OPERATION (i)(3)</p> <p>Comment: UK CAA suggests that it would be appropriate for the detection of unauthorised changes to be addressed in this clause regarding Maintenance of configuration: Unauthorised changes/adjustments/modifications/patches introduced (perhaps with good intent) by errant personnel, including software updates and configuration/parameter changes.</p> <p>Malicious modifications – vandalism, introduction of malware, etc.</p> <p>Justification: Clarity of scope.</p>
response	<p>Partially accepted</p> <p>Please see the response to comment No 815.</p>
comment	<p>988 comment by: DGAC/DSAC - french NSA</p> <p>Degraded modes generally also cover non-nominal case with failure not impacting the behavior of the service (a) or the level of service (b). It happens when the system has been designed with enough redundancy or when a back-up system has the same performance than the main system. A clear definition of what is a degraded mode is needed as a guidance. Do you make a difference in meanings between degraded mode and degraded mode of operations ? In that case, it should be explained clearer.</p> <ul style="list-style-type: none"> • paragraph (i) (2) : <p>If the configuration is changed, this is a change, not a degraded mode.</p>
response	<p>Not accepted</p> <p>(1) No distinction is made between degraded mode and degraded mode of operations. Definition is given in (b). This is not the same as that described by the commentator.</p> <p>(2) If the configuration changes, then the assurance case becomes invalid. This is a failure of</p>



a maintenance activity and is described as a degraded mode. This is explained in (i). The configuration may change unintentionally, or the behaviour of an element of the functional system may deviate from what is expected (then it requires a change), but before a change is introduced, the system may continue to work under a degraded mode.)

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM1 ATS.OR.205(b)(2) Safety assessment and assurance of changes to the functional system p. 169-170

comment 135 comment by: ENAIRE

It is included:

(vi) human performance, including restrictions due to fatigue and medical conditions...

In order to face this, more specific guidance/material/methods in human performance is needed. This additional material should be common for all ANSPs.

(2) Hazards introduced in the context

in which ATM/ANS functional system operates...

(ii) personal factors...

(iii) organisational factors...

Again, to systematically approach this, either a more specific material (what we understand is not easy at all) is needed or this should be removed.

response Not accepted

The Agency recognises the need of additional guidance on this aspect. However, at this stage, we can only highlight the need for it and the intention to complete the GM package. There are some pieces missing that need to be prioritised. Nevertheless, this is not a reason to eliminate the aspect from the guidance. The need is to complete it, not to hide the fact that those aspects are sources of hazards.

In any case, there are many literature and studies on human factors.

comment 350 comment by: ATCEUC - Air Traffic Controllers European Unions Coordination

GM1 ATS.OR.205(b)(2) Safety assessment and assurance of changes to the functional system

Training of personnel is clearly a way to identify and deal with hazards.

GM1 ATS.OR.205(b)(2)

(c) Methods to identify hazards

(1) The ATS provider may use a combination of tools and techniques, including functional



	<i>analysis, what if techniques, brain storm sessions, expert judgement, literature search (including accident and incident reports), queries of accident and incident databases in order to identify hazards, and will train its personnel accordingly.</i>
response	Partially accepted The training on these methods and techniques is already included, but in a different paragraph.
comment	1287 comment by: <i>European Transport Workers Federation - ETF</i> In order to maintain a high standard of competence and in order to ensure a high level of performance, appropriate training is required. ETF proposes to move the content of the GM1 ATS.OR.205(b)(2) to AMC, to ensure that when hazards are identified they are done so by appropriately trained personnel.
response	Not accepted The text reflects the need for training, but there is no need to move to AMC. In addition, it is not a means to comply with the IR text. Anyway, there are already IR requirements for the ATS to appropriately train their personnel, and more explicit reference has been added in GM.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM1 ATS.OR.205(b)(3) Safety p. 170-171 assessment and assurance of changes to the functional system

comment	136 comment by: <i>ENAIRE</i> The introduction of proxy concept is a positive evolution, but additional explanation is needed in order to be able to apply this concept.
response	Noted This is the first step. In the future, the need to add additional guidance will be considered and evaluated. The commentator does not explain what is missing in the provided material, so it is difficult to identify what is needed. Anyway, the Agency provides high-level guidance and not all the details in this material.
comment	146 comment by: <i>EUROCONTROL Safety Team</i>



response	<p>Point (e) on page 171 Reference should be to GM2 ATS.OR.205(b)4 on page 187.</p> <p>Accepted</p> <p>The reference is being amended to refer to the right GM containing examples of proxies.</p>
comment	<p>217 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>GM1 ATS.OR.205(b)(3) Page 171</p> <p>At point (e), GM2 ATS.OR.205(b) is referred to, however this GM is to do with safety assessment methods and not proxies. Understanding the use of proxies is vital so please correct the reference or provide the details on the use of proxies.</p>
response	<p>Accepted</p> <p>The reference is being amended to refer to the right GM containing examples of proxies.</p>
comment	<p>409 comment by: <i>EUROCONTROL</i></p> <p>GM1 ATS.OR.205(b)(3) Safety assessment and assurance of changes to the functional system - Page 170</p> <p>EUROCONTROL recommends bringing more clarity to the notion of 'proxies for safety risks'. At Article (e) of page 171, reference should be to GM2 ATS.OR.205(b)4 on page 187.</p>
response	<p>Accepted</p> <p>The reference is being amended to refer to the right GM containing examples of proxies.</p> <p>The text has been restructured in a way that it is believed that is clearer now. All AMC and GM related to proxies are given in ATS.OR.210. Examples remain linked to this requirement ATS.OR.205.</p>
comment	<p>922 comment by: <i>UK CAA</i></p> <p>Page No: 170 Paragraph No: GM1 ATS.OR.205(b)(3) Safety assessment and assurance of changes to the functional system SAFETY CRITERIA IN TERMS OF PROXIES FOR SAFETY RISKS (b) Comment: “the difficulties” mentioned in the second sentence are not introduced, making the logic of the paragraph difficult to follow. Justification: Clarity.</p>



response	<p>Proposed Text: Suggest change “the difficulties’ to ‘the size of the extra effort’</p> <p>Accepted</p> <p>The text has been amended.</p>
comment	<p>924 comment by: UK CAA</p> <p>Page No: 171</p> <p>Paragraph No: GM1 ATS.OR.205(b)(3) Safety assessment and assurance of changes to the functional system SAFETY CRITERIA IN TERMS OF PROXIES FOR SAFETY RISKS (d)</p> <p>Comment: The point being made in the sentence “However, the level of the proxy should be measurable” is unclear. Perhaps it is suggesting that the disadvantage (of using proxies) in the first sentence is somewhat compensated for (philosophically) by the increased confidence that can be had in measured rates of proxies, compared to the confidence in overall risk predictions.</p> <p>Justification: Clarity.</p>
response	<p>Accepted</p> <p>The text has been amended to emphasise that the proxy has to be measurable, which was the intent of the sentence.</p> <p>The advantage mentioned by the commentator is one possibility (not always), but it may not be the only one (see point c in the same GM).</p>
comment	<p>1025 comment by: DGAC/DSAC - french NSA</p> <p>The definition of proxy must be introduced in IR or in AMC, not only at the level of a GM.</p> <p>Some examples of proxy seems difficult to be considered as measurable, for example reduced vigilance and distraction of controller's attention.</p> <p>This NPA clearly supports the introduction of proxy in the safety assessment. We fear that it could be consider as an easy alternative to the classic safety analysis methodology (hazard identification and so on). Consequently, in line with our previous comment to ATS/OR.205, we strongly suggest to add, at the level of this GM or higher if deemed more adequate, an obligation for the ATSP to give a rationale for choosing proxy (for example at this end at this paragraph b). This will give CA a means to question this choice. Proposition "Proxies might be preferred ... and increase the quality of the risk analysis. In any case, the rationale for choosing proxy in the safety assessment must be provided". Refer also to our comment to ATS.OR.210.</p>



response	<p>Not accepted</p> <p>A definition cannot be given in the AMC material. It is either provided in the IR (Annex I) when the term/concept is used in the IR, or in GM, when the term is used in AMC.</p> <p>The commentator is reminded that a definition is not a requirement.</p> <p>The proxy does not exclude the need to identify hazards, set safety criteria, assess risks, etc. It only allows the use of different metrics (i.e. proxies) when the calculation of risks is not possible or too cumbersome. Pros and cons of the use of proxies are explained in the GM, and the criteria for valid proxies are contained clearly in AMC2 ATS.OR.210(a). The ATS providers need to show compliance with that AMC and therefore that information is always available to the CA.</p>
comment	<p>1128 comment by: <i>Belgocontrol</i></p> <p>Point (e) on page 171 Wrong reference: should be to GM2 ATS.OR.205(b)4 on page 187 instead of GM2 ATS.OR.205(b).</p>
response	<p>Accepted</p> <p>The reference has been amended to refer to the right GM containing examples of proxies.</p>

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM1 ATS.OR.205.(b)4 Safety assessment and assurance of changes to the functional system p. 171-187

comment	<p>13 comment by: <i>AIRBUS</i></p> <p>From a general point of view, this section does not provide guidance for a uniform interpretation and application of the corresponding IR text. In fact, it opens the doors for the development and the use of different methods for the risk analysis that could make the safety support activity by aviation undertakings even more complex.</p>
response	<p>Noted</p> <p>Not knowing what the main concern of the commentator is, it is difficult to fix it. The size of GM has been reduced and most of the text has been moved to other section. Hopefully, the current version provides more useful guidance.</p>



comment	14	comment by: AIRBUS
	For the figure page 172, please remove bbb in the title.	
response	Accepted	
	The title has been updated.	

comment	15	comment by: AIRBUS
	(d) Severity schemes Title As this scheme is related with safety, the title should be "Safety effect on operations".	
	(1) Severity schemes resulting in a single value of risk (i) The text states that this scheme is in contrast to the severity classification scheme used for aircraft certification, Airbus proposes to replace this statement by the following: "This scheme has been designed to be compatible with the aircraft certification, with the following aircraft equivalent classification: Class 1: CAT, Class 2: HAZ, Class 3: MAJ, Class 4: MIN, Class 5: NSE".	
	(2) Background to multiple risk value severity schemes (i) The link between severity class and safety objective is not established. Please clarify.	
response	Not accepted	
	(1) The common term for such schemes is 'severity schemes'. In this case, the severity of the effects are related to harm to humans. The severity scheme of (1) is not compatible with aircraft certification since the HAZ and MAJ categories admit to cause harm to humans whereas classes 2 & 3 of the scheme of (1) do not.	
	(2) The comment implies there should be a link between a severity class and a safety objective. There is no such link intended.	

comment	137	comment by: ENAIRE
	The introduction of proxy concept is a positive evolution, but additional explanation is needed in order to be able to apply this concept.	
response	Noted	
	This is the first step. In the future, the need to add additional guidance will be considered and evaluated. The commentator does not explain what is missing in the provided material, so it is difficult to identify what is needed. Anyway, the Agency provides high-level guidance	



and not all the details in this material.

comment 138

comment by: *ENAIRE*

We cannot accept a severity scheme based on fatalities.

response Not accepted

The severity scheme is based on the harmful effects on humans, being fatalities the worst effect possible. The comment is not supported by any rationale as why this is not acceptable.

comment 147

comment by: *EUROCONTROL Safety Team*

Unnumbered figure “taxonomy of safety” on Page 172 and
Unnumbered figure “full cause / hazard / accident model” on Page 175
Suggest to remove these figures because as they do not foresee that:

1. Mitigation could work well and lead to “no safety effect”,
2. Mitigation could fail and lead to an “incident”,
3. “incidents” could be “harmful effect”; accidents are a restrictive set of effects,
4. There are so few accidents in ATM that it looks very counterproductive to look at “accidents” only for effect of hazards.

response Partially accepted

Numbering references for the figures have been added. However, the figures have not been removed.

The comment implies that because accidents are so rare, incidents should be used in risk analysis and evaluation (ATS.OR.205(b)(3) & (4)).

One of the purposes of the safety assessment of changes is to predict the risk of introducing a change. Risk relates to the harmful effects of events induced by hazards. These are accidents for the purposes of a safety analysis as an incident does not cause harm to humans.

The fact that accidents are rare is not relevant to the risk analysis. It simply means that the risks should be small — this is desirable.

As pointed out in the GM ((g)(1)), accidents and incidents do not use the same scale to measure severity and so cannot be combined in a single measure of risk.

This is not to say that incident analysis is not useful. The commentators correctly point out that incidents occur more frequently than accidents and can give useful information on safety. This has already been accepted and is a fundamental part of this GM — see (g) where it is used in relation to safety assessment and assurance is explained fully.



With regard to the specific comments about the diagram of the taxonomy of safety:

By definition, once a service level hazard has occurred, all events are incidents. This is explained in Note 1 to (c)(4). There is no sense in which a mitigation that works (whether well or less well) can effectively result in an event that appears to suggest that the hazard did not occur.

If mitigation works, then progress towards an accident is halted and an incident happens instead. If the mitigation fails, then progress towards an accident continues. This is explained in (c)(4)

The diagram shows only one mitigation between the hazard and the accident, but in real life there will be many mitigations and a failure of mitigation means all mitigations failed.

Incidents are not considered harmful in safety terms because they cause no harm to humans. They may be levels of some kind of harm associated with different incidents but these would have to be treated (measured) on a different scale.

comment 182

comment by: EUROCONTROL Safety Team

Page 176 (d) Severity schemes

1. An ANSP cannot assess how many fatalities there could be in an aircraft accident.
2. A low speed TWY accident could still lead to multiple fatalities.
3. From the ANSP's point of view an accident involving one fatality is as bad as one involving 500. Consequently the number of fatalities is immaterial.
4. For harmonisation (as part of SES) the Severity Classification Scheme should be part of the implementing rule. Recognising that the existing one is sometimes inappropriate should lead to the formulation of better one(s) not to its removal.

response Not accepted

With regard to the ability of ATSP to differentiate between accidents, please see the response to comment No 182.

The argument given here suggests that the ANSP does not accept a risk-based approach. However, this has been required since ESARR 4.

comment 183

comment by: EUROCONTROL Safety Team

Page 187 (11)

The practice is that the ATM system needs be demonstrated as being "safe" without safety nets. The reference to STCA hints the contrary. It is important to clearly define and explain how Safety Nets shall be considered.

response Not accepted

Ground-based safety nets are part of the functional system and may themselves introduce



new hazards or modifying existing hazards; therefore, the implementation of them, or their change, are subject to assessment of changes, i.e. hazard analysis, risk assessment and mitigation.

Whilst this practice may have been recommended in the early days of ESARR 4, the practice to demonstrate the ATM system is safe without the use of safety net, and then add the safety net without risk assessment, was debunked in the latest version of EUROCONTROL SRC Policy Doc 2 as modified by SRC28.06 – Item 6.3 dated 15/03/07.

Safety nets are a valuable means of improving safety and should be treated in the same way as any other mitigation. Consequently, there is no need for special consideration or for additional GM.

comment

218

comment by: *NATS National Air Traffic Services Limited***GM1 ATS.OR.205(b)4****Page 171**

At point (a) it is not necessary to repeat definitions already in Annex I. It is not appropriate to argue a different meaning for safety risk as opposed to the risk definition in this GM. If such a distinction is to be made better to amend the definitions. It is misleading to suggest that the use of risk is synonymous with safety risk. If safety risk is meant then safety risk should be defined and used. Burying this subtle distinction in GM is duplicitous.

Whilst it could be inferred it is not always the case that the use of risk necessarily means safety risk, e.g. security risk assessment (ATM/ANS.OR.D.010 Security management).

The underlined text above the figure does not appear to be a correct reference.

Point (b)(5) refers to the risk of the potential harmful effects. Given that risk is a combination of overall probability, or frequency of occurrence of a harmful effect induced by a hazard and the severity of that effect then where is the EASA guidance on establishing probabilities such that risk can be determined? It is noted that there is copious guidance on severity but none on probabilities. Without this guidance there is a considerable shortfall that will impact the standardised application of risk across all service providers and would appear contrary EASA's desire (as detailed in the RIA) for uniformity.

Point (d)(1)(i) -only severity 1 can be used in safety risk analysis and evaluation because only events classified as severity class 1 can possibly cause harm to humans. The text goes on to say that risk associated with a mid-air collision between two airliners is higher than between two small aircraft. This may not be true (as a commercial airliner may carry very few passengers) but it really misses the point that ANSPs do not provide a differential service based on the size of aircraft.

Point (d)(4) – the examples of severity schemes are, for the most part, unhelpful. For the



	<p>majority of ATS providers the worst case scenario would have to be assumed (meaning severity class 1) as the CAT under their control have (potentially, but unknown to the ATS provider) a significant number of passengers who could be placed at harm; not to mention the potential additional injuries on the ground. Even for small ATS providers whose aerodromes may limit the size of aircraft and hence potential fatalities the potential ground based fatalities may well constrain the severity to class 1. Additionally such ATS providers would effectively limit the expansion of the aerodrome for larger aircraft</p>
response	<p>Partially accepted</p> <p>Paragraphs 1 and 2: Not accepted. The information relating to ATS, of which this is a part, is contained in the SMS section of the IR. Consequently, the risk being described here is intended to be a safety risk. It is accepted that there are many forms of risk but these others are not of concern to an SMS. The reason for the definition guidance is to make that clear.</p> <p>The reference of the figure has been amended.</p> <p>Comment on point (b)(5) is partially accepted. It is true that probability has not been dealt with in as much depth as severity. This is because it was felt to be a topic that was reasonably well understood. Furthermore, sufficient detailed guidance already existed.</p> <p>However, it may be appropriate to provide some high-level guidance since the same rules apply to probability categories as do to severity categories, besides the fact that they are dealing with different properties.</p> <p>The need for GM will be re-assessed in the future and may lead to a future update.</p> <p>Comments on points (d)(1)(i) and (d)(4) are not accepted. Please see the response to comment No 182.</p>
comment	<p>341 comment by: <i>BAF-M.Jancokova</i></p> <p>Paragraph (g)(1): The term "accident" must be clarified as it seems to be used in a non-consistent way in this NPA. If accidents are only associated with harm to people then one could ask for the category of an event where an aircraft is damaged without people being killed or injured. Is this not considered an accident any more?</p>
response	<p>Not accepted</p> <p>There is no intended inconsistency.</p> <p>In this GM, an accident is treated as a terminal event. It may or may not harm people. The severity scale is used to indicate the potential amount of harm caused by an accident. This represents a scalar whose lower value can be zero (in the case that an accident cannot cause harm to people then the severity would be zero, e.g. two UAS flying in restricted airspace in</p>



the desert with no possibility to damage people on the ground.

Although not described in detail, each severity table in (d) could have a final row like the the one in table in (d)(1) which is used when there is no harm caused, i.e. it represents the scalar value of zero.

comment 366

comment by: *Finavia*

Severity classification should not be divided in too many sub-classes. The need for review is decided based on the highest severity class anyway.

response Not accepted

The need for review has changed with this proposal. It is no longer based on the severity class only (see ATM/ANS.AR.C.035 (b)).

No reason is given for the assertion. It is correct in that it is unlikely that a valid severity scale can be made with many categories of harm.

comment 457

comment by: *NAV Portugal E.P.E*

GM1 ATS.OR.205.(b)4

Knowing that, fortunately, accidents are very rare in aviation, especially with the contribution of ATC, NAV Portugal does not agree that the severity scheme should only address the magnitude of accidents. Degradations of the service (incidents), which could lead to accidents if other barriers also failed, should also be considered. For example, the wrong identification of a flight could lead to an accident if all the other barriers fail. Using the provided guidance material, how would one classify this hazard? How can the ANSP “guess” the number of fatalities?

response Noted

Hazards are not classified, the severity of the effects (accidents) are. For the argument that severity is based on accidents, please refer to the response to comment No 147.

comment 582

comment by: *Frasie Loredana*

Review the text to eliminate the provisions related to the assignment of a harmful effect to a severity category.

Justification

The assignment of a harmful effect to a severity category is irrelevant in the context of safety assessment of changes to ATM/ANS functional system.



The assignment of a harmful effect to a severity category brings no benefit to the ATM system.

This is mostly associated with accidents and in this case the ATM system fails. The ATS provider cannot plan for an accident which results in injuries only. Furthermore, this is unacceptable. This evaluation could be subjective.

We do not agree that the severity of 10 fatalities equals 101 minor injuries. We believe that this cannot be compared.

response **Not accepted**

Since the definition of risk includes severity of a 'harmful effect', it would be impossible to describe a severity scheme without reference to harmful effects.

With regard to the ability of ATSP to differentiate between accidents, please see the response to comment No 182. There is no compulsion to create an equivalence scheme. It has been found to be useful in other transport domains and hence it is explained in the GM.

comment 736

comment by: *DFS Deutsche Flugsicherung GmbH*

(a): Does this explanation mean that - although many definitions exist e.g. for the term "safety" - the Oxford dictionary was used to modify/create the definition for "safety risk"? And it is based on the definition of "harm", which was also taken out of the Oxford dictionary?

Without further information, this looks rather strange and not very "scientific".

Does that also mean that:

- a "safety risk" is not tied to a hazard anymore as in CRD to NPA 2013-08?
- the term "risk" is used as a synonym for "safety risk"? So, the current definition would not be used anymore?
- the definition of "risk" from CRD to NPA 2013-08 is changed in a GM?!

Is this still compliant with ED-125 chapter 3.1?

This is confusing, wrong and unnecessary.

We suggest to remove GM1 ATS.OR.205 (b) 4 part (a) and only leave the figure on page 172 and the text afterwards.

Reference to high level comment "c.i"

response **Not accepted**



(1) No, the OED definition is intended to clarify the meaning of risk. Most definitions are similar. However, there does seem to be confusion over the meaning of risk and safety risk which is why this section has been included.

(2) A safety risk is always related to one or more hazards. It is not 'tied' to a single hazard — see section (c)(2).

(3) The GM is simply pointing out that there are many types of risk. Safety risk is only one of them. However, since this part of the IR deals with safety, it is easier to simply use 'risk' as a synonym for 'safety risk'. This only works in Annex IV. In other Annexes, if risk is used, then the specific type of risk should be identified.

(4) The definition of risk in Annex 1 is a general definition of risk. It is true for the whole IR. However, this is not useful as, for any use of risk, the specific type of risk should be described. In Annex IV, where safety is paramount, the definition of risk used is that of a safety risk, i.e. where the harmful effect is that of the injury or death of a human being.

(5) Section 3.1 in ED-125 does not have a definition of safety risk, so it is assumed the same concept applies.

(6) It is not clear what is confusing and unnecessary to the commentator. As stated above, this section clarifies the meaning of safety risk and is appropriate for Annex IV.

comment 737

comment by: *DFS Deutsche Flugsicherung GmbH*

“(2)” “Note that causes are also hazards”

This sentence is wrong and in contradiction to the figure above. Therefore, we suggest to rephrase (e.g. "causes" and "hazards" are "events") or remove it.

Reference to high level comment "c.v"

response Not accepted

The comment does not provide a complete quote, which is 'Note that causes are also hazards but are called causes here to differentiate them from the hazard of interest (Service Level Hazard - Hn).'

The note is correct. It simply points out that things called hazards (not necessarily events) can occur at any level in a system. It is just convenient to call 'cause' the hazards to the left



of the service level hazard and ‘failures in mitigation’ the hazards to the right.

comment 738

comment by: *DFS Deutsche Flugsicherung GmbH*

(d) (1) (ii): What are “harmful events”?! Why is a new term introduced?

This is confusing, please add explanation.

GM1 ATS.OR.205.(b) 4 (page 171-187) rather long and complicated; it might help to divide it into several GM.

response

Partially accepted

There is no intention of introducing a new term. The use of ‘harmful event’ is to distinguish the harm (the effect on a person) from the accident (the event) that causes the effect.

Explanatory text has been added to make this clearer.

The GM has been divided up. Section (a) is now part of the definition Section 1.4 of Appendix I to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities, Sections (b) and (f) remain, while Sections (c) (d) and (g) have been moved to Section 5.2.1 of the same Appendix.

comment 739

comment by: *DFS Deutsche Flugsicherung GmbH*

d (2) (ii) "risk profile" : this is not a bad concept, but in this NPA we are looking at risk assessment of changes; a complete assessment of an service provider or one of its units is not part of this regulation! Therefore the resulting risk profile will be full of holes.

We suggest to remove GM1 ATS.OR.205.(b) 4 - (2) (ii), because this could lead to interpretations that can become infeasible demands for service providers.

Reference to high level comment "c.v"

response

Not accepted

The concept of a risk profile is not limited to the risk profile of a unit, although it can be



included. In this GM, the concept can be taken to cover just the risk profile of the changed system.

It is not clear why the commentator believes this would be 'full of holes'. Knowing the profile of the changed system does not give any information about the profile of the whole. Nonetheless, the profile of the changed part of the system would not be incomplete and would consequently be useful in the way outlined in (d)(2).

comment

740

comment by: *DFS Deutsche Flugsicherung GmbH*

d (3) (iii): since we are looking into the future in safety assessments - we are assessing changes that did not go operational yet - it should be considered, if it makes sense to distinguish too many details, e. g. if an injury would be life shortening.

If we would discuss details like this in our workshops, the operational experts might not take us serious anymore.

We suggest to remove this GM1 ATS.OR.205.(b) 4- (3) (iii).
Reference to high level comment "c.v"

response

Not accepted

The premise does not seem to relate to the comment. Furthermore, there is no recommendation to go to any particular level of detail, besides that which is appropriate for the change being considered. The GM describes a set of possible attributes for a severity scheme because a universal scheme has not been recommended. These attributes will be more or less relevant depending on the circumstances of the change, and the service provider can use them to construct a severity scheme that best matches its own context of operation.

comment

741

comment by: *DFS Deutsche Flugsicherung GmbH*

(g): It should be mentioned that in reality accidents and incidents do not necessarily develop sequentially (in a timeline) as suggested by the barrier model and that barriers might also occur in a different order in real incidents and accidents (e.g. the pilot can resolve a situation "earlier" than shown in the figure on page 185).



We suggest to add this explanation to this document.
Reference to high level comment "c.v"

response **Accepted**

A footnote has been added.

comment **742**

comment by: *DFS Deutsche Flugsicherung GmbH*

(g)

Delete (9) ; doesn't help, but confuses
Reference to high level comment "c.v"

response **Not accepted**

It is neither clear what aspect of the paragraph is confusing nor why it does not help.

It is pointing out that while it may be normal for the incident rates to be balanced, i.e. form a pyramid, in some cases a mitigation might be strengthened and so unbalance the incident rates. Re-balancing should not be an overriding consideration, since the safety of the system has in fact improved.

comment **931**

comment by: *UK CAA*

Page No: 172

Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (b)(3)

Comment: The models on pages 172 to 175 do not generally accommodate modelling 'a combination of hazards' leading to a single accident, or to different 'Harmful effects' from a single accident according to combinations of hazards.

The UK CAA suggests that this could be addressed by an analysis (perhaps an event tree or outcome table) that defines the 'Causes' 'Harmful effect' part of the diagram. An alternative way to address this may be by defining each combination of hazards as a single compound hazard.

In any case, the GM here is not sufficient.

Justification: Completeness of guidance.



response **Not accepted**

It is not clear which models the commentator is referring to.

The diagrams on pages 173 and 174 clearly show combinations of causes leading to a single hazard and a combination of hazards leading to a single accident.

Different harmful effects from a single hazard are also shown. They are shown as different accidents stemming from the same hazard.

(c)(3) points out that the diagram on page 174 is a realistic diagram for any reasonably complex system. It then goes on to say that the Bow Tie model, used later, is a simplification and is used to aid thinking and communication. It is not intended to represent a complete system.

(c)(3) also states that the Bow Tie provides a simplified view of what could be represented as a conjunction of fault trees and event trees.

On this basis, it is not clear what the comment in the second paragraph is about. GM will never be complete and this GM can only give a 'flavour' of what risk analysis is. It is difficult to respond to the final point as it is not specific.

comment 932 comment by: UK CAA

Page No: 173
Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (c)(2)
Comment: "If the procedure is flawed, i.e. it creates a hazard, ..."
 This seems to suggest that a flaw in a procedure necessarily creates a hazard. Unless 'flaw' is defined in a manner that makes this statement tautological, this statement does not seem likely to be true.
Justification: Clarity/Accuracy.
Proposed Text: Suggest deletion of this text

response **Partially accepted**

While it is not strictly true that all flaws in a procedure will inevitably lead to a service level hazard, it is likely to be the case for most of them.

The text has been altered but not deleted as it is felt to provide a useful example.

comment 935 comment by: UK CAA

Page No: 173



	<p>Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (c)(2)</p> <p>Comment: "... taxiing a/c over many different routes. ... each transition over a different route."</p> <p>There is insufficient consistency of terminology for this text to be widely understood, and 'transition' is more widely used for change implementation than aircraft movement, where the term 'transiting' is more widely accepted.</p> <p>It is also believed that the spelling 'taxiing' is more widely accepted.</p> <p>Justification: Clarity.</p> <p>Proposed Text: "... taxiing aircraft transiting over many different routes ... each transit over a different route."</p>
response	<p>Partially accepted</p> <p>The second part of the proposal has been adopted and the spelling of 'taxiing' changed.</p> <p>The first sentence is clear enough without the proposed addition.</p>
comment	<p>937 comment by: UK CAA</p> <p>Page No: 174</p> <p>Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (c)(3)</p> <p>Comment: "The Bow Tie Model represents an appropriate way of doing this."</p> <p>It is believed that this model has some limitations, and so to say that it is 'appropriate' without qualification seems inappropriate. E.g. (5) on page 175.</p> <p>Justification: Clarity.</p>
response	<p>Not accepted</p> <p>The text states that the Bow Tie model is an appropriate way of working on a single hazard at a time. The text makes it clear that it has limitations and suggests ways round these.</p>
comment	<p>939 comment by: UK CAA</p> <p>Page No: 175</p> <p>Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (c)(4)</p> <p>Comment: UK CAA suggests adding an additional note regarding mitigations that change the resulting accident, perhaps reducing severity.</p> <p>Whilst proposing the text below we are aware that it could be improved upon, especially the last sentence.</p> <p>Justification: Clarity and usefulness of guidance.</p>



	<p>Proposed Text: “Note 3: Mitigations may also cause the accident trajectory to divert towards a different accident. Whereas an event tree shows these as diverging end trajectories from a single initial trajectory, a Bow Tie presents this as two separate accident trajectories between a hazard and the end accidents. Therefore this discussion does not address mitigations that result in a different accident, perhaps of reduced severity.”</p>
response	<p>Not accepted</p> <p>The commentator rightly points out that a Bow Tie model represents a change in accident trajectory, due to a mitigation working differently in different circumstances, as two accident trajectories. These different circumstances are described for each trajectory.</p> <p>The intent behind the proposed note is actually covered in Note 2.</p>
comment	<p>941 comment by: UK CAA</p> <p>Page No: 175 Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (c)(4) Comment: The figure shows M1 to M4 appearing on both the left-hand causal side and on the right-hand consequence side of the hazard H1. The UK CAA assumes this is an error, but seeks Agency clarification as to whether this is the case or not. If it is not, the rationale behind this is requested. Justification: Clarity/ Accuracy.</p>
response	<p>Accepted</p> <p>The diagram represents different mitigations in all places. The apparent re-use of mitigations is not intended and has been corrected.</p>
comment	<p>942 comment by: UK CAA</p> <p>Page No: 175 Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (c)(5) Comment: The level of guidance given here is not as detailed as the other guidance, as it points out a complication without proposing how the situation is modelled. Justification: Completeness / consistency of guidance.</p>
response	<p>Not accepted</p> <p>The complications are addressed, as described in (5) by common cause and common mode analyses and as described in (3) by the use of fault trees and event trees.</p>



There are many methods that could be used and the GM does not propose specific methods.

The reader is also warned, a number of times, that the Bow Tie model is a useful but simplified representation. There is no recommendation to necessarily use the model. It is simply used in this GM as a means of explaining risk analysis.

comment 944

comment by: UK CAA

Page No: 176

Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (d)

Comment: Each severity scheme is described without any value judgement being placed upon it, or any statement of acceptability. We suggest that the guidance needs to explicitly state whether each scheme is acceptable, and whether this is true only under specific circumstances.

If certain schemes are depreciated or recommended, this needs to be stated clearly.

Justification: Clarity.

response Not accepted

The purpose of the GM is to describe a range of severity classification schemes and to explain the circumstances in which they may be used.

It is not the intention to put a value on individual schemes but just to point out their similarities and differences.

The Rulemaking Group could not decide upon a single scheme to recommend and so took the view that AMC would provide the criteria for the creation of a severity scheme and the GM provides some examples of schemes using different criteria.

comment 945

comment by: UK CAA

Page No: 176

Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (d)(1)(i)

Comment: "accident pre-cursor analysis" is a suggestive description, but needs to be clearly explained.

Justification: Clarity

response Partially accepted

Accident precursor analysis is self-explanatory. Section (g) expands on its use in validating risk analyses.



The footnote has been extended to include a forward reference to (g).

comment 963

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX IV SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS) GM1 ATS.OR.205(b)(4)	<p>(a): Definition of harm includes "<i>material damage</i>" and "<i>actual or potential ill effects or danger</i>".</p> <p>Why should we understand as a safety risk only the one that has a harmful effect on people?</p>	<p>Material damage and potential ill effects or danger should be considered when determining the severity of the effects of a hazardous event.</p> <p>The fact of only considering as relevant the hazards that result in accidents (material damage) goes against ICAO principles as enshrined in Annex 19 (the "<i>iceberg</i>" model).</p>

response Not accepted

An accident is an event. It does not have 'potential ill effects or danger' because the potential has already been realised.

A hazard is an event with the potential to cause harm. The harm is realised when an accident occurs. Consequently (and according to the definition), hazards that do not result in potential accidents are not hazards.

In any risk analysis, the hazards are identified and the risks then evaluated. This is not to say that the analysis of incidents is not useful — see 5.1.4 Validating risk analyses in Appendix I to GM1 to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities.

This does not go against the ICAO principles.

comment 964

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments	<p>(d): the new approach proposed for the use of the</p>	<p>The principal aim of severity classification matrix -at least in respect to the change</p>



<p>Section 3.2 <i>Draft AMC & GM</i> <i>(Draft EASA Decision)</i></p> <p>ANNEX IV <i>SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS)</i></p> <p>GM1 ATS.OR.205(b)4</p>	<p>severity classification matrices has no sense for the change management.</p> <p>A severity classification matrix should be kept, completed as needed and with the nuances that may be required, that provides a common reference for all ATS providers as it is current practice.</p>	<p>management- should be to provide a reference for the assessment of the level of effect that a particular change has in the safety of the system and not to make statistics or provide mechanisms for risk control and management, which seems more appropriate for the SMS in general.</p> <p>Having a common reference for what is considered more severe and what is considered less severe is fundamental when approaching complex risk management situations, as are the ones related to the world of aviation in which many actors are involved in each change.</p> <p>Depending on the level of severity assigned, the ANSPs will be forced to prove a higher or lower level of safety assurance thus having to implement particular mitigation measures in the cases where the severity be very high. It is thus not acceptable for a regulation intended to regulate change management that concepts like these be left undefined.</p> <p>We kindly refer EASA to our comment of Section 2.3 on the <i>Removal of Severity classification scheme from IR</i>.</p>
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response **Not accepted**

Change management requires a safety assessment, part of which is risk analysis and risk evaluation (ATS.OR.205(b)(3) and (4) respectively). Risk is composed of the probability of an event and the severity of the harm it causes. Consequently, if we are to assume that the severity of a harmful event can vary (otherwise why would we be doing a risk analysis?), then a severity classification scheme is needed. In developing the Opinion, the Rulemaking Group was of the opinion that a single severity scheme could not be established and so opted to provide AMC & GM for the creation of a small number of appropriate schemes, with the intention of rationalising them down to perhaps one or two when the industry has gained



sufficient experience.

Putting a scheme that cannot be used by everyone into law is counterproductive.

The concepts of the confidence needed in assuring higher levels of risk and in the use of mitigation is covered in other GM.

comment 965

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX IV SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS) GM1 ATS.OR.205(b)4</p>	<p><i>(d)(1) and (d)(3) and (d)(4):</i> in connection with the comment on <i>GM1 ATS.OR.205(b)4 (d)</i>, and taking into account that the aim of assigning a severity to a risk derived from the introduction of a change is to have available an assessment as objective and standard as possible of how this changes affects the safety of operations and set mitigations based on that assessment, any change that entails a serious damage or death to people (irrespective of the number of people affected) should be considered within the category of maximum severity as there are no different levels of tolerability based on the number of casualties.</p> <p>The mission of the CAs is that there be no accidents and, therefore, no casualty is tolerable.</p>	<p>We do not understand the need to differentiate between a mid-air collision between to big aircraft (with the loss of hundreds of people) and the case where just a little number of people (4, 5,...) die. In both accidents there are deaths and the purpose of the risk analysis should be to prevent both.</p> <p>We wonder what benefit can be derived from establishing different levels to an unacceptable situation.</p>

response **Noted**

The comment implies concern but does not state what the commentator wishes to be done.



The reason for risk analysis is explained in (d)(2).

The purpose of the risk analysis is twofold:

- (1) To establish if the risk posed by the change is acceptable; and
- (2) To optimise the use of resources towards reducing the risk where the risk posed by the change will not be acceptable without some mitigations.

With regard to the ability of ATSP to differentiate between accidents, please see the response to comment No 182.

comment 966

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.2 <i>Draft AMC & GM</i> <i>(Draft EASA Decision)</i> ANNEX IV SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES <i>(Part-ATS)</i> GM1 ATS.OR.205(b)4	<i>(d)(3):</i> Giving the possibility to use different severity classifications depending on the particular change that is under analysis makes it impossible to use the information gathered during the change management for statistical purposes as different references result in incomparable outcomes.	Would the analysis of the risks associated to the changes be based on a severity classification matrix common to all the changes, the use of the information gathered from the change management would indeed result in comparable outcomes.

response Not accepted

The point made is a valid one but does not seem relevant to this section.

There is no suggestion, in (d)(3), that different severity schemes should be developed for different changes, although the GM does not outlaw this notion either.

However, the advice given in (d)(2) supports the point being made here and so it is difficult



to see what change the commentator would wish for.

comment 967

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX IV SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS) GM1 ATS.OR.205(b)4	<i>(f)</i> : A common severity classification matrix should be established at least for all the European ATS service providers.	The implications fderived from the need for coordination required for each change, be it only for ATS providers, represent an added complexity to the process for the development and analysis of the change and could lead to quite serious delays in the implementation of that change. We kindly refer EASA to our comment of <i>Section 2.3</i> on the <i>Removal of Severity classification scheme from IR</i> and comment to GM1 ATM/ANS.OR.A.045(e)(3)(f) .

response Not accepted

As stated in the Explanatory Note, the Rulemaking Group was of the opinion that a single severity scheme could not be established and so opted to provide AMC & GM for the creation of a small number of appropriate schemes, with the intention of rationalising them down to perhaps one or two when the industry has gained sufficient experience.

Please see the response to comment No 924 for the comment on Section 2.3 referred to here.

comment 969

comment by: UK CAA

Page No: 177

Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (d)(1)(iii)



	<p>Comment: The UK CAA considers the term ‘reduced’ implies that this is a bad thing. If this is intentional, then the reasons should be clearly stated. Otherwise, perhaps the word ‘simplified’ should be used, as it seems to have positive consequences.</p> <p>Justification: Clarity.</p>
response	<p>Not accepted</p> <p>The purpose of the management of change is to perform a risk analysis on the change. To perform a probability analysis alone defeats the intention of the IR.</p> <p>It does not have positive consequences and can hardly be thought of as a simplification.</p>
comment	<p>970 comment by: UK CAA</p> <p>Page No: 177 Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (d)(2)(ii) Comment: The first paragraph appears to promote having a well-balanced risk profile as being desirable. This is not at all obvious. A risk profile may reflect a natural characteristic of the environment, the service or some other aspect, or even a characteristic of the severity scheme itself. Striving for a balanced profile could in fact be unnecessary or divert resources from more important matters. Justification: Clarity and accuracy.</p>
response	<p>Not accepted</p> <p>It does not promote what the commentator says. It gives it as an example ‘at the simplest level’. Other examples follow.</p> <p>The purpose is clearly stated: ‘to facilitate the management and control of risk.’</p> <p>The rationale for the balance is given in (d)(2)(ii). It neither says it should be achieved above all else, nor that it should be the primary goal.</p>
comment	<p>972 comment by: UK CAA</p> <p>Page No: 179 Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (d)(4) Footnotes 158 and 159 Comment: There are a number of issues with footnotes 158 and 159: 1) The mention of a skyscraper is unnecessary, and might be considered in bad taste given recent historical events. Consider changing to ‘terminal building’. 2) The i.e. appears to be an e.g.</p>



3) It appears that the sentence has some omitted text at the end of the first line, perhaps intending to say that the accident described causes a single fatality, and additionally the injuries mentioned

4) The tables use “Serious Injuries”, whereas the footnotes use “major injuries”. Consistent use of terminology would appear appropriate.

Justification: Clarity and consistency.

response

Partially accepted

1) ‘Skyscraper’ has been replaced by ‘building’.

2) This has been amended.

3) All passengers could be killed and it would still be a severity class 2 accident. The text has been clarified.

4) The terminology has been aligned.

comment

976

comment by: UK CAA

Page No: 180**Paragraph No:** GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (d)(5)(iii)**Justification:** Typographic error.**Proposed Text:** Change “a combination of (A) & (B)” to “a combination of (i) & (ii)”

response

Accepted

The text has been amended.

comment

980

comment by: UK CAA

Page No: 180 to 182**Paragraph No:** GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (d)(5)(iii)**Comment:** Whilst it is appreciated that a number of examples have been given, in consideration of the role of the NPA in cross-continent standardisation, The UK CAA suggests that it would be good to explicitly address the en-route environment.

In particular it would be helpful to support or refute the existing philosophy that the ATS does not differentiate between aircraft of different sizes or types, such that aircraft size is not considered (and therefore neither is the number of pax), and speed does not vary as at an airport.

Justification: Clarity, standardisation.

response	<p>Not accepted</p> <p>The case is covered in (d)(5)(iv). It is not the role of GM to support or refute the philosophy referred to in the comment. The GM simply points out that should a service provider wish to adopt the policy, it may do so using a single element of the tables described in (5).</p>
comment	<p>985 comment by: UK CAA</p> <p>Page No: 184 Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (f) Comment: This seems a very important point, and the UK CAA recommends that it should also be mentioned directly in the text relating to multi-actor changes. Justification: Usefulness.</p>
response	<p>Accepted</p> <p>This has been moved as suggested.</p>
comment	<p>987 comment by: UK CAA</p> <p>Page No: 184 Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (g) Justification: Typographic error. Proposed Text: Amend “to the closeness an event is to an accident” to read “to the closeness of an event to an accident”.</p>
response	<p>Accepted</p> <p>The text has been amended.</p>
comment	<p>989 comment by: UK CAA</p> <p>Page No: 184 Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (g)(2) Comment: In order to aid clarity we suggest that the text in the last line of the paragraph is amended. Justification: Clarity. Proposed Text: Amend “for the purposes of validating risk analyses” to read “for the purposes of measuring operational performance to validate the risk analyses”.</p>



response [Not accepted](#)

The suggested change would introduce a tautology (i.e. ‘measures for measuring’). The sentence appears clear enough without change.

comment 990 comment by: UK CAA

Page No: 185
Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (g)(3)
Comment: The diagram is not optimally clear or consistent, although it can be resolved with a little effort, once the supporting text has been understood.
 From the diagram alone, is unclear what the vertical lines denote. To the reader, the vertical lines could denote the edges of the barriers, or represent the barriers themselves. In fact they are superfluous, but very distracting.
 The four annotations “Resolved by ...” suggest that the four coloured areas are supposed to be system states, but clearly the mitigations cannot take place outside of the barrier, we therefore suggest that ‘Resolved by’ should be deleted (as this is really associated with the outcome ‘Succeeds’).
Justification: Clarity, accessibility.
Proposed Text: The diagram should be revised. Suggestion: delete the five vertical lines; Remove 4 x ‘Resolved by’; replace ‘Succeeds’ with ‘Resolves’; add a little white space between the three barriers and Providence (as it is not a barrier).

response [Partially accepted](#)

The diagram has been amended as suggested.

comment 991 comment by: UK CAA

Page No: 185
Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (g)(5)
Comment: The first barrier is not explicitly stated, whereas the second and third are.
Justification: Clarity, consistency.

response [Partially accepted](#)

The first barrier is explicitly stated. It is the second one that is not.

comment 992 comment by: UK CAA



	<p>Page No: 185</p> <p>Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (g)(6)</p> <p>Comment: The sentence “The third barrier, ‘resolved by pilot’ on the diagram, is, therefore, the pilot.” This is self-contradictory and in trying to resolve this uses too many sub-clauses. (The reasons for this textual complexity arising are removed if the suggestion made regarding the diagram is adopted).</p> <p>Justification: Clarity, consistency.</p> <p>Proposed Text: ‘The third barrier is the pilot’.</p>
response	<p>Partially accepted</p> <p>It is agreed that the sentence is confusing. However, it was resolved differently to the proposal.</p>
comment	<p>993 comment by: UK CAA</p> <p>Page No: 185</p> <p>Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (g)(6)</p> <p>Comment: The second barrier is ATCO with assistance, and this paragraph makes clear that the third barrier, the pilot, is in receipt of equivalent assistance. It is therefore inconsistent to have a single barrier for the pilot, equivalent to two for the controller. The UK CAA recommends that the text should either explain that there is no barrier ‘pilot without assistance’ (and rename the third barrier ‘pilot with assistance’), or else explain why the two barriers ‘pilot without assistance’ and ‘pilot with assistance’ are treated as a single barrier ‘pilot’, and why this is not done for the ATCO.</p> <p>Justification: Completeness, consistency.</p>
response	<p>Partially accepted</p> <p>The diagram has been re-drawn rather than adopting either of the solutions proposed by the commentator.</p>
comment	<p>994 comment by: UK CAA</p> <p>Page No: 186</p> <p>Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (g)(7)</p> <p>Comment: The UK CAA suggests that the sentence “Research has shown that in some airspaces the probability of a collision, when both ATCO and pilot barriers have failed, is approximately 300:1, which may well make it stronger than most of the barriers” should be reconsidered as:</p>



	<p>1) No reference is given for the research. 2) 'has shown' is a strong statement for research, consider 'suggests' 3) The comparison with the performance of other barriers is unnecessary, and potentially inflammatory.</p>
response	<p>Partially accepted:</p> <p>No reference is necessary as the source of the research results is given. If there were interest in the detail, it could be provided by the UK CAA.</p> <p>The other two points are accepted.</p>
comment	<p>995 comment by: UK CAA</p> <p>Page No: 186 Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (g)(7) Comment: The sentence "Its strength relies on the generally low density of the airspace and on airspace policy" is clearly suggestive, but the UK CAA suggests that the intended point is made explicitly (i.e. that high density airspace or poor policy could have a serious impact on the mitigation currently provided by providence). Justification: Clarity.</p>
response	<p>Not accepted</p> <p>The suggestion paints an unnecessarily negative picture of airspace density and policy, which is not intended.</p> <p>The barrier is strong because in the normal state of affairs density is low and policy is appropriate for the circumstances.</p>
comment	<p>996 comment by: UK CAA</p> <p>Page No: 186 Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (g)(8) Comment: The figure shows M1 to M4 appearing on both the left-hand causal side and on the right-hand consequence side of the hazard H1. If this is not an error, the rationale for this should be explained. Justification: Clarity/ accuracy.</p>
response	<p>Accepted</p> <p>The diagram represents different mitigations in all places. The apparent reuse of mitigations</p>



is not intended and has been corrected.

comment 997

comment by: UK CAA

Page No: 186

Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (g)(9)

Comment: This appears to promote having a balanced incident profile as being desirable.

This is not at all obvious. It seems to be based on the idea that the law of diminishing returns means that one area that is underperforming can be improved with less effort than improving other areas that are already performing better, whereas differences (e.g. in technologies or the difficulty of successful resolution) are likely to militate against this.

An incident profile may reflect a natural characteristic of the environment, the service or some other aspect of the system. Striving for a balanced profile could in fact be unnecessary or divert resources or attention from more important matters.

Justification: Clarity and possibly accuracy.

response Not accepted

It is considered good practice to aim for a balanced incident pyramid, although, as pointed out in the comment, this should not be an overriding principle.

There seems to be no reason to remove or change a paragraph that emphasises this.

comment 998

comment by: UK CAA

Page No: 187

Paragraph No: GM1 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system RISK ANALYSIS IN TERMS OF SAFETY RISK (g)(12)

Comment: The benefits of / reasons for using the practices promoted here are not sufficiently explained.

Justification: Clarity.

response Not accepted

The closing paragraph summarises the guidance given above and puts it in perspective.

Consequently, the benefits/reasons for the advice are given in the section as a whole and have been sufficiently explained. It is hoped that in responding to the comments on the section, the sufficiency has been improved.

comment 1034

comment by: DGAC/DSAC - french NSA



- Paragraph (b) :

The worst credible case (WCC) methodology, commonly accepted and used, seems no longer possible with such guidance. If it is the intention of this guidance , it should be stated and the real impact should be measured.

- Diagram p172 :

There is a reference not updated : OR.ATM/ANS.bbb.(2),(4) & (5).

- In paragraph (d) (5) :

You should replace combination of (A) & (B) by (i) & (ii).

response

Partially accepted

We cannot say if the WCC is no longer possible. However, if the use of the WCC does not satisfy the risk analysis requirements of this IR, then it may need to be adapted so that it does. In general, the IR deals with all risks although, of course, if they can be demonstrated to be of little significance when compared to others, that can be eliminated from the analysis. It is difficult to see how this could be done a priori.

The title of diagram has been changed.

The reference has been changed.

comment

1129

comment by: *Belgocontrol*

Suggest to remove figures on page 172 and 175 because they do not foresee that:

1. Mitigation could work well and lead to “no safety effect”,
2. Mitigation could fail and lead to an “incident”,
3. “incidents” could be “harmful effect”; accidents are a restrictive set of effects,

There are so few accidents in ATM that it looks very counterproductive to look at “accidents” only as an effect of hazards.



response [Not accepted](#)

[Please see the response to comment No 147.](#)

comment **1130**

comment by: *Belgocontrol*

Page 176 (d) Severity schemes

1. ANSPs cannot assess how many fatalities there could be in an aircraft accident.
2. A low speed TWY accident could still lead to multiple fatalities.
3. From the ANSP's point of view an accident involving one fatality is as bad as one involving 500. Therefore the number of fatalities is immaterial.

For harmonisation (as part of SES) the Severity Classification Scheme should be part of the IR. Recognising that the existing one is sometimes inappropriate should lead to the formulation of better one(s) not to its removal.

response [Not accepted](#)

[Please see the response to comment No 147.](#)

comment **1131**

comment by: *Belgocontrol*

Page 187 (11)

In practice the ATM system needs to demonstrate to be acceptably safe without safety nets. The reference to STCA hints the contrary. It is important to clearly define and explain how Safety Nets shall be considered.

response [Not accepted](#)

[Please see the response to comment No 183.](#)

comment **1166**

comment by: *EUROCONTROL*

GM1 ATS.OR.C.205 (b) (4) Safety support assessment and assurance of changes to the functional system – Page 170

RISK ANALYSIS IN TERMS OF SAFETY RISK

Parentheses are missing around the “4” of the header.

Concerning (c) (2) EUROCONTROL notices that no reference is made to Common Cause Analysis and proposes to include such a reference.

EUROCONTROL suggests also deleting the “Taxonomy of Safety” diagram on p.172 as the



same applies in the “Bow-Tie Model” diagram presented on p.175. In addition the model does not foresee situations where:

- mitigation could work well and lead to “no safety effect”;
- mitigation could fail and lead to an “incident”;
- “incidents” could be “harmful effect”;

More generally, there are so few accidents in ATM that it looks very counterproductive to look at “accidents” only for effect of hazards. Accidents are a restrictive set of effects.

Concerning (d) (1) (i) on page 176, EUROCONTROL makes the following comments:

- ANSP cannot assess how many fatalities could occur in an a/c accident;
- a low speed TWY accident could lead to multiple fatalities;
- within the SES harmonization perspective the severity classification scheme should be part of the rule; however, since the existing scheme may be sometimes difficult to use in the APT environment, the creation of a second 2nd scheme could be envisaged to better suit the changes related to APT operations.

Concerning (g) (10), (g) (11) on page 187, EUROCONTROL makes the following comments:

Should the ATM system be demonstrated as being “safe” without safety nets? The practice is that the ATM system needs to be demonstrated as being “safe” without safety nets. The reference to STCA seems to provide a hint of the contrary. It is therefore important to clearly define and explain how safety nets shall be considered.

response

[Partially accepted](#)

[Parentheses are added.](#)

[The common cause analysis is already mentioned in point \(c\)\(5\) of the GM \(new point \(e\)\).](#)

[Regarding the deletion of the Figure of taxonomy of safety and the use of accidents/incidents in safety analysis, please refer to the response to comment No 147.](#)

[Concerning the comment about \(d\) \(1\) \(i\) and the ability of ANSP to differentiate between the type of accidents \(i.e. number of fatalities\), please see the response to comment No 182.](#)

[Regarding the comment about safety nets, please refer to the response to comment No 183.](#)

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM2 ATS.OR.205(b)(4) Safety p. 187-192 assessment and assurance of changes to the functional system

comment

219

comment by: *NATS National Air Traffic Services Limited*

GM2 ATS.OR.205(b)(4)
Page 187



Point (b)(1) appears to suggest that returning the level of safety to that which existed before the wind farm is introduced would be acceptable (the wording implies there should be another option by the use of “also” but the sentence is poorly written). That being the case it is unclear how the argument for this can be made given the explanation in the GM as the GM argues that the risks cannot be summed (see (7)). Therefore it is not clear how this example helps to understand the use of proxies.

response

Noted

The example argues that because the risks cannot be summed with the measurements of proxies, the only way to convincingly demonstrate that the risks are mitigated is via a logic argument. The introduction of a new surveillance system or the improvement of the current one should be such that compensate for the unmitigated effect of the flicker (measured by a proxy). The use of proxies, as well as their difficulties, seems clear with this example.

comment

416

comment by: EUROCONTROL

EUROCONTROL recommends bringing more clarity to the notion of 'proxies for safety risks'.

response

Noted

The material has been restructured with this aim. The Agency hopes that this helps bring additional clarity.

comment

743

comment by: DFS Deutsche Flugsicherung GmbH

(b) (1) “It is assumed [...] the safety risk of the ATS services being provided at the aerodrome was acceptable. To return to this level after, the change would also be acceptable.”

This is a dangerous example. One could conclude that the risk of a change consisting of a transition is allowed to be unacceptable / does not matter / does not have to be assessed!

We suggest to change this example and add more explanation.

Reference to high level comment "c.v"

response

Not accepted

The comment is not well understood. The Agency does not find a well-justified reason to remove this example. There is nothing in the example that says that during transition the risk can be unacceptable. It is not clear how the commentator reaches that conclusion.



comment	<p>744 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>b (4) “so the risk of the wind farm, in response to flicker, cannot be completely mitigated.”</p> <p>We agree that these cases exist. But this contradicts with the requirement of ATS.OR.201 (b) that the service will be at least as safe after the change as it was before the change”, if no success cases are performed or risks are summed up, which is not state of the art yet an therefore should not be required in an IR. Reference to high level comment "c.v"</p>
response	<p>Not accepted</p> <p>Point to the text in section (7)</p> <p>The risks in response to the flicker cannot be completely mitigated, but the example argues that the mitigation in the introduction of an improved surveillance system compensates for the increase in risk by the flicker. What is at stake here is the TOTAL risk of the change, not partial risks. One part of the change can compensate for another part of the change.</p> <p>If the commentator means that ‘success case’ is to evaluate the actual risk that is introduced by the change, then this is exactly the intention of the whole regulation. This means that the risk has to be evaluated, with positive and negative contributions of different parts of the change.</p> <p>The ‘as safe as before’ objective has been anyway removed from the IR.</p>
comment	<p>745 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>b (6)</p> <p>We totally disagree that risks can be combined or summed up, since they are not scalar and can be compared to vectors with more than one dimension!!! We do not exclude that it might be possible to sum up risks resulting of the same hazard <u>and</u> leading to the same effect. This also applies for (7). We think that the “subjective” argument of comparing risks of another system can only be called qualitative at best. The only possibility of correctly combining risks, we have so far seen, is in the SESAR methodology. Here, all “influences” on a specific barrier, expressed in percentage of influence on the barrier, can be summed up.</p> <p>We suggest to remove all parts related to the combination of risk until a harmonized solution is found.</p> <p>If the whole IR / AMC / GM was written in the spirit that risks can be combined /summed up /subtracted, it must be revised with regard to this matter.</p> <p><input type="checkbox"/> Reference to high level comment "c.v"</p>



response Not accepted

The proposal to evaluate risks is detailed in the general guidance material in Section 5.1 of Appendix I to GM1 to GM1 to Article 5 Service Providers and Article 6(2) Oversight capabilities. The use of severity categories would also require to assign a value to every severity class (which represents the severity of consequences of that category). The sum of probabilities within a severity class multiplied by the value assigned to that class will represent the risk associated with that class (transformed then in an scalar). The total risk would be the sum of the risks in each severity class.

Even in the case that the risk analysis does not include the use of these values for every severity class, the risk would be a vector bi-dimensional, which in the end can be summed as well.

It is accepted that the argument that shows that the increase in the measure of proxy (related to an increase in the risk) can be compensated by the decrease in risks associated with the introduction of mitigations in the surveillance system is based on a logic argument (somehow certain subjectivity needs to be used), and it is acknowledged in the example, but this does not mean that the whole evaluation and assessment is based on subjective judgements.

comment 746

comment by: *DFS Deutsche Flugsicherung GmbH*

c (4) Figure 3: How do I know that the “acceptance criterion” “formulated for the amount the proxy value might increase or decrease” is acceptable – i.e. does not raise the risk of the provided service in an unacceptable manner – if no relation to the risk can be established? How can I argue to the NSA that I picked a sensible criterion and a sensible value?!

Good ideas, but might not be ready for use yet and need to be worked on more.

Reference to high level comment "c.v"

response Noted

The only way is using a rational argument that justifies an acceptable proxy value as a criterion. Note that the relationship between the proxy and the risks cannot be easily established mathematically; otherwise, it would be more beneficial to use risks and the proxy as an auxiliary or complementary function. However, the proxy must be related to risk (see AMC2 ATS.OR.210(a)). Setting the acceptable criterion may be done by measuring the



proxy in the current system and using that value as the criterion.

comment

747

comment by: DFS Deutsche Flugsicherung GmbH

c (7) What are we trying to demonstrate? That the risk is not changing? One proxy goes up and one down ... they cannot be compared or related or summed up though, even though they might cover all hazards!

Please, add explanation.

Reference to high level comment "c.v"

response

Noted

The example demonstrates that both proxies improve safety. Since they are independent, there is an objective improvement in safety. The difficulty is when one achieves its safety criterion, and the other does not. A solution to this is provided in the previous example.

comment

1028

comment by: UK CAA

Page No: 189

Paragraph No: GM2 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system SAFETY ANALYSIS IN TERMS OF PROXIES (b)(8)

Comment: The UK CAA suggests that an additional sentence is required to fully cover the subject.

Justification: Completeness.

Proposed Text: Add the following sentence: "It also demonstrates that the strategies available to demonstrate safety are not generic, but are dependent on identifying analysable qualities or quantities related to specific properties of the system or service that are impacted by the change."

response

Accepted

The sentence has been added.

comment

1029

comment by: UK CAA

Page No: 192

Paragraph No: GM2 ATS.OR.205(b)(4) Safety assessment and assurance of changes to the functional system SAFETY ANALYSIS IN TERMS OF PROXIES (c)(7)



Comment: Although there seems to be a case for independence of the two proxies in the example, completeness (i.e. that the two proxies cover all hazards/possible accident sequences associated with the introduction of digital strips) does not appear to be addressed. We suggest that this is included.

This is not a major shortcoming.

Justification: Completeness.

response

Accepted

The text has been amended to address this concern. The example indicates that the completeness has to be argued as well.

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM1 ATS.OR.205(b)(5) Safety p. 192-193 assessment and assurance of changes to the functional system

comment

748

comment by: *DFS Deutsche Flugsicherung GmbH*

(b) What does the simplification do for us? Doesn't it increase the uncertainty?

Please, add explanation

Reference to high level comment "c.v"

response

Noted

The simplification may be needed to estimate the risk (precise estimation increases the effort and is not always possible), and in most cases it increases the uncertainty.

comment

1030

comment by: *UK CAA*

Page No: 192

Paragraph No: GM1 ATS.OR.205(b)(5) Safety assessment and assurance of changes to the functional system OUTCOME OF RISK EVALUATION

Comment: If this guidance will, in its final presentation, remain distant from the referenced figure, it would be best to repeat the figure with this text.

Justification: Presentation and comprehension.

response

Partially accepted

It is recognised that the readability of the GM is not optimal. However, the text without the reference to the figure is simple and clear enough that the need to refer to the figure is not considered very relevant. The references have been removed.



comment	<p>1037</p> <p>In both paragraphs (a) and (b), reference GM4 ATS.OR.205 (b) instead of GM3 ATS.OR.205 (b).</p>	comment by: DGAC/DSAC - french NSA
response	<p>Accepted</p> <p>In any case, the references have been removed, as the text is simple and clear.</p>	

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM2 ATS.OR.205(b)(5) Safety assessment and assurance of changes to the functional system p. 193

comment	<p>968</p> <table border="1" style="width: 100%; background-color: #ffff00;"> <thead> <tr> <th style="text-align: left;">PART</th> <th style="text-align: left;">COMMENT</th> <th style="text-align: left;">JUSTIFICATION</th> </tr> </thead> <tbody> <tr> <td style="vertical-align: top;"> <p>Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX IV SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS) GM2 & GM3 & GM4 ATS.OR.205(b)(5)</p> </td> <td style="vertical-align: top;"> <p>The explanations on risk evaluation are not clear enough.</p> <p>Maybe some examples should be provided.</p> </td> <td style="vertical-align: top;"> <p>This NPA is quite important for the functioning of the whole system and it should be as clear as possible in order to avoid present and future misunderstandings.</p> </td> </tr> </tbody> </table>	PART	COMMENT	JUSTIFICATION	<p>Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX IV SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS) GM2 & GM3 & GM4 ATS.OR.205(b)(5)</p>	<p>The explanations on risk evaluation are not clear enough.</p> <p>Maybe some examples should be provided.</p>	<p>This NPA is quite important for the functioning of the whole system and it should be as clear as possible in order to avoid present and future misunderstandings.</p>	comment by: AESA / DSANA
PART	COMMENT	JUSTIFICATION						
<p>Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX IV SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS) GM2 & GM3 & GM4 ATS.OR.205(b)(5)</p>	<p>The explanations on risk evaluation are not clear enough.</p> <p>Maybe some examples should be provided.</p>	<p>This NPA is quite important for the functioning of the whole system and it should be as clear as possible in order to avoid present and future misunderstandings.</p>						
response	<p>Partially accepted</p> <p>At this stage, there is no time to elaborate additional examples (other than those provided to illustrate the use of proxies and the explanations in the GM); however, this request is taken on board and the Agency will consider to elaborate examples after this CRD (e.g. in a 2nd NPA).</p>							

comment	<p>1031</p>	comment by: UK CAA
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	<p>Page No: 193</p> <p>Paragraph No: GM2 ATS.OR.205(b)(5) Safety assessment and assurance of changes to the functional system RISK EVALUATION - UNCERTAINTY</p> <p>Comment: Punctuation error leads the reader to interpret the text as a list.</p> <p>Justification: Clarity.</p> <p>Proposed Text: delete the comma after 'justifying'.</p>
response	<p>Accepted</p> <p>The comma has been removed.</p>

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM3 ATS.OR.205(b)(5) Safety assessment and assurance of changes to the functional system p. 193

comment	<p>749 comment by: DFS Deutsche Flugsicherung GmbH</p> <p>(a) Who decides, if a set of safety requirements is sufficient (- without risk analysis)? CA?</p> <p>Please, add explanation. Reference to high level comment "c.v"</p>
response	<p>Noted</p> <p>Guidance about the criteria to decide if a set of safety requirement is sufficient is given in GM3 ATS.OR.205(a)(2), which ensures the argument is complete. The ATS provider decides if the set is sufficient and argues that it is in the safety case.</p>

comment	<p>750 comment by: DFS Deutsche Flugsicherung GmbH</p> <p>(c) Who decides, if all relevant proxies were identified? CA?</p> <p>Please, add explanation. Reference to high level comment "c.v"</p>
response	<p>Noted</p> <p>The ATS provider is who decides on a necessary set of proxies and argues that it is necessary. That is done in the safety case.</p>



comment 968 ❖

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX IV SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS) GM2 & GM3 & GM4 ATS.OR.205(b)(5)	<p>The explanations on risk evaluation are not clear enough.</p> <p>Maybe some examples should be provided.</p>	<p>This NPA is quite important for the functioning of the whole system and it should be as clear as possible in order to avoid present and future misunderstandings.</p>

response Partially accepted

At this stage, there is no time to elaborate additional examples (other than those provided to illustrate the use of proxies and the explanations in the GM); however, this request is taken on board and the Agency will consider to elaborate examples after this CRD.

comment 1032

comment by: UK CAA

Page No: 193
Paragraph No: GM3 ATS.OR.205(b)(5) Safety assessment and assurance of changes to the functional system RISK EVALUATION – FORMS OF RISK EVALUATION (a)
Comment: This seems to contain a truism – justifying that a ‘sufficient set of safety requirements’ (that ‘can be unambiguously and directly related to the safety criteria’) ‘satisfy the safety criteria’.
Justification: Clarity.

response Accepted

‘Sufficient’ has been removed.

comment 1033

comment by: UK CAA

Page No: 193
Paragraph No: GM3 ATS.OR.205(b)(5) Safety assessment and assurance of changes to the



functional system RISK EVALUATION – FORMS OF RISK EVALUATION (a) and (c).

Comment: It is unclear how these two clauses are different.

Justification: Clarification.

response [Noted](#)

[\(a\) is expressed in terms of risks and \(c\) in terms of proxies.](#)

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM4 ATS.OR.205(b)(5) Safety p. 193-194 assessment and assurance of changes to the functional system

comment 343

comment by: *BAF-M.Jancokova*

The figure is found in GM4 ATS.OR.205(b) and not as in OR.205(b)(5) stated.

response [Accepted](#)

[The reference has been amended.](#)

comment 968 ❖

comment by: *AESA / DSANA*

PART	COMMENT	JUSTIFICATION
Proposed amendments Section 3.2 <i>Draft AMC & GM (Draft EASA Decision)</i> ANNEX IV SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS) GM2 & GM3 & GM4 ATS.OR.205(b)(5)	The explanations on risk evaluation are not clear enough. Maybe some examples should be provided.	This NPA is quite important for the functioning of the whole system and it should be as clear as possible in order to avoid present and future misunderstandings.

response [Partially accepted](#)

[At this stage, there is no time to elaborate additional examples \(other than those provided to](#)



illustrate the use of proxies and the explanations in the GM); however, this request is taken on board and the Agency will consider to elaborate examples after this CRD.

comment 1039

comment by: UK CAA

Page No: 193 - 194

Paragraph No: GM4 ATS.OR.205(b)(5) Safety assessment and assurance of changes to the functional system RISK EVALUATION SCHEMES (a) to (d)

Comment: This complete section lacks the clarity of overall message and expression of the rest of the GM.

Two specific issues:

1) The use of the term 'fixed' in (b) and (d), along with (b)(3), mix in the idea of persistent targets that are establish to span changes for the foreseeable future. This long-term target setting has not been introduced elsewhere: the general approach is that everything in the NPA relates to a single change, even if implemented in stages, and so all work required and described is essentially specific to that single change.

2) It seems to try to accommodate different current approaches, rather than provide clear guidance (e.g. which are intended by the NPA and considered best).

UK CAA recommends complete revision of this section

Justification: Clarity.

response Not accepted

1) There is neither intentional 'general approach', nor is every part of the GM related to a single change, e.g. transitions associated with changes, change management procedures, change drivers. Consequently, it should not be expected here.

The guidance on risk evaluation schemes relates to a single change or spans a number of changes is deliberate. The pros and cons of such schemes are dealt with in (b) & (c)

2) Two approaches are considered in the GM. These are introduced in (a). They may or may not be current. In fact, most schemes known to the Agency use (a)(1). The NPA opens up the possibility of using the other scheme described in (a)(2).

The GM is neither intended to be complete nor does it attempt to say which scheme is best. The GM contrasts the two types of scheme for which guidance is provided so that service providers may consider which best suits their own circumstances. The service provider is free to choose, provided the IR/AMC requirements are met.

The service provider may also use a different scheme, which, provided the IR/AMC requirements are met, will also be acceptable.



comment	1040	comment by: UK CAA
	<p>Page No: 193</p> <p>Paragraph No: GM4 ATS.OR.205(b)(5) Safety assessment and assurance of changes to the functional system RISK EVALUATION SCHEMES (a)(1) and (2)(ii)</p> <p>Comment: This appears to imply a one-to-one relationship between accidents and proxies. The UK CAA suggests that this relationship may be incorrect. For example, one proxy could seem to be in the accident trajectory for many potential accidents.</p> <p>Justification: Accuracy.</p>	
response	<p>Partially accepted</p> <p>Proxy values are associated with accidents. The text does not imply that there is a one-to-one relationship. It is expected that a proxy will be related to one or more accidents.</p>	
comment	1041	comment by: UK CAA
	<p>Page No: 193</p> <p>Paragraph No: GM4 ATS.OR.205(b)(5) Safety assessment and assurance of changes to the functional system RISK EVALUATION SCHEMES (a)(1).</p> <p>Comment: This appears to imply that design with intent to meet the risk targets is sufficient to evaluate risk - such that, risk is evaluated by designing something.</p> <p>Justification: Clarity.</p>	
response	<p>Accepted</p> <p>The commentator's interpretation is correct.</p>	

<p>3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM5 ATS.OR.205(b)(5) Safety assessment and assurance of changes to the functional system</p>	<p>p. 195</p>
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comment	139	comment by: ENAIRE
	<p><i>Risk Mitigation:</i></p> <p><i>(c) the implementation of safety net</i></p> <p>It must be clarify the consideration of safety nets in safety assessment. Today, safety nets are not considered when assessing a functional change.</p>	
response	<p>Noted</p> <p>The proposal regulation and guidance material does not support the concept that the safety</p>	



nets are not part of the functional system. Please see the response to comment No 183.

comment	345	comment by: <i>BAF-M.Jancokova</i>
	Are safety nets officially considered now as risk mitigation means and can they, thus, be used for the demonstration of acceptable risk?	
response	<p>Noted</p> <p>Safety nets are considered part of the functional system, and as such they can reduce or increase risks and their contribution should be assessed. Please see the response to comment No 183.</p>	

comment	351	comment by: <i>ATCEUC - Air Traffic Controllers European Unions Coordination</i>
	<p>GM5 ATS.OR.205(b)(5) Safety assessment and assurance of changes to the functional system</p> <p>Training of personnel is clearly a way to mitigate the risk, therefore we specify it in (f).</p> <p>GM5 ATS.OR.205(b)(5) Safety assessment and assurance of changes to the functional System</p> <p>TYPE RISK MITIGATION</p> <p><i>Risk mitigation may be achieved in the following ways:</i></p> <p><i>(a) an improvement of the performance of a functional subsystem;</i></p> <p><i>(b) an additional change of the ATM/ANS functional system;</i></p> <p><i>(c) the implementation of a safety net;</i></p> <p><i>(d) an improvement of the services delivered by third parties;</i></p> <p><i>(e) a change in the physical environment;</i></p> <p><i>(f) <u>an adequate training of the personnel affected by the change; or</u></i></p> <p><i>(g) any combination of the above-mentioned methods</i></p>	
response	<p>Not accepted</p> <p>Training is part of the safety case and it has to be adequate and considered from the beginning of the assessment of the change and not as a mitigation to be added after the risk assessment; otherwise, the safety case will be invalid.</p>	

comment	1038	comment by: <i>DGAC/DSAC - french NSA</i>
	The implementation of safety net as a mitigation risk is a major evolution that cannot be introduced in this GM without being strongly analysed and largely accepted by all the actors.	



	We strongly suggest to remove this subparagraph (c) and any other reference to safety net as a possible mitigation risk in this IR.
response	<p>Not accepted</p> <p>A safety net is part of the functional system and, as such, may or may not reduce risks. The benefits, if any, of safety nets have to be probed, in particular that risks are reduced. Please see the response to comment No 183.</p>
comment	<p>1288 comment by: <i>European Transport Workers Federation - ETF</i></p> <p>In order to maintain a high standard of competence and in order to ensure a high level of performance, appropriate training is required. ETF proposes to move the content of the GM1 ATS.OR.205(b)(2) to AMC, to ensure that when hazards are identified they are done so by appropriately trained personnel.</p>
response	<p>Not accepted</p> <p>Even though the statement is agreed, there is no need to include training at the AMC level. It is already required in the IR in the management system.</p>

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM1 ATS.OR.205(b)(7) Safety assessment and assurance of changes to the functional system p. 195

comment	<p>1042 comment by: <i>UK CAA</i></p> <p>Page No: 195 Paragraph No: GM1 ATS.OR.205(b)(7) Safety assessment and assurance of changes to the functional system Comment: The UK CAA recommends that this should also address monitoring smaller changes. Justification: Utility.</p>
response	<p>Noted</p> <p>The monitoring is not limited to small or big change. Nothing is implied in the GM about the size of the change. It is applicable to every change.</p>
comment	<p>1043 comment by: <i>UK CAA</i></p>



Page No: 195
Paragraph No: GM1 ATS.OR.205(b)(7) Safety assessment and assurance of changes to the functional system (b)
Comment: Typographical error.
Justification: Correction.
Proposed Text: Change 'multiply' to 'multiple'.

response [Accepted](#)

[The typo has been corrected.](#)

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM1 ATS.OR.205(b)(1)(i) Safety assessment and assurance of changes to the functional system p. 195-196

comment 1044

comment by: UK CAA

Page No: 196
Paragraph No: GM1 ATS.OR.205(b)(1)(i) Safety assessment and assurance of changes to the functional system DEFINITIONS (i)
Comment: An important aspect of a component is that all properties of interest must be sufficiently known for the purposes of the current analysis, otherwise it must be treated as a system, recognising that it must be subject to more analytical work.
Justification: Clarification.

response [Noted](#)

3. Proposed amendments — 3.2. Draft EASA Decision — AMC/GM to ANNEX IV — Specific requirements for the provision of Air Traffic Services (Part-ATS) — GM1 ATS.OR.210(b)(1) Safety criteria p. 196

comment 431

comment by: EUROCONTROL

Please refer to EUROCONTROL's recommendation concerning the notion of 'proxy' made when commenting page 170 (GM1 ATS.OR.205(b)(3)).

response [Accepted](#)

[The reference is being amended to refer to the right GM containing examples of proxies.](#)

[The text has been restructured in a way that it is believed that is clearer now. All AMC and](#)



GM related to proxies are given in ATS.OR.210. Examples remain linked to this requirement ATS.OR.205.

4. Regulatory Impact Assessment (RIA) — 4.1. Issues to be addressed — General overview

p. 197

comment 583

comment by: *Frasie Loredana*

Review the regulatory impact assessment using valid data.

Justification

The RIA is not supported by valid arguments.

The assessment presents the justification for the selected options using terms such: *is likely, is expected, little impact*; and without sufficient /proper data for the selected option.

response Partly accepted

The RIA has been reviewed but in order to cover areas not assessed in the NPA. No data has been provided by any commentator or stakeholder to support a quantitative analysis and thus the assessment has been kept qualitatively and based on expert judgement.

4. Regulatory Impact Assessment (RIA) — 4.3. Risk-based review decision by the competent authorities

p. 197-201

comment 184

comment by: *EUROCONTROL Safety Team*

Page 200 - 201 4.3.8 (risk-based review decision by the C.A.)

Page 204 - 205 4.4.8 (risk-based review by the C.A.)

How could the “do nothing” be negative and the “do nothing now and do something later” be positive? At best, it could be considered that when and if additional compelling GM material is provided some improvement could be expected.

NSAs are already using risk-based approaches to this decision. The real issue is that most of the NSAs are understaffed and lack experience.

response Noted

The benefit is considered over time. Potential short-term cost which is legitimate for every regulatory change should be compensated with the long-term benefits expected for all stakeholders.

comment 220

comment by: *NATS National Air Traffic Services Limited*

4.3.4 How could the issue/problem evolve?**Page 198**

Harmonisation that supports the implementation of SESAR is welcomed. That being the case where is the mapping of the proposed provisions to the SESAR Reference Material so that it can be demonstrated that compliance with EASA gives compliance with SESAR and so not jeopardise SESAR deployment?

response Noted

Such mapping to the SESAR Reference Material does not exist at this stage. This would have to be a separate exercise.

However, during the development of the IR, several meetings were held with representatives of SESAR and they also commented on the proposed IR material during its development.

comment 221

comment by: *NATS National Air Traffic Services Limited***4.3.6 Policy options****Page 198**

Option 2 refers to a study already done by the UK CAA. It would only be meaningful to understand Option 2 if that study were to be made available. Even with the lack of sight of the study Option 2 appears to be the option to be selected. This is on the basis that it would be contrary to best use of scarce resources and continuous improvement to publish a rule that nobody knows how to comply with and set a timescale for its introduction that does not have a high degree of confidence given EASA's rulemaking track record. Option 3 is not feasible at this time. Where is the Agency/EC policy published?

response Partly accepted

The study report can be made available upon request.

Option 3 was selected because it gives a clear indication in the proposed rule and GM of the proposed implementation. Only AMC is missing. The proposed applicability date is 2 years after the entry into force (after adoption by the European Commission). This should give sufficient time for the model proposed in the GM to be developed and validated and the AMC to be proposed.

Moreover, during the development and validation of the model, CAs will be involved and be briefed on the progress and the likely impact and so will be aware of the concept and could make plans for its implementation in their business.

comment 222

comment by: *NATS National Air Traffic Services Limited*

4.3.7.1 Safety impact**Page 199**

The justification for Option 3 is that when the IR and its supporting AMC/GM have been implemented a positive safety impact is expected. Selection of Option 3 does not take into account the feasibility of developing the necessary AMC/GM in a reasonable timescale.

response

Partially accepted

Please see the response to comment No 221.

comment

223

comment by: *NATS National Air Traffic Services Limited***4.3.7.2****Page 199**

Question 8

The significant risk of the AMC not being available when the transition period is over is a significant cost driver insofar that there will be a rule to comply with and no published means of complying with it. Even if AMC is available it will lack maturity. In order to develop any training the AMC needs to be available ahead of the transition period ending so that the training itself can be developed. Service providers personnel that interface with the CA for changes to the functional system would also benefit from some form of training. Within NATS some 100 personnel (from Directorate of Safety, Projects and Engineering and Units) have a direct interface with the CA. As a coarse estimate for suitable training to be developed, trialed and delivered to 100 pax a cost in excess of £100,000 would not be unreasonable. It is not a convincing argument that ultimately there will be a cost benefit given the early notification advocated by these rules and the scarcity of information for the CA to make a risk-based review decision meaning that there will be a need for increased interaction between service provider and CA which ultimately drives up the costs for both service provider and CA.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency. The Agency, however, does not see how this provision has impact on service providers, as it only deals with the way a CA decides to review the change.

comment

224

comment by: *NATS National Air Traffic Services Limited***4.3.7.3**

response	<p>Page 200</p> <p>The justification for Option 3 is that when the IR and its supporting AMC/GM have been implemented a positive safety impact is expected. Selection of Option 3 does not take into account the feasibility of developing the necessary AMC/GM in a reasonable timescale.</p> <p>Partially accepted</p> <p>Please see the response to comment No 221.</p>
comment	<p>225 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>4.3.8.2 Page 201</p> <p>Given the content of this paragraph Option 3 does not appear feasible at this time. Option 3 contains a significant risk of failure with only a limited alternative which is as yet undefined.</p>
response	<p>Not accepted</p> <p>Other commentators argue that the proposal in Option 3 is feasible. It may turn out to be impractical and this will be shown during the development and validation of the AMC. Even if this does not result in a viable AMC, the experience gained will be valuable in proposing a different model for selection.</p>
comment	<p>562 comment by: <i>Federal Office of Civil Aviation FOCA</i></p> <p>Question 8: An increase in costs is expected in order to adopt those changes to the process, documentation, etc. of the new model. Furthermore training will be required for staff in the technical, operational, safety division and as well for oversight activities. From a today's point of view it is difficult to provide an estimate in what time frame the costs will decrease since other additional needs and harmonization activities influence the safety management system as well.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.</p>
comment	<p>804 comment by: <i>AESA / DSANA</i></p>



PART	COMMENT	JUSTIFICATION
Regulatory Impact Assessment (RIA) Section 4.3.7.2 <i>Economic impact</i>	Question 8: The Agency would like to seek the stakeholders' views on the economic impact analysis. If a stakeholder does not agree, the Agency would appreciate it if cost estimates are provided in justification.	We are, in principle and subject to the particular comments made to this NPA, satisfied with the economic impact analysis included in the document.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.

comment

1020

comment by: *DSNA*

Question 8:

The implementation of this regulation and the new proposed provisions will have a cost, not only for competent authorities but also for ANSP. Write that the impact will be negligible over the long term is false because this regulation imposes new obligations to the ANSP and therefore also to the competent authorities. The arguments provided to demonstrate the usefulness of this regulation seems to be entirely unfounded.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency. The question was addressing only the economic part of one provision, and not the entire set of provisions.

comment

1045

comment by: *UK CAA*

Page No: 199

Paragraph No: QUESTION 8

Comment:

Whilst it is likely that *"in the long term, the costs may well decrease as the certainty associated with the rule improves the efficiency of both the competent authorities and the*



service providers”, the UK CAA disagrees with the assumption in Option 3 that “the overall economic impact can be set to 0 when implementing the new proposed provisions”. Costs (as yet unquantified) will occur during the transition period; even if these were averaged out over a specified period the costs would still be incurred – this is an inescapable fact, only the scale of the costs is uncertain.

Justification: Lack of clarity regarding regulatory impacts and flawed assumptions regarding costs.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to this RIA for additional information on the final position taken by the Agency.

comment 1091

comment by: LVNL

Response to Question 8:

The Netherlands supports this policy. This requires the development of methods to perform this activity in a harmonized way throughout Europe. Where this is new we support the EASA approach to give time to develop methods at a national level.

Exchanges of experience would be needed to get a good picture of the progress made.

The Netherlands proposes a more pragmatic approach to the review of changes, in which changes with a smaller safety impact can be implemented without explicit approval of the CA, but is arranged on a procedural level. See our amended proposal for ATM/ANS.AR.C 035 and related articles and AMC.

Clear criteria for selection of changes to review are missing. The current option for providers to only file changes with sufficient safety impact is missing. This will lead to additional activities of the CA without safety benefit. The option is needed for CA to agree with the provider on a process related to changes with a small safety impact where the approval is arranged on a procedural level .

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to this RIA for additional information on the final position taken by the Agency.

comment 1093

comment by: LVNL

Response to Question 9:

The Netherlands agrees, including the uncertainty related to the economic impacts initially and on the long term. This requires the development of methods to perform this activity in a harmonized way throughout Europe. Where this is new we support the EASA approach to



give time to develop methods at a national level. We encourage EASA to disseminate best practices, as exchanges of experience would be needed to get a good picture of the progress made.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.

comment

1144

comment by: DSAE

Question 8 : The Agency would like to seek the stakeholders' views on the economic impact analysis. If a stakeholder does not agree, the Agency would appreciate it if cost estimates are provided in justification.

DIRCAM's answer : Impact for DIRCAM would be low if option 3 was chosen. It would probably be higher for ANSPs.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.

comment

1217

comment by: CAA-NL

Question 8: The Agency would like to seek the stakeholders' views on the economic impact analysis. If a stakeholder does not agree, the Agency would appreciate it if cost estimates are provided in justification. (P. 199)

The Netherlands supports this policy. This requires the development of methods to perform this activity in a harmonized way throughout Europe. Where this is new we support the EASA approach to give time to develop methods at a national level.

Exchanges of experience would be needed to get a good picture of the progress made.

The Netherlands proposes a pragmatic approach to the review of changes, in which changes with a smaller safety impact can be implemented without explicit approval of the CA, but is arranged on a procedural level.

Clear criteria for selection of changes to review are missing. The current option for providers to only file changes with sufficient safety impact is missing. This will lead to additional activities of the CA without safety benefit. The option is needed for CA to agree with the provider on a process related to changes with a small safety impact where the approval is arranged on a procedural level. See our amended proposal for ATM/ANS.AR.C 035 and related articles and AMC.



response	Noted The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.
comment	1239 comment by: EUROCONTROL 4.3 Risk-based review decision by the competent authorities - Page 197 EUROCONTROL makes the following comments on Article 4.3.8 Comparison and conclusion on page 200: Concerning the risk-based review decision by CA, one question arises: how could the “do nothing” be negative and the “do nothing now and do something later” be positive? Additional compelling GM material is no doubt necessary to answer the question. It is important to note that NSAs are already following risk-based approaches. The real issue for most of them is their understaffing and lack of experience.
response	Noted The ‘do nothing’ implies continued disharmony. This has a cost impact. The ‘something’ to be done later is the publication of the rules for selection which will have been developed and validated based on a model already described in the GM. Consequently, harmonisation should ensue leading to a reduction in cost.
comment	1245 comment by: Icetra Question 8: We agree.
response	Noted The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.

4. Regulatory Impact Assessment (RIA) — 4.4. Risk-based review by the competent authorities	p. 201-205
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comment	184 ❖ comment by: EUROCONTROL Safety Team
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	<p>Page 200 - 201 4.3.8 (risk-based review decision by the C.A.) Page 204 - 205 4.4.8 (risk-based review by the C.A.) How could the “do nothing” be negative and the “do nothing now and do something later” be positive? At best, it could be considered that when and if additional compelling GM material is provided some improvement could be expected. NSAs are already using risk-based approaches to this decision. The real issue is that most of the NSAs are understaffed and lack experience.</p>
response	<p>Not accepted</p> <p>The rationale is explained already in the commented NPA.</p> <p>The negative impact is due to disharmony and will remain until the rule is changed. The ‘do something later’ will encourage harmony at a later date without a rule change.</p>
comment	<p>226 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>4.4.4 Page 202</p> <p>Harmonisation that supports the implementation of SESAR is welcomed. That being the case where is the mapping of the proposed provisions to the SESAR Reference Material so that it can be demonstrated that compliance with EASA gives compliance with SESAR and so not jeopardise SESAR deployment?</p>
response	<p>Noted</p> <p>Such mapping to the SESAR Reference Material does not exist at this stage. This would have to be a separate exercise.</p> <p>However, during the development of the IR, several meetings were held with representatives of SESAR and they also commented on the proposed IR material during its development.</p>
comment	<p>227 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>4.4.6 Page 202</p> <p>Option 2 appears to be the option to be selected. This is on the basis that it would be contrary to best use of scarce resources and continuous improvement to publish a rule that nobody knows how to comply with and set a timescale for its introduction that does not have a high degree of confidence given EASA’s rulemaking track record. Option 3 is not feasible at this time. Where is the Agency/EC policy published?</p>



response	<p>Accepted:</p> <p>This has now been accepted and Option 3 has been rejected. See modified RIA. This is explained in the Opinion.</p>
comment	<p>228 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>4.4.7.1 Page 203</p> <p>The justification for Option 3 is that when the IR and its supporting AMC/GM have been implemented a positive safety impact is expected. Selection of Option 3 does not take into account the feasibility of developing the necessary AMC/GM in a reasonable timescale.</p>
response	<p>Partially accepted</p> <p>The timescale did take into account the feasibility of developing the AMC/GM, but the study referred to in the RIA has shown that there is no straightforward solution either to the identity of the risk or for a model for modulating the review.</p>
comment	<p>229 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>4.4.7.2 Page 204</p> <p>Question 9</p> <p>The significant risk of the AMC not being available when the transition period is over is a significant cost driver insofar that there will be a rule to comply with and no published means of complying with it. Even if AMC is available it will lack maturity. In order to develop any training the AMC needs to be available ahead of the transition period ending so that the training itself can be developed. Service providers personnel that interface with the CA for changes to the functional system would also benefit from some form of training. Within NATS some 100 personnel (from Directorate of Safety, Projects and Engineering and Units) have a direct interface with the CA. As a coarse estimate for suitable training to be developed, trialed and delivered to 100 pax a cost in excess of £100,000 would not be unreasonable (this is in addition to the cost estimate in Question 8). It is not a convincing argument that ultimately there will be a cost benefit given the early notification advocated by these rules and the scarcity of information for the CA to make a risk-based review decision meaning that there will be a need for increased interaction between service provider and CA which ultimately drives up the costs for both service provider and CA.</p>



response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency. The Agency considers that most of the training due to this specific provision would impact CAs as they would have to apply it. It does not seem that service providers will have to train their personnel in this particular item.

comment 230 comment by: *NATS National Air Traffic Services Limited*

4.4.7.3
Page 204

The justification for Option 3 is that when the IR and its supporting AMC/GM have been implemented a positive safety impact is expected. Selection of Option 3 does not take into account the feasibility of developing the necessary AMC/GM in a reasonable timescale.

response Partially accepted

Please see the response to comment No 228.

comment 231 comment by: *NATS National Air Traffic Services Limited*

4.4.8.2
Page 205

Given the content of this paragraph Option 3 does not appear feasible at this time. Option 3 contains a significant risk of failure with only a limited alternative which is as yet undefined.

response Accepted

This has now been accepted and Option 3 has been rejected. This is explained in the Opinion.

comment 592 comment by: *Federal Office of Civil Aviation FOCA*

RIA chapter 4.4, Risk based review by the competent authority: FOCA is in favour of option 3. Reasoning: It seems almost impossible to provide a commitment as the on-going feasibility study has not been yet completed and no results are available to address a high level view on the risk to be used and to modulate a review. Additional clarification is required to understand the definitions and rules as the IR is written too generically. Furthermore, the solution is based to some degree on the result of the study which has yet to provide details to all parties concerned.



response Accepted

It is believed that what the commentator actually means is that they do not support Option 3 for the reasons given in the justification.

This has now been accepted and Option 3 has been rejected. This is explained in the Opinion.

comment 807 comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Regulatory Impact Assessment (RIA) Section 4.4.7.2 Economic impact	Question 9: The Agency would like to seek the stakeholders' views on the economic impact analysis. If a stakeholder does not agree, the Agency would appreciate it if cost estimates are provided in justification.	We are, in principle and subject to the particular comments made to this NPA, satisfied with the economic impact analysis included in the document.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.

comment 859 comment by: Naviair

Regarding 4.4.7.2

Question 9: If NPA 2014-13 is becoming a regulation in the full we expect a need of more people. We expect the cost to be somewhat higher than today.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency. The question Q9 is related to the risk review of changes by the CA and does not seem to affect the activities of service providers.

comment 1046 comment by: UK CAA



	<p>Page No: 204</p> <p>Paragraph No: QUESTION 9</p> <p>Comment: UK CAA does not believe that the costs are sufficiently predictable to form an opinion on this question.</p> <p>Justification: Clarity of Agency argument.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency. No additional cost estimates have been provided by stakeholders.</p>
comment	<p>1052 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>Question 9 Yes, DFS expects a slight negative economic impact during implementation.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.</p>
comment	<p>1110 comment by: <i>DSNA</i></p> <p>Question 9: See answer to question 8 above.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.</p>
comment	<p>1145 comment by: <i>DSAE</i></p> <p>Question 9 : The Agency would like to seek the stakeholders' views on the economic impact analysis. If a stakeholder does not agree, the Agency would appreciate it if cost estimates are provided in justification.</p> <p>DIRCAM's answer : Impact for DIRCAM would be low if options 2 or 3 were chosen. It would probably be higher for ANSPs.</p>



response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.</p>
comment	<p>1218 comment by: CAA-NL</p> <p>Question 9: The Agency would like to seek the stakeholders' views on the economic impact analysis. If a stakeholder does not agree, the Agency would appreciate it if cost estimates are provided in justification.</p> <p>The Netherlands agrees, including the uncertainty related to the economic impacts initially and on the long term. This requires the development of methods to perform this activity in a harmonized way throughout Europe. Where this is new we support the EASA approach to give time to develop methods at a national level. We encourage EASA to disseminate best practices, as exchanges of experience would be needed to get a good picture of the progress made.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency. The intent is to disseminate these best practices when they are known by the Agency.</p>
comment	<p>1240 comment by: EUROCONTROL</p> <p>4.4 Risk-based review by the competent authorities - Page 201</p> <p>EUROCONTROL makes the same comments on Article 4.4.8 of page 204 as the ones made on Article 4.3.8 of page 200.</p>
response	<p>Noted</p> <p>The 'do nothing' implies continued disharmony. This has a cost impact.</p> <p>The 'something' to be done later will encourage harmony at a later date without a rule change.</p>
comment	<p>1246 comment by: Icetra</p> <p>Question 9: We agree.</p>



response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.

4. Regulatory Impact Assessment (RIA) — 4.5. CNS providers performing safety support assessment instead of safety assessment

p. 206-210

comment

232

comment by: *NATS National Air Traffic Services Limited***4.5****Page 206**

The title of this RIA is misleading and incomplete. It is not just about CNS providers performing a safety support assessment instead of a safety assessment but also about extending the scope of safety support assessments to all service providers other than ATS providers. It is therefore considered that the RIA is incomplete e.g. the "Who is affected?" does not consider service providers other than CNS providers, the "Safety impact" only considers CNS, the "Economic impact" only considers CNS, the "Impact on "better regulation" and harmonisation" only considers CNS. The impact of the significant decision to extend safety support assessment to all service providers other than ATS providers has been omitted. Thus there is no justification for extending the scope of safety support assurance.

response

Accepted

The Agency does acknowledge that the scope of the option was not completely reflected in the impact analysis section where mainly CNS providers were mentioned. In fact, the impact analysis applies to all service providers other than ATS providers. The reassessment of the impact of the change is addressed in the Opinion.

comment

233

comment by: *NATS National Air Traffic Services Limited***4.5.7.2****Page 208**

Question 10

The title of this RIA is misleading. It is not just about CNS providers performing a safety support assessment instead of a safety assessment but also about extending the scope of safety support assessments to all service providers other than ATS providers. It is therefore considered that the RIA is incomplete e.g. the "Who is affected?" does not consider service



providers other than CNS providers, the “Safety impact” only considers CNS, the “Economic impact” only considers CNS, the “Impact on “better regulation” and harmonisation” only considers CNS. The impact of the significant decision to extend safety support assessment to all service providers other than ATS providers has been omitted. Thus there is no justification for extending the scope of safety support assurance.
As such it is not possible to ascertain economic impact as the scope of the RIA is incomplete.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to this RIA for additional information on the final position taken by the Agency. The scope has been updated and addressed in the Opinion.

comment 247

comment by: *NATS National Air Traffic Services Limited*

4.5.7.3
Page 208

Option 0 – The reference to Annex 19 is in regard to a Note and not a SARP. Thus harmony, or not, with ICAO cannot be claimed.

response Partially accepted

The Note’s purpose is to clarify the intent of the Annex and, therefore, can be considered relevant to the requirements of the Annex. The argument about Option 0 is aligned with the intent of Annex 19.

comment 248

comment by: *NATS National Air Traffic Services Limited*

4.5.8.1
Page 209

Option 2 is the preferred option (which includes CNS and other non-ATS providers); however none of the impact statements includes this consideration. The RIA is fundamentally flawed.

response Accepted

The Agency does acknowledge that the scope of the option was not completely reflected in the impact analysis section of the RIA where mainly CNS providers were mentioned. In fact, the impact analysis applies to all service providers other than ATS providers. The reassessment of the impact of the change is addressed in the Opinion.



comment	<p>563 comment by: <i>Federal Office of Civil Aviation FOCA</i></p> <p>Question 10: FOCA refers to its answer to Q9: we consider a negative economic impact probable.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to this RIA for additional information on the final position taken by the Agency.</p>

comment	<p>753 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>Question 10 DFS agrees that the positive economic impacts may outweigh the negative ones. But DFS has practiced this for years and therefore has no change.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to this RIA for additional information on the final position taken by the Agency.</p>

comment	<p>809 comment by: <i>AESA / DSANA</i></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 25%;">PART</th> <th style="width: 45%;">COMMENT</th> <th style="width: 30%;">JUSTIFICATION</th> </tr> </thead> <tbody> <tr> <td style="background-color: #e6e6fa;"> Regulatory Impact Assessment (RIA) Section 4.5.7.2 <i>Economic impact</i> </td> <td style="background-color: #e6e6fa;"> Question 10: The Agency would like to seek the stakeholders’ views on the economic impact analysis. If a stakeholder does not agree, the Agency would appreciate it if cost estimates were provided in justification. </td> <td style="background-color: #e6e6fa;"> We are, in principle and subject to the particular comments made to this NPA, satisfied with the economic impact analysis included in the document. </td> </tr> </tbody> </table>	PART	COMMENT	JUSTIFICATION	Regulatory Impact Assessment (RIA) Section 4.5.7.2 <i>Economic impact</i>	Question 10: The Agency would like to seek the stakeholders’ views on the economic impact analysis. If a stakeholder does not agree, the Agency would appreciate it if cost estimates were provided in justification.	We are, in principle and subject to the particular comments made to this NPA, satisfied with the economic impact analysis included in the document.
PART	COMMENT	JUSTIFICATION					
Regulatory Impact Assessment (RIA) Section 4.5.7.2 <i>Economic impact</i>	Question 10: The Agency would like to seek the stakeholders’ views on the economic impact analysis. If a stakeholder does not agree, the Agency would appreciate it if cost estimates were provided in justification.	We are, in principle and subject to the particular comments made to this NPA, satisfied with the economic impact analysis included in the document.					
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to this RIA for additional information on the final position</p>						



taken by the Agency.

comment	861	comment by: Naviair
response	<p>Regarding 4.5.7.2 Question 10: See question 9.</p> <p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.</p>	
comment	1021	comment by: DSNA
response	<p>Question 10: DSNA as a CNS service provider estimates that the Safety Support Assessment will be useful and that the cost may be not as important as the article might suggest.</p> <p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.</p>	
comment	1047	comment by: UK CAA
response	<p>Page No: 208 Paragraph No: QUESTION 10 Comment: The UK CAA supports the views in the economic impact analysis but can offer no cost evidence to support the analysis.</p> <p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.</p>	



comment	<p data-bbox="360 241 424 271">1146</p> <p data-bbox="1251 241 1485 271">comment by: DSAE</p> <p data-bbox="360 331 1485 443">Question 10 : The Agency would like to seek the stakeholders' views on the economic impact analysis. If a stakeholder does not agree, the Agency would appreciate it if cost estimates are provided in justification.</p> <p data-bbox="360 454 1485 566">DIRCAM's answer : Impact for DIRCAM would be extremely low if option 2 was chosen. CNS providers already perform fully safety assessment in coordination with ATSPs. It is likely not to be a big issue for CNS providers to change the way they assess the risk.</p>
response	<p data-bbox="360 600 440 629">Noted</p> <p data-bbox="360 667 1485 779">The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.</p>
comment	<p data-bbox="360 875 424 904">1219</p> <p data-bbox="1224 875 1485 904">comment by: CAA-NL</p> <p data-bbox="360 965 1305 1077">Question 10: The Agency would like to seek the stakeholders' views on the economic impact analysis. If a stakeholder does not agree, the Agency would appreciate it if cost estimates were provided in justification.</p> <p data-bbox="360 1088 1485 1323">In our view the economic impact is limited as the introduction of a safety support assessment is not primarily a matter of economy but clarity of responsibilities and the analyses to be made. This clarity focuses both on the CNS provider as well as the user of the services. For the user of the services it clarifies the analyses does not cover the impact on the safety of their own operation. This implies they will need to determine the consequences. The later is introduced into this regulation as well.</p>
response	<p data-bbox="360 1361 440 1391">Noted</p> <p data-bbox="360 1429 1485 1541">The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.</p>
comment	<p data-bbox="360 1637 424 1666">1247</p> <p data-bbox="1244 1637 1485 1666">comment by: Ictetra</p> <p data-bbox="360 1727 520 1794">Question 10: We agree.</p>
response	<p data-bbox="360 1832 440 1861">Noted</p> <p data-bbox="360 1899 1485 2011">The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.</p>



4. Regulatory Impact Assessment (RIA) — 4.6. Removal of Severity classification scheme from IR p. 210-213
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comment	<p>185 comment by: <i>EUROCONTROL Safety Team</i></p> <p>Page 213 4.6.8 (removal of “severity classification scheme” - SCS) Complex SCS could create a false sense of precision and take the attention of the service provider away from real operational risk. Removing the SCS from the rule would NOT support the harmonisation and would NOT support strong collaboration between ANSPs. It is therefore very difficult to understand the positive mark given to option 2.</p>
response	<p>Partially accepted</p> <p>It is acknowledged that a complex SCS could create a false sense of precision. However, AMC1 ATS.OR.205(b) provides a set of rules for the creation of SCS and their application should minimise this negative effect.</p> <p>The arguments for and against the impact on harmonisation is given in the RIA and also in the GM.</p> <p>The use of the AMC/GM could perhaps be improved by providing more focussed GM in the 2nd NPA.</p>
comment	<p>250 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>4.6.3 Page 210</p> <p>Given that the severity scheme currently only applies to ATS and CNS why are all service providers included in the “Who is affected?”?</p>
response	<p>Accepted</p> <p>However, it has no impact on the outcome of the RIA.</p>
comment	<p>251 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>4.6.4 Page 210</p> <p>What aspect of the current regulations is probability-based? If there is a severity scheme and probability is there not a basis for risk?</p>



response	<p>Not accepted</p> <p>The reason safety is currently probability-based rather than risk-based is because there is only one severity category that relates to safety risk. Consequently, the risk is proportional only to the probability of the accident and not to its consequences. This is explained in paragraph(d) of GM1 ATS.OR.205(b)(4).</p>
comment	<p>253 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>4.6.7.1 Page 212</p> <p>Option 2 – this option advocates development of the appropriate risk evaluation method and that examples are provided. Examples of severity schemes are in GM but there is no explicit GM on risk evaluation as the probability component is required and this component, and its relationship to risk, is not considered insofar as an ATS provider would be able to determine an acceptable risk classification scheme. The text refers to the benefit of mitigation efforts on the highest risks – in order to do this there needs to be a means of determining risk. Whilst it is acknowledged that a single severity scheme is not necessarily appropriate and that, similarly, a single set of probabilities or a single RCS is appropriate there needs to be more guidance on these subjects.</p>
response	<p>Noted</p> <p>The reason for the comment is not well understood as the risk evaluation is covered in the GM.</p> <p>The risk evaluation is dealt with in GM 1, 2, 3 & 4 to ATS.OR.205(b)(5). GM 4 specifically deals with risk evaluation schemes.</p> <p>Paragraph (b)(4) of ATS.OR.205 is also related to risk evaluation. It shows the relationship between hazards and accidents, including the effects of mitigation. Whilst no worked examples are given, it is clear that the risk is a combination of the rate of the accident and its severity. The accident rate is the same as the hazard rate multiplied by the probability that the mitigations will fail.</p> <p>The need for additional GM will be considered when update of that material is performed</p>
comment	<p>255 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>4.6.7.2 Page 212</p> <p>Question 11</p>



	<p>The EASA proposal to allow multiple severity schemes and presumably therefore multiple probability schemes and risk classification schemes will undoubtedly have significant cost implications on service providers. This is because there will be a plethora of schemes, possibly on per change basis, that will lead to a lack of uniformity and consistency both within the service provider and between service providers (whilst this is self-imposed it is almost inevitable). It is likely that any cost savings would be outweighed by the cost of training, implementation and oversight.</p> <p>It is difficult to see from as EASA Standardisation perspective how this could be a sound approach or that this promotes “better regulation” and harmonization.</p> <p>The EASA impact assessment is very imprecise acknowledging that cost will go up in the first instance but “should” come down in the longer term with no definitive costing.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to this RIA for additional information on the final position taken by the Agency. The commentator should note that the ATS are not obliged to use different SCS; they may decide to use just one. This approach only provides flexibility, though there is a risk of lack of harmonisation.</p>
comment	<p>352 comment by: <i>BAF-M.Jancokova</i></p> <p>4.6.1: The argument</p> <p><i>"However, the severity table in the current regulation has only one level of severity that relates to harm to humans, thus, there is only one suitable for use in a safety risk assessment, i.e. level 1. It should be noted that this NPA does not propose the abandonment of the other severity classes in point 3.2 of Annex II to Regulation (EU) No 1035/2011, however, it does point out that they are not safety risk severity classes as they do not relate to harm to humans."</i></p> <p>is not fully understood. Why should safety risk only be limited to harm to people. This limited notion falls short of other safety related events such as separation minima infringement or damage to aircraft.</p>
response	<p>Not accepted</p> <p>GM1 ATS.OR.205(b)4 explains the rationale behind this statement. The other safety-related events are precursor events, but carry no safety risk. They are still useful. This is explained in GM1 ATS.OR.205(b)4–(g) Validating risk analyses.</p>
comment	<p>565 comment by: <i>Federal Office of Civil Aviation FOCA</i></p> <p>Question 11: Rising costs at the beginning of the implementation period for the new method is expected. However, there is also the possibility to achieve a reduction of costs, but only</p>



over long term perspective.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to this RIA for additional information on the final position taken by the Agency.

comment 754 comment by: DFS Deutsche Flugsicherung GmbH

Question 11
DFS agrees that in the long term, costs should decrease a little bit.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to this RIA for additional information on the final position taken by the Agency.

comment 811 comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Regulatory Impact Assessment (RIA) Section 4.6.7.2 <i>Economic impact</i>	Question 11: The Agency would like to seek the stakeholders’ views on the economic impact analysis. If a stakeholder does not agree, the Agency would appreciate it if cost estimates were provided in justification.	We are, in principle and subject to the particular comments made to this NPA, satisfied with the economic impact analysis included in the document.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency’s responses to comments related to this RIA for additional information on the final position taken by the Agency.

comment 862 comment by: Naviair



response	<p>Regarding 4.6.7.2 Question 11: See question 9.</p> <p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.</p>
comment	<p>1022 comment by: <i>DSNA</i></p> <p>Question 11: DSNA is for the removal of severity classification scheme from IR to allow sufficient flexibility depending of the cases and also according to the service supplied by the provider.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.</p>
comment	<p>1048 comment by: <i>UK CAA</i></p> <p>Page No: 212 Paragraph No: QUESTION 11 Comment: The UK CAA broadly supports the notion that the economic impacts are assumed to be neutral, with positive economic impacts possibly outweighing the negative ones in the long term.</p>
response	<p>Noted</p> <p>The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.</p>
comment	<p>1147 comment by: <i>DSAE</i></p> <p>Question 11 : The Agency would like to seek the stakeholders' views on the economic impact analysis. If a stakeholder does not agree, the Agency would appreciate it if cost estimates are provided in justification. DIRCAM's answer : Impact for DIRCAM would be extremely low if option 2 was chosen.</p>



response	Noted The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.
comment	1220 comment by: CAA-NL Question 11: The Agency would like to seek the stakeholders' views on the economic impact analysis. If a stakeholder does not agree, the Agency would appreciate it if cost estimates were provided in justification. The Netherlands agrees with the analyses made on the economic impact.
response	Noted The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.
comment	1242 comment by: EUROCONTROL 4.6 Removal of severity classification scheme from IR - Page 210 'Severity' in the header does not need to start with a capital S. Concerning Article 4.6.8 Comparison and conclusion on page 213 EUROCONTROL makes the following comments: Complex severity classification schemes (SCSs) could very much create a false sense of precision and bring the attention of the service provider away from real operational risk. However, removing the SCS from the rule would NOT support harmonization and would NOT support strong collaboration between ANSPs. It is therefore difficult to understand the rationale behind the positive mark given to Option 2.
response	Partially accepted The title has been changed. Please see the response to comment No 185.
comment	1248 comment by: Ictetra Question 11: We agree.
response	Noted



The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.

4. Regulatory Impact Assessment (RIA) — 4.7. Changes affecting software and Regulation (EC) No 482/2008

p. 213-216

comment

186

comment by: *EUROCONTROL Safety Team*

Page 213 4.7 Changes affecting software and Regulation EC 482/2008

EC 482/2008 requires more from the ANSPs (and their suppliers) than this NPA. The argument on repealing EC 482/2008 would have a positive impact is consequently false.

This NPA does not cover the variation of rigour mandated in EC 482/2008 because that regulation is is very detailed although one may consider that the requirements of EC 482/2008 are broadly integrated in this NPA. On the other hand Option 2 increases the scope of the proposed requirements because it covers the whole functional system and it extends these requirements also to the DAT and Airspace design services. Current ANSPs are all compliant with the EC 482/2008 requirements and the repeal of this regulation would lead to a relaxation of requirements which might negatively impact the safety of the service. The extension of the scope of requirements to cover the whole functional system and also the DAT and Airspace design service is welcomed. However, no AMCs or GM is proposed on this subject although one finds reference to various assurance levels in the proposed text without such text referring to appropriate standards, specifications or methodology.

response

Partially accepted

The Agency does not share the view that 'EC 482/2008 requires more from the ANSPs (and their suppliers) than this NPA.' Specifically, the variation in the level of rigour is covered. Assurance levels are used in Regulation (EC) No 482/2008 to determine 'the rigour to which the assurances are established'. This can only be understood as a means to provide the required level of confidence. The proposal in this NPA allows the level of confidence to be established directly, without the need for assurance levels. Nevertheless, as described in GM2 ATS.OR.205(a)(2), the use of software assurance levels might be helpful in generating appropriate and sufficient evidence to show that ATS.OR.205 and ATM.ANS.OR.C.005 are satisfied.

It is acknowledged that Option 2 increases the scope of the software assurance activities to cover DAT (not ASD as they are not conclusively included in the definition of service provider in CRD to NPA 2013-08). The impact of this change in the scope on Option 2 has been reassessed and included in the Opinion.

It is not acknowledged that the repeal of Regulation (EC) No 482/2008 will lead to a relaxation of requirements, The requirements remain, as shown in Appendix II — 6.2, and



any procedures currently approved should also be applicable to the proposed IR.

It is also acknowledged that the assurance of people, procedures and hardware is not fully covered. This will be tackled in the 2nd NPA and by future additions to the AMC/GM.

comment 257

comment by: NATS National Air Traffic Services Limited

4.7 Changes affecting software and Regulation (EC) No 482/2008

Page 213

As stated in 4.7.2 EASA has extended the detailed assurance criteria to the assurance of the other parts of the functional system however in so doing EASA has not provided any AMC as to how this is to be achieved. Whilst ANSPs will have SSAS which will presumably be sufficient to satisfy the software elements they may satisfy the remaining elements in a number of perfectly acceptable ways that may not be compatible with the detailed assurance criteria suggested by EASA. EASA suggest that this “could” lead to an improvement in safety – to bring about such a fundamental change on the basis of a “could” appears to be completely lacking in understanding the impact upon the service providers in terms of cost and safety benefit.

4.7.3 suggests that only ANSPs and providers of ATFM and ASM are affected. However the Table at 6.2 cross refers to, effectively, ATS providers (ATS.OR) and non ATSP (ATM/ANS.OR) in which case all service providers are affected. Therefore not only has EASA imposed the software assurance but also the remaining elements upon those service providers that currently do not have to comply with 482.

4.7.5 notes “where applicable” – can EASA explain what criteria is being used to determine “where applicable” as it appears that all service providers must comply for all elements of a functional system?

As stated in previous comments the GM on assurance levels is woefully inadequate and to introduce such a requirement without adequate and sufficient AMC/GM is not acceptable.

In the light of these comments it is strongly suggested that the RIA is revisited as it appears to be founded on an incorrect understanding and scope.

response Partially accepted

It is acknowledged that the assurance of people, procedures and hardware is not fully covered. This will be tackled in the 2nd NPA and by future additions to the AMC/GM. However, the argument that the ways providers may choose to satisfy the regulations for the other elements may not be compatible with it seems to be a non sequitur.

It is also acknowledged that Options 1 & 2 increase the scope of the software assurance activities to cover DAT. The impact of this change in scope of Option 2 has been reassessed and included in the Opinion.

Accepted — ‘where applicable’ has been removed.



The provision of an acceptable assurance argument relies on satisfying the requirements of the IR and its associated AMC. It does not rely, at the level of the rule, on assurance levels. Nevertheless, as described in GM2 ATS.OR.205(a)(2), the use of assurance levels might be helpful in generating appropriate and sufficient evidence. There are many standards available that deal with assurance levels, and it may be appropriate to use one or more of them. However, this is a level of detail below that of the proposed IR.

comment 259 comment by: *NATS National Air Traffic Services Limited*

4.7.7.2
Page 215

Question 12

The EASA proposals mean, in effect, that all service providers (not just those that were encompassed by 1035) must now provide assurance for all elements of the change to the functional system whereas previously the specific requirement was with regard to software. Whilst ANSPs are obliged (under 1035) to provide assurance for all elements of the functional system there is no guarantee that the existing methods used will be deemed acceptable given the prescriptive nature of the IR and AMC. For service providers, other than ANSPs, there could be a significant cost in establishing adequate means of assuring all elements of their functional systems given that there is currently no such requirement.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.

comment 567 comment by: *Federal Office of Civil Aviation FOCA*

Question 12: FOCA agrees on the economic impact assessment and the considerations made under 4.7.7.2.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.

comment 593 comment by: *Federal Office of Civil Aviation FOCA*



RIA Chapter 4.7 Changes affecting software and regulation (EC) Nr. 482/2008: FOCA is in favour of option 2. Reasoning: Based on the experience made with the two existing regulations, we strongly see the need to include all safety relevant elements in one view (functional system). Clear and detailed explanation of the terms is required as a baseline, in order to enable all persons involved in the organisation to share the same level of understanding. In addition, the term software needs a precise description, i.e: programs, source code, executables, configuration data, data to be processed, etc.). More detailed guidance is desired for COTS and network infrastructure as a transport layer.

response

Accepted
However, this is not presently available and will be developed later.

comment

812

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Regulatory Impact Assessment (RIA) Section 4.7.7.2 Economic impact	Question 12: The Agency would like to seek the stakeholders' views on the economic impact analysis. If a stakeholder does not agree, the Agency would appreciate it if cost estimates were provided in justification.	We are, in principle and subject to the particular comments made to this NPA, satisfied with the economic impact analysis included in the document.

response

Noted
The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.

comment

863

comment by: Naviair

Regarding 4.7.7.2
Question 12: It is not possible at this point to determine economic implications. However we believe that it will be an extra cost if we are to include the assurance criteria from EU 482/2008 in all parts of the functional system.

response

Noted



The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.

comment 1023

comment by: DSNA

Question 12:

DSNA agrees to remove the commission regulation (EC) N° 482/2008 and then transpose the requirements of the Regulation in a GM and do not over-regulate other parts of the functional system.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.

comment 1049

comment by: UK CAA

Page No: 215

Paragraph No: QUESTION 12

Comment:

The UK CAA broadly supports the notion that the economic impacts are assumed to be neutral, with positive economic impacts possibly outweighing the negative ones in the long term.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.

comment 1054

comment by: DFS Deutsche Flugsicherung GmbH

Question 12

DFS agree that Option 2 could have a slight positive economic impact.

response Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position



taken by the Agency.

comment

1132

comment by: *Belgocontrol*

Page 213 4.7 Changes affecting software and Regulation EC 482/2008

EC 482/2008 requires more from the ANSPs (and their suppliers) than this NPA. The argument that repealing EC 482/2008 would have a positive impact is therefore not correct. This NPA does not cover the variation of rigor of EC 482/2008. Current ANSPs are all compliant with the EC 482/2008 requirements and the repeal of this regulation may lead to a relaxation of requirements which might negatively impact the safety of the service.

The extension of the scope of requirements to cover the whole functional system and also the DAT and Airspace design service is welcomed. However, no AMCs or GM is proposed on this subject although one finds reference to various assurance levels in the proposed text without referring to appropriate standards, specifications or methodology.

response

Partially accepted

Please see the response to comment No 186.

comment

1148

comment by: *DSAE*

Question 12 : The Agency would like to seek the stakeholders' views on the economic impact analysis. If a stakeholder does not agree, the Agency would appreciate it if cost estimates are provided in justification.

DIRCAM's answer : Impact for DIRCAM would be extremely low if option 2 was chosen.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.

comment

1221

comment by: *CAA-NL*

Question 12: The Agency would like to seek the stakeholders' views on the economic impact analysis. If a stakeholder does not agree, the Agency would appreciate it if cost estimates were provided in justification.

The Netherlands agrees.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position



taken by the Agency.

comment

1249

comment by: *Icetra*

Question 12:
We agree.

response

Noted

The Agency takes due consideration of the answer to the question. Please see the Agency's responses to comments related to this RIA for additional information on the final position taken by the Agency.

comment

1257

comment by: *EUROCONTROL*

4.7 Changes affecting software and Regulation (EC) No 482/2008 - Page 213

EUROCONTROL makes the following comments:

As EC482/2008 is requiring more from the ANSPs (and their suppliers) than this NPA does, it can be argued that the repealing of EC482/2008 cannot have a positive impact. ANSPs have invested a lot of resources to become compliant with EC 482/2008 in the past years. Saying that repealing EC 482/2008 would have a positive impact is consequently wrong. Strong evidence should be given to support the comparison and conclusion found at Article 4.7.8.1 Comparison of options (page 216).

response

Not accepted

The opinion that the repeal of Regulation (EC) No 482/2008 will lead to a service provider having to replace his SSAS is not shared by the Agency. The Regulation (EC) No 482/2008 requirements remain, as shown in Appendix II — 6.2, and any procedures currently approved should also be applicable to the proposed IR.



5. Appendix — Attachments

 [Paper 4 CANSO proposed changes to IR in NPA 2014-13 v1 2.pdf](#)

Attachment #1 to comment [#569](#)

 [Appendix A – CANSO detailed proposals on the format of the proposed IR AMC within NPA 2014-13.pdf](#)

Attachment #2 to comment [#656](#)

 [NATS additional comments against NPA 2014-13.pdf](#)

Attachment #3 to comment [#1156](#)

 [NATS Appendix A - Resulting Text NPA 2014-13.pdf](#)

Attachment #4 to comment [#25](#)

 [Attachment DFS final.pdf](#)

Attachment #5 to comment [#757](#)

 [NPA 2014-13 NAV Portugal.pdf](#)

Attachment #6 to comment [#458](#)

 [RATIONALE for Question 2 on R\(EC\) No 482_2008 \(final\) EN with analysis of cross-reference table vf.pdf](#)

Attachment #7 to comment [#793](#)

