



Comment-Response Document 2014-13

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

CRD TO NPA 2014-13 — RMT.0469 & RMT.0470 — 12.12.2014

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.

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.

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.

The resulting rule text is provided in:

- Annex I: Definitions;
- 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 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.



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

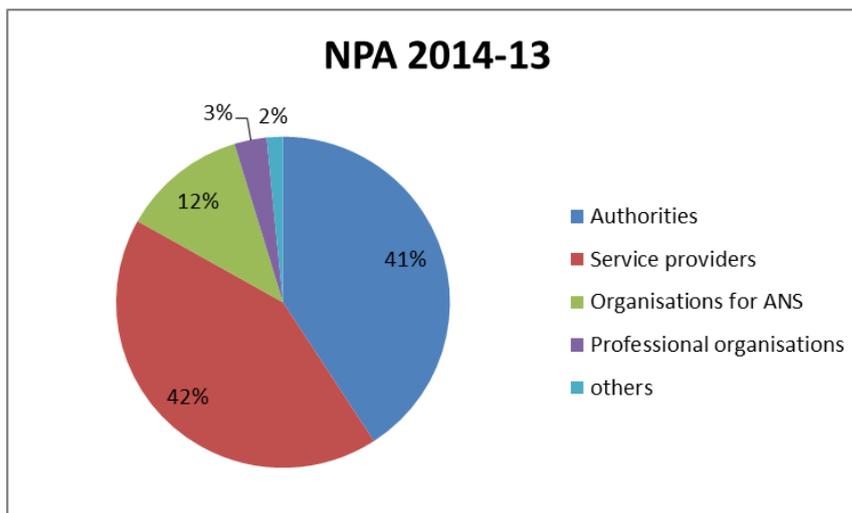


Figure 1: Distribution of the comments received according to stakeholders’ sectors

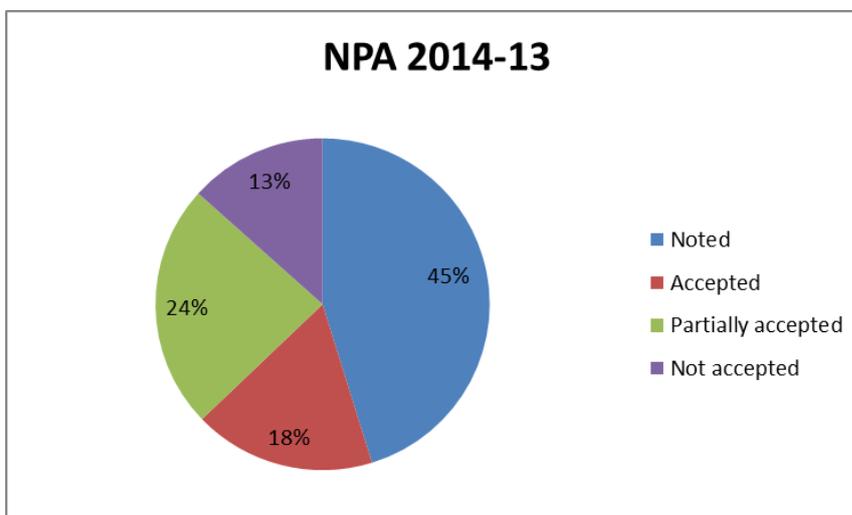


Figure 2: Distribution of the responses in CRD to NPA 2014-13



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’.



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)

-

comment

2

comment by: EUROCONTROL Safety Team

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.

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.

Examples are:

- 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

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. 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>
comment	<p>5 comment by: EUROCONTROL Safety Team</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	<p>6 comment by: EUROCONTROL Safety Team</p> <p>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.</p> <p>It is quite significant to note that although this NPA was published almost at the same as A-NPA 2014-12 it seems that NPA 2014-13 does not follow the basic principles expounded in A-</p>



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.

comment

235

comment by: UK CAA



	<p>Page No: general Paragraph No: general Comment: All GM</p> <p>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.</p> <p>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.</p> <p>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</p> <p>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'.</p> <p>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> <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:</p> <p>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</p>



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.

If the above is not addressed we believe that industry will be impacted as follows:

- 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.

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.

Justification: Clarity, practicality

response

Partially accepted

Please refer to the responses to comments No 3 and No 235

comment

237

comment by: UK CAA

Page No: general

Paragraph No: general

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	<p>Partially accepted</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>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.</p>
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comment	238	comment by: UK CAA
<p>Page No: general</p> <p>Paragraph No: general</p> <p>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.</p> <p>The NPA appears to suggest that there are parts of ATM/ANS that are low risk in terms of</p>		



	<p>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.</p> <p>Justification: Proportionate regulation.</p>
response	<p>Partially accepted</p> <p>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.</p>
comment	<p>239 comment by: UK CAA</p> <p>Page No: general Paragraph No: general 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. 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>



This is certainly something that will be needed once the rule is adopted, but not at this stage where the requirements are being defined.

comment

241

comment by: UK CAA

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

response

Partially accepted

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 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 providers 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.

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 is 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.

comment

274

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

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.

"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]

The proposed IR will also result in a Wide range of severity classification schemes [ref page 16]

Furthermore it is not acceptable that a single requirement in the IR requires extensive number of GM and AMCs to be understood.

response

Partially accepted

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.

The general comments on AMC/GM will be responded to in the CRD associated with them.

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.

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.

comment

275

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

The proposed regulation significantly increases complexity for the both for CA and Service 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).

response

Noted

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.

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.

comment

276

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

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.

This is not in line with the performance regulation EU No 390/2013

response

Partially accepted

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.

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.

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: <i>BAF-M.Jancokova</i>
	EASA AMC + GM must be comprehensive but considered just as a <u>possible</u> 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.	
comment	316	comment by: <i>BAF-M.Jancokova</i>
	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.	
comment	317	comment by: <i>BAF-M.Jancokova</i>
	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?

response

Noted

No additional responsibilities are envisaged. Please see comment No 840 for a detailed response to the concerns over the use of 'approve'.

comment

357

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

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.

response

Noted

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.

comment

369

comment by: *skyguide Corporate Regulation Management*

SUMMARY

ISSUES:

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.

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 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	<p>374 comment by: <i>Air Navigation Services of the Czech Republic</i></p> <p>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"):</p> <ul style="list-style-type: none"> • 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	<p>Partially accepted</p> <p>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.</p>
comment	<p>455 comment by: <i>NAV Portugal E.P.E</i></p> <p>General Comments:</p> <p>NAV Portugal supports CANSO and EUROCONTROL comments (positions) since they were coordinated and they reflect NAV Portugal's views.</p> <p>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.</p> <p>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.</p> <p>Regarding the NPA structure, NAV Portugal would like to highlight these topics:</p> <p>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.</p> <p>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> <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>



response

- 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.

The guidance material should be reviewed as it is unfocused, incomplete, confusing and even contradictory.

Partially accepted

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.

For a detailed response to the comment on the level of detail in the IR, please see comment No 2.

For a detailed response to the comment on the overlapping area with CRD 2013-08, please see comment No 5.

For a detailed response to the other comments that are coincident to CANSO's comments, please see the response to comment No 369.

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 necessarily 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. 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.

comment

466

comment by: CAA CZ

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.

response

Noted

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.

comment 569 comment by: *skyguide Corporate Regulation Management*

Attachment [#1](#)

We agree with the proposed changes in the attached file - Appendix A - made by CANSO.

response Partially accepted

Please see the responses to the specific comments that justify the proposal in this Annex addressing each individual modification.

comment 656 comment by: *CANSO*

Attachment [#2](#)

In the attachment (Appendix A), please find the CANSO's detailed proposals on the format of the proposed IR/AMC within NPA 2014-13.

response Partially accepted

Please see the responses to the specific comments that justify the proposal in this Annex addressing each individual modification.

comment 668 comment by: *Swedavia*

Swdavia agree CNS providers shall perform safety support assessment. We also want to propose that the authority should get a limited time to respond to avoid unnecessary time delay.

response Partially accepted

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.

comment 675 comment by: *ROMATSA*

1. SUMMARY ISSUES:



a.

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.

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.

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.

d. Performance Based Regulation. ROMATSA supports CANSO opinion that the IR (and AMC) is not performance based as the NPA contains much prescriptive regulation.

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).

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

i. providers and CAs that are not possible to demonstrate compliance with (see specific 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> 'Functional system', <i>GM1 Article 2(2) Definitions</i> which is nowhere to be found within the NPA).	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

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
General Comment	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. 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</u>	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.



	<u>application is mandatory.</u>	
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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
General Comment	We wonder where are the concepts of 'Declaration of Verification of Systems' and 'Declaration of Conformity/Suitability for Use' addressed, both within this NPA and, further to this, within the ATM/ANS new structure set by EASA in the overall NPA 2013-08 .	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 .

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	This NPA is difficult to follow as it is fully cross-referenced and intimately intertwined with NPA 2013-08 .	We would recommend a clear use of terms and concepts in order to avoid current and future misunderstandings in



	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.	the application of the regulation.
response	<p>Noted</p> <p>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.</p>	

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



	<p>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.</p> <p>6. Explanatory Note (EN) and Regulatory Impact Assessment (RIA): Naviar 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.</p>
response	<p>Partially accepted</p> <p>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).</p> <p>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.</p> <p>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.</p>
comment	<p>953 comment by: CAA Norway</p> <p>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.</p> <p>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.</p> <p>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.</p>



response	Accepted
	<p>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.</p> <p>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.</p>
comment	<p>1067 comment by: <i>bmvit/CAA/NSA</i></p> <p>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.</p>
response	<p>Noted</p> <p>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.</p>
comment	<p>1076 comment by: <i>Belgocontrol</i></p> <p>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.</p>
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.



	<p>· In some of the AMCs and also GM, both “should” and “shall” are used. 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>
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 been addressed in CRD 2013-08</p>
response	<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>



	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.
response	Not accepted Please see the response to comment No 6.

comment	1087 comment by: <i>Belgocontrol</i>
	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).
response	Partially accepted 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.

comment	1113 comment by: <i>Isavia ltd.</i>
	In general Isavia agrees with what is proposed in the NPA. We would like to make one comment/question: 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> 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.” 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?
response	Noted 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.

comment

1153

comment by: NATS National Air Traffic Services Limited

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:

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.

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).

AMC1 ATM/ANS.OR.A.045(d) effectively repeats the related IR.

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.

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).

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?

AMC1 ATM/ANS.OR.C.005(a)(2) requires a safety support case and similar wording to that of the related IR.

AMC1 ATM/ANS.OR.C.005(b)(1) relates to completeness of the scope of the safety support assessment whereas the related 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.

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 ATS.OR.205(a)(2) to GM5 ATS.OR.205(a)(2))

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.



The level of referencing is high and, even though it hinders readability, it improves precision.
Please refer to the responses to comments Nos 3 and 235 for additional clarifications.

comment	<p>1156</p> <p style="text-align: right;">comment by: <i>NATS National Air Traffic Services Limited</i></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</p> <p style="text-align: right;">comment by: <i>Avinor ANS</i></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 and service providers.</p> <p>d. Performance Based Regulation. Avinor ANS believe that the IR (and AMC) is <u>not</u> 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</p>
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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
	<p>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).</p>	
response	<p>Noted</p> <p>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.</p>	

Notice of Proposed Amendment 2014-13

p. 1

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

EXECUTIVE SUMMARY

p. 1

comment	131	comment by: ENAIRE
	<p>The use of new terms, concepts (safety support assessment, unsound), in our opinion, introduces even more complexity instead of clarify.</p>	
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>	



The term 'safety support assessment' is extensively explained in AMC/GM. For additional explanation, see the response to comment No 273.

comment 132

comment by: ENAIRE

The use of subjective and ambiguous terms (as "unsound") is not appropriate for an NPA.

response Accepted

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.

comment 176

comment by: DSNA

general remarks :

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, **the key concept of change is still missing** 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 **a very academic approach and an unrealistic approach to safety.**

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, 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.

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.

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 necessarily 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 Sate 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 N° 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 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						
	<table border="1"> <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="background-color: #ffff00;">Table of Contents (page 2)</td> <td style="background-color: #ffff00;">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>.</td> <td style="background-color: #ffff00;">Typographical error</td> </tr> </tbody> </table>		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
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response	<p>Accepted</p> <p>This has been corrected.</p>							

comment	975	comment by: AESA / DSANA						
	<table border="1"> <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="background-color: #ffff00;">Table of Contents (page 3)</td> <td style="background-color: #ffff00;"><i>GM1 ATM/ANS.OR.A.045(e)(3)</i> appears twice (pages 114 and 116). Wouldn't the second instance be in fact <u><i>GM2</i></u> <i>ATM/ANS.OR.A.045(e)(3)</i>?</td> <td style="background-color: #ffff00;">Typographical error</td> </tr> </tbody> </table>		PART	COMMENT	JUSTIFICATION	Table of Contents (page 3)	<i>GM1 ATM/ANS.OR.A.045(e)(3)</i> appears twice (pages 114 and 116). Wouldn't the second instance be in fact <u><i>GM2</i></u> <i>ATM/ANS.OR.A.045(e)(3)</i> ?	Typographical error
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response Accepted
This will be corrected.

comment 977 comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Table of Contents (page 4)	GM3 ATM/ANS.OR.B.010(a) follows GM3 ATM/ANS.OR.B.010(a). Shouldn't this ought to be GM ₂ 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.	Typographical error

response Accepted
This will be corrected.

comment 978 comment by: AESA / DSANA

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

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.
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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.

DFS wishes to make some general comments. In many cases our detailed comments support one of these.

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]".



	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.
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 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 ...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 <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)).
response	<p>Partially accepted</p> <p>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</p>



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	<p>358 comment by: <i>Air Navigation Services of the Czech Republic</i></p> <p>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.</p> <p>EASA seems to interpret 1034/2011 and 1035/2011 to suit its own RIA and the selected options (retrospectively):</p> <ul style="list-style-type: none"> • 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 <p>Some cross references to 1034/2011 and 1035/2011 appear incorrect (e.g. 1034/2011 Art 9(2) should be Art 10(2)).</p>
response	<p>Partially accepted</p> <p>Please refer to the response to comment No 17.</p>
comment	<p>371 comment by: <i>skyguide Corporate Regulation Management</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.</p> <p>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.</p> <p>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)).</p> <p>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.</p> <p>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 Partially accepted
Please refer to the response to comment No 17.

comment 594 comment by: *DFS Deutsche Flugsicherung GmbH*

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"

response Partially accepted
Please refer to the response to comment No 17.

comment 625 comment by: *CANSO*

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.

response Partially accepted
Please refer to the response to comment No 17.

comment 676 comment by: *ROMATSA*

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
<p>Explanatory Note Section 2.1 <i>Overview of the issues to be addressed</i></p>	<p>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.</p>	<p>We would like to understand the context of this assertion in order to better assess the NPA.</p>

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: <i>"'Equipment' is an assembly of the framework for locating hardware, the hardware itself (including its contained software) and possibly a cover to act as a barrier between the internal and external environments."</i></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 <i>"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"</i> 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: <i>ENAIRE</i></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: <i>ENAIRE</i></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>



	<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.</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>375 comment by: skyguide Corporate Regulation Management</p> <p>requirement applies to all the <i>constituent</i> 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.</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>377 comment by: skyguide Corporate Regulation Management</p> <p>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.</p>



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	559	comment by: <i>Romanian CAA</i>
	<p>QUESTION 1</p> <p>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	596	comment by: <i>DFS Deutsche Flugsicherung GmbH</i>
	<p>Question 1:</p> <p>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.</p> <p>Info: without further information from EASA it was unclear when the two-years period would have started.</p> <p>For justification and arguments we support the CANSO opinion.</p> <p>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	597	comment by: <i>DFS Deutsche Flugsicherung GmbH</i>
	<p>Question 2:</p> <p>For DFS it is ok to repeal Regulation (EC) No 482/2008.</p> <p>But in the proposal some changes should be done. Here we support the CANSO arguments:</p> <p>For software: there is no variation in rigor.</p> <p>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	<p>847</p> <p>comment by: <i>Naviair</i></p> <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 1010 440 1041">Noted</p> <p data-bbox="360 1075 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 1641 440 1673">Noted</p> <p data-bbox="360 1706 1485 1823">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 1845 1485 1998">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>1051 comment by: DGAC/DSAC - french NSA</p> <p><u>Answer to question 1 :</u></p> <p>If major comments made by french NSA are taken into account, the 2 year transition period should be ok.</p> <p><u>Answer to question 2 :</u></p> <p>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>Question 1: Noted</p> <p>Question 2: 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 provision on coordination arrangements 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>1072 comment by: LVNL</p> <p><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>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</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	<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	1269	comment by: <i>European Transport Workers Federation - ETF</i>
	<p>ETF agrees on the proposed 2-year transition period</p>	
response	<p>Noted</p>	

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	<i>comment by: 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	<i>comment by: 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	Noted
	<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	327 comment by: <i>BAF-M.Jancokova</i>
	Question 4: No need is seen to regulate the coordination arrangements between CAs.
response	Noted
	<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	328 comment by: <i>BAF-M.Jancokova</i>
	<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	Noted
	The Agency would like to apologise, as the reference appears in CRD to NPA 2013-08 and not in NPA 2014-13.
comment	334 comment by: <i>ATCEUC - Air Traffic Controllers European Unions Coordination</i>
	Question 3: we have a different proposal: "... of the likelihood of the argument being unsound <u>the probability of the assurance case to be likely to happen...</u> "
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 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>



evaluation of the argument itself. FOCA sees the following problem with this approach:

- 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.

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.

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 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.

As for the term 'the criticality of the potential risk', elaboration on it is missing, rendering a discussion on its appropriateness not possible.

comment

550

comment by: *Federal Office of Civil Aviation FOCA*

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.

An additional reason not to proceed with this proposition is that it will only remotely contribute to safety.

Therefore, changes affecting cross border should be addressed by the ANSP with the respective NSA concerned.

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.



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

comment

557

comment by: *Romanian CAA*

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="359 235 422 280">1074</p> <p data-bbox="1252 235 1484 280" style="text-align: right;">comment by: LVNL</p> <p data-bbox="359 324 646 369"><i>Response to question 3:</i></p> <p data-bbox="359 369 1484 481"><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="359 492 486 526"><i>Rationale:</i></p> <p data-bbox="359 526 1484 817"><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="359 828 438 873">Noted</p> <p data-bbox="359 907 1484 1064">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="359 1086 1484 1164">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="359 1220 422 1265">1083</p> <p data-bbox="1125 1220 1484 1265" style="text-align: right;">comment by: bmvit/CAA/NSA</p> <p data-bbox="359 1321 534 1355"><i>ad question 3:</i></p> <p data-bbox="359 1355 1484 1444"><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="359 1444 965 1478"><i>This might end in a wrong conclusion from the CA.</i></p> <p data-bbox="359 1478 1484 1556"><i>We recommend that the criteria should include the size, scope, complexity, criticality and safety risk as well.</i></p>
response	<p data-bbox="359 1579 438 1624">Noted</p> <p data-bbox="359 1657 1484 1814">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="359 1836 1484 1915">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 extend. 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>



	It works today without regulation, thus no regulation required.
response	<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. 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 information on the final position taken by the Agency. For instance, please see the responses</p>



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.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.</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

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. This way the CAA CZ receives full picture of the service provider's SMS, QMS and of overall



	<p>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 responses to comments related to continuous improvement of performance for additional</p>



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>Romanian CAA</i></p> <p>QUESTION 5 We consider that the question should identify the Basic Regulation and SARPS provisions that it makes reference to. We do not agree with the proposal for proactive performance management in the context of this NPA. Justification To prevent misinterpretation of the question. The document addresses the safety assessment of changes and therefore the proposal for proactive performance management is exceeding the scope of the document. 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 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. We do not support ATM/ANS.OR.B.005 d)(2) and we propose to eliminate it. Justification 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. 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. 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

601

comment by: *DFS Deutsche Flugsicherung GmbH*

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.

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

657

comment by: *CANSO*

2.4.4 and 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

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.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

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



benefit.

Supporting comment to summary issue: Explanatory Note – does not support the Implementing Rule

response 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. In fact, we would welcome a simplification in the terminology used.</p>	
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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



	<p>requirements to monitor. The workload used would be too disproportionate compared to the safety gain.</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>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</p> <p>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</p> <p>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</p> <p>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="363 495 1485 815">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 1055">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 1249 1485 1361">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 1532 1485 1608">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 1883">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.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.</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>69 comment by: EUROCONTROL Safety Team</p> <p>Page 30 The set of safety criteria, as a whole, shall satisfy the “objective for safety” (middle of page)</p> <p>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 ATS.OR.201(b)</i>. 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>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.</p> <p>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>126 comment by: ENAIRE</p> <p>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>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 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 temporally</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>Romanian CAA</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: Navair

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

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

1085

comment by: LVNL

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.

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.

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.

response

Noted

Please see the response to comment No 1216.

comment

1097

comment by: Belgocontrol

Page 29 Question 7

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.

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.

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: *lcetra*

Question 7:



	<p>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.</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>1173 comment by: Avinor ANS</p> <p>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>Please see the response to comment No 66.</p>
comment	<p>1191 comment by: ENAIRE</p> <p>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.</p>
response	<p>Not accepted</p> <p>The term ‘objective for safety’ is not used as a technical term and not used in the IR at all. The definition seems unnecessary.</p>
comment	<p>1216 comment by: CAA-NL</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</p>



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: CANSO</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: EUROCONTROL</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>



response	<p>CRD 2013-08 introduces the potential for internal inconsistencies, duplicate regulation and a lack of legal certainty.</p> <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: Romanian CAA

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>



response	<p>Supported by CAA CZ.</p> <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="363 772 480 810">Accepted</p> <p data-bbox="363 846 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="363 981 1498 1064">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 1137 427 1176">1175</p> <p data-bbox="1177 1137 1498 1176" style="text-align: right;">comment by: <i>Avinor ANS</i></p> <p data-bbox="363 1227 970 1265">“... verify changes made to the functional system:”</p> <p data-bbox="363 1272 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 1473 746 1512">It has been moved to AMC/GM.</p>
comment	<p data-bbox="363 1594 427 1632">1176</p> <p data-bbox="1177 1594 1498 1632" style="text-align: right;">comment by: <i>Avinor ANS</i></p> <p data-bbox="363 1684 683 1722">ATM/ANS.AR.C.010(b)(1)?</p> <p data-bbox="363 1729 1498 1812">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 1818 480 1856">Accepted</p> <p data-bbox="363 1886 746 1924">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 "functional system" 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 "staff affected by the change shall be consulted during audits and oversight assessments."</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: <i>EUROCONTROL Safety Team</i>
	<p>ATM/ANS.AR.C.030</p> <p>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.</p> <p>The text is more appropriate as specific AMC on changes to the MS/SMS.</p> <p>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.</p>	
response	<p>Partially accepted</p> <p>Please refer to the response to comment No 36.</p>	

comment	177	comment by: <i>DSNA</i>
	<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.</p> <p>Furthermore, the competent authority is required to review (a)(2) all modifications to procedures referred to in (1). DSNA believes this is infeasible.</p> <p>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</p>	
response	<p>Partially accepted</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.

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

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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>



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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

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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 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 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 develop 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 and 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: *Romanian CAA*

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

Not accepted

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.

comment 609

comment by: *DFS Deutsche Flugsicherung GmbH*

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"

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 637

comment by: *CANSO*

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. 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
Proposed amendments Section 3.1 <i>Draft Regulation (Draft</i>	An option to modify the decision should	After informing the decision to not review the change, the CA may continue with the general oversight of that change before its



<p><i>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>be included.</p>	<p>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>
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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: *Avinor ANS*

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. Please see the response to comment No 39.

comment 1194

comment by: ENAIRE

Everything lies on the competent authority criteria.
In our opinion, the Agency should provide some criteria in order to objectify the competent authority decision.

response Not accepted;

This has been already done.

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.

comment 1224

comment by: CAA-NL

ATM/ANS.AR.C.035 Decision to review the notified change

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 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)

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



response	basis.
	<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

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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	Accepted See also response to comment No 34. 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.
comment	46 comment by: <i>NATS National Air Traffic Services Limited</i> ATM/ANS.AR.C.040(a)(3) Page 34 The “and/or” is unnecessary as the two are mutually exclusive (unless an ATS provider can produce a safety support assessment). Proposal: Points (a)(3) amended as proposed in Appendix A (document attached to NATS Comment number 25).
response	Accepted ‘And/or’ has been changed to ‘or’. 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.
comment	263 comment by: <i>DSNA</i> The concept of « risk-based » seems still immature. Shall it be kept in the IR ? (a)(1) : over regulated, this requirement is unnecessary, DSNA proposes to delete (a)(1). (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. (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. 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 the change”.
response	Partially accepted



(a)(1) is deleted.

(a)(4) Accepted. Nothing indicates the contrary.

(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).

comment 265

comment by: UK CAA

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;

response Partially accepted

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.

comment 266

comment by: UK CAA

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

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.’

	<p>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'.</p>
response	<p>Noted</p> <p>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.</p>
comment	<p>364 comment by: <i>Air Navigation Services of the Czech Republic</i></p> <p>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).</p>
response	<p>Not accepted</p> <p>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.</p>
comment	<p>480 comment by: <i>CAA CZ</i></p> <p>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.</p>
response	<p>Noted</p> <p>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.</p>
comment	<p>551 comment by: <i>Romanian CAA</i></p>



	<p>(c) (1) To replace the term approve with accept. Justification The term <i>accept</i> is used in current regulations. The term <i>accept</i> reflects better the statement used in the same sentence ...<i>and so inform the service provider of their <u>acceptability</u>, or</i> 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.</p>
response	<p>Not accepted</p> <p>Please see the response to comment No 840 about the use of the term 'approve' vs the term 'accept'.</p> <p>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.</p>
comment	<p>585 comment by: <i>Federal Office of Civil Aviation FOCA</i></p> <p>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.</p>
response	<p>Accepted</p> <p>The provision has been removed.</p>
comment	<p>622 comment by: <i>DGAC/DSAC - french NSA</i></p>



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 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 . 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".

response

Partially accepted

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.

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.

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'.

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).

Paragraph (c): Not accepted. Please see the response to comment No 840 about the use of the term 'approve' vs the term 'accept'.

'Acceptability' and 'unacceptability' have been removed.

comment 701

comment by: ROMATSA

Answer to Question 4

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.

ROMATSA fully supports CANSO recommendation not to regulate this at present, but to await sufficient experience, then evaluate need again.

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

1226

comment by: CAA-NL

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 para (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’.

3. Proposed amendments — 3.1. Draft EASA Opinion — ANNEX III — ATM/ANS.OR.A.045
Changes to the functional system

p. 35

comment

47

comment by: *NATS National Air Traffic Services Limited***ATM/ANS.OR.A.045****Page 35**

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.

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).

response

Not accepted

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 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

Partially accepted

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.

(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)).

(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.

comment 50 comment by: *NATS National Air Traffic Services Limited*

ATM/ANS.OR.A.045(e)(1)

Page 35

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?

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).

response Accepted

The phrase 'where feasible' has been added.

comment 51 comment by: *NATS National Air Traffic Services Limited*

ATM/ANS.OR.A.045(e)(3)

Page 35

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?

response Accepted

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 74 comment by: EUROCONTROL Safety Team

General comment ATM/ANS.OR.A.045

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...).

response Accepted

This has been amended. The action towards other service providers and aviation undertakings is 'inform'.

comment 75 comment by: EUROCONTROL Safety Team

ATM/ANS.OR.A.045 (e)

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.

Recommend to amend text to include *where feasible*, similar to the approach in ATM/ANS.OR.A.045(a)(3).

response Accepted

The phrase 'where feasible' has been added.

Please see also response to comment No 49.

comment 269 comment by: UK CAA

Page No: 35

Paragraph No: ATM/ANS.OR.A.045 (c) & (d)

Comment: The meaning of "parts of the change" is unclear. The UK CAA requests clarification of this term in order to make meaningful comment.

Justification: Clarity.

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	<p>Partially accepted</p> <p>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.</p> <p>‘Acceptance vs approval’ — Please see the response to comment No 840 about the use of the term ‘approve’ vs the term ‘accept’.</p> <p>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.</p> <p>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.</p> <p>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.</p> <p>(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.</p>
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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 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.

response Partially accepted



Please see the responses to comments Nos 47, 49 and 50.

comment 449

comment by: EUROCONTROL

Annex III
Subpart A

ATM/ANS.OR.A.045 (a) - Page 35

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).

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.

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.

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)**

The notification of a change is extended to include other providers and also aviation undertakings.

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)**

EUROCONTROL's comment

ANSP's cannot force aviation undertakers who do not fall under the EC216/2008 regulation 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.



response

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.

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	<p>610 comment by: DFS Deutsche Flugsicherung GmbH</p> <p>(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 <u>necessary</u>, aviation undertakings affected by the planned change.” Reference to high level comment "c.ii"</p>
response	<p>Not accepted</p> <p>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.</p>
comment	<p>632 comment by: DGAC/DSAC - french NSA</p> <p>The french NSA has four comments related to ATM/ANS.OR.A.045 :</p> <ul style="list-style-type: none"> • paragraph (a) : <p>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.</p> <ul style="list-style-type: none"> • paragraph (a) : <p>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.</p> <ul style="list-style-type: none"> • paragraph (b) : <p>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 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>



response

- paragraph (e) :

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)).

Partially accepted

- 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*

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 approach is advocated for (e).



	<p>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	<p>Accepted</p> <p>The assessment is normally performed by service providers, not by aviation undertakings. Anyway, provisions have been amended to account for this situation.</p>
comment	<p>846 comment by: AESA / DSANA</p>



PART	COMMENT	JUSTIFICATION
<p>Proposed amendments Section 3.1 <i>Draft Regulation (Draft EASA Opinion)</i> Annex III COMMON REQUIREMENTS FOR SERVICE PROVIDERS <i>(Part-ATM/ANS.OR)</i> 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>
<p>response</p>	<p>Noted</p> <p>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.</p> <p>b) The purpose of the notification is to make the CA aware of the planned change and its extent.</p> <p>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</p>	



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: *Navair*

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.

comment

885

comment by: *Navair*

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 <i>Draft Regulation (Draft EASA Opinion) Annex III COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR)</i>	We wonder whether the partial approval of a change introduced in this new provision ATM/ANS.OR.A.045(c) & (d) is a sensible way to proceed.	The change is presented as an integral 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.

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
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 (d)	A similar requirement should be included to prevent service providers to introduce a change before the CA has informed of its decision on whether to review or not.	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 case of an explicitly declared review.

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.

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: Romanian CAA

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.



	<p>Proposal: Delete ATM/ANS.OR.B.005 (a)(5) as proposed in Appendix A (document attached to NATS Comment number 25)</p>
response	<p>Accepted</p> <p>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.</p> <p>Planning a change includes the intent of the provider to implement the change.</p>
comment	<p>53 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>ATM/ANS.OR.B.005(a)(6) Page 36</p> <p>Point (a)(6) requires ANSPs to <u>consider</u> changing their functional system if it is technically and economically feasible to improve performance by doing so.</p> <p>“Consider” is not appropriate wording for IR. Furthermore, the IR implies a requirement to document why changes have <u>not</u> 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.</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>Proposal: Delete ATM/ANS.OR.B.005 (a)(6) as proposed in NATS Appendix A (document attached to Comment number 25)</p>
response	<p>Accepted</p> <p>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</p>



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 54

comment by: *NATS National Air Traffic Services Limited***ATM/ANS.OR.B.005(d)****Page 36**

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.

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)

response

Partially accepted

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.

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.

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.

The (d)(2) clause can be moved to AMC as this is part of the underperformance limited to the monitoring criteria of changes.

comment

76

comment by: EUROCONTROL Safety Team

ATM/ANS.OR.B.005 (a)(5)

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 *Circumstances, that may* 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.

This requirement is thus rather unclear and somewhat infeasible. Furthermore no AMCs or GM are provided on this topic.

Recommend to delete ATM/ANS.OR.B.005 Para (a)(5).

response

Accepted

Please see the response to comment No 52.

comment

77

comment by: EUROCONTROL Safety Team

ATM/ANS.OR.B.005 (a)(6)

1. The requirement is unbounded and uses subjective language. *Consider* 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.

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 78 comment by: EUROCONTROL Safety Team

ATM/ANS.OR.B.005 (d)

1. The requirement is uses subjective language because *substandard performance* 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.

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 79 comment by: EUROCONTROL Safety Team

ATM/ANS.OR.B.005(d)

There is a discrepancy between this requirement and the EN. The requirement is that *a service provider shall monitor the behaviour of the functional system* but the EN refers to *monitor the behaviour of the service*.

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.

Recommend to adjust text to require *monitoring the behaviour of the service*.

response Not accepted
Please see the response to comment No 680.

comment 272 comment by: DSNA

(a)(5) :

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. **DSNA suggests to delete ATM/ANS.OR.B.005 Para (a)(5)** or at the very least suggest to move to AMC and develop appropriate GM.

(a)(6) :

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



response	<p>the safety assessment plan and the change design.</p> <p>Noted</p> <p>The comment is appreciated. The requirement — redrafted — remains in the IR.</p>
comment	<p>381 comment by: skyguide Corporate Regulation Management</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>We suggest to delete ATM/ANS.OR.B.005 Para (a)(5) as proposed in Appendix A</p> <p>ATM/ANS.OR.B.005(a)(6)</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>“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.</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> <p>To improve performance and safety (or to improve performance without degrading safety – we think it’s important to keep the focus on safety)</p> <p>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</p>



	<p>benefit.</p> <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 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).</p> <p>The formal process to meet this requirement is considered to be hardly feasible.</p> <p>Also, the terms with not clear interpretation like "circumstances" and "may affect" should not be used at the IR level.</p> <p>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.</p> <p>Furthermore, EASA provides no AMC or GM to this topic.</p> <p>We propose to delete the points (a) (5) and (a) (6).</p> <p>We also propose to delete the points (d) (1) and (d) (2) as it duplicates ATM/ANS.OR.B.005 (c).</p> <p>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>



(a)(6) has been deleted, as suggested. Please see the response to comment No 53.

(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.

comment 481

comment by: CAA CZ

CAA CZ suggest to make the provisions of para 5 and 6 even more descriptive by adding word "documented" such in:

„(5) a formal documented process to identify circumstances...“

„(6) a formal documented process to consider changing...“

response Not accepted

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.

comment 573

comment by: Romanian CAA

(d) (2) Referring to Question 6

Eliminate the provision: *or provide a valid argument.*

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)



response	Accepted (d)(2) has been removed.
comment	611 comment by: <i>DFS Deutsche Flugsicherung GmbH</i> (a) (5) Point (a)(5) seems to duplicated CRD to NPA 2013-08 ATM/ANS.OR.B.005(a)(4). Reference to high level comment "b"
response	Accepted Please see the response to comment No 52.
comment	612 comment by: <i>DFS Deutsche Flugsicherung GmbH</i> (a) (5) The wording "circumstances" and "that may" opens the IR to wide interpretation. Reference to high level comment "c.iii"
response	Accepted Please see the response to comment No 52.
comment	613 comment by: <i>DFS Deutsche Flugsicherung GmbH</i> 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"
response	Accepted Please see the response to comment No 53.
comment	614 comment by: <i>DFS Deutsche Flugsicherung GmbH</i> (a) (6) Additional GM for this requirement is missing. Reference to high level comment "c.v"
response	Noted



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.

comment 615 comment by: DFS Deutsche Flugsicherung GmbH

(d)
The definition of substandard performance 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.
Reference to high level comment "c.iii"

response Partially accepted
Please see the response to comment No 54.

comment 616 comment by: DFS Deutsche Flugsicherung GmbH

(d)
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.
Reference to high level comment "b"

response Not accepted
Please see the response to comment No 54.

comment 639 comment by: CANSO

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.
CANSO suggests to delete ATM/ANS.OR.B.005 Para (a)(5) as proposed in Appendix A



response Accepted
Please see the response to comment No 52.

comment 640 comment by: *CANSO*

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.
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 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.

Supporting comment to summary issue: Explanatory Note – does not support the Implementing Rule

response 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 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).

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.

comment 690

comment by: ROMATSA

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).

Supporting comment to summary issue: Specific Example of MS / SMS Split

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.
ROMATSA supports CANSO suggestion to delete ATM/ANS.OR.B.005 Para (a)(5) as proposed in Appendix A.

Supporting comment to summary issue: The IR is unbounded and uses subjective language and is not appropriate for inclusion in the IR.

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.

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)</i>	It should state <i>'substandard performance is identified, (...) and, if necessary, shall initiate a</i>	Maybe the implications of such substandard performance are neither relevant for the behaviour of the service provided nor for the



Annex III COMMON REQUIREMENTS FOR SERVICE PROVIDERS (Part-ATM/ANS.OR) ATM/ANS.OR.B.005(d)(1)	change to eliminate or mitigate such causes'.	safety so that no additional change needs to be performed.
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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



	<p><i>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)</i></p>
response	<p>Accepted</p> <p>Please see the response to comment No 53.</p>
comment	<p>1059 comment by: LVNL</p>
	<p><i>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)</i></p>
response	<p>Partially accepted</p> <p>'substandard performance' has been substituted by 'underperformance'. Please see the response to comment No 54.</p>
comment	<p>1104 comment by: Belgocontrol</p>
	<p>ATM/ANS.OR.B.005 (a)(5)</p> <p>1. This requirement looks like a duplicate to what is mandated in CRD 2013-08 ATM/ANS.OR.B.005 (a)(4).</p> <p>2. Words such as <i>Circumstances, that may</i> is subjective language and can be interpreted in several ways.</p> <p>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> <p>This requirement is thus rather unclear and somewhat infeasible. Furthermore no AMCs or GM are provided on this topic.</p> <p><u>Recommend</u> to delete ATM/ANS.OR.B.005 Para (a)(5).</p>
response	<p>Accepted</p> <p>Please see the response to comment No 52.</p>
comment	<p>1105 comment by: Belgocontrol</p>
	<p>ATM/ANS.OR.B.005 (a)(6)</p>



1. The requirement is unbounded and uses subjective language. *Consider* 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



	<p>system would ask a lot of resource for little benefit. <u>Recommend</u> to adjust to <i>'monitoring the behaviour of the service'</i> in the explanatory note.</p>
response	<p>Partially accepted</p> <p>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>
comment	<p>1181 comment by: <i>Avinor ANS</i></p> <div style="border: 1px solid black; padding: 10px; margin: 10px 0;"> <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>Accepted</p> <p>Please see the response to comment No 52.</p>
comment	<p>1182 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>



response	<p>We suggests to delete ATM/ANS.OR.B.005 Para (a)(6) as proposed in Appendix A.</p> <p>Accepted</p> <p>Please see the response to comment No 53.</p>
comment	<p>1183 comment by: <i>Avinor ANS</i></p> <div style="border: 1px solid gray; padding: 5px; margin: 5px 0;"> <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> </div>
response	<p>Partially accepted</p> <p>Please see the response to comment No 54.</p>
comment	<p>1228 comment by: <i>CAA-NL</i></p> <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</p>



have been removed.

comment 1235

comment by: *Icetra*

(d)

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: <i>NATS National Air Traffic Services Limited</i>
	<p>ATM/ANS.OR.B.010 Page 36</p> <p>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.</p> <p>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)</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 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.</p>	
comment	286	comment by: <i>DSNA</i>
	<p>(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:</p>	
response	<p>Partially accepted</p>	



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.

comment

454

comment by: EUROCONTROL

ATM/ANS.OR.B.010 (a) Change management procedures - Page 36

EUROCONTROL'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>
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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: *lctetra*

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. 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	<p data-bbox="359 235 406 280">574</p> <p data-bbox="1133 235 1484 280">comment by: <i>Romanian CAA</i></p> <p data-bbox="359 324 391 369">b)</p> <p data-bbox="359 369 1484 448">Modify the requirements for the content of the safety support assessment to include provisions on safety support requirements.</p> <p data-bbox="359 448 510 492">Justification</p> <p data-bbox="359 492 1484 571">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.</p> <p data-bbox="359 571 1484 649">There are no requirements to include Safety Support Requirements in the Safety Support Assessment.</p>
response	<p data-bbox="359 672 438 716">Noted</p> <p data-bbox="359 739 1484 862">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)).</p> <p data-bbox="359 884 1484 1008">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.</p> <p data-bbox="359 1030 1484 1108">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).</p>
comment	<p data-bbox="359 1176 406 1220">587</p> <p data-bbox="877 1176 1484 1220">comment by: <i>Federal Office of Civil Aviation FOCA</i></p> <p data-bbox="359 1265 1484 1433">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.</p> <p data-bbox="359 1433 1484 1512">Additionally, the concept of "supporting evidence" before the implementation of the change avoids that tests are performed in the operational environment.</p>
response	<p data-bbox="359 1545 526 1590">Not accepted</p> <p data-bbox="359 1612 1484 1691">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 data-bbox="359 1758 406 1803">650</p> <p data-bbox="1013 1758 1484 1803">comment by: <i>DGAC/DSAC - french NSA</i></p> <p data-bbox="359 1848 1181 1892">The french NSA has three comments related to ATM/ANS.OR.C.005 :</p> <ul data-bbox="406 1926 566 1971" 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><u>"service will be at least as safe after the change as it was before the change"</u></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)	<p>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 .</p> <p>Further to this, we wonder what kind of agreement could be reached in that situation that would be acceptable for the CA.</p> <p>Some GM should be provided.</p>	<p>We would welcome clarification on these points in order to better understand and assess this NPA.</p>

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="363 241 395 271">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="363 331 576 360">ATS.OR.205(b)(1)</p> <p data-bbox="363 376 459 405">Page 38</p> <p data-bbox="363 416 1406 445">It is considered better grammar to change "...,which consists of..." to "...consisting of..."</p> <p data-bbox="363 499 1485 566">Proposal: Amend text as proposed in NATS Appendix A (document attached to Comment number 25)</p>
response	<p data-bbox="363 600 475 629">Accepted</p> <p data-bbox="363 667 703 696">The text has been amended.</p>
comment	<p data-bbox="363 792 395 822">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="363 882 576 911">ATS.OR.205(b)(7)</p> <p data-bbox="363 927 459 956">Page 39</p> <p data-bbox="363 967 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="363 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="363 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="363 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="363 1646 576 1675">Partially accepted</p> <p data-bbox="363 1713 895 1742">Please see the response to comment No 61.</p>
comment	<p data-bbox="363 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="363 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>(20 The commentator misunderstood the concept of proxies. Proxies do not substitute hazards, but they are a surrogate of safety risk. 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>
comment	<p>346 comment by: ATCEUC - Air Traffic Controllers European Unions Coordination</p> <p>ATM/ANS.OR.B.005 (d) Management System</p> <p>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</p> <p>Paragraph No: ATS.OR.205(b)(1)(iv)</p> <p>Comment: [partial statement of the safety 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". [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</p>



	(v) planned degraded modes'
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. 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. 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 it.</p>
comment	<p>624 comment by: <i>EUROCONTROL</i></p> <p>ATS.OR.205 – Safety assessment and assurance of changes to the functional system - Page</p>



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 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
Proposed amendments Section 3.1 <i>Draft Regulation (Draft EASA Opinion)</i> <i>Annex IV</i>	We wonder whether the "sufficient confidence" required by provision <i>ATS.OR.205 (a)(2)</i> is	We see this term as too vague and subjective. This could open the gate to divergence in the assessment of changes within one



<p><i>SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS)</i></p>	<p>really <u>sufficient</u>.</p>	<p>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>
<p>response</p>	<p>Noted</p> <p>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.</p>	
<p>comment</p>	<p>1170</p> <p>There need to be a clear definition of what is technical ATS services and what is CNS services, since the regulation differs between them.</p> <p>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?</p> <p>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?</p> <p>Or will all equipment supporting the ATS functional system be considered CNS services, and the CNS-regulation apply?</p>	<p>comment by: <i>LFV</i></p>
<p>response</p>	<p>Noted</p> <p>The second interpretation seems to be the correct one; depending on what 'technical ATS service' means.</p>	
<p>comment</p>	<p>1199</p> <p>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.</p>	<p>comment by: <i>ENAIRE</i></p>



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: <i>European Transport Workers Federation - ETF</i> 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: <i>NATS National Air Traffic Services Limited</i> 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. Proposal: Points (b) and (c) recast as AMC to ATS.OR.210 as proposed in NATS Appendix A (document attached to comment number 25).
response	Partially accepted 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.

comment

66

comment by: *NATS National Air Traffic Services Limited***ATS.OR.210(b)****Page 39**

It is noted that the proxy approach is missing from point (b) although it is discussed extensively in the GM.

Proposal: Amend (b) in to add:

“(3) proxies; and” as proposed in NATS Appendix A (document attached to Comment number 25)

response

Partially accepted

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).

Proxies have been added explicitly to the AMC stemming from comment No 65.

comment

67

comment by: *NATS National Air Traffic Services Limited***ATS.OR.210(b)(3)****Page 39**

It is considered that point (b)(3) should refer to the functional system.

Proposal:

Amend (b)(3) to read the safety performance of the existing functional system or similar functional system elsewhere” as proposed in NATS Appendix A (document attached to comment number 25).

response

Accepted

The text will be amended when the AMC is published

comment

95

comment by: *EUROCONTROL Safety Team*

	<p>The GM discusses at length the proxy approach but this is not included in the requirement. Recommend to add text in (b) (3) <i>proxies; and</i>.</p>
response	<p>Partially accepted</p> <p>Please see the response to comment No 66.</p>
comment	<p>290 comment by: <i>DSNA</i></p> <p>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)</p> <p>(b)(1):proposed text : “explicit quantitative or qualitative acceptable safety levels” to be consistent with AMC p160.</p> <p>(b)(3):proposed text : “the safety performance of the existing functional system or a similar system elsewhere”.</p>
response	<p>Partially accepted</p> <p>Please see the response to comment No 65.</p> <p>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’.</p> <p>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.</p>
comment	<p>368 comment by: <i>Air Navigation Services of the Czech Republic</i></p> <p>We propose to add a new bullet for (b), (4) <i>proxies</i>; the use of proxies is extensive in the GM (also 2.4.5), yet it is not reflected in the IR itself.</p>
response	<p>Partially accepted</p> <p>Please see the response to comment No 66. The provision is moved to AMC.</p>
comment	<p>384 comment by: <i>skyguide Corporate Regulation Management</i></p> <p>It is noted that the proxy approach is missing from point (b) although it is discussed extensively in the GM.</p>



response	<p>Amend (b) in to add: “(3) proxies; and” as proposed in Appendix A</p> <p>Partially accepted</p> <p>Please see the response to comment No 66.</p>
comment	<p>391 comment by: UK CAA</p> <p>Page No: 39 Paragraph No: ATS.OR.210(b) Safety criteria Comment: The UK CAA recommends - Insert new ATS.OR.210(b)(4): ‘exceptionally, other measures as agreed with the competent authority’ Justification: The ATS 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 <i>adequately</i> specify the safety criteria in accordance with the listed measures. The proposed text therefore presents the a degree of flexibility to the ATS 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.</p>
response	<p>Not accepted</p> <p>Since the measure of safety is defined as safety risk and ATS.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.</p>
comment	<p>621 comment by: EUROCONTROL</p> <p>ATS.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.</p>
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	623	comment by: EUROCONTROL
	<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	683	comment by: ROMATSA
	<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	760	comment by: CAA Norway
	<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	<p>Partially accepted</p> <p>Please see the response to comment No 66.</p>	
comment	771	comment by: DGAC/DSAC - french NSA
	<p>The french NSA has only one comment related to ATS.OR.210 :</p>	



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) Annex IV SPECIFIC REQUIREMENTS FOR THE PROVISION OF AIR TRAFFIC SERVICES (Part-ATS)</i>	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	<p data-bbox="359 235 422 280">1290</p> <p data-bbox="1125 235 1484 280" style="text-align: right;">comment by: EUROCONTROL</p> <p data-bbox="359 324 486 403">Annex IV Subpart A</p> <p data-bbox="359 414 845 448">ATS.OR.210 (a) Safety criteria - Page 39</p> <p data-bbox="359 459 1484 571">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.</p> <p data-bbox="359 582 1484 649">It is suggested to refine the sentence as follows: “(...) <u>appropriate, correct</u>, specific and verifiable safety criteria (...)”</p> <p data-bbox="359 660 582 694">ATS.OR.210 (c)(2)</p> <p data-bbox="359 705 861 739">The following wording is not understood:</p> <p data-bbox="359 750 1268 784">“(...) support the improvement of safety whenever reasonably practicable”.</p> <p data-bbox="359 795 1484 1142">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.</p> <p data-bbox="359 1153 1069 1187">EUROCONTROL suggests to refine the wording accordingly.</p>
response	<p data-bbox="359 1220 582 1254">Partially accepted</p> <p data-bbox="359 1276 1484 1388">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.</p> <p data-bbox="359 1411 1484 1523">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.</p> <p data-bbox="359 1545 1484 1624">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.</p>

4. Regulatory Impact Assessment (RIA) — 4.3. Risk-based review decision by the competent authorities

p. 197-201

comment	<p data-bbox="359 1881 414 1915">184</p> <p data-bbox="965 1881 1484 1915" style="text-align: right;">comment by: EUROCONTROL Safety Team</p> <p data-bbox="359 1971 1085 2004">Page 200 - 201 4.3.8 (risk-based review decision by the C.A.)</p> <p data-bbox="359 2016 981 2049">Page 204 - 205 4.4.8 (risk-based review by the C.A.)</p>
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	<p>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.</p> <p>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>Noted</p> <p>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.</p>
comment	<p>220 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>4.3.4 How could the issue/problem evolve? Page 198</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>221 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>4.3.6 Policy options Page 198</p> <p>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?</p>
response	<p>Partly accepted</p>



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	<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 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.</p>
comment	<p>224 comment by: <i>NATS National Air Traffic Services Limited</i></p>
	<p>4.3.7.3 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>
response	<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</p>



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.

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

804

comment by: AESA / DSANA

PART	COMMENT	JUSTIFICATION
Regulatory Impact Assessment (RIA) Section 4.3.7.2 Economic impact	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 <i>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.</i>
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

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

Not accepted

The rationale is explained already in the commented NPA.

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.

comment

226

comment by: NATS National Air Traffic Services Limited

4.4.4

Page 202

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	<p data-bbox="363 241 411 271">227</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="363 331 475 405">4.4.6 Page 202</p> <p data-bbox="363 456 1485 651">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 data-bbox="363 680 485 710">Accepted:</p> <p data-bbox="363 752 1390 826">This has now been accepted and Option 3 has been rejected. See modified RIA. This is explained in the Opinion.</p>
comment	<p data-bbox="363 920 411 949">228</p> <p data-bbox="820 920 1485 949" style="text-align: right;">comment by: <i>NATS National Air Traffic Services Limited</i></p> <p data-bbox="363 1010 475 1084">4.4.7.1 Page 203</p> <p data-bbox="363 1135 1485 1247">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 data-bbox="363 1279 576 1308">Partially accepted</p> <p data-bbox="363 1346 1485 1458">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 data-bbox="363 1547 411 1576">229</p> <p data-bbox="820 1547 1485 1576" style="text-align: right;">comment by: <i>NATS National Air Traffic Services Limited</i></p> <p data-bbox="363 1637 475 1711">4.4.7.2 Page 204</p> <p data-bbox="363 1765 496 1794">Question 9</p> <p data-bbox="363 1809 1485 2040">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</p>



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.

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 <i>Economic impact</i>	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: *Navair*

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

Page No: 204
Paragraph No: QUESTION 9
Comment:
 UK CAA does not believe that the costs are sufficiently predictable to form an opinion on this question.
Justification: Clarity of Agency argument.

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. No additional cost estimates have been provided by stakeholders.

comment 1052 comment by: DFS Deutsche Flugsicherung GmbH

Question 9
 Yes, DFS expects a slight negative economic impact during implementation.

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 1110 comment by: DSNA

Question 9:
 See answer to question 8 above.

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

1145

comment by: *DSAE*

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.

DIRCAM's answer : Impact for DIRCAM would be low if options 2 or 3 were 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

1218

comment by: *CAA-NL*

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.

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. The intent is to disseminate these best practices when they are known by the Agency.

comment

1240

comment by: *EUROCONTROL*

4.4 Risk-based review by the competent authorities - Page 201

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.



response	Noted The 'do nothing' implies continued disharmony. This has a cost impact. The 'something' to be done later will encourage harmony at a later date without a rule change.
comment	1246 comment by: <i>Icetra</i> Question 9: 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) — 4.5. CNS providers performing safety support assessment instead of safety assessment

p. 206-210

comment	232 comment by: <i>NATS National Air Traffic Services Limited</i> 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	<p>233 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>4.5.7.2 Page 208</p> <p>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.</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 scope has been updated and addressed in the Opinion.</p>
comment	<p>247 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>4.5.7.3 Page 208</p> <p>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.</p>
response	<p>Partially accepted</p> <p>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.</p>
comment	<p>248 comment by: <i>NATS National Air Traffic Services Limited</i></p> <p>4.5.8.1 Page 209</p>



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

Question 10: FOCA refers to its answer to Q9: we consider a negative economic impact probable.

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 753 comment by: *DFS Deutsche Flugsicherung GmbH*

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.

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 809 comment by: *AESA / DSANA*

PART	COMMENT	JUSTIFICATION
Regulatory Impact Assessment (RIA) Section 4.5.7.2	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	We are, in principle and subject to the particular comments made to this NPA, satisfied with the economic impact analysis



<i>Economic impact</i>	were provided in justification.	included in the document.
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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 this RIA for additional information on the final position taken by the Agency.

comment

861

comment by: *Naviair*

Regarding 4.5.7.2
Question 10: See question 9.

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

1021

comment by: *DSNA***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.

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

1047

comment by: *UK CAA***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.



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 1146 comment by: DSAE

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.

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.

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 1219 comment by: CAA-NL

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.

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.

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 1247 comment by: Ictetra

Question 10:



response	We agree.
	<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>

4. Regulatory Impact Assessment (RIA) — 4.6. Removal of Severity classification scheme from IR p. 210-213

comment	185	comment by: <i>EUROCONTROL Safety Team</i>
	<p>Page 213 4.6.8 (removal of “severity classification scheme” - SCS)</p> <p>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	250	comment by: <i>NATS National Air Traffic Services Limited</i>
	<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	251	comment by: <i>NATS National Air Traffic Services Limited</i>



	<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>



4.6.7.2**Page 212**

Question 11

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.

It is difficult to see from an EASA Standardisation perspective how this could be a sound approach or that this promotes “better regulation” and harmonization.

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.

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 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.

comment

352

comment by: *BAF-M.Jancokova*

4.6.1: The argument

"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."

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.

response

Not accepted

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.



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 over long term perspective.</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>754 comment by: <i>DFS Deutsche Flugsicherung GmbH</i></p> <p>Question 11 DFS agrees that in the long term, costs should decrease a little bit.</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>811 comment by: <i>AESA / DSANA</i></p> <table border="1" style="width: 100%; border-collapse: collapse;"> <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;"> Regulatory Impact Assessment (RIA) Section 4.6.7.2 <i>Economic impact</i> </td> <td style="vertical-align: top;"> 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. </td> <td style="vertical-align: top;"> 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 4.6.7.2 <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.
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	<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 862 comment by: *Navair*

Regarding 4.6.7.2
Question 11: See question 9.

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 1022 comment by: *DSNA*

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.

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 1048 comment by: *UK CAA*

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.

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	<p>1147 comment by: DSAE</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.</p> <p>DIRCAM's answer : Impact for DIRCAM would be extremely low if option 2 was chosen.</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>1220 comment by: CAA-NL</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 were provided in justification.</p> <p>The Netherlands agrees with the analyses made on the economic impact.</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>1242 comment by: EUROCONTROL</p> <p>4.6 Removal of severity classification scheme from IR - Page 210</p> <p>'Severity' in the header does not need to start with a capital S.</p> <p>Concerning Article 4.6.8 Comparison and conclusion on page 213 EUROCONTROL makes the following comments:</p> <p>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.</p>
response	<p>Partially accepted</p> <p>The title has been changed.</p> <p>Please see the response to comment No 185.</p>



comment	1248	comment by: <i>Icetra</i>
	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: <i>EUROCONTROL Safety Team</i>
	<p>Page 213 4.7 Changes affecting software and Regulation EC 482/2008</p> <p>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.</p> <p>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.</p>	
response	Partially accepted	
	<p>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.</p>	



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 thr 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*



	<p>Regarding 4.7.7.2</p> <p>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.</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>1023 comment by: DSNA</p> <p>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.</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>1049 comment by: UK CAA</p> <p>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.</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>1054 comment by: DFS Deutsche Flugsicherung GmbH</p> <p>Question 12</p>



response	<p>DFS agree that Option 2 could have a slight positive economic impact.</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>1132 comment by: <i>Belgocontrol</i></p> <p>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.</p>
response	<p>Partially accepted</p> <p>Please see the response to comment No 186.</p>
comment	<p>1148 comment by: <i>DSAE</i></p> <p>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.</p> <p>DIRCAM's answer : Impact for DIRCAM would be extremely low if option 2 was chosen.</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>1221 comment by: <i>CAA-NL</i></p> <p>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.</p>



	The Netherlands agrees.
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>1249 comment by: <i>Icetra</i></p> <p>Question 12: We agree.</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>1257 comment by: <i>EUROCONTROL</i></p> <p>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).</p>
response	<p>Not accepted</p> <p>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.</p>



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](#)

