# COMMENT RESPONSE DOCUMENT (CRD) TO NOTICE OF PROPOSED AMENDMENT (NPA) 2009-01

**For a draft Opinion of the European Aviation Safety Agency for a Commission Regulation amending Commission Regulation (EC) No 1702/2003 of 24 September 2003 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations**

**and**

**for a draft Decision amending Decision No. 2003/1/RM of the Executive Director of the European Aviation Safety Agency of 17 October 2003 on acceptable means of compliance and guidance material for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations ("AMC and GM to Part 21")**

***"Operational Suitability Certificate" and " Safety Directives"***

**Reactions to this CRD should be submitted via the CRT by clicking the '*add a general reaction*' button. Please indicate clearly the applicable paragraph.**

# Explanatory Note

## I. General

1. The purpose of the Notice of Proposed Amendment (NPA) 2009-01 was to consult on the draft Opinion of the Agency for a regulation amending Commission Regulation (EC) No 1702/2003 of 24 September 2003 to introduce the concept of operational suitability and additional airworthiness specifications for operations. The scope of this rulemaking activity is outlined in the Terms of Reference (ToR) 21.039.

## II. Consultation

2. NPA 2009-01 was published on the web site (http://www.easa.europa.eu) on 16 January 2009.

3. The consultation period of the NPA was extended in accordance with Article 6(6) of the Rulemaking Procedure[1] , at the request of stakeholders, to ensure sufficient time for analysing and commenting on the NPA.

4. By the closing date of 30 June 2009, the European Aviation Safety Agency ("the Agency") had received 1011 comments from 80 National Aviation Authorities, professional organisations and private companies.

## III. Publication of the CRD

5. This CRD does not follow the traditional format. Due to the high number of comments received, and changes made in the principles of the structure of the text resulting from incorporating the comments, the Agency considered it inefficient to draft a response to each individual comment. Therefore, the Agency adopted an alternative method for processing all comments posted via the CRT. This alternative method is the comment response summary. This approach was supported by the Commission and Management Board in September 2009.

6. All comments received have been acknowledged and summarised into this comment response summary with the general responses of the Agency. All comments received are published on the Agency's CRD web page: **CRD 2009-01 (list of comments received on NPA 2009-01)** but are not included in the CRT.

7. The resulting text which is published in Appendix 1 to this CRD highlights the changes as compared to the current rule.

8. The Agency Opinion will be issued at least two months after the publication of this CRD to allow for any possible reactions of stakeholders regarding possible misunderstandings of the comments received and answers provided.

9. Such reactions should be received by the Agency not later than **13 July 2011** and should be submitted using the Comment-Response Tool at http://hub.easa.europa.eu/crt. When submitting their reactions, stakeholders are kindly invited to follow the recommendations in the "stakeholder guidance for reactions"

[1] EASA Management Board Decision 08-2007, amending and replacing the Rulemaking Procedure, adopted at the Management Board meeting 03-2007 of 13 June 2007.

## Comment Response Summary

### 0. General

As mentioned in the explanatory note the Agency received 1011 comments on the NPA. In order to handle these comments the Agency established a comment review group. This group was composed of members of the drafting group including two additional experts. The full composition of the drafting group was published together with the ToR. It contained experts from manufacturing industry, operators associations, aviation personnel associations, EASA and national aviation authorities. The review group met three times in 2009 and 2010. All of the below issues were extensively discussed in the group and even though full consensus on all issues could not be achieved, the Agency has drafted this CRD and the resulting text taking into account all the views of the individual experts.
The opportunity of this proposal has been taken to introduce changes in the text of Regulation No 1702/2003 to align with the latest amendment of Regulation No 216/2008 as reflected in Regulation No 1108/2009. In the new articles 18 and 19 the term "airworthiness code" is deleted and therefore in Regulation 1702/2003 this term is replaced systematically by "certification specifications".

### 1. Operational Suitability Certificate (OSC) concept

*Summary of comments:*
Many commentators are opposed to the OSC concept in general as they see it as adding too much bureaucratic burden without any safety gain. Several comments indicate that the new rules could increase liability of certain players.

*Response to comments:*
The principle that the type certificate (TC) holder/applicant is responsible for establishing minimum training syllabi for type rating training, simulator data and Master Minimum Equipment List (MMEL), has its roots in the basic regulation[2]. The purpose of this rulemaking task is to establish the necessary implementing rules and other regulatory material needed for the implementation of this principle. Within the context of this rulemaking task the above principle is not open for debate. However the Agency agrees to find the most efficient way to implement the principle, respecting as much as possible the existing processes and keeping the administrative burden to a minimum.
The benefits of the Operational Suitability Data (OSD)[3] concept were already explained in the NPA but are repeated here for convenience:
OSD will contribute to closing the gap between certification, operations and maintenance processes. The need to close such gap has been demonstrated by recent studies in Europe and in the USA.
With the introduction of rules regarding type training for personnel and MMEL in the form of OSD being the mandatory minimum for all operators and training organisations, supported by standardisation activities, it is expected that all training courses and MEL are approved using the same standard. This will contribute to a uniform high level of safety.
Responsibilities will be more clearly defined thus leaving no gap in the responsibilities related to minimum syllabi for type rating training and MMEL:

- The responsibility for establishing the initial OSD with all the necessary elements will be with the TC holder of the aircraft. The Agency considers that the TC holder is best placed to develop these elements because it has all the necessary background information that is available from the design and airworthiness exercise. For example for developing a safe MMEL it is necessary to have insight in the systems safety analysis of the aircraft.

[2] Article 5(4)(e)
[3] See chapter 2 for an explanation of the change to "OSD" in stead of "OSC".

Confirming the responsibility of the TC holder for the OSD elements is therefore also expected to give a positive impact on safety.

- At the same time, making the Agency responsible for the approval of the minimum syllabi and the MMEL will allow the involvement of the expertise that was also used to do the airworthiness approval of the design.
- There will be a pro-active approach towards safety aspects of type training and MMEL by introducing the concept of "continued operational suitability": The originator of the OSD will be responsible for the continued validity of the approved OSD element(s). It will be clear that this responsible entity shall monitor the experience with using the approved elements and will have to react in case of safety occurrences. In the worst case when there are immediate safety concerns the Agency can issue Airworthiness Directives to correct deficiencies in OSD that need to be implemented at operator level. Finally, the rule will also impose on third parties making design changes (Supplemental Type Certificate - STC) the need to consider the effects of that design change on OSD, and if necessary to propose amendments to the OSD elements.

The Agency acknowledges that there may be some change in liability for the TC holders; however, as explained below, there are reasons to believe that the OSD rules will not have a major effect on liability. Moreover, the OSD rules also introduce factors that may decrease the liability.

First of all, it should be noted that liability of manufacturers is already established by the general doctrine of product liability.

A products liability claim is usually based on one or more of the following causes of action:

- design defect,
- manufacturing defect,
- a failure to warn.

The claims may succeed even when products were used incorrectly by the consumer, as long as the incorrect use was foreseeable by the manufacturer. The failure to warn can be seen to include a failure to provide adequate training criteria for the user of the product.

Depending on the legal system and the circumstances of the particular case, the way product liability is determined by a court of justice, ranges from strict liability, where causation is the only requirement for legal liability, to liability based on negligence, where it is determined if the product's design or warning is reasonable.

Strict liability is determined regardless of any negligence by the manufacturer so the regulator cannot affect this type of liability.

The Agency acknowledges that by defining (new) responsibilities for a manufacturer in law, the legislator can affect the liability based on negligence. Failure to discharge those responsibilities can be a reason for determining negligence. On the other hand, by establishing a regulatory standard for compliance the conclusion of negligence cannot easily be drawn in case the manufacturer has shown compliance with these regulatory standards and compliance has been confirmed by an authority certification. There will be an EASA certificate confirming compliance with the applicable rules which will protect the TC holder. So in the worst case there would be shared liability. Moreover, even without confirmation of the manufacturer's responsibilities in the current regulations, a court of justice could well establish negligence in case the manufacturer would not have produced the necessary training elements.

In the case of MMEL, the liability for Community (S)TC holders does not change because under the former JAR-MMEL/MEL provisions within the JAA, they were already required to produce an MMEL for authority approval. It is also the case for Brazilian manufacturers but not for American or Canadian Manufacturer industry.

## 2. OSC as a separate certificate

*Summary of comments:*

Several commentators challenge the legal basis for issuing a new certificate and propose to add the OSC elements in some way to the TC. Some commentators propose to treat OSC similar to Instructions for Continuing Airworthiness (ICA).

*Response to comments:*
As mentioned above the Agency agrees to find the most efficient way to implement the principle as introduced in the basic regulation, respecting as much as possible the existing processes and keeping the administrative burden to a minimum. The ICA approach as proposed by some commentators combined with an approach similar to environmental certification is therefore seen as the best way forward. This means that the idea of a new Subpart C in Part 21 creating the OSC is abandoned. Instead the necessary amendments to Subparts B, D and E will be made to incorporate the new TC holders/applicants responsibilities in the existing rules for issuing a TC and approving changes. Such concept will still need new Certification Specifications (CSs) to provide the standards for approval. Please refer to the NPA 2009-01 for the explanation of the CSs.
In order to avoid confusion and to make clear that the concept has changed, the new name Operational Suitability Data (OSD) is introduced.

*Resulting changes in rule text:*
The Part 21 Subpart C as proposed by the NPA is deleted. Instead, the responsibility for the TC applicant to include the OSD at a certain moment in its application, is included in the existing Subpart B for the issuance of the TC.
The main principles in the NPA proposal related to OSC approval are kept into the new text for OSD.
Provisions are made to allow the TC applicant to include OSD in his application immediately or at a later stage. Also the important principle allowing the issuance of the TC while the OSD are not yet (fully) approved, is kept. This reflects the current practice that operational evaluation starts later than the initial type certification and can also finish later than the issuance of the TC but before the aircraft enters into service in the EU.
Similar to environmental certification a new paragraph introducing a separate certification basis for OSD is included. This separate OSD certification basis will also allow a different reference date.
Similar to ICA a new paragraph is included to require the TC holder to make the OSD available to operators and others who are required to use the OSD.
Also in Subparts D and E amended text is introduced to allow the approval of changes to OSD associated to a design change as well as stand alone changes to OSD. The concept that a third party designing a change to the aircraft needs to consider possible effects on OSD and if needed, has to propose changes or supplements to OSD, is kept.

## 3. Use by operators of minimum syllabi for type rating training

*Summary of comments:*
Many operators comment strongly against the OSC concept on the “user” side. They are against mandating the output of OSC related to training syllabi to operators. Because they have experience and knowledge in training they think that they should have more flexibility when establishing training courses. Therefore they propose that this output of OSC should get the status of Acceptable Means of Compliance only. They will then have more flexibility to deviate from its contents.
Other commentators claim that the Agency should not be involved in the approval of changes to a training programme.

*Response to comments:*
The Agency acknowledges that operators and training organisations have valuable knowledge and experience in establishing training courses for type rating training. Nevertheless the Agency is also convinced that the designer of the aircraft is the best placed to identify the minimum building blocks of type training needed for flight and maintenance crew to safely operate or maintain its design. Furthermore the Agency considers the existence of a mandatory minimum syllabus the best basis for harmonisation within the EU. Therefore the Agency believes that certain elements of the minimum syllabi as developed by the designer should remain mandatory for the operator. Other elements could get the status of AMC. The

exact classification of which elements of the minimum syllabus shall be mandatory or not will be in the respective certification specifications for the flight crew, cabin crew and maintenance staff. However, the following general guidelines apply:
What will be mandatory for the operator/training organisation:

- The determination of the type rating;
- Training areas of special emphasis for the type;
- Training areas of special emphasis in differences training (when included in the OSD by the designer).

The other parts of what is currently in the Operational Evaluation Board (OEB) report related to type training (e.g. the footprint training course) will be recommendations and have the status of AMC.
It means that operators/training organisations can deviate from those recommendations using the alternative MoC process. The alternative can be agreed by the local competent authority and will be sent to the Agency. The Agency can use this information for standardisation purposes. So the Agency will not be directly involved in the approval of training courses.
During the discussion of this new concept in the 21.039 review group the representatives of the associations of cabin crew, maintenance engineers and flight crew have expressed their disagreement. They are of the opinion that the entire OSD should be mandatory for operators to ensure the highest possible safety standard and a level playing field. The Agency is of the opinion that the concept as described above satisfies the intents of the basic regulation and will ensure a consistent high level of safety while at the same time it respects the knowledge and experience of operators and training organisations to develop their own training tools and methods and associated variations in training courses. The Agency considers the alternative MoC process a good tool to achieve a level playing field with enough flexibility for industry to adjust to its own business.

*Resulting changes in rule text:*
The partially accepted comments above do not impact the proposed amendments to Part 21 but do have an impact on the drafting of the OSD certification specifications and also on the implementing rules and associated AMCs applicable to operators and training organisations when establishing a type rating training course. These rules and AMC are already envisaged for Part-OPS and Part-FCL through their respective CRDs and Opinions. For Part-66/-147 they are included in resulting text of this CRD.
Guidance Material to Part 21 to explain the concept is added as well.

## 4. Master Minimum Equipment list

*Summary of comments:*
Some commentators insist that the MMEL should not be made mandatory as it is an alleviating document. Other commentators request that the Operational and Maintenance (O&M) procedures should be part of the approved MMEL.

*Response to comments:*
The MMEL will have to remain mandatory in total. First of all the principle that a Minimum Equipment List (MEL) cannot be less restrictive than the MMEL is anchored in the basic regulation[4]. Secondly the MMEL is also included into the new provision of the basic regulation as mentioned in paragraph 1 above[5]. Therefore the question of mandating MMEL is not open for debate in the framework of this NPA/CRD 01-2009.
The establishment of an MMEL requires detailed knowledge of the system safety analysis which only the designer has. That is the reason that the TC holder/applicant will be required to propose the MMEL for approval by the Agency.

[4] Annex IV paragraph 8.a.3(iii)
[5] Article 5(4)(e)

The O&M procedures are required to be produced by the TC holder if the MMEL item relies on such procedure for its implementation. The exact level of checking by the Agency as well as the status those procedures will have when transposed into an MEL by the operator is discussed in the framework of the drafting of CS-MMEL. The result will be the subject of a separate NPA consultation.

*Resulting changes in rule text:*
No

## 5. Applicability to small aircraft

*Summary of comments:*
The "small aircraft community" has commented strongly against introducing a new certificate and sees no need for it. They see it as creating a big administrative burden and subsequently additional costs without a real safety benefit.

*Response to comments:*
First of all, by the change as indicated under 2 above to treat OSC(D) similar to ICA and to include the approval in the type certification process, one of the concerns is addressed: there will be no separate certificate but in stead the OSD approval process is included in the TC approval.
Secondly the requirement to produce minimum syllabi for type training of pilots and maintenance staff is only applicable when the aircraft has a type rating. For most small aircraft this is not the case as they are in a class or group rating. Whether a new aircraft type should have a type rating or can be in a class rating will be part of the OSD approval process and finally decided by the Agency. The assessment is based on objective criteria that will be included in guidance material. By default, most small aircraft will be in a class or group rating unless there are performance, design or other features that require specific training. When no type rating is defined for the aircraft it means that the relevant OSD elements are not required[6].
Thirdly the type specific data for cabin crew training is only required when the operational rules require cabin crew for the maximum approved passenger seating capacity[7].
Finally the requirement to establish an MMEL is applicable to all aircraft that can be used for commercial operations because the relevant operators must have MELs for those aircraft. However, in order to minimise the burden for the TC applicants, the Agency will establish generic MMELs for all categories of non-complex aircraft by means of a certification specification. The TC applicant for an aircraft within those categories can suffice with confirming that this generic MMEL is appropriate for its design. The applicant can nevertheless decide to establish its own MMEL with possible additional items.
With all the above changes to the principles of Operational Suitability certification the Agency is of the opinion that the remaining burden for manufacturers and operators of small aircraft is proportional to the activity while enhancing the level of safety for those small aircraft that are commercially operated.

*Resulting changes in rule text:*
The move from a separate certificate (OSC) to data that is approved under the TC process is already covered under item 2.
The exclusion of aircraft in a class or group rating does not require a change to the Part 21 proposal. The current description of the OSD elements relative to training syllabi already limits its applicability to aircraft for which there is a type rating.

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6 The applicant can always voluntarily provide a minimum syllabus for type rating training to be approved under OSD.

7 Currently for a maximum approved passenger seating configuration of more than 19

## 6. Cabin crew

*Summary of comments:*
Many commentators think that the cabin crew type related data should not be part of the OSC(D) because they see no legal basis in the basic regulation. A small amount of commentators support the inclusion of cabin crew and insist on treating cabin crew type training similar to pilot type training.

*Response to comments:*
The Agency acknowledges that the legal basis for including cabin crew type training in the OSD is different from those for pilots and maintenance staff. However the Agency considers that the legal basis exists in article 5(4)(e)(vi) through the reference to article 6b which in turn refers to the essential requirements for operations in Annex IV which contains training requirements for cabin crew. Moreover, the Agency considers that keeping cabin crew type training part of the OSD is in the interest of safety. The aircraft type may have design features that require specific training also for cabin crew. The designer of the aircraft is the best placed to identify these specific training needs.

*Resulting changes in rule text:*
No

## 7. Flight Simulators

*Summary of comments:*
Several comments questioned the need for including the aircraft reference data to support the qualification of simulators and some asked for clarification what exactly was required.

*Response to comments:*
The first aspect of the comment is already responded under chapter 1 above; the amendment to the basic regulation related to operational suitability data specifically refers to simulators.
The second part of the comments is more complicated. In order to answer this question an ad hoc group of simulator experts from various stakeholders was established. This group met two times and had proposed changes to the description of the OSD element relative to simulators to clarify its content, bringing it in line with the practical possibilities. However this new text only defines the content of this OSD element at a the high level. The details will be provided in the relevant certification specification which is currently under development and is scheduled to be issued as an NPA in the 3rd quarter of 2011.

*Resulting changes in rule text:*
Change to the text in 21A.15(d)2. (previously in 21A.62(a)1.)

## 8. Transition / grandfathering

*Summary of comments:*
In general most commentators consider that OSC(D) should be applicable to new aircraft types only.
Manufacturers are against mandatory catch-up, and think that everything approved by NAAs before should be grandfathered.
On the other hand many operators judge that catch-up should be manufacturer's responsibility.

*Response to comments:*
Based on the above comments and considerations of practicality and proportionality the Agency will propose the following transition and grandfathering provisions to the European Commission:

*a. Grandfathering for TC holders*
All JOEB and EASA OEB reports will be grandfathered automatically for the content that corresponds to the OSD as required and/or allowed by Part 21.

*b. Grandfathering for operators/training organisations*
This grandfathering is not covered by the rulemaking task 21.039. It will be covered by the relevant operational rules (Part-OPS etc.) The idea is that existing nationally approved or accepted type rating training courses and MEL would be grandfathered. However, when an OSD (new, grandfathered or caught up) for the type is established, operators/training organisations would have 24 months to adapt their training courses to the mandatory part of the OSD elements. For adapting the MEL to more stringent MMEL provisions the period is the standard 90 days.
In case of the development of a new[8] training course it would be mandatory to use OSD when available. If not available; the training course should be established using the rules in Part-FCL, Part-OPS or Part-66 respectively. A new MEL can only be established when based on an EASA approved MMEL. This would mean that in such case the operator should also initiate the approval of MMEL. However the catch-up exercise for existing types (see C. below) will be relatively simple.
In case of an urgent safety problem the Agency can issue an Airworthiness Directive (AD) to impose certain (parts of) OSD elements on operators/training organisations for all aircraft including those without OSD (see also paragraph 12 below).

*c. Catch-up (of all OSD elements) for TC holders:*
Catch-up is a process to establish approved OSD for an aircraft type that was already certified. The catch-up process is a light touch process compared to the initial certification.
Application for catch-up is mandatory for aircraft models still in production and being delivered to EU operators[9] within 2 years of the amendment to Part 21 except for minimum syllabus of maintenance certifying staff type rating training and the aircraft validation source data to support the objective qualification of simulators for which catch-up is voluntary. When a model re-enters in production after a period of being dormant, the OSD shall be approved before the new aircraft starts operation by an EU operator.
Catch-up is voluntary for other models that are no longer in production.

*d. Ongoing certifications*
Aircraft types or variants for which the certification is ongoing on the date of the amendment to Part 21 cannot benefit from grandfathering due to the lack of a formal document/certificate to be grandfathered. Therefore the relevant applicants will have to extend their TC application to EASA to include OSD. However, if that applicant had already applied for an OEB evaluation, the work already done under that OEB process when transitioning to the OSD process will be accepted without further verification. The applicant of an ongoing type certification can decide to extend its application to include the OSD immediately after [*8 April 2011*]. In any case the OSD approval should be obtained within 2 years of the new rule being in place or before the aircraft is operated by an EU operator if that is after that 2 years timeframe.

*e. Design Organisation Approvals (DOA)*
When a type certificate includes operational suitability data either through grandfathering or catch-up, the TC holder shall obtain approval of an extension of the scope of its DOA or alternative procedures to DOA as applicable to include operational suitability aspects within two years after the applicability of the rule.
New TC applicants that have to include OSD in their application shall obtain extension of the scope of their DOA or alternative procedures to DOA before the OSD is approved.

[8] new for the operator/training organisation
[9] This means that when production has stopped but then restarted at a later date, an OSD is required.

*Resulting changes in rule text:*
The above principles of grandfathering and catch-up are reflected in a new article 3a in the cover Regulation (EC) No 1702/2003.

## 9. OSD for engine TC

*Summary of comments:*
Comments were raised regarding the possibility to require an OSD also for engine and propeller type certificates because certainly for the syllabus for maintenance certifying staff type rating training a considerable share of the data should come from those TC holders.

*Response to comments:*
The Agency acknowledges that for establishing the minimum syllabus for maintenance certifying staff type rating training a considerable contribution is needed from the engine TC holder. However the Agency believes that this in itself would not justify requiring an OSD for engine. The maintenance certifying staff type rating is established at the aircraft level even though it takes into account the engine type. Also when integrating the engine in the aircraft design the airframe TC applicant needs input from the engine TC holder. The integration of engine maintenance training data in the aircraft OSD can follow the same logic. Therefore the Agency will not propose a separate OSD for engines and propellers.
Nevertheless the Agency agrees to emphasise the need for engine and propeller TC holders to provide inputs for the aircraft OSD through a dedicated requirement in Part 21.

*Resulting changes in rule text:*
In Part 21A.44 related to obligations of the TC holder a new subparagraph is introduced requiring engine and propeller TC holders to make available operational suitability data regarding their engine or propeller to the aircraft TC applicant.

## 10. Changes to OSD resulting from design changes and stand alone changes.

*Summary of comments:*
Comments were raised against the concept of Supplemental OSC that would be required in case someone not being the OSC holder would propose a change to the OSC. Other comments suggest that the concept of classification of changes to OSC is not mature and should be delayed. Further comments highlight confusion on the stand-alone OSC changes. Finally commentators raise questions regarding the applicability of Part 21A.101 (“Changed Product Rule”)

*Response to comments:*
The OSD will be included in the TC. Therefore, changes to the OSD will have to be approved using the existing provisions of Part 21 related to changes to TC. There are two categories of changes to the OSD.
The first category entails OSD changes that are necessary as a result of a change to design. The applicant for approval of a change to design or a Supplemental Type Certificate will have to assess whether the design change has an effect on the OSD. Only when the TC of the changed aircraft includes OSD, there is a need to consider the possible effect of the design change on these data. This is the case if the change would require additional training for pilots, cabin crew or maintenance certifying staff. This would also be the case if the change affects the definition of scope of the aircraft validation source data to support the objective qualification of simulators or if it would affect in a more restrictive way an existing item in the MMEL. The possible addition of an MMEL item to cover new equipment would not be considered a mandatory change associated to the design change and can be added on a voluntary basis and can even be handled under a separate approval process. In case it has been determined that the design change affects the OSD, the applicant needs to provide the necessary changes

or supplements to the affected OSD elements in association with the change approval or STC process. In such case, the change to operational suitability data (OSD) is considered a change associated to the change to type design and both together are considered to constitute the change that requires approval.
In the classification of such a change it could be split in a type design part and an OSD part. When the classification is not consistent (i.e. the type design part is minor but the OSD part is major, or vice versa) the whole change is considered major. However, the approved design organisation can approve the minor part before submitting the whole change for approval to the Agency. The Agency will then process the major change approval without verifying the minor part.
Similar provisions apply to the approval of the OSD changes as they do for the initial TC. For example the approval of the changed OSD elements can be postponed until after the design approval but before the changed aircraft is operated by an EU operator.

The second category of OSD changes consists of stand alone changes to the OSD, so not associated to a design change. Approval of those changes could be requested for example by an operator or training organisation that wants to deviate from the mandatory elements of the OSD (see also under 3. above). These stand alone changes will also have to be approved using the existing provisions of Part 21. This means using Subpart D or E. For deviating from the non-mandatory part of the OSD there is no need to obtain EASA approval. Such approval can be granted by the national aviation authority e.g. within the framework of approving alternative means of compliance or training programmes.

Design Organisation Approval holders can be granted the privilege to approve minor changes to OSD. Therefore it is also necessary that OSD changes are classified in major and minor. To help in the classification of changes to OSD specific guidance will be developed. This guidance is not yet available at the time of the publication of this CRD.

Part 21A.101 regarding the determination of the applicable certification specifications for the change will also be applicable to changes to OSD. However, there are two reasons why this should not induce a big burden for applicants.
First of all, the Certification Specifications for OSD elements are not expected to be amended very often. It would therefore not be an issue to comply with the latest standard.
Secondly, even if the standard would have been updated it is expected that applying the latest standard for developing the changes to OSD will not create huge additional burden. The OSD consists of data only and a change to the standard has no effect on the design.

*Resulting changes in rule text:*
The existing paragraphs in Part 21 Subparts D and E that deal with approval of changes and STCs have been amended to include the concepts as described above.

## 11. Availability of data

*Summary of comments:*
Some comments were made on availability of data. A commentator challenges the requirement to make the OSD available to any person required to comply with the data (previously in 21A.76, now in 21A.62, -.108 and -.120). He has difficulty with making proprietary data available to certain entities and claims that certain restrictions should be allowed. There is also a request for further clarification of the requirement. Another commentator expects that the operators will be faced with additional costs for obtaining the documents.

*Response to comments:*
The Agency understands the concerns of the commentators but cannot accept deleting this requirement. The current and proposed requirements for type rating training have the possibility of independent training organisations. These training organisations have to comply with the relevant requirements for establishing type training courses and in that context are

required to use the OSD. To whom the data should be made available is also further explained in the GM 21A.21(f).
The cost issue is outside the scope of these regulations but it seems justified that the efforts by the TC applicant to obtain OSD approval may be reflected in a fee when providing the data to third parties.
In addition the Agency has also realised that NAAs also need access to the OSD as they are the authorities approving the individual training courses and MEL and need to check that they comply with the applicable OSD.

*Resulting changes in rule text:*
The requirement to make the data available to NAAs was added and several changes were made to improve readability and to make all requirements relative to availability of data consistent.

## 12. Safety Directives (SD)

*Summary of comments:*
Many commentators question the legal basis for SD and some strongly oppose to the concept.
One commentator proposes to include retroactive requirements into IR-OPS.
Another commentator insists that SD should be split into two. Many commentators consider the proposals related to SD too complicated and impractical.

*Response to comments:*
The purpose of the SD tool was a combination of reacting to a general safety problem and correcting deficiencies to the OSC. By adopting the ICA approach and including the OSD in the type certificate there is no more need to use the SD for corrections to the OSC(D). The Agency can use Airworthiness Directives (ADs) for that purpose. This will reduce the complexity of the rule.
The remaining purpose is reacting to general safety problems. This is different from the AD tool which is intended for reacting to safety problems (usually design deficiencies) in a particular type.
Another difference with ADs is that an AD is issued to restore the level of safety as established by the applicable certification basis, whereas the SD tools are meant to enhance the certification basis.
One natural reaction to a general safety problem is to improve the relevant certification specification (CS). However a change to a CS is only applicable to new designs and does not affect already certificated types. So if the Agency identifies the need to make the new CS provision also applicable to already certified aircraft, a new legal tool is needed.
The Agency has decided that two legal tools will be used for this purpose.
The first tool is to develop a new implementing rule.
The second one is in an amendment to Part 21 allowing the Agency to require holders of existing TC[10]s to show compliance with a new CS and to issue Safety Directives (SD).
The choice between the two tools will be made by the Agency based upon considerations of the expected impact of the measure. The choice will be substantiated each time a new measure is proposed as part of the respective NPA and will be subject to comments. Based on the comments received during the rulemaking process it will be possible to change from one tool to the other. The technical content of the measure is not affected by the choice of legal implementation tool.

The first tool is the development of an implementing rule or an amendment to that implementing rule for each intended measure. This will follow the normal rulemaking processes for implementing rules; an EASA rulemaking process leading to an Opinion to be submitted to the European Commission, followed by the EC adoption process including commitology. The proposal is that the first measure following this tool (most likely the fuel tank flammability

[10] For readability only TCs are mentioned but everything applies equally to STCs and major repairs.

reduction requirement) will create a new Part-26 in a new Commission Regulation. This Part-26 will be amended each time a new measure needs to be added. Each Part-26 measure will contain its own applicability provisions and is independent from other IR. The measures can be directed to design approval holders, approved organisations, operators and individuals as appropriate. A measure may include a cascaded approach where first an action is required by a design approval holder, to be followed by an action of an operator to implement the result of the compliance by the design approval holder.

The second tool is composed of two elements: a tool to impose new provisions of CSs to holders of existing TC and a tool to impose measures on the existing fleet called Safety Directive. This latter element is referred to as the "SD-tool" in the remainder of this chapter.
The first element provides the legal tool for imposing a new provision in a certification specification to the TC holder of an already certificated aircraft. It can be seen as a mandatory supplement to the certification basis to which the TC holder must show compliance.
It was considered to also apply this to ongoing projects but the Agency considers that the existing provision of Part 21A.16B(a)(3) already covers this case.
Before requiring the TC holder to show compliance, the measure will be included in CS-26 following a normal rulemaking process. This is necessary because the requirement for new designs cannot always be applied to existing designs. It may need some tailoring to cater for retrofit. See figure 1 for an overview of the different regulatory products.
At the same time it has the benefit to have a dedicated consultation on the retrofit issue which by definition will have a negative economic impact on stakeholders. However a comprehensive NPA with Regulatory Impact Assessment (RIA) will allow the Agency to properly justify the measure from a global perspective reducing the need to justify for each individual TC holder. The development of the CS-26 provision can largely be done in parallel with the development of the basic airworthiness CS amendment so that no time is lost.
The TC Holder will be required to comply with a particular CS-26 provision through a dedicated notification by the Agency. This notification will activate the requirement to comply.
Non-compliance or not-in-time compliance by the TC holder will be a potential reason for revocation, limitation or suspension of the TC.
The compliance showing can have three different results:

1. The existing design complies already;
2. In order to comply, a change in the ICA or MMEL is needed.
3. In order to comply, a change in the design, OSD or any limitation is needed;

In all cases the TC will be amended to record compliance with the applicable CS-26 provision. Depending on the applicability of the measure the TCDS will also specify the type of operation that is affected.
Case No 1 and 2 do not require further action. For case 1 this is obvious; for case 2 the implementation by operators will be achieved through existing requirements in Part-M or the OPS rules relative to MEL.
For case 3 there is a need for a legal tool to impose the change to operators (or production organisations in case of production cut-in). This legal tool is the Safety Directive. It is in fact one of the three purposes of the SD tool.

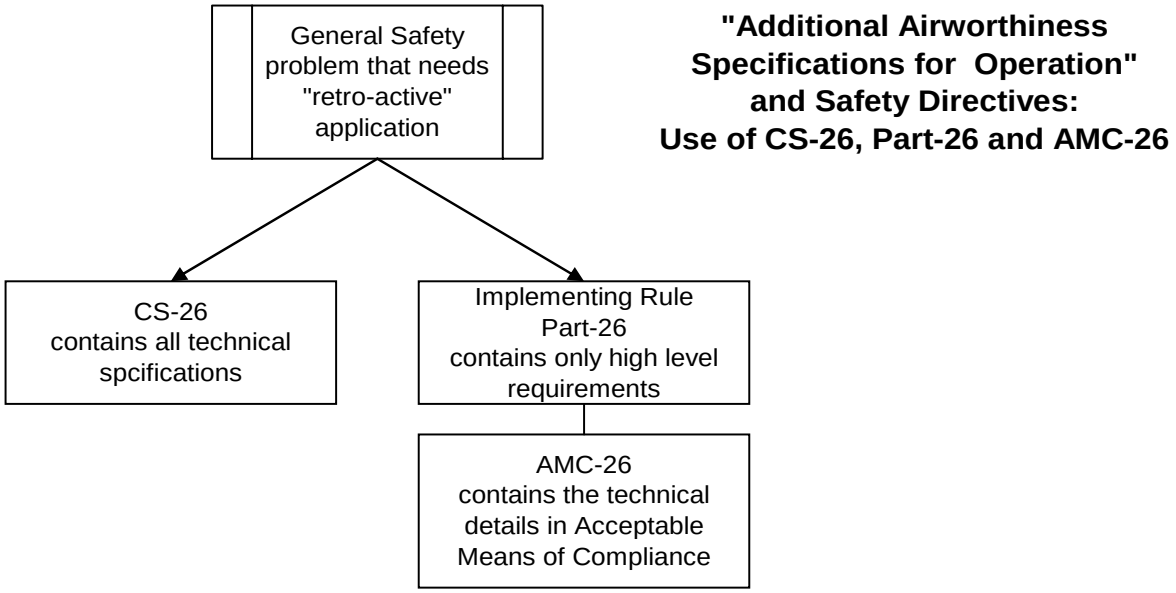
The SD-tool regulates the issuance of SDs and has three different purposes.

1. The SD is used to impose a change to a design or limitation resulting from 21A3C, to the users of the aircraft type.
2. In case it is not practical to impose the compliance to a new CS to the TC holder, an SD can be issued directly without support from the TC holder and will nevertheless impose the measure to operators. (this is similar to the way JAR-26 was imposed)
3. This case is more or less self contained and allows the Agency to issue an SD in case of the need to react immediately to a general safety problem by imposing a general measure directly to the users of the affected aircraft types.

In all cases the SD will have to list the TCs to which the measure applies and will have to be legally notified to each relevant TC holder.
The implementation of SDs by the users of the aircraft will be required through new provisions in Part-M, Part-NCO[11], Part-SPO[12] and Part-OR[13].

The new rule also provides for a possibility to deviate from the SD upon approval by the Agency. This is similar to the AMOC (Alternative Methods Of Compliance) used for deviating from ADs. It also allows the operator to develop an alternative design solution to comply with the relevant CS-26 provision than the one established by the TC holder.

Figure 1

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In existing European legislation related to Air Traffic Management/Air Navigation Services[14] the term “Safety Directive” is already used. Moreover, Opinion No 02/2010 of the Agency for two new Commission Regulations on common requirements for the provision of air navigation services, as regards working methods and operating procedures and on safety oversight in air traffic management and air navigation services was published on 28 May 2010 with the aim to transpose the existing Community legislation relevant to the subject matter into implementing rules. Due to the ‘fast-track’ process and its limited mandate, the Agency did not have any other choice than to use this term in the proposed regulation. In order to avoid confusion with the concept behind that term the Agency decided to change the term Safety Directive in the context of Part 21 into “Safety Enhancement Directive”. While acknowledging the fact that the term Safety Directive (SD) already exists with the appropriate meaning within ATM/ANS domain, the Agency is of the opinion that in order to align this term in all aviation domains the term SD should be used as general term for enhancing and restoring the level of safety and in ATM/ANS domain it should be re-named ‘safety ATM/ANS directive’.

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11 Non Commercial Other than complex motor powered aircraft
12 Operational requirements for Special Operations (aerial work)
13 Requirements for approved organisations
14 Commission Regulation (EC) No 1315/2007 of 8 November 2007 on safety oversight in ATM and amending Regulation (EC) no 2096/2005

*Resulting changes in rule text:*
The original paragraph 21A.3C has been split into two paragraphs 21A.3C and 21A.3D. This was done to clearly separate the requirements for the design approval holders in 21A.3C from the requirements related to Safety Enhancement Directives in 21A.3D.
Furthermore, the text has been reorganised to improve readability and various text improvements were made to respond to individual comments.

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# Appendix 1 to CRD 2009-01

Proposal from the Agency
for amending **Regulation 1702/2003 (Part 21)** and
for amending **Regulation 2042/2003** and
for amending **Decision No. 2003/1/RM (AMC and GM to Part 21)**
to include the
**Operational Suitability Data** concept
and
**Additional airworthiness specifications for operations and Safety Enhancement Directives** concept

Appendix 1 table of contents

## A. Proposed Amendment to Regulation (EC) No. 1702/2003

REGULATION 1702/2003

*Article 1*

*Scope and definitions*

1. ……..

(i) "European Union operator" means an operator having its principle place of business in a Member State

*Article 2f*

**Operational Suitability Data**

1. The holder of an aircraft type certificate issued before *[8 April 2012]*[15] delivering a new aircraft to an European Union operator on or after *[8 April 2012]*, shall obtain approval in accordance with Part 21A.21(e) of operational suitability data except for the minimum syllabus of maintenance certifying staff type rating training and except for aircraft validation source data to support the objective qualification of simulator(s), before *[8 April 2014]* or before the aircraft is operated by an European Union operator, whichever is the latest. The operational suitability data can be limited to the model which is delivered.

2. The applicant for an aircraft type certificate for which the application was filed before *[8 April 2012]* and for which a type certificate is not issued before *[8 April 2012]* shall obtain approval in accordance with Part 21A.21(e) of operational suitability data except for the minimum syllabus of maintenance certifying staff type rating training and except for aircraft validation source data to support the objective qualification of simulator(s), before *[8 April 2014]* or before the aircraft is operated by an European Union operator, whichever is the latest. Findings made by the authorities in Operational Evaluation Board processes conducted under the responsibility of the Joint Aviation Authorities (JAA) or EASA before [*8 April 2012*] shall be accepted by the EASA without further verification.

3. Operational Evaluation Board Reports issued in accordance with JAA procedures or by the Agency before *[8 April 2012]* shall be deemed to constitute the Operational Suitability Data approved in accordance with Part 21A.21(e) and shall be deemed to have been included in the relevant type certificate. The data shall be deemed to be distinguished in mandatory data or recommended data in accordance with the applicable certification specifications issued by the Agency.

4. Holders of a type certificate including operational suitability data shall obtain approval of an extension of the scope of their design organisation approval or alternative procedures to design organisation approval as applicable, to include operational suitability aspects before *[8 April 2014]*.

[15] All dates in this article 3a depend on the entry into force of the amending regulation; it is assumed to be 8 April 2012.

*ANNEX*

# PART 21

Certification of aircraft and related products, parts and appliances, and of design and production organisations

## 21.1 General

For the purpose of this Part, "Competent Authority" shall be:

(a) for organisations having their principal place of business in a Member State, the authority designated by that Member State; or the Agency if so requested by that Member State; or

(b) for organisations having their principal place of business in a non-member State, the Agency.

## SECTION A

TECHNICAL REQUIREMENTS

SUBPART A – GENERAL PROVISIONS

## 21A.1 Scope

This Section establishes general provisions governing the rights and obligations of the applicant for, and holder of, any certificate issued or to be issued in accordance with this Section.

## 21A.2 Undertaking by another person than the applicant for, or holder of, a certificate

The actions and obligations required to be undertaken by the holder of, or applicant for, a certificate for a product, part or appliance under this Section may be undertaken on its behalf by any other natural or legal person, provided the holder of, or applicant for, that certificate can show that it has made an agreement with the other person such as to ensure that the holder's obligations are and will be properly discharged.

## 21A.3 Failures, malfunctions and defects

(a) System for Collection, Investigation and Analysis of Data. The holder of a type-certificate, restricted type-certificate, supplemental type-certificate, European Technical Standard Order (ETSO) authorisation, major repair design approval or any other relevant approval deemed to have been issued under this Regulation shall have a system for collecting, investigating and analysing reports of and information related to failures, malfunctions, defects or other occurrences which cause or might cause adverse effects on the operational suitability of the aircraft or on the continuing airworthiness of the product, part or appliance covered by the type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, major repair design approval or any other relevant approval deemed to have been issued under this Regulation. Information about this system shall be made available to all known operators of the product, part or appliance and, on request, to any person authorised under other associated implementing Regulations.

(b) Reporting to the Agency.

1. The holder of a type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, major repair design approval or any other relevant approval deemed to have been issued under this Regulation shall report to the Agency any failure, malfunction, defect or other occurrence of which it is aware related to a product, part, ~~or~~ appliance or operational suitability data of the aircraft covered by the type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, major repair design approval or any other relevant approval deemed to have been issued under this Regulation, and which has resulted in or may result in an unsafe condition.
2. These reports shall be made in a form and manner established by the Agency, as soon as practicable and in any case dispatched not later than 72 hours after the identification of the possible unsafe condition, unless exceptional circumstances prevent this.

(c) Investigation of Reported Occurrences.

1. When an occurrence reported under paragraph (b), or under 21A.129(f)(2) or 21A.165(f)(2) results from a deficiency in the design, the operational suitability data or a manufacturing deficiency, the holder of the type-certificate, restricted type-certificate, supplemental type-certificate, major repair design approval, ETSO authorisation, or any other relevant approval deemed to have been issued under this Regulation, or the manufacturer as appropriate, shall investigate the reason for the deficiency and report to the Agency the results of its investigation and any action it is taking or proposes to take to correct that deficiency.
2. If the Agency finds that an action is required to correct the deficiency, the holder of the type-certificate, restricted type-certificate, supplemental type-certificate, major repair design approval, ETSO authorisation, or any other relevant approval deemed to have been issued under this Regulation, or the manufacturer as appropriate, shall submit the relevant data to the Agency.

**21A.3B Airworthiness directives**

(a) An airworthiness directive means a document issued or adopted by the Agency which mandates actions to be performed on an aircraft to restore an acceptable level of safety, when evidence shows that the safety level of this aircraft may otherwise be compromised.

(b) The Agency shall issue an airworthiness directive when:

1. an unsafe condition has been determined by the Agency to exist in an aircraft, as a result of a deficiency in the aircraft, or an engine, propeller, part or appliance installed on this aircraft; or
2. an unsafe condition has been determined by the Agency to exist with an aircraft, as a result of a deficiency in the operational suitability data of this aircraft; and
3. ~~2~~ that condition is likely to exist or develop in other aircraft.

(c) When an airworthiness directive has to be issued by the Agency to correct the unsafe condition referred to in paragraph (b), or to require the performance of an inspection, the holder of the type-certificate, restricted type-certificate, supplemental type-certificate, major repair design approval, ETSO authorisation or any other relevant approval deemed to have been issued under this Regulation, shall:

1. Propose the appropriate corrective action or required inspections, or both, and submit details of these proposals to the Agency for approval.

2. Following the approval by the Agency of the proposals referred to under subparagraph (1), make available to all known operators or owners of the product, part or appliance and, on request, to any person required to comply with the airworthiness directive, appropriate descriptive data and accomplishment instructions.

(d) An airworthiness directive shall contain at least the following information:

1. An identification of the unsafe condition;
2. An identification of the affected aircraft;
3. The action(s) required;
4. The compliance time for the required action(s);
5. The date of entry into force.

**21A.3C Additional airworthiness specifications for operations**

(a) The holder of a type certificate, supplemental type certificate or major repair design approval shall demonstrate compliance with additional airworthiness specifications for operations, when:
1. An amendment to the certification specifications containing additional airworthiness specifications for operations, has been issued by the Agency in accordance with 21A.16A; and
2. The Agency has notified to the holder of the type certificate, supplemental type certificate or major repair design approval:
(i) the amended or new paragraphs of the certification specifications containing additional airworthiness specifications for operations, that must be complied with; and
(ii) the period within which compliance shall be demonstrated.

(b) When the Agency is satisfied that compliance is demonstrated with the applicable specifications as notified under (a)(2)(i) of this paragraph or with provisions that provide for an equivalent level of safety it shall amend the type certificate, supplemental type certificate or major repair design approval accordingly to record compliance with the amended certification specifications containing additional airworthiness specifications for operations.

**21A.3D Safety enhancement directives**

(a) A safety enhancement directive is issued by the Agency to ensure safe operation of already certificated products by imposing additional airworthiness specifications for operations. It reflects a mandatory amendment to the type certificate or supplemental type certificate with which individual products or operations shall conform.

(b) The Agency shall issue a safety enhancement directive when:
1. the amendment to the type certificate, supplemental type certificate or major repair design approval in accordance with 21A.3C(b) contains a change in the approved design, operational suitability data or any limitations; or
2. an amendment to the certification specifications containing additional airworthiness specifications for operations has been issued by the Agency in accordance with 21A.16A and the Agency has determined that demonstration of compliance with the additional airworthiness specifications for operations by the holder of the type certificate, supplemental type certificate or major repair design approval is impractical; or
3. it is necessary to react to a safety problem.

(c) A safety enhancement directive shall contain at least the following information:
1. An identification of the affected products;
2. The required action(s) or the additional airworthiness specifications for operations that must be complied with;

3. The compliance time;
4. The date of entry into force;
5. The type of operation to which the safety enhancement directive applies.

(d) The holder of the type certificate, supplemental type certificate or major repair design approval shall make available to all known European Union operators or owners of the affected product and on request, to any person required to comply with a safety enhancement directive issued in accordance with subparagraph (b)(1) of this paragraph, appropriate descriptive data and accomplishment instructions.

(e) Any person may apply for approval of a deviation to the safety enhancement directive in a form and manner established by the Agency. The Agency shall approve such deviation when it is satisfied that the deviation provides an acceptable level of safety.

### 21A.4 Co-ordination between design and production

Each holder of a type-certificate, restricted type-certificate, supplemental type-certificate, ETSO authorisation, approval of a change to type design or approval of a repair design, shall collaborate with the production organisation as necessary to ensure:

(a) The satisfactory co-ordination of design and production required by 21A.122 or 21A.133 or 21A.165(c)(2) as appropriate, and

(b) The proper support of the continued airworthiness of the product, part or appliance.

SUBPART B – TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES

### 21A.11 Scope

This Subpart establishes the procedure for issuing type-certificates for products and restricted type-certificates for aircraft, and establishes the rights and obligations of the applicants for, and holders of, those certificates.

### 21A.13 Eligibility

Any natural or legal person that has demonstrated, or is in the process of demonstrating, its capability in accordance with 21A.14 shall be eligible as an applicant for a type-certificate or a restricted type-certificate under the conditions laid down in this Subpart.

### 21A.14 Demonstration of capability

(a) Any organisation applying for a type-certificate or restricted type-certificate shall demonstrate its capability by holding a design organisation approval, issued by the Agency in accordance with Subpart J.

(b) By way of derogation from paragraph (a), as an alternative procedure to demonstrate its capability, an applicant may seek Agency agreement for the use of procedures setting out the specific design practices, resources and sequence of activities necessary to comply with this Part, when the product is one of the following:

1. a very light aeroplane or rotorcraft, a sailplane or a powered sailplane, a balloon, a hot air airship; or
2. a small aeroplane meeting all of the following elements:

(i) Single piston engine, naturally aspirated, of not more than 250 hp Maximum Take-Off Power (MTOP);

(ii) Conventional configuration;

(iii) Conventional material and structure;

(iv) Flights under VFR, outside icing conditions;

(v) Maximum 4 seats including the pilot and maximum take off mass limited to 3000 lb. (1361 kg);

(vi) Unpressurised cabin;

(vii) Non-power assisted controls;

(viii) Basic aerobatic flights limited to +6/-3g; or

3. a piston engine; or

4. an engine or a propeller type-certificated under the applicable ~~airworthiness code~~ certification specifications for powered sailplanes; or

5. a fixed or adjustable pitch propeller.

**21A.15 Application**

(a) An application for a type-certificate or restricted type-certificate shall be made in a form and manner established by the Agency.

(b) An application for an aircraft type-certificate or restricted type-certificate shall be accompanied by a three-view drawing of that aircraft and preliminary basic data, including the proposed operating characteristics and limitations.

(c) An application for an engine or propeller type-certificate shall be accompanied by a general arrangement drawing, a description of the design features, the operating characteristics, and the proposed operating limitations, of the engine, or propeller.

(d) The application for a type-certificate or restricted type-certificate for an aircraft shall include, or be supplemented after the initial application to include the application for approval of operational suitability data, consisting of, as applicable:

1. the minimum syllabus of pilot type rating training, including determination of type rating;

2. the definition of scope of the aircraft validation source data to support the objective qualification of simulator(s) associated to the pilot type rating training, or provisional data to support their interim qualification;

3. the minimum syllabus of maintenance certifying staff type rating training including determination of type rating;

4. determination of type or variant for cabin crew and type specific data for cabin crew training and;

5. the master minimum equipment list;

The applicant shall specify the type(s) of operation(s) that is (are) covered by his application.

**21A.16A ~~Airworthiness codes~~Certification Specifications**

The Agency shall issue in accordance with Article ~~14~~ 19 of the Basic Regulation ~~airworthiness codes~~certification specifications, including certification specifications for operational suitability data or containing additional airworthiness specifications for operations, as standard means to demonstrate compliance of products, parts and appliances with the relevant essential requirements of Annex I, III and IV to the Basic Regulation. Such ~~codes~~specifications shall be sufficiently detailed and specific to indicate to applicants the conditions under which certificates will be issued, amended or supplemented.

**21A.16B Special conditions**

(a) The Agency shall prescribe special detailed technical specifications, named special conditions, for a product, if the related ~~airworthiness code~~ certification specifications does not contain adequate or appropriate safety standards for the product, because:

1. The product has novel or unusual design features relative to the design practices on which the applicable ~~airworthiness code~~ certification specifications is based; or
2. The intended use of the product is unconventional; or
3. Experience from other similar products in service or products having similar design features, has shown that unsafe conditions may develop.

(b) The special conditions contain such safety standards as the Agency finds necessary to establish a level of safety equivalent to that established in the applicable ~~airworthiness code~~ certification specifications.

**21A.17A Type-certification basis**

(a) The type-certification basis to be notified for the issuance of a type-certificate or a restricted type-certificate shall consist of:

1. The applicable ~~airworthiness code~~ certification specifications established by the Agency that ~~is~~are effective on the date of application for that certificate unless:
   (i) Otherwise specified by the Agency; or
   (ii) Compliance with later effective amendments is elected by the applicant or required under paragraphs (c) and (d).
2. Any special condition prescribed in accordance with 21A.16B(a).

(b) An application for type-certification of large aeroplanes and large rotorcraft shall be effective for five years and an application for any other type-certificate shall be effective for three years, unless an applicant shows at the time of application that its product requires a longer period of time for design, development, and testing, and the Agency approves a longer period.

(c) In the case where a type-certificate has not been issued, or it is clear that a type-certificate will not be issued, within the time limit established under paragraph (b); the applicant may:

1. File a new application for a type-certificate and comply with all the provisions of paragraph (a) applicable to an original application; or
2. File for an extension of the original application and comply with the applicable ~~airworthiness codes~~ certification specifications that were effective on a date, to be selected by the applicant, not earlier than the date which precedes the date of issue of the type-certificate by the time limit established under paragraph (b) for the original application.

(d) If an applicant elects to comply with an amendment to the ~~airworthiness codes~~ certification specifications that is effective after the filing of the application for a type-certificate, the applicant shall also comply with any other amendment that the Agency finds is directly related.

**21A.17B Operational suitability data certification basis**

(a) When the application for a type-certificate or restricted type-certificate for an aircraft includes, or is supplemented after the initial application to include operational suitability data, the Agency shall notify to the applicant the operational suitability data certification basis. It shall consist of:

1. The applicable certification specifications for operational suitability data issued in accordance with 21A.16A that are effective on the date of application or application supplement, unless:

   (i). The Agency accepts other means to demonstrate compliance with the relevant essential requirements of Annexes I, III and IV to the basic Regulation;

   (ii). Compliance with later effective amendments is elected by the applicant; and

2. Any special condition prescribed in accordance with 21A.16B(a).

(b) If an applicant elects to comply with an amendment to the certification specifications that are effective after the filing of the application for a type-certificate, the applicant shall also comply with any other amendment that the Agency finds is directly related.

**21A.18 Designation of applicable environmental protection requirements and certification specifications**

(a) The applicable noise requirements for the issue of a type-certificate for an aircraft are prescribed according to the provisions of Chapter 1 of Annex 16, Volume I, Part II to the Chicago Convention and:

1. for subsonic jet aeroplanes, in Volume I, Part II, Chapters 2, 3 and 4, as applicable;
2. for propeller-driven aeroplanes, in Volume I, Part II, Chapters 3, 4, 5, 6 and 10, as applicable;
3. for helicopters, in Volume I, Part II, Chapters 8 and 11, as applicable; and
4. for supersonic aeroplanes, in Volume I, Part II, Chapter 12, as applicable.

(b) The applicable emission requirements for the issue of a type-certificate for an aircraft and engine are prescribed in Annex 16 to the Chicago Convention:

1. for prevention of intentional fuel venting, in Volume II, Part II, Chapter 2;
2. for emissions of turbo-jet and turbofan engines intended for propulsion only at subsonic speeds, in Volume II, Part III, Chapter 2; and
3. for emissions of turbo-jet and turbofan engines intended for propulsion only at supersonic speeds, in Volume II, Part III, Chapter 3.

(c) The Agency shall issue, in accordance with Article 14 of the Basic Regulation, certification specifications providing for acceptable means to demonstrate compliance with the noise and the emission requirements laid down in paragraphs (a) and (b) respectively.

**21A.19 Changes requiring a new type-certificate**

Any natural or legal person proposing to change a product shall apply for a new type-certificate if the Agency finds that the change in design, power, thrust, or mass is so extensive that a substantially complete investigation of compliance with the applicable type-certification basis is required.

**21A.20 Compliance with the type-certification basis, operational suitability data certification basis and environmental protection requirements**

(a) The applicant for a type-certificate or a restricted type-certificate shall show compliance with the applicable type-certification basis, the applicable operational suitability data certification basis and environmental protection requirements and shall provide to the Agency the means by which such compliance has been shown.

(b) The applicant shall declare that it has shown compliance with all applicable type-certification basis, the applicable operational suitability data certification basis and environmental protection requirements.

(c) Where the applicant holds an appropriate design organisation approval, the declaration of paragraph (b) shall be made according to the provisions of Subpart J.

**21A.21 Issue of a type-certificate**

The applicant shall be entitled to have a product type-certificate issued by the Agency after:

(a) demonstrating its capability in accordance with 21A.14;

(b) submitting the declaration referred to in 21A.20(b); and

(c) it is shown that:

1. The product to be certificated meets the applicable type-certification basis and environmental protection requirements designated in accordance with 21A.17 and 21A.18;
2. Any airworthiness provisions not complied with are compensated for by factors that provide an equivalent level of safety;
3. No feature or characteristic makes it unsafe for the uses for which certification is requested; and
4. The type-certificate applicant has expressly stated that it is prepared to comply with 21A.44.

(d) In the case of an aircraft type-certificate, the engine or propeller, or both, if installed in the aircraft, have a type-certificate issued or determined in accordance with this Regulation.

(e) In the case of an aircraft type-certificate, it is shown that the operational suitability data meets the applicable operational suitability data certification basis designated in accordance with 21A.17B.

(f) By derogation from points (b) and (e) the declaration referred to in 21A.20(b) may include a statement that compliance with the applicable operational suitability data certification basis will be declared after the date of issuance of the type certificate, but before the operational suitability data must be used by a training organisation or an European Union operator.

**21A.23 Issue of a restricted type-certificate**

(a) For an aircraft that does not meet the provisions of 21A.21(c), the applicant shall be entitled to have a restricted type-certificate issued by the Agency after:

1. complying with the appropriate type-certification basis established by the Agency ensuring adequate safety with regard to the intended use of the aircraft, and with the applicable environmental protection requirements;
2. expressly stating that it is prepared to comply with 21A.44.
3. In the case of an aircraft restricted type-certificate, it is shown that the operational suitability data meets the applicable operational suitability data certification basis designated in accordance with 21A.17B.

(b) By derogation from point (a)(3) the applicant may make a statement that compliance with the applicable operational suitability data certification basis will be declared after the date of issuance of the restricted type certificate, but before the operational suitability data must be used by a training organisation or an European Union operator.

(~~b~~c) The engine or propeller installed in the aircraft, or both, shall:

1. have a type-certificate issued or determined in accordance with this Regulation; or
2. have been shown to be in compliance with the certification specifications necessary to ensure safe flight of the aircraft.

**21A.31 Type design**

(a) The type design shall consist of:

1. The drawings and specifications, and a listing of those drawings and specifications, necessary to define the configuration and the design features of the product shown to comply with the applicable type-certification basis and environmental protection requirements;
2. Information on materials and processes and on methods of manufacture and assembly of the product necessary to ensure the conformity of the product;
3. An approved airworthiness limitations section of the instructions for continued airworthiness as defined by the applicable ~~airworthiness code~~ certification specifications; and
4. Any other data necessary to allow by comparison, the determination of the airworthiness, the characteristics of noise, fuel venting, and exhaust emissions (where applicable) of later products of the same type.

(b) Each type design shall be adequately identified.

**21A.33 Investigation and tests**

(a) The applicant shall perform all inspections and tests necessary to show compliance with the applicable type-certification basis, the applicable operational suitability data certification basis and environmental protection requirements.

(b) Before each test required by paragraph (a) is undertaken, the applicant shall have determined:

1. For the test specimen:

(i) That materials and processes adequately conform to the specifications for the proposed type design;

(ii) That parts of the products adequately conform to the drawings in the proposed type design;

(iii) That the manufacturing processes, construction and assembly adequately conform to those specified in the proposed type design; and

2. That the test equipment and all measuring equipment used for tests are adequate for the test and are appropriately calibrated.

(c) The applicant shall allow the Agency to make any inspection necessary to check compliance with paragraph (b).

(d) The applicant shall allow the Agency to review any report and make any inspection and to perform or witness any flight and ground test necessary to check the validity of the declaration of compliance submitted by the applicant under 21A.20(b) and to determine that no feature or characteristic makes the product unsafe for the uses for which certification is requested.

(e) For tests performed or witnessed by the Agency under paragraph (d):

1. The applicant shall submit to the Agency a statement of compliance with paragraph (b); and

2. No change relating to the test that would affect the statement of compliance may be made to a product, part or appliance between the time compliance with paragraph (b) is shown and the time it is presented to the Agency for test.

**21A.35 Flight Tests**

(a) Flight testing for the purpose of obtaining a type-certificate shall be conducted in accordance with conditions for such flight testing specified by the Agency.

(b) The applicant shall make all flight tests that the Agency finds necessary:

1. To determine compliance with the applicable type-certification basis and environmental protection requirements, and

2. For aircraft to be certificated under this section, except (i) hot-air balloons, free gas balloons, tethered gas balloons, sailplanes and powered sailplanes and (ii) airships and aeroplanes of 2722 kg or less maximum take-off mass (MTOM), to determine whether there is reasonable assurance that the aircraft, its parts and appliances are reliable and function properly.

(c) (Reserved)

(d) (Reserved)

(e) (Reserved)

(f) The flight tests prescribed in subparagraph (b)(2) shall include:

1. For aircraft incorporating turbine engines of a type not previously used in a type-certificated aircraft, at least 300 hours of operation with a full complement of engines that conform to a type-certificate; and

2. For all other aircraft, at least 150 hours of operation.

**21A.41 Type-certificate**

The type-certificate and restricted type-certificate are both considered to include the type design, the operating limitations, the operational suitability data, the type-certificate data sheet for airworthiness and emissions, the applicable type-certification basis, the applicable operational suitability data certification basis and environmental protection requirements with which the Agency records compliance, and any other conditions or limitations prescribed for the product in the applicable certification specifications and environmental protection requirements. The aircraft type-certificate and restricted type-certificate, in addition, both include the type-certificate data sheet for noise. The engine type-certificate data sheet includes the record of emission compliance.

**21A.44 Obligations of the holder**

(a) Each holder of a type-certificate or restricted type-certificate shall:

1. undertake the obligations laid down in 21A.3, 21A.3B, 21A.4, 21A.55, 21A.57, and 21A.61 and 21A62; and, for this purpose, shall continue to meet the qualification requirements for eligibility under 21A.14; and

2. specify the marking in accordance with Subpart Q.

(b) Each holder of an engine or propeller type-certificate or restricted type-certificate shall make available the relevant operational suitability data for its engine or propeller to the holder or applicant of the aircraft type certificate in which the engine or propeller is installed and shall make available changes to this data necessary to ensure the continued operational suitability.

**21A.47 Transferability**

Transfer of a type-certificate or restricted type-certificate may only be made to a natural or legal person that is able to undertake the obligations under 21A.44, and, for this purpose, has demonstrated its ability to qualify under the criteria of 21A.14.

**21A.51 Duration and continued validity**

(a) A type-certificate and restricted type-certificate shall be issued for an unlimited duration. They shall remain valid subject to:

1. The holder remaining in compliance with this Part; and

2. The certificate not being surrendered or revoked under the applicable administrative procedures established by the Agency.

(b) Upon surrender or revocation, the type-certificate and restricted type-certificate shall be returned to the Agency.

**21A.55 Record keeping**

All relevant design information, drawings and test reports, including inspection records for the product tested, shall be held by the type-certificate or restricted type-certificate holder at the disposal of the Agency and shall be retained in order to provide the information necessary to ensure the continued airworthiness, continued operational suitability and compliance with applicable environmental protection requirements of the product.

**21A.57 Manuals**

The holder of a type-certificate or restricted type-certificate shall produce, maintain and update master copies of all manuals required by the applicable type-certification basis, the applicable operational suitability data certification basis and environmental protection requirements for the product, and provide copies, on request, to the Agency.

**21A.61 Instructions for continued airworthiness**

(a) The holder of the type-certificate or restricted type-certificate shall furnish at least one set of complete instructions for continued airworthiness, comprising descriptive data and accomplishment instructions prepared in accordance with the applicable type-certification basis, to each known owner of one or more aircraft, engine or propeller upon its delivery or upon issue of the first certificate of airworthiness for the affected aircraft, whichever occurs later and thereafter make those instructions available on request to any other person required to comply with any of the terms of those instructions. The availability of some manual or portion of the instructions for continued airworthiness, dealing with overhaul or other forms of heavy maintenance, may be delayed until after the product has entered into service, but shall be available before any of the products reaches the relevant age or flight-hours/cycles.

(b) In addition, changes to the instructions for continued airworthiness shall be made available to all known operators of the product and shall be made available on request to any person required to comply with any of those instructions. A programme showing how changes to the instructions for continued airworthiness are distributed shall be submitted to the Agency.

**21A.62 Availability of operational suitability data**

The holder of the type-certificate or restricted type-certificate shall make available:

(a) at least one set of complete operational suitability data prepared in accordance with the applicable operational suitability certification basis, to all known European Union operators of the aircraft, before the operational suitability data must be used by a training organisation or an European Union operator; and

(b) any change to the operational suitability data to all known European Union operators of the aircraft; and

(c) on request, the relevant data in (a) and (b) above, to:

1. the competent authority responsible for verifying conformity with one or more elements of this set of operational suitability data; and
2. any person required to comply with one or more elements of this set of operational suitability data.

(SUBPART C – NOT APPLICABLE)

SUBPART D – CHANGES TO TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES

**21A.90 Scope**

This Subpart establishes the procedure for the approval of changes to type designs and type-certificates, and establishes the rights and obligations of the applicants for, and holders of, those

approvals. In this Subpart, references to type-certificates include type-certificate and restricted type-certificate.

**21A.91 Classification of changes in type ~~design~~ certificate**

(a) Changes in type design are classified as minor and major. A "minor change" is one that has no appreciable effect on the mass, balance, structural strength, reliability, operational characteristics, noise, fuel venting, exhaust emission, or other characteristics affecting the airworthiness of the product. Without prejudice to 21A.19, all other changes are "major changes" under this Subpart. Major and minor changes shall be approved in accordance with 21A.95 or 21A.97 as appropriate, and shall be adequately identified.

(b) Changes to operational suitability data are classified as minor and major. A "minor change" to operational suitability data is one that has no appreciable effect on the operational suitability of the aircraft. All other changes are "major changes" under this Subpart. Major and minor changes to operational suitability data shall be approved in accordance with 21A.95 or 21A.97 as appropriate, and shall be adequately identified.

**21A.92 Eligibility**

(a) Only the type-certificate holder may apply for approval of a major change to a type design or to operational suitability data under this Subpart; all other applicants for a major change to a type design or to operational suitability data shall apply under Subpart E.

(b) Any natural or legal person may apply for approval of a minor change to a type design or to operational suitability data under this Subpart.

**21A.93 Application**

An application for approval of a change to a type ~~design~~ certificate shall be made in a form and manner established by the Agency and shall include:

(a) A description of the change identifying

1. All parts of the type design and the approved manuals affected by the change; and
2. The certification specifications and environmental protection requirements with which the change has been designed to comply in accordance with 21A.101.

(b) Identification of any re-investigations necessary to show compliance of the changed product with the applicable certification specifications and environmental protection requirements.

(c) If the applicant has determined or the Agency has found that the change affects the operational suitability data, the application shall include, or be supplemented after the initial application to include the necessary changes to the operational suitability data.

**21A.95 Minor changes**

Minor changes in a type ~~design~~ certificate shall be classified and approved either:

(a) By the Agency; or

(b) By an appropriately approved design organisation under a procedure agreed with the Agency.

**21A.97 Major changes**

(a) An applicant for approval of a major change shall:

1. Submit to the Agency substantiating data together with any necessary descriptive data for inclusion in the type design;
2. Show that the changed product complies with applicable certification specifications, including the specifications for the operational suitability data as applicable, and environmental protection requirements, as specified in 21A.101;
3. Declare that it has shown compliance with the applicable type-certification basis, and the operational suitability data certification basis as applicable, and environmental protection requirements and shall provide to the Agency the basis on which such a declaration is made; and
4. Where the applicant holds an appropriate design organisation approval, make the declaration of subparagraph (a)(3) according to the provisions of Subpart J;
5. Comply with 21A.33 and, where applicable, 21A.35.

(b) Approval of a major change in a type ~~design~~ certificate is limited to that or those specific configuration(s) in the type design upon which the change is made.

**21A.101 Designation of applicable certification specifications and environmental protection requirements**

(a) An applicant for a change to a type-certificate shall demonstrate that the changed product complies with the ~~airworthiness code~~ certification specifications that ~~is~~are applicable to the changed product and that is in effect at the date of the application for the change, and with the applicable environmental protection requirements laid down in 21A.18.

(b) By derogation from paragraph (a), an applicant may show that the changed product complies with an earlier amendment of the ~~airworthiness code~~ certification specifications defined in paragraph (a), and of any other certification specification the Agency finds is directly related. However, the earlier amended ~~airworthiness code~~ certification specifications may not precede the corresponding ~~airworthiness code~~ certification specifications incorporated by reference in the type-certificate. The applicant may show compliance with an earlier amendment of ~~an airworthiness code~~ the certification specifications for any of the following:

1. A change that the Agency finds not to be significant. In determining whether a specific change is significant, the Agency considers the change in context with all previous relevant design changes and all related revisions to the applicable certification specifications incorporated in the type-certificate for the product. Changes that meet one of the following criteria are automatically considered significant:
   (i) The general configuration or the principles of construction are not retained.
   (ii) The assumptions used for certification of the product to be changed do not remain valid.
2. Each area, system, part or appliance that the Agency finds is not affected by the change.
3. Each area, system, part or appliance that is affected by the change, for which the Agency finds that compliance with ~~an airworthiness code~~ the certification specifications described in paragraph (a) would not contribute materially to the level of safety of the changed product or would be impractical.

(c) An applicant for a change to an aircraft (other than a rotorcraft) of 2 722 kg (6 000 lbs.) or less maximum weight or to a non-turbine rotorcraft of 1 361 kg (3 000 lbs.) or less maximum weight may show that the changed product complies with the type-certification basis

incorporated by reference in the type-certificate. However, if the Agency finds that the change is significant in an area, the Agency may designate compliance with an amendment to the type-certification basis incorporated by reference in the type-certificate, in effect at the date of the application, and any certification specification that the Agency finds is directly related, unless the Agency also finds that compliance with that amendment or certification specification would not contribute materially to the level of safety of the changed product or would be impractical.

(d) If the Agency finds that the ~~airworthiness code~~ certification specifications in effect at the date of the application for the change does not provide adequate standards with respect to the proposed change, the applicant shall also comply with any special conditions, and amendments to those special conditions, prescribed under the provisions of 21A.16B, to provide a level of safety equivalent to that established in the ~~airworthiness code~~ certification specifications in effect at the date of the application for the change.

(e) An application for a change to a type-certificate for large aeroplanes and large rotorcraft is effective for five years, and an application for a change to any other type-certificate is effective for three years. In a case where the change has not been approved, or it is clear that it will not be approved under the time limit established under this subparagraph, the applicant may :

1. File a new application for a change to the type-certificate and comply with all the provisions of paragraph (a) applicable to an original application for a change; or

2. File for an extension of the original application and comply with the provisions of paragraph (a) for an effective date of application, to be selected by the applicant, not earlier than the date which precedes the date of approval of the change by the time period established under this subparagraph for the original application for the change.

(f) When the application for a change to a type-certificate for an aircraft includes, or is supplemented after the initial application to include changes to the operational suitability data, the operational suitability data certification basis shall be designated in accordance with points (a) through (d) above.

**21A.103 Issue of approval**

(a) The applicant shall be entitled to have a major change to a type ~~design~~ certificate approved by the Agency after:

1. submitting the declaration referred to in 21A.97(a)(3); and

2. It is shown that:

   (i) The changed product meets the applicable certification specifications and environmental protection requirements, as specified in 21A.101;

   (ii) Any airworthiness provisions not complied with are compensated for by factors that provide an equivalent level of safety; and

   (iii) No feature or characteristic makes the product unsafe for the uses for which certification is requested.

3. In the case of a change affecting the operational suitability data, it is shown that the necessary changes to the operational suitability data meet the applicable operational suitability data certification basis designated in accordance with 21A.101(f).

4. By derogation from points 1 and 3 the declaration referred to in point 1 may include a statement that compliance with the applicable operational suitability data certification basis will be declared after the date of approval of the change to the type certificate, but before

the operational suitability data must be used by a training organisation or an European Union operator.

(b) A minor change to a type ~~design~~ certificate shall only be approved in accordance with 21A.95 if it is shown that the changed product meets the applicable certification specifications, as specified in 21A.101.

**21A.105 Record keeping**

For each change, all relevant design information, drawings and test reports, including inspection records for the changed product tested, shall be held by the applicant at the disposal of the Agency and shall be retained in order to provide the information necessary to ensure the continued airworthiness, continued validity of the operational suitability data and compliance with applicable environmental protection requirements of the changed product.

**21A.107 Instructions for continued airworthiness**

(a) The holder of a minor change approval to type design shall furnish at least one set of the associated variations, if any, to the instructions for continued airworthiness of the product on which the minor change is to be installed, prepared in accordance with the applicable type-certification basis, to each known owner of one or more aircraft, engine, or propeller incorporating the minor change, upon its delivery, or upon issuance of the first certificate of airworthiness for the affected aircraft, whichever occurs later, and thereafter make those variations in instructions available, on request, to any other person required to comply with any of the terms of those instructions.

(b) In addition, changes to those variations of the instructions for continued airworthiness shall be made available to all known operators of a product incorporating the minor change and shall be made available, on request, to any person required to comply with any of those instructions.

**21A.108 Availability of operational suitability data**

In the case of a change affecting the operational suitability data, the holder of the minor change approval shall make available:

(a) at least one set of changes to the operational suitability data prepared in accordance with the applicable operational suitability certification basis, to all known European Union operators of the changed aircraft, before the operational suitability data must be used by a training organisation or an European Union operator; and

(b) any further change to the affected operational suitability data, to all known European Union operators of the changed aircraft; and

(c) on request, the relevant parts of the changes in (a) and (b) above to:

1. the competent authority responsible for verifying conformity with one or more elements of the affected operational suitability data; and
2. any person required to comply with one or more elements of this set of operational suitability data.

**21A.109 Obligations and EPA marking**

The holder of a minor change approval to type ~~design~~ certificate shall:

(a) undertake the obligations laid down in 21A.4, 21A.105, ~~and~~ 21A.107 and 21A.108; and

(b) specify the marking, including EPA (hereinafter "European Part Approval") letters, in accordance with 21A.804(a).

SUBPART E – SUPPLEMENTAL TYPE-CERTIFICATES

**21A.111 Scope**

This Subpart establishes the procedure for the approval of major changes to the type ~~design~~ certificate under supplemental type-certificate procedures, and establishes the rights and obligations of the applicants for, and holders of, those certificates.

**21A.112A Eligibility**

Any natural or legal person ('organisation') that has demonstrated, or is in the process of demonstrating, its capability under 21A.112B shall be eligible as an applicant for a supplemental type-certificate under the conditions laid down in this Subpart.

**21A.112B Demonstration of capability**

(a) Any organisation applying for a supplemental type-certificate shall demonstrate its capability by holding a design organisation approval, issued by the Agency in accordance with Subpart J.

(b) By way of derogation from paragraph (a), as an alternative procedure to demonstrate its capability, an applicant may seek Agency agreement for the use of procedures setting out the specific design practices, resources and sequence of activities necessary to comply with this Subpart.

**21A.113 Application for a supplemental type-certificate**

(a) An application for a supplemental type-certificate shall be made in a form and manner established by the Agency.

(b) An application for a supplemental type-certificate shall include the descriptions, ~~and~~ identification and changes to the operational suitability data required by 21A.93. In addition, such an application shall include a justification that the information on which those identifications are based is adequate either from the applicant's own resources, or through an arrangement with the type-certificate holder.

**21A.114 Showing of compliance**

Any applicant for a supplemental type-certificate shall comply with 21A.97.

**21A.115 Issue of a supplemental type-certificate**

The applicant shall be entitled to have a supplemental type-certificate issued by the Agency after:

(a) complying with 21A.103(a);

(b) demonstrating its capability in accordance with 21A.112B;

(c) where, under 21A.113(b), the applicant has entered into an arrangement with the type-certificate holder,

1. The type-certificate holder has advised that its has no technical objection to the information submitted under 21A.93; and
2. The type-certificate holder has agreed to collaborate with the supplemental type-certificate holder to ensure discharge of all obligations for continued airworthiness of the changed product through compliance with 21A.44 and 21A.118A.

**21A.116 Transferability**

A supplemental type-certificate shall only be transferred to a natural or legal person that is able to undertake the obligations of 21A.118A and for this purpose has demonstrated its ability to qualify under the criteria of 21A.112B.

**21A.117 Changes to that part of a product covered by a supplemental type-certificate**

(a) Minor changes to that part of a product covered by a supplemental type-certificate shall be classified and approved in accordance with Subpart D.

(b) Each major change to that part of a product covered by a supplemental type-certificate shall be approved as a separate supplemental type-certificate in accordance with this Subpart.

(c) By way of derogation from paragraph (b), a major change to that part of a product covered by a supplemental type-certificate submitted by the supplemental type-certificate holder itself may be approved as a change to the existing supplemental type-certificate.

**21A.118A Obligations and EPA marking**

Each holder of a supplemental type-certificate shall:

(a) undertake the obligations:

1. Laid down in 21A.3, 21A.3B, 21A.4, 21A.105, 21A.119, ~~and~~ 21A.120A and 21A.120B;
2. Implicit in the collaboration with the type-certificate holder under 21A.115(c)(2);

and for this purpose continue to meet the criteria of 21A.112B

(b) specify the marking, including EPA letters, in accordance with 21A.804(a).

**21A.118B Duration and continued validity**

(a) A supplemental type-certificate shall be issued for an unlimited duration. It shall remain valid subject to:

1. The holder remaining in compliance with this Part; and
2. the certificate not being surrendered or revoked under the applicable administrative procedures established by the Agency.

(b) Upon surrender or revocation, the supplemental type-certificate shall be returned to the Agency.

**21A.119 Manuals**

The holder of a supplemental type-certificate shall produce, maintain, and update master copies of variations in the manuals required by the applicable type-certification basis the applicable operational suitability data certification basis and environmental protection requirements for the

product, necessary to cover the changes introduced under the supplemental type-certificate, and furnish copies of these manuals to the Agency on request.

**21A.120A Instructions for continued airworthiness**

(a) The holder of the supplemental type-certificate for an aircraft, engine, or propeller, shall furnish at least one set of the associated variations to the instructions for continued airworthiness, prepared in accordance with the applicable type-certification basis, to each known owner of one or more aircraft, engine, or propeller incorporating the features of the supplemental type-certificate, upon its delivery, or upon issuance of the first certificate of airworthiness for the affected aircraft, whichever occurs later, and thereafter make those variations in instructions available, on request, to any other person required to comply with any of the terms of those instructions. Availability of some manual or portion of the variations to the instructions for continued airworthiness, dealing with overhaul or other forms of heavy maintenance, may be delayed until after the product has entered into service, but shall be available before any of the products reaches the relevant age or flight-hours/cycles.

(b) In addition, changes to those variations of the instructions for continued airworthiness shall be made available to all known operators of a product incorporating the supplemental type-certificate and shall be made available, on request, to any person required to comply with any of those instructions. A programme showing how changes to the variations to the instructions for continued airworthiness are distributed shall be submitted to the Agency.

**21A.120B Availability of operational suitability data**

In the case of a change affecting the operational suitability data, the holder of the supplemental type-certificate shall make available:

(a) at least one set of changes to the operational suitability data prepared in accordance with the applicable operational suitability certification basis, to all known European Union operators of the changed aircraft, before the operational suitability data must be used by a training organisation or an European Union operator; and

(b) any further change to the affected operational suitability data, to all known European Union operators of the changed aircraft; and

(c) on request, the relevant parts of the changes in (a) and (b) above, to:

1. the competent authority responsible for verifying conformity with one or more elements of the affected operational suitability data; and

2. any person required to comply with one or more elements of this set of operational suitability data.

…….

SUBPART J – DESIGN ORGANISATION APPROVAL

**21A.263 Privileges**

……..

(c) The holder of a design organisation approval shall be entitled, within its terms of approval and under the relevant procedures of the design assurance system:

1. to classify changes to type design, changes to operational suitability data and repairs as "major" or "minor".
2. to approve minor changes to type design, minor changes to operational suitability data and minor repairs.

……

- / -

**B. Proposed Amendment to Decision No. 2003/1/RM of 17 October 2003 (AMC/GM to Part 21)**

# AMC and GM to Part-21

*AMC 21A.3B(b) is renamed AMC No. 1 to 21A.3B(b)*

*Insert new AMC and GM as follows:*

**AMC No. 2 to 21A.3B(b)**
**Unsafe Condition resulting from a deficiency in the operational suitability data**

(a) .The assessment whether an unsafe condition resulting from a deficiency in the OSD exists should consider at least the following:

(1) Crew and maintenance personnel errors due to lack of knowledge of an aircraft;

(2) The existence of similar previous events and whether or not they resulted in unsafe conditions resulting from a deficiency in the OSD;

(3) In case of a relation with the MMEL consideration should also be given to AMC No 1 to 21A.3B(b) and GM 21A.3B(b)

Note 1: An unsafe condition resulting from a deficiency in the OSD may exist even though applicable certification specifications are complied with.

Note 2: The above definition covers the majority of cases where the Agency considers there is an unsafe condition resulting from a deficiency in the OSD. There may be other cases where overriding safety considerations may lead the Agency to issue an airworthiness directive.

**GM to 21A.3C and 21A.3D**
**Additional airworthiness specifications for operations and safety enhancement directives**

NOTE: For readability, where in this GM "Type Certificate" (TC) is mentioned it includes Supplemental Type Certificates (STCs) and major repair approvals.

(a) Both 21A.3C and 21A.3D are covering the case where the Agency wants to react to a general safety problem. This is different from the Airworthiness Directive (AD) tool of 21A.3B which is intended for reacting to safety problems (usually design deficiencies) in a particular type.

Another difference with ADs is that an AD is issued to restore the level of safety as established by the applicable certification basis, whereas the 21A.3C and 21A.3D tools are meant to enhance the certification basis.

Because Operational Suitability Data (OSD) is included in the Type Certificate (TC), ADs can also address a case where the OSD of one particular type has been found to create a safety problem and a correction is needed.

The natural reaction to a general safety problem is to improve the relevant certification specification (CS) to mitigate the identified risk. However a change to a CS is only applicable to new designs and does not affect already certificated types. So if the Agency identifies the need to make the new CS provision also applicable to already certified aircraft, a new legal tool is needed.

(b) The Agency has decided that two legal tools are used for this purpose.

The first tool is to develop (an amendment to) an Implementing Rule (IR) each time a particular retro-active measure is deemed necessary.

The second one is a provision in Part 21 allowing the Agency to require holders of existing TCs to show compliance with a new CS and to issue Safety Enhancement Directives (SED).

The choice between the two tools is made by the Agency based upon considerations of the expected impact of the measure. The choice is substantiated each time a new measure is proposed as part of the respective Notice of Proposed Amendment (NPA) and is subject to comments. Based on the comments received during the rulemaking process it will be possible to change from one tool to the other. The technical content of the measure is not affected by the choice of legal implementation tool.

(c) The first tool is the development of an implementing rule or an amendment to that IR for each intended measure. This will follow the normal rulemaking processes for IRs; an EASA rulemaking process leading to an Opinion to be submitted to the European Commission, followed by the EC adoption process. This IR-26 will be amended each time a new measure needs to be added. Each measure will contain its own applicability provisions and is independent from other IR. The development of the IR-26 provision can largely be done in parallel with the development of the basic airworthiness CS amendment so that no time is lost.

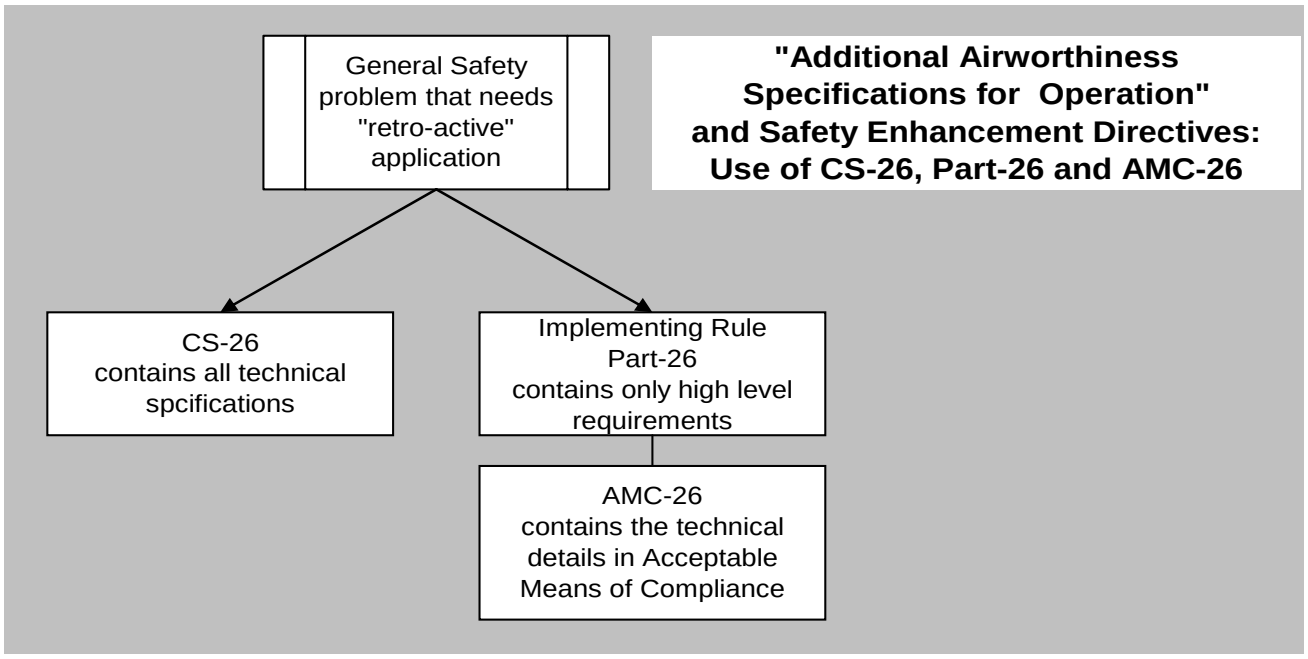
The measures can be addressed to design approval holders, approved organisations and individuals as appropriate. A measure may include a cascaded approach where first an action is required by a design approval holder, to be followed by an action of an operator to implement the result of the compliance by the design approval holder. The requirement in the IR is kept at a high level and additional detail is provided in accompanying AMC provisions.

(d) The second tool is composed of two elements: 21A.3C and 21A.3D:

21A.3C provides the legal tool for imposing a new provision in a CS to the TC holder of an already certificated aircraft. It can be seen as a mandatory supplement to the certification basis to which the TC holder must show compliance.

Before requiring the TC holder to show compliance, the measure will be included into Certification Specifications containing additional airworthiness specifications for operations (CS-26) following a normal rulemaking process. This is necessary because the requirement for new designs in the basic airworthiness (CS-25, CS-23, etc.) cannot always be applied to existing designs. It may need some tailoring to cater for retrofit. See figure 1 for an overview of the different regulatory products.

Figure 1



At the same time it has the benefit to have a dedicated consultation on the retrofit issue which may have a considerable impact on stakeholders. However a comprehensive NPA with RIA will allow the Agency to properly justify the measure from a global perspective reducing the need to justify it for each individual TC holder. The development of the CS-26 provision can largely be done in parallel with the development of the basic airworthiness CS amendment so that no time is lost.

The TC Holder will be required to comply with a particular CS-26 provision through a dedicated notification by the Agency based on 21A.3C(a)(2). This notification will activate the requirement to comply.

Non-compliance or not-in-time compliance by the TC holder will be a potential reason for revocation, limitation or suspension of the TC.

The compliance showing can have three different results:

(1) The existing design complies already;

(2) In order to comply, a change in the ICA or MMEL is needed.

(3) In order to comply, a change in the design, other OSD or any limitation is needed;

In all cases the TCDS will be amended to record compliance with the applicable CS-26 provision. Depending on the applicability of the measure the TCDS will also specify the type of operation that is affected.

Case No 1 and 2 do not require further action. For case 1 this is obvious; for case 2 the implementation by operators will be achieved through existing requirements in Part-M or the OPS rules relative to MEL.

For case 3 there is a need for a legal tool to impose the change to operators (or production organisations in case of production cut-in). This legal tool is the Safety Enhancement Directive (SED). It is one of the three purposes of the SED tool (see below).

21A.3D regulates the issuance of SEDs and has three different purposes.

(1) The SED is used to impose a change to a design, OSD or limitation resulting from 21A3C (3rd case as described above), to the users of the aircraft type.

(2) In case it is not practical to impose the showing of compliance with a new CS to the TC holder, an SED can be issued directly without support from the TC holder and will impose the measure to operators.

(3) This case is more or less self contained and allows the Agency to issue an SED in case of the need to react immediately to a general safety problem by imposing a general measure indirectly to the users of the affected aircraft types.

In all cases the SED will list the TCs to which the measure applies and will be legally notified to each relevant TC holder.

The implementation of SEDs by the users of the aircraft is required through provisions in Part-M, Part-NCO, Part-SPO and Part-OR.

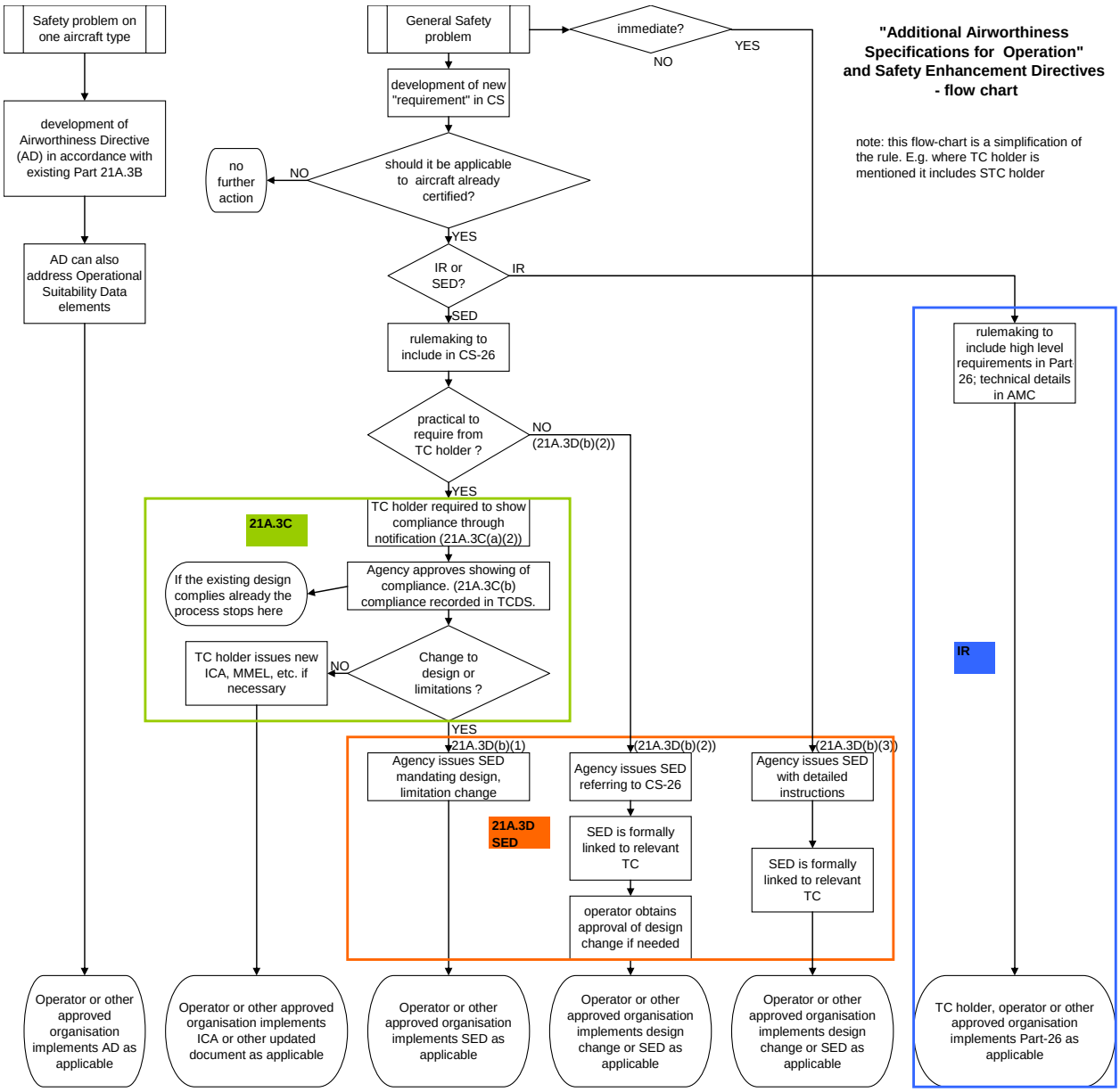
NCO = Non Commercial Other than complex motor powered aircraft

SPO = Operational requirements for Special Operations

OR = Requirements for approved organisations

21A.3D also provides for a possibility to deviate from the SED upon approval by the Agency. This is similar to the AMOC (Alternative Methods Of Compliance) used for deviating from ADs. It also allows the operator to develop an alternative design solution to comply with the relevant CS-26 provision than the one established by the TC holder under 21A.3C.

All the above possibilities are illustrated in the below flow chart.




## GM No. 1 to 21A.15(d)
## Clarification of the term "as applicable".

The term "as applicable" indicates that not all elements as listed in 21A.15(d)(1) through (4) are always part of the OSD. For example, when the operational rules do not require cabin crew for an aircraft with a certain number of passenger seats, the element of (d)(3) is not required for the OSD of this aircraft. Another example is that a minimum syllabus for pilot type rating training is not required if the aircraft is in a class rating.

If a new aircraft type is considered a variant for licensing purposes a full syllabus for type rating training is not required, but the applicant can suffice with the syllabus for differences training.

## GM No. 2 to 21A.15(d)
## Determination of type or variant

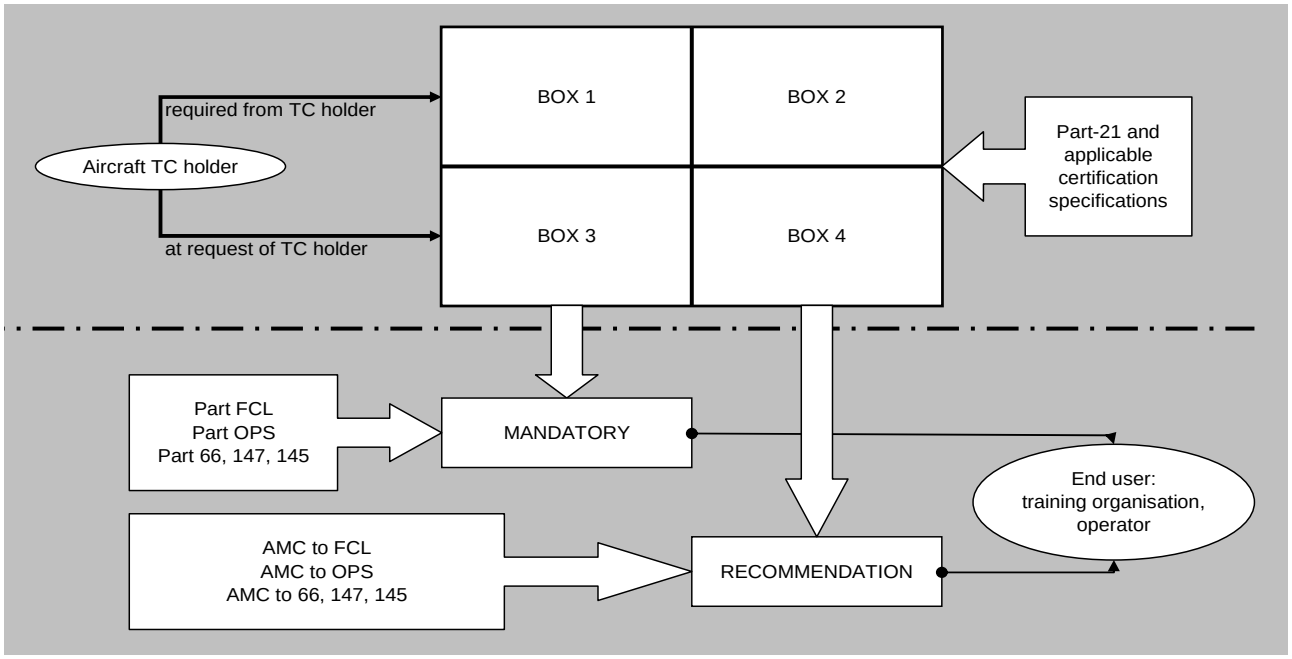
The criteria for the determination whether an aircraft with a new type certificate (TC) is considered a new type or is a variant with reference to another aircraft type from the same TC

holder for the purpose of the specific OSD element, are provided in the applicable Certification Specifications for maintenance certifying staff, pilots and cabin crew.

**GM No. 3 to 21A.15(d)**
**OSD content**

The OSD will typically consist of elements that are required to be included by the TC applicant and elements that can be added at the request of the TC applicant. (see also GM No.4 to 21A.15(d)).

Both the required elements and the additional elements will have a part that is mandatory to be used by the operator or training organisation (status of rule) and a part which is considered recommendation to the operator or training organisation (status of AMC). For illustration of this concept the below figure is included.




Box 1: required from TC holder; mandatory for end-users

Box 2: required from TC holder; recommendation to end-users

Box 3: at request of TC holder; mandatory for end-users

Box 4: at request of TC holder; recommendation to end-users

The exact content of the four boxes in the above figure is determined by the certification specification that is applicable to the specific element.

The status the data will have on the side of the operator or training organisation should be indicated in the OSD by segregating the data in a section called “Mandatory” and a section called “Recommendations”.

**GM No. 4 to 21A.15(d)**
**Types of operations**

(a) In the application-extension for approval of operational suitability data, the TC applicant may apply for the approval of different types of operations. If the aircraft is certificated

for certain types of operations (e.g. ETOPS, RNP, LVO) the impact on the elements of 21A.15(d) should be addressed.

(b) The TC applicant may wish to apply for the approval of differences training between variants or types to reduce training, checking or currency requirements for operations of more than one type or variant. This is regarded as an optional element in addition to the required elements of 21A.15(d).

(c) Under the term "Types of operations" there are several possibilities for including elements in the OSD at the request of the TC applicant in addition to the required elements. These additional elements should be linked to one of the required elements or should concern the operational suitability of the aircraft type.

**GM 21A.16A**
**Certification Specifications**

The certification specifications containing additional airworthiness specifications for operations will be amended when :

- an amendment to other certification specifications such as CS-25, CS-23 etc has been issued; and
- the amendment should also apply to already issued certificates to ensure an appropriate level of safety.

**GM 21A.17B (a)(1)**
**Reference date for operational suitability certification basis**

The date of application as referred to in 21A.17B (a)(1) is the date of the TC application when this includes operational suitability data, or the date the application was supplemented to include operational suitability data.

**GM 21A.21(f)**
**Availability of Operational Suitability Data**

It is acknowledged that it may not always be possible to have the operational suitability data available at the date of the issuance of the type certificate. The derogation provided by point 21A.21(f) is intended for that case. The type certificate can be issued before compliance with the operational suitability data certification basis has been shown provided the applicant declares that the OSD are available before the operational suitability data must be used by a training organisation for the purpose of obtaining a European license, rating or attestation or by an EU operator. This is normally at the entry into service of the first aircraft by an EU operator but could also be later for some of the elements such as the data for simulators which should only be available when a simulator has to be qualified..

However, there may be a need to make one or several OSD elements available before the entry into service. For example, there may be a need to start training activities before all elements contained in the OSC application can be approved.

Therefore, before the availability of a complete OSD, the Agency can certify compliance of only one or several OSD elements under the TC, the use of which can then be limited to specific purposes.

**GM 21A.90**
**Scope**

In case of changes to operational suitability data, the term "changes" includes amendments, deviations, additions and supplements.

*GM 21A.91 is renamed GM 21A.91(a)*

*Insert new GM as follows:*

**GM 21A.91(b)**
**Classification of changes to operational suitability data**

**1. PURPOSE OF CLASSIFICATION**

Classification of changes to operational suitability data into MAJOR or MINOR is to determine the approval route to be followed in Part 21 Subpart D, i.e., either 21A.95 or 21A.97, or alternatively whether application and approval has to be made in accordance with Part 21 Subpart E.

**2. ASSESSMENT OF CHANGE TO OSD ELEMENTS FOR CLASSIFICATION**

(a) Changes to the elements of the OSD

A change to any of the elements of an OSD is considered a change to the OSD.

(b) Classification Process

21A.91 requires all changes to be classified as either major or minor.

Wherever there is doubt as to the classification of a change, the Agency should be consulted for clarification.

Reasons for a classification decision should be recorded and made readably available to Agency staff upon request

(c) Complementary guidance for classification of changes.

A change to the OSD elements is judged to have an "appreciable effect on the operational suitability of the aircraft" and therefore should be classified major, in particular but not only, when one or more of the following conditions are met:

(1) Where the change requires an adjustment of the operational suitability data certification basis established for the initial TC in accordance with 21A.17B.

(2) Where the applicant proposes a new interpretation of the applicable certification specifications, that have not been published as AMC material or otherwise agreed with the Agency.

(3) Where the demonstration of compliance uses methods that have not been previously accepted as appropriate for the nature of the change to the elements of the OSD or for similar changes to OSD elements for other products designed by the applicant.

(4) The change is made mandatory by an airworthiness directive issued by the Agency (refer to Note 1).

Note: The change previously classified minor and approved prior to the airworthiness directive issuance decision needs no re-classification. However, the Agency retains the right to review the change and re-classify/re-approve if found necessary.

**3. EXAMPLES OF CRITERIA FOR CLASSIFICATION OF CHANGES TO OSD**

Examples of Major Changes per discipline

The information below is intended to provide a few major change examples per discipline, resulting from application of 21A.91 and paragraph 2.c conditions. It is not intended to present a comprehensive list of all major changes. Examples are categorised per OSD element.

In the Part 21 a negative definition is given of minor changes only. However in the following list of examples it was preferred to give examples of major changes.

Where in this list of examples the words “has effect” or “affect(s)” are used, they have always to be understood as being the opposite of “no *appreciable* effect” as in the definition of minor change in 21A.91. Strictly speaking the words “has appreciable effect” and “appreciably affect(s)” should have been used, but this has not been done to improve readability.

(a). Minimum syllabus for pilot type rating training

*tbd*

(b) Minimum syllabus for maintenance certifying staff type rating training

*tbd*

(c) Definition of scope of the aircraft validation source data to support the objective qualification of simulator(s),

*tbd*

(d) Type specific data for cabin crew training

*tbd*

(e) Master Minimum Equipment list

*tbd*

**GM 21A.93(c) Changes affecting operational suitability data**

(a) Only when the type certificate of the changed aircraft includes operational suitability data (OSD) there is a need to consider the possible effect of the design change on these data.

(b) Design changes affecting the OSD are generally changes that would require additional or different training for pilots, cabin crew or maintenance certifying staff or that would change the existing MMEL or change the definition of scope of the aircraft validation source data to support the objective qualification of simulators.

(c) In the case of pilot training this would typically consist of the installation of new equipment in the cockpit that requires operational approval such as HUD, EVS, EFB, etc.

(d) Due to the alleviating nature of the MMEL, adding a new item to the MMEL resulting from a change to type design is not mandatory. Adding a new item to the MMEL can therefore be processed under a separate application as a voluntary stand alone change to the OSD. However, when a design change has an effect in a more restrictive sense on an existing item of the MMEL this would typically require a change to the MMEL.

**GM 21A.95 Minor changes**

A change to the type design may require also a change to the operational suitability data. In such case the change to operational suitability data (OSD) is considered a change associated to the change to type design and both together are considered to constitute the change that requires approval.

In the classification of such a change it can be split in a type design part and an OSD part. When the classification is not consistent (i.e. the type design part is minor but the OSD part is major, or vice versa) the whole change is considered major. However the appropriately approved design organisation can approve the minor part before submitting the whole change

for approval to the Agency. The Agency will then process the major change approval without verifying the minor part.

## C. Proposed Amendment to Regulation (EC) No. 2042/2003

Note: Because some of the below paragraphs are changed by the proposals of Opinion 05/2009 the approval of which by the European Commission is pending (as discussed at EASA Committee held on 9 February 2011), it is decided to use the text as agreed by this Committee as the basis for introducing the Operational Suitability Data concept. This will improve the compatibility and alignment of the two proposals.

### I. Part M

*Commission Regulation (EC) No 2042/2003 Annex I (Part M) is amended as follows:*

*The following paragraphs of Part-M are amended by adding the words "and safety enhancement directives" each time "airworthiness directives" are mentioned:*

- M.A.301 Continuing airworthiness tasks
- M.A.303 Airworthiness directives
- M.A.305 Aircraft continuing airworthiness record system
- M.A.401(b) Maintenance data
- M.A.501 Installation
- M.A.503 Service life limited components
- M.A.708(b) Continuing airworthiness management
- M.A.710 Airworthiness review
- Appendix II: EASA Form 1; Use of the EASA Form 1 for maintenance
- Appendix VIII: Limited Pilot-Owner Maintenance

### II. Part 145

*Commission Regulation (EC) No 2042/2003 Annex II (Part 145) is amended as follows:*

**145.A.35 Certifying staff and category B1 and B2 support staff**

(a) In addition to the appropriate requirements of 145.A.30(g) and (h), the organisation shall ensure that certifying staff and category B1 and B2 support staff have an adequate understanding of the relevant aircraft and/or components to be maintained together with the associated organisation procedures. In the case of certifying staff, ~~this~~ the competency shall be evaluated by a satisfactory assessment and must be accomplished before the issue or re-issue of the certification authorisation according to an organisation procedure.

(i) 'Support staff' means those staff holding a Part-66 aircraft maintenance licence in category B1, B2 and/or B3 with the appropriate aircraft ratings, working in a base maintenance environment while not necessarily holding certification privileges.

(ii) 'Relevant aircraft and/or components', means those aircraft or components specified in the particular certification authorisation.

(iii) 'Certification authorisation' means the authorisation issued to certifying staff by the organisation and which specifies the fact that they may sign certificates of release to service within the limitations stated in such authorisation on behalf of the approved organisation.";

In addition, certifying staff and category B1 and B2 support staff can only exercise their privileges if the organisation has ensured that certifying staff and category B1 and B2 support staff comply with the terms of Airworthiness Directives resulting from shortcomings of training.

……

(e) The organisation shall establish a programme for continuation training for certifying staff and category B1 and B2 support staff, including a procedure to ensure compliance with the relevant paragraphs of 145.A.35 as the basis for issuing certification authorisations under this Part to certifying staff, and a procedure to ensure compliance with Part 66 and Part 21.

*The following paragraphs of Part-145 are amended by adding the words "and safety enhancement directives" each time "airworthiness directives" are mentioned:*

- 145.A.42(b) Acceptance of components
- 145.A.45 Maintenance data

## III. Part 66

*Commission Regulation (EC) No 2042/2003 Annex III (Part 66) is hereby amended as follows:*

**Appendix I**

**Basic knowledge requirements**

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MODULE 10. AVIATION LEGISLATION

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10.5 Aircraft Certification

(a) *General*

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Operational Suitability Data;

……

10.7 Applicable National and International Requirements for (if not superseded by EU requirements)

(a)

……

Airworthiness Directives and Safety Enhancement Directives;

……

*Appendix III*
**Aircraft Type Training and Examination Standard.**
**On the Job Training**

**1. General**

~~Aircraft type training shall consist of theoretical training and examination, and, except for the category C ratings, practical training and assessment.~~

The type training course shall consist of theoretical training and examination and, except for the category C ratings, practical training and assessment. The type training course shall be based on the mandatory training elements for the relevant type as defined in the operational suitability data established in accordance with Part-21 or, if the operational suitability training elements are not available, on the elements listed in paragraph 3.

(a) Theoretical training and examination shall comply with the following requirements:

…/…

**IV. Part 147**

*No changes*