



Explanatory Note to Decision 2016/007/R

Acceptable means of compliance and guidance material to Part-21 for changes to operational suitability data

RELATED NPA/CRD 2015-12 — RMT.0607 — 25.4.2016

EXECUTIVE SUMMARY

This draft ED Decision includes acceptable means of compliance (AMC) and guidance material (GM) to Part-21 (Annex I to Regulation (EU) No 748/2012) to facilitate the implementation of the rules related to the approval of changes to operational suitability data (OSD).

The purpose of the draft AMC/GM annexed to this Decision is to reduce the administrative burden on applicants for the approval of a change. The guidance should allow these applicants to come easily to a decision with regard to:

- whether a design change impacts on OSD or not;
- the classification of changes to OSD as 'minor' or 'major' ones;
- the certification basis for the OSD change; and
- the use of their design organisation approval (DOA) for OSD changes.

Applicability		Process map	
Affected regulations and decisions:	ED Decision 2012/020/R (AMC/GM to Part-21)	Terms of reference:	13.8.2013
Affected stakeholders:	Type certificate (TC)/supplemental type certificate (STC) holders/applicants; applicants for the approval of minor changes	Concept paper:	No
Driver/origin:	Efficiency/proportionality	Rulemaking group:	Yes
Reference:	N/a	RIA type:	Light
		Technical consultation during NPA drafting:	No
		Publication date of the NPA:	20.8.2015
		Duration of NPA consultation:	10 weeks
		Review group:	No
		Focused consultation:	No
		Publication date of the Opinion:	N/a



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1. Procedural information

1.1. The rule development procedure

The European Aviation Safety Agency (hereinafter referred to as the 'Agency') developed ED Decision 2016/007/R in line with Regulation (EC) No 216/2008¹ (hereinafter referred to as the 'Basic Regulation') and the Rulemaking Procedure².

This rulemaking activity is included in the Agency's [5-year Rulemaking Programme](#) under RMT.0607 (21.039(b)). The scope and timescale of the task were defined in the related [Terms of Reference \(ToR\)](#).

The draft text of this Decision has been developed by the Agency based on the input of the rulemaking group RMT.0607 (21.039(b)). All interested parties were consulted through [NPA 2015-12](#)³. 81 comments were received from interested parties, including industry and national aviation authorities (NAAs).

The Agency reviewed the comments received during the NPA public consultation based on the input of the Rulemaking Group RMT.0607. The comments received and the Agency's responses thereto are presented in the Comment-Response Document (CRD) 2015-12⁴ which is published together with this Decision.

The final text of this Decision with the AMC/GM has been developed by the Agency based on the input of the Review Group RMT.0607.

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

1.2. Structure of the related documents

Chapter 1 contains the procedural information related to this task. Chapter 2 explains the core technical content. Chapter 3 contains references. The text of the AMC/GM is annexed to this Decision.

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

² The Agency is bound to follow a structured rulemaking process as required by Article 52(1) of the Basic Regulation. Such process has been adopted by the Agency's Management Board and is referred to as the 'Rulemaking Procedure'. See Management Board (MB) Decision 01-2012 of 13 March 2012 concerning the procedure to be applied by the Agency for the issuing of opinions, certification specifications and guidance material.

³ In accordance with Article 52 of the Basic Regulation and Articles 5(3) and 6 of the Rulemaking Procedure.

⁴ <https://easa.europa.eu/document-library/comment-response-documents>



2. Explanatory Note

This amending Decision provides the AMC and GM which illustrate the means to demonstrate compliance with the requirements of Regulation (EU) No 748/2012⁵, as amended by Commission Regulation (EU) No 69/2014⁶, with regard to changes to TCs.

2.1. Overview of the issues to be addressed

On 28 January 2014, the European Commission adopted Regulations (EU) Nos 69/2014⁷ (amending Regulation (EU) No 748/2012 (Part-21)), 70/2014 (amending Regulation (EU) No 1178/2011⁸ (Part-FCL)) and No 71/2014⁹ (amending Regulation (EU) No 965/2012¹⁰ (the 'Air Ops' Regulation)) on OSD.

The objective of OSD is to ensure that certain data, necessary for the safe operation of aircraft by an EU operator, is made available to and used by the operators, training organisations, and manufacturers of flight simulator training devices. This data is considered specific to an aircraft type and should, therefore, be produced by the designer of that aircraft type. It consists of:

- a minimum syllabus for pilot type rating training;
- aircraft reference data to support the qualification of simulators;
- a minimum syllabus for type rating training of maintenance certifying staff MCS;
- type-specific data for cabin crew training; and
- a master minimum equipment list (MMEL).

The OSD proposed by the designer will be approved by the Agency as part of the TC.

Once approved, the core of the OSD must be used by operators and training organisations when establishing their customised training courses and minimum equipment lists (MELs).

The OSD contributes to bridging the gap between airworthiness (AW) and air operations (OPS) and, therefore, to improving safety. Furthermore, the OSD provides the basis to enable greater standardisation in the EU for type training and MEL.

The first batch of AMC/GM to these new Regulations has already been published by the Agency on 31 January 2014 with ED Decision 2014/007/R.

⁵ Commission Regulation (EU) No 748/2012 of 3 August 2012 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 (OJ L 224, 21.8.2012, p. 1).

⁶ Commission Regulation (EU) No 69/2014 of 27 January 2014 amending Regulation (EU) No 748/2012 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 (OJ L 23, 28.1.2014, p. 12).

⁷ Commission Regulation (EU) No 70/2014 of 27 January 2014 amending Regulation (EU) No 1178/2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 23, 28.1.2014, p. 25).

⁸ Commission Regulation (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 311, 25.11.2011, p. 1).

⁹ Commission Regulation (EU) No 71/2014 of 27 January 2014 amending Regulation (EU) No 965/2012 laying down technical requirements and administrative procedures related to Air Operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 23, 28.1.2014, p. 27).

¹⁰ Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1).



The new OSD Regulation also includes the requirement that anyone proposing a change to design has also to assess the impact of that change on the OSD. It also contains requirements on how to handle stand-alone changes to OSD. However, the details on how these requirements should be implemented were not fully clear. The present AMC/GM clarify all the issues related to changes to OSD.

2.2. Objectives

The overall objectives of the EASA system are defined in Article 2 of the Basic Regulation. This proposal will contribute to the achievement of the overall objectives by addressing the issues outlined in Chapter 2.

The specific objective of this Decision is, therefore, to provide AMC and GM to the new requirements of Regulation (EU) No 748/2012 to facilitate the implementation of the changes to the OSD requirements, once they become mandatory on 19 December 2016.

The purpose of the AMC/GM annexed to this Decision is to reduce the administrative burden on applicants for the approval of a change. The guidance should allow these applicants to come easily to a decision with regard to:

- whether a design change impacts on OSD or not;
- the classification of changes to OSD as ‘minor’ or ‘major’ ones;
- the certification basis for the OSD change; and
- the use of their DOA for OSD changes.

2.3. Overview of the amendments

The main changes introduced by NPA 2015-12 and the comments received thereto are highlighted below:

Amendments to Part-21

The amendments to Part-21 (as explained in NPA 2015-12) are not part of said NPA but were already included in [NPA 2015-03](#) ‘Embodiment of Level of Involvement (LOI) requirements into Part-21’. They are repeated here to provide a comprehensive overview of all OSD related-amendments.

In 21.A.91, the word ‘data’ has been deleted to prevent a circular logic. Since OSD is part of the TC, stating that ‘a change to the TC would be minor if it has no appreciable effect on OSD’ would be similar to stating that ‘a change to the TC would be minor if it has no appreciable effect on the TC’.

The content of 21.B.70 has not been changed, but proposed to be moved to the new 21.B.107(c).

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

Use of the term ‘OSD constituent’: in this GM, and in several others, the term ‘element’ or ‘OSD element’ is replaced by the term ‘OSD constituent’. This was done to agree on a consistent terminology trying to avoid confusion over the term ‘element’ carrying its normal dictionary meaning (see also GM No 4 to 21.A.15(d)). The term ‘OSD constituent’ is now exclusively used to indicate one of the five regulatory parts of OSD:

- flight crew data (FCD);



- simulator data (SIMD);
- cabin crew data (CCD);
- maintenance certifying staff data (MCSD); and
- MMEL.

The term 'element' is still used with its normal dictionary meaning also for other parts of the OSD as captured under 21.A.15(d)(6) and explained in GM No 1 to 21.A.15(d)(6).

Furthermore, some minor improvements have been introduced in this GM.

The possibility for applicants for a small-aircraft TC to not develop an MMEL, but to rely instead on the concept of required equipment has been extended to cover all ELA1 and ELA2 aircraft.

A table has been added clarifying the applicability of the different OSD constituents in detail.

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

The term 'OSD element' has been replaced by 'OSD constituent'.

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

The term 'OSD element' has been replaced by 'OSD constituent'.

GM No 4 to 21.A.15(d) Scope of OSD

The term 'OSD element' has been replaced by 'OSD constituent'.

Additional explanation has been added regarding the possible content of OSD constituents.

The previous 21.A.15(b) has been deleted and replaced by the dedicated GM No 1 to 21.A.15(d)6 (see below).

GM No 1 to 21.A.15(d)6 Other type-related operational suitability elements

During the rulemaking activity leading to the introduction of OSD in Part-21, the Agency acknowledged that in addition to the five defined OSD constituents, there may be other data which could qualify as OSD when it is important for the operational suitability of the aircraft type not included in the type design and specific to that aircraft type. That was the reason for adding the related requirement in 21.A.15(d)6. However, at the time of the said rulemaking activity, no clear examples of the additional elements were provided. Practical cases will be handled by the Agency on an ad hoc basis; the proposal for additional OSD can be included in the application at the request of the applicant, and the Agency will decide if it meets the criteria that are now elaborated in the GM, and if it can be included in the approved OSD. The Agency will use these cases to establish more guidance for future applicants to be shared with stakeholders initially through frequently asked questions (FAQs) or a certification memorandum (CM).

GM to 21.A.21(f), 21.A.23(b) and 21.A.103(a)4 Approval of OSD

The term 'OSD element' has been replaced by 'OSD constituent'.

The GM has been improved to better explain the case where not all OSD constituents are ready at the time of issuing the TC. The ready OSD constituents will be approved under the TC, and the non-ready



ones can be added at a later stage. Until all applicable OSD constituents are included in the TC, the Agency may define limitations or restrictions in the type certificate data sheets (TCDSs) for the use of the aircraft. The already included and approved OSD constituents can be used by operators or training organisations.

The GM now also explains the case where certain OSD constituents can be agreed by the Agency for provisional use by operators or training organisations before they are formally approved under the TC. For example, this will allow an operator to train their pilots before the new aircraft type enters into service, with a high degree of certainty that this training will also comply with the final OSD.

It has been made clear that the possibility to have the OSD changes that are triggered by a design change ready after the approval of this design change is applicable to all major changes, so to all changes where one of the parts is 'major' and the other ones are 'minor'.

GM to 21.A.90A Scope

This GM explains the consequences of the amendments to Part-21, as introduced by Regulation (EU) No 69/2014, regarding the use of the term 'change to type certificate' instead of 'change to type design'. The new term clarifies that changes to all parts of a TC can and must be approved in accordance with Part-21, Subpart D or E.

A note has been added to explain that OSD is only applicable to aircraft TCs and not to engine or propeller TCs, which also applies to changes to these TCs.

GM to 21.A.91 Classification of changes to type certificate

This GM has been amended to include also the classification of changes to OSD into the overall classification of changes as 'minor' and 'major' ones.

The new GM 21.A.91(3.5) introduces specific guidance on the classification of changes to the OSD constituents. All OSD constituents have specific guidance except the constituent MCSD. The relevant GM has been reserved. This GM will be drafted under RMT.0106 (21.039(e)), which will also produce CS-MCSD. The Agency considers that it is impossible to establish criteria for the classification of changes to an OSD constituent for which the necessary certification specifications (CS) is not yet available. A Decision is planned to be issued under RMT.0106 (21.039(e)) by 2018.

The proposed classification criteria are different in nature from the criteria for classifying classic AW changes. This is due to the fact that the OSD CSs are more procedural by nature and do not contain technical standards.

It should also be noted that the criteria for the classification of changes as 'minor' and 'major' will mostly be used by DOA holders who will determine the exact approval route of these changes. Therefore, the criteria in the GM are general, and it is expected that the DOA holders will develop their own criteria, based on those provided in the GM.

The existing Appendix A to GM to 21.A.91: Examples of Major Changes per discipline as well as the flow chart remain unchanged.

Several small improvements to the text have been made, as well as several redundancies removed.

The classification criteria for stand-alone changes to CCD are further elaborated.



An explanation of the scope of the simulator data has been added.

GM No 1 to 21.A.93(c) Interaction of changes to the type design and changes to OSD

This new GM provides guidance on determining when a change to type design is expected to have an impact on OSD. When an impact on OSD is expected, the application for approval of the change needs to be complemented by the necessary change to the OSD. One important piece of guidance is that design changes that are classified as minor are considered not to have an impact on OSD. These changes can then be approved as before, without any further consideration of OSD. For major design changes, a table with examples has been included.

21.A.93(d) and (e) explain that in most cases, a design change cannot trigger the need to add an OSD constituent when this constituent was not part of the TC before the change.

The guidance is applicable to all OSD constituents except MMEL for which a dedicated GM has been proposed.

Further clarification has been provided of the case where design changes are made to aircraft for which no OSD or not all OSD constituents were established or grandfathered. Changes to such aircraft cannot trigger the need to add an OSD constituent.

GM No 2 to 21.A.93(c) Interaction of changes to the type design with changes to MMEL

The purpose of this GM is the same as that of the previous one, except that this one is dedicated to the OSD constituent MMEL. Due to the alleviative nature of MMEL, in many cases, there is no immediate need to change the MMEL when a design change is proposed for approval. If a new piece of equipment is introduced through a change to the design, the possible MMEL relief for that equipment can be treated as a stand-alone OSD change.

However, there can also be design changes that do have an impact on the MMEL, but necessitate an immediate change to the MMEL, which has to be considered as a change associated with the design change.

All this is explained in the GM with the support of a flow chart to further illustrate the concept.

Various improvements have been made for clarification, and the drafting logic of the criteria and examples has been made consistent with the graph.

GM No 1 to 21.A.101(g) Establishment of the OSD certification basis of changed type certificates

This GM provides guidance on establishing the OSD certification basis for changes to the TC.

The guidance is based on a few, simple principles and is aimed to allow easy and straightforward implementation of 21.A.101 to OSD changes. The result is that most OSD changes do not need to comply with the latest amendment of the related CSs. This is considered to be in line with the principles of 21.A.101 because of the different nature of the relevant CSs as compared to regular AW CSs: OSD CSs do not contain detailed technical standards, but instead they prescribe the methods for establishing the OSD. Therefore, the Agency expects that OSD CSs will not change very often, and the implementation of 21.A.101, whose aim is to apply the latest standard to changed products, is less relevant for CSs that contain detailed technical standards and change frequently (such as CS-25).

Various amendments have been made to the text for clarification.



GM No 1 to 21.A.103, 21.A.115 and 21.B.70 Approval of changes to type certificates

This new GM explains two aspects of the approval of changes to TCs.

It explains that the requirement for a separate classification and approval process is mainly applicable to stand-alone OSD changes.

It confirms that the various parts of one change to a TC ultimately have to be approved under one approval, but it also explains how a DOA holder can benefit from separating the classification of OSD changes from the classification of design changes. NPA 2015-12 contains two versions of the GM, acknowledging the ongoing RMT.0262 (MDM.060) that will introduce the LOI concept in Part-21. Based on the related NPA 2015-03, published on 2 March 2015, an Agency Opinion will be issued to be submitted to the European Commission in Q2/2016. It is expected that the Regulation will be amended in Q4/2016.

The first version of the GM, introduced by this Decision, is based on the current Part-21, explaining how the DOA holder can take credit of a separate classification process for OSD changes associated with a design change.

The second version of the GM is based on the text of Part-21 after incorporating the LOI concept. This version will be included in the AMC/GM package for LOI and will be published as soon as Part-21 has been amended.

The applicability of this GM has been extended to 21.A.115.

Several improvements in the text have been made for clarification, and the two graphs have been combined in one.

GM 21.A.112B Demonstration of capability for supplemental type-certificate cases

Several small amendments to this GM were also necessary to address the concept of changes to OSD.

AMCs to 21.A.263

- AMC No 1 to 21.A.263(c)(1) Procedure for the classification of changes to type certificate and repairs as 'minor' or 'major'
- AMC No 2 to 21.A.263(c)(1) Privileges — Organisations designing minor changes to a type certificate or minor repairs to products: classification procedure
- AMC No 1 to 21.A.263(c)(2) Procedure for the approval of minor changes to a type certificate or minor repairs
- AMC No 2 to 21.A.263(c)(2) Privileges — Organisations designing minor changes to a type certificate or minor repairs to products: procedure for the approval of minor changes to a type certificate or minor repairs

These AMCs have been amended to reflect the changes to Part-21 that were introduced with Regulation (EU) No 69/2014. Furthermore, the language has been adapted to the nature of the AMCs.



3. References

3.1. Related regulations

Commission Regulation (EU) No 748/2012 of 3 August 2012 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 (OJ L 224, 21.8.2012, p. 1)

3.2. Affected decisions

Decision N° 2012/020/R of the Executive Director of the Agency of 30th October 2012 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')

3.3. Reference documents

N/a

