



# Embodiment of level of involvement requirements into Part-21

RELATED NPA/CRD 2015-03 — RMT.0262 (MDM.060) — 23.5.2016

## EXECUTIVE SUMMARY

This Opinion addresses a systemic issue of introduction of safety management principles into the process of airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as changes and repairs thereto in accordance with Part-21 (Annex I to Regulation (EU) No 748/2012).

The Opinion is linked with the [European Plan for Aviation Safety \(EPAS\) 2016-2020](#) action RMT.0262.

The main specific objective is to further strengthen the Part-21 certification processes performance in general, and the verification part of these processes by the European Aviation Safety Agency (hereinafter referred to as 'the Agency') in particular, so that their safety and environmental goals are consistently met in an effective and efficient manner. This will be achieved by introducing into Part-21 the new rules accommodating a risk-based approach to compliance verification through embodiment of the concept of level of involvement (LoI) of the Agency in the certification process. The risk-based LoI concept is in line with the safety risk management standards of International Civil Aviation Organization (ICAO) Annex 19, and will enable the Agency to better identify the areas of product certification more prone than others to risk with regard to safety and environmental protection. This will allow the Agency to focus its certification resources primarily on these areas that need a direct and high LoI in order to thoroughly verify that compliance has been demonstrated by applicants. In other certification areas, where the risk to product safety or environmental protection is assessed lower, the Agency may, when justified by their adequate performance, rely on approved design organisations. Moreover, this proposal will further enhance the oversight system of design organisations to become 'performance-based'. Some design organisations may obtain new design organisation approval (DOA) privileges to certify certain major changes to type-certificates (TCs), supplemental type-certificates (STCs), and/or major repair designs without the Agency's involvement, but only in technical domains where they demonstrate to the Agency their satisfactory experience and performance in compliance assurance.

The present opinion is the first step towards transposing the ICAO Annex 19 'Safety Management' standards into Part-21. A further proposal to amend Part-21 in accordance with the ICAO safety management system (SMS) standards for design and production organisations, State Safety Programme (SSP) standards, and critical elements of a safety oversight system for the competent authorities (CAs), including the Agency, is being established by the Agency in a separate rulemaking task (RMT).

Applicability		Process map	
Affected regulations and decisions:	— Annex I to Regulation (EU) No 748/2012 (Part-21) — ED Decision 2012/020/R	Terms of reference (ToR), Issue 1:	27.8.2013
Affected stakeholders:	Applicants for and holders of any certificate issued in accordance with Part-21; national aviation authorities (NAAs) contracted by the Agency to perform certain certification tasks on its behalf.	Concept paper (CP):	Yes
Driver/origin:	Safety, efficiency/proportionality, level playing field	Rulemaking group (RMG):	No
Reference:	Please refer to Section 3.3	Regulatory impact assessment (RIA) type:	Full
		Technical consultation during notice of proposed amendment (NPA) drafting:	Yes
		NPA publication date:	2.3.2015
		NPA consultation duration:	3 months
		Review group (RG):	No
		Focused consultation:	Yes
		Decision expected publication date:	2017/Q2



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## 1. Procedural information

### 1.1. The rule development procedure

The Agency developed this Opinion in line with Regulation (EC) No 216/2008<sup>1</sup> (hereinafter referred to as the 'Basic Regulation') and the Rulemaking Procedure<sup>2</sup>.

This rulemaking activity is included in the Agency's [5-year Rulemaking Programme](#) under RMT.0262 (MDM.060). The scope and timescales of the task were defined in the related [ToR](#).

The *draft* text of this Opinion has been developed by the Agency based on the input of the LoI Steering Group (SG) with representatives of design and manufacturing industry. In addition, all interested parties were publicly consulted through [NPA 2015-03](#)<sup>3</sup>. 347 comments by 38 commentators were received during the NPA public consultation, including industry and NAAs. The NPA 2015-03 proposal is the outcome of LoI Project Phase I, focused on the development of amendments to the Part-21 implementing rules (IRs).

The Agency has addressed and responded to the comments received on NPA 2015-03. The comments received and the Agency's responses thereto are presented in CRD 2015-03<sup>4</sup>.

The *final* text of this Opinion and the draft regulation have been developed by the Agency considering the inputs from the LoI SG.

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

### 1.2. The structure of this Opinion and related documents

Chapter 1 of this Opinion contains the procedural information related to this task. Chapter 2 'Explanatory note' explains the core technical content. Chapter 3 points to the relevant reference material. The draft rule text proposed by the Agency (draft Commission Regulation amending Commission Regulation (EU) No 748/2012<sup>5</sup>) is annexed to this Opinion and published on the Agency's website<sup>6</sup>.

### 1.3. The next steps in the procedure

This Opinion contains proposed amendments to Regulation (EU) No 748/2012. It is submitted to the European Commission to be used as a technical basis to prepare a legislative proposal.

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<sup>1</sup> 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)

<sup>2</sup> The Agency is bound to follow a structured rulemaking process as required by Article 52(1) of the Basic Regulation. Such a process has been adopted by the Agency's Management Board (MB) and is referred to as the 'Rulemaking Procedure'. See [MB Decision No 18-2015](#) of 15 December 2015 replacing Decision 01/2012 concerning the procedure to be applied by the Agency for the issuing of opinions, certification specifications and guidance material.

<sup>3</sup> In accordance with Article 52 of the Basic Regulation and Articles 6(3) and 7 of the Rulemaking Procedure.

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

<sup>5</sup> 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)

<sup>6</sup> <https://www.easa.europa.eu/document-library/opinions>



NPA 2015-03 contained a few draft acceptable means of compliance (AMC) and guidance material (GM) to support correct interpretation of the new Lol rules. The ED Decision to which these AMC/GM will be annexed will be published by the Agency when the related regulation is adopted by the European Commission. In addition, more detailed AMC/GM will be developed during Phase II of this rulemaking activity, including an NPA to be consulted upon, and a related comment-response document (CRD), leading to an ED Decision. This decision is planned to be issued towards the end of 2017.



## 2. Explanatory note

### 2.1. Issues to be addressed

The proposed amendments to Part-21 address issues that can be grouped under the following topics:

- (a) risks related to the non-exhaustiveness of the compliance verification process;
- (b) inconsistencies related to the type-certification basis;
- (c) inconsistencies related to the structure of Part-21 IRs; and
- (d) other existing inconsistencies and errors in Part-21.

#### 2.1.1 Risks related to the non-exhaustiveness of the compliance verification process

##### *Background*

- (a) The Part-21 procedures for certification of products, parts and appliances have proven to ensure a high level of product safety and environmental protection in aircraft operations. This is achieved by following the robust certification processes prescribed by Part-21, which ensures that each aeronautical product (i.e. an aircraft, engine, or propeller), part or appliance complies with the applicable airworthiness and operational suitability data (OSD) certification specifications (CSs) and environmental protection (EP) requirements designated by the Agency for the certification basis, as complemented, if applicable, by other items (*special conditions (SCs)*, *equivalent safety findings (ESFs)* and *deviations* (see below)). The Part-21 certification process is a joint exercise of the applicant's certification team and the Agency's certification team. While the applicant's team role is to exhaustively demonstrate compliance with each item of the certification basis, the Agency's team role is to establish the certification basis and to verify that compliance therewith has been demonstrated.
- (b) It is implicit in today's certification practice in the EU as well as worldwide that the authority's verification of compliance demonstration is not exhaustive. The authority varies its verification exercises by applying different methods, which can be risk-based, a random sampling or similar.
- (c) The European product certification system is supported by the concept of approved design organisations. Those organisations are approved in accordance with Part-21, Subpart J, as a standard means to both demonstrate their capability to design a product, part or appliance in compliance with all the items of the applicable (TC, OSD, EP) certification basis, and demonstrate and verify (only for holders of a design organisation approval (DOA)) their compliance. The DOA system already recognises the non-exhaustiveness of verification by granting a privilege to DOA holders to have their compliance documents not selected by the Agency for review (21.A.257(b) automatically accepted without further verification (21.A.263(b))).
- (d) Furthermore, it is the current practice that the Agency's certification staff selects which applicant's compliance demonstrations (including those applicants that have demonstrated their capability by means alternative to the DOA of Subpart J) will be verified and in which other cases the design organisation will be credited for to ensure compliance without the Agency's involvement. In other words, the Agency already today determines its Lol in each certification project.



- (e) With no relevant requirements in Part-21, the determinations and recording of the certification team's Lol in each certification project were recently introduced in a very basic form into the Agency's internal certification working procedures.

#### Issues

- (a) *Criteria for Lol determinations:* Part-21 does not specify any criteria for a selection by the Agency of the DOA compliance documents to be reviewed. There is also no explicit mention in Part-21 of safety and environmental risks as a factor linked with these selections.
- (b) *Means for Lol determinations:* even if the Agency's certification staff already uses today safety and environmental risks as a main criterion in their decisions on what to verify and what not, they are not supported in these decisions either by Part-21 or by the related AMC and GM to Part-21. These requirements do not contain any risk assessment apparatus, risk models, assessment methods or methodologies.
- (c) *Consistency of the Lol determinations:* without joint assessment criteria and joint assessment methodologies, consistency of the Lol decisions both within a certification project and across all certification projects of the Agency cannot be ensured. Moreover, these criteria and the Lol determinations should be derived from a structured internal decision-making process resulting into consolidated decisions in each particular certification domain or discipline, involving, besides the certification experts in charge of the verification, a wider circle of the certification staff, including project certification managers (PCMs), chief experts or, if necessary, the applicable panels of experts and other relevant management staff. Otherwise, there is a risk that the Agency's Lol decisions are subjective and inconsistent.
- (d) *Transparency of the Lol determinations:* while today the Agency determines its Lol on the basis of internal working procedures, it does so without any explicitly specified criteria. The determination process then lacks transparency towards the applicants and also internally. The criteria for the Lol determinations, including those specific for each domain or discipline, should be publicly available, either in the IRs or in the related AMC/GM. The Agency's Lol determinations should be recorded and notified to the applicants. This will provide the applicants with a better insight into the upcoming certification process and help them understand the reasoning of the Agency's Lol determinations.
- (e) *Transposition of ICAO Annex 19 SMS standards:* Part-21 needs to be amended in order to include, among other elements of the SSP framework, standards for hazard identification and safety risk assessment and mitigation. Hazard identification shall be based on a combination of reactive, proactive and predictive methods of safety data collection. The primary focus of any oversight activity shall be on areas of greater concern to safety. For the product certification process, namely its verification parts by the Agency, this means that the Agency needs to proactively focus its verification activity on areas of compliance demonstration with greater risk to safety and environmental protection based on the results of a risk assessment.

#### 2.1.2 Inconsistencies related to the type-certification basis

- (a) *ESFs:* Article 20(1)(a) of the Basic Regulation specifies that 'the provisions for which an equivalent level of safety has been accepted' are elements of the type-certification basis. However, these elements are not listed under the current 21.A.17A 'Type-certification basis'.



They are only addressed in 21.A.21(c)(2), as if they were only taken into account right before the issuance of the TC, which is not the case. 21.A.17A is also inconsistent with Article 20(1)(a) of the Basic Regulation specifying the content of the type-certification basis.

- (b) *Deviations*: in the MB's 'Products Certification Procedures' ([EASA MB Decision 12-2007](#)), which is the basis for the Agency's internal certification working instructions, the term 'deviations' is used. In the context of said Decision, it appears that 'deviations' are additional elements of the type-certification basis but distinct from the ESFs and special conditions (SCs) of Article 3.2(b) of the Decision. They are used in certification practice for the type-certification basis when some part of the design cannot comply with the applicable CS(s); at the same time, such a deviation does not qualify for an equivalent safety finding where a CS is the reference for safety. However, in order for a product to be eligible for a standard TC, any deviation can only qualify for the type-certification basis when it will ensure conformity with the essential requirements of Annex I to the Basic Regulation (see Article 20(1)(a)). Otherwise, the aircraft would only be eligible for a restricted type certificate (RTC) and/or restricted certificate of airworthiness (CofA). These limiting conditions for the use of deviations from the applicable CS(s) are not explicitly stated in the current 21.A.17A, which makes its scope wider than actually set out in the Basic Regulation.
- (c) *Notification of the type-certification basis*: another inconsistency of Part-21 with the Basic Regulation is that Part-21 does not explicitly require the Agency to notify applicants of the applicable certification basis for the certification of products and changes/repairs thereto as it is required by the Basic Regulation (see Article 5(5)).

### 2.1.3 Inconsistencies related to the structure of Part-21

Part-21 consists of Section A and Section B. Section A should contain requirements governing the rights and obligations of the applicants for, and holders of, Part-21 certificates and approvals. Requirements applicable to competent authorities, including the Agency, should be included in Section B. However, some parts of Part-21, Section A currently contain a mix of requirements applicable to applicants for and holders of certificates and approvals, and requirements applicable to the Agency.

## 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 these overall objectives. The specific objectives of this proposal are, therefore, to:

- (a) improve *performance* of the Part-21 processes for certification of and oversight over aircraft and related products, parts and appliances, and of organisations involved in their design, by:
- (1) improving effectiveness and efficiency of the verification process by explicitly recognising the *risk-based approach* to compliance verification by the Agency based on safety and environmental risk assessments with clear criteria;
  - (2) explicitly recognising the *performance and experience* of design organisations, in particular their capability to design a product, part or appliance in compliance with the applicable technical requirements and specifications, as well as their capability to credibly and reliably ensure compliance therewith;



- (3) strengthening and making better use of the *approved design organisations* as the supportive pillar of the EU product certification system by giving those organisations credit for *compliance assurance* in those areas where the risk, i.e. the likelihood of non-compliance with the certification basis in combination with the severity of its consequences on product safety or environmental protection, is acceptable;
  - (4) further strengthening and making better use of the *approved design organisation* pillar of the EU product certification system by granting the approved design organisation new *privileges* to certify certain major changes to TCs, issue certain STCs and/or approve certain major repair designs, when the performance of the design organisation proven in previous similar certification projects is found satisfactory and when the risk of non-compliance with the certification basis in combination with the severity of its consequences is acceptable;
  - (5) effectively and efficiently deploying the Agency's certification resources on most safety- and environmental-protection-relevant tasks, based on a risk assessment;
  - (6) improving the internal exchange of information and cooperation between the Agency's certification teams and DOA oversight teams, for instance with extended participation of experts and PCMs in DOA audits on one side, and involvement of the DOA team leaders in certification projects on the other side;
  - (7) improving the system of collection, analysis and exchange of safety data and other information, both internally among the relevant certification staff of the Agency, including the accredited NAAs contracted to conduct certain certifications on behalf of the Agency, and externally via swift exchange of safety-relevant data with the stakeholders, using modern information technology (IT) platforms; and
  - (8) improving the transparency of the process by sharing the relevant information and improving mutual trust between the Agency and the stakeholders.
- (b) comply with the safety oversight standards of the ICAO Annex 19 SSP framework that are relevant to product certification, namely the risk-based approach to compliance verification with an identification of hazards and a related safety risk assessment and mitigation;
  - (c) align Part-21 with the Basic Regulation as regards the type-certification basis and the notification of the type certification basis to the applicant;
  - (d) align the Part-21 structure by transferring those requirements applicable to the competent authorities, including the Agency, to Part-21, Section B; and
  - (e) improve consistency in and streamline the text of various Part-21 requirements affected by the proposal (Subparts A, F, G, H, I, K, and Q, and to a large extent also Subpart J, are not affected).

### 2.3. Outcome of the consultation

347 comments by 38 commenters were received during the NPA 2015-03 consultation.

#### *Commentators*

6 EU NAAs and the Federal Aviation Authority (FAA) responded. The feedback from industry stakeholders represents opinions of design and production associations, big-sized companies designing



large aircraft and related engines, as well as small-and-medium-sized enterprises (SMEs) involved in the lower range of the General Aviation (GA) sector — designers and manufacturers of smaller products, including sailplanes, design organisations focused on modifications to products, as well as designers and producers of European technical standard orders (ETSOs) articles.

#### *Summary of comments and responses thereto*

The comments were mainly positive with regard to the Lol concept as well as to the content of the other proposed amendments, with constructive suggestions for further improvement of the proposals. For more details, see Chapter 2 of CRD 2015-03.

## **2.4. Summary of the RIA**

The RIA from NPA 2015-03 has been updated by taking into account the comments received.

### **2.4.1 List of options**

The RIA assesses the 2 following options:

- Option 0 ‘Do nothing’ is the baseline scenario where there would be no change to the current rules; and
- Option 1 ‘Transparent Lol’ represents a risk-based approach embedded in the draft rules proposed in this Opinion.

Option 1 is mainly described in Sections 2.5.1 — Lol and 2.5.2 — New DOA privileges below.

### **2.4.2 Safety impacts**

#### Option 0

Today, the Agency already determines its Lol under the current certification system — although without any given criteria and without a set of transparent procedures — which has been proven to provide a high level of aviation safety in Europe.

#### Option 1

A risk-based approach to compliance verification has a potential to further reduce the certification process risks. If this concept is properly implemented, the Agency will focus its compliance verification activities on those parts of the certification projects for which there is a greater risk that non-compliance with a part of the certification basis has a severe impact on product safety (or on safety associated with the environment). Consequently, it may be expected that the implementation of the Lol concept would help further reduce occurrences of unsafe conditions embedded in certified designs and/or lower their severity, thus improving the level of product safety in general.

### **2.4.3 Social impacts**

N/a

### **2.4.4 Economic impacts**

There are two types of impacts assessed in this Section. The first one is on the general implementation of the Lol concept: this is qualitatively assessed. A second type of impact is then further assessed in a



quantified way based on a specific consequence of the Lol implementation: the potential reduction in the number of 'major changes to a TC' and applications for 'a STC issuance' submitted to the Agency.

#### 2.4.4.1 General implementation aspects of the Lol concept

- Option 0: no impacts.
- Option 1:

In a general manner, the proposed approach is expected to remain neutral on the overall workload of the Agency. The Agency will focus its available resources on the part of the certification projects for which there is a greater risk to product safety due to potential non-compliance with the certification basis. The Agency will also focus more on the oversight over the organisations where there is no or limited involvement of the Agency in compliance verification, and where the Agency has granted additional privileges to such organisations.

The proposed approach is expected to improve the effectiveness, efficiency, transparency and predictability of the certification process, allowing for better planning with fewer delays and better allocation of both the Agency's and the applicant's certification staff resources. However, this assessment cannot be quantified at this stage.

#### 2.4.4.2 Reduction in the number of 'major changes' and 'STC approval' applications

Option 1 may lay the basis for DOAs to be granted additional privileges. The Lol concept introduces a possibility to grant, under strictly specified conditions, new privileges to DOA holders to certify certain major changes to TC and STCs, and major repair designs of the scope established by the Agency. This will reduce the need to pay the related certification fees.

The Agency has estimated the potential impacts of the reduction in the applications' numbers, based on the applications received over the period 2013–2015, as regards Table 3 'Supplemental Type Certificates' and Table 4 'Major changes and major repairs' of Regulation (EU) No 319/2014<sup>7</sup>. The following Table A shows the results per general category of product:

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<sup>7</sup> Commission Regulation (EU) No 319/2014 of 27 March 2014 on the fees and charges levied by the European Aviation Safety Agency, and repealing Regulation (EC) No 593/2007 (OJ L 93, 28.3.2014, p. 58).



Product	Simple applications		Standard applications		Complex applications		Average annual total costs (EUR)	Average annual cost savings (EUR)	
	Average number of applications per year (2013–2015)	Percentage of applications which could be subject to the new privilege	Average number of applications per year (2013–2015)	Percentage of applications which could be subject to the new privilege	Average number of applications per year (2013–2015)	Percentage of applications which could be subject to the new privilege		Low range	High range
<b>EASA Major Change/Major Repair Approval</b>							<b>4 482 223</b>	<b>639 968</b>	<b>1 289 933</b>
<b>Large</b>									
<b>Aeroplane</b>	<b>166.0</b>	<b>30–50 %</b>	<b>275.7</b>	<b>15–30 %</b>	<b>8.7</b>	<b>up to 15 %</b>			
<b>General</b>									
<b>Aviation</b>	<b>68.3</b>	<b>20–40 %</b>	<b>63.0</b>	<b>10–20 %</b>	<b>5.0</b>	<b>up to 10 %</b>			
<b>Rotorcraft</b>	<b>113.7</b>	<b>20–40 %</b>	<b>145.7</b>	<b>10–20 %</b>	<b>3.7</b>	<b>up to 10 %</b>			
<b>Propulsion</b>	<b>136.0</b>	<b>20–40 %</b>	<b>84.3</b>	<b>10–20 %</b>	<b>0.7</b>	<b>up to 10 %</b>			
<b>EASA STC Approval</b>							<b>2 374 257</b>	<b>255 527</b>	<b>523 493</b>
<b>Large</b>									
<b>Aeroplane</b>	<b>69.3</b>	<b>20–40 %</b>	<b>158.3</b>	<b>10–20 %</b>	<b>2.3</b>	<b>up to 10 %</b>			
<b>General</b>									
<b>Aviation</b>	<b>40.0</b>	<b>20–40 %</b>	<b>40.3</b>	<b>10–20 %</b>	<b>1.0</b>	<b>up to 10 %</b>			
<b>Rotorcraft</b>	<b>23.0</b>	<b>20–40 %</b>	<b>42.7</b>	<b>10–20 %</b>	<b>1.0</b>	<b>up to 10 %</b>			
<b>Propulsion</b>	<b>0.7</b>	<b>20–40 %</b>	<b>2.0</b>	<b>10–20 %</b>	<b>0.0</b>	<b>up to 10 %</b>			
<b>Overall total</b>							<b>6 856 480</b>	<b>895 495</b>	<b>1 813 426</b>
<b>Relative impacts</b>								<b>13 %</b>	<b>26 %</b>



### *Impact on stakeholders*

For DOA holders granted additional privileges, the cost savings in reduced fees due to a lower number of applications are estimated to be EUR 900 000–1 900 000 per year after a transition period, representing a decrease between 13 % and 26 % of the costs paid by the DOA holder. However, the stakeholders would also need to invest in resources which allow them to exercise the new privileges (e.g. slight increase in the oversight over the DOA holder). This is difficult to quantify.

In addition, the proposed approach, and in particular the possibility to receive additional privileges, is valued very high in qualitative terms from the applicant's point of view. It is a matter of removing uncertainty from the planning of the certification process, where currently some applications may be delayed due to additional checks performed by the Agency.

### *Impact on the Agency*

The economic impact on the Agency through the reduced fees due to a lower number of applications is estimated to be EUR 900 000–1 900 000 million per year after a transition period, i.e. in the range of 1 % to 2 % of the Agency's 'Fees & Charges' budget (EUR 100 million).

#### **2.4.4.3 Overall economic impact**

The assessment of Option 1 shows that there is a slight positive economic impact on industry.

#### **2.4.5 GA and proportionality issues**

There is no specific impact on GA.

As regards Option 0, no impacts in general are expected.

The stakeholders who will benefit the most from Option 1 are the DOA holders, as the proposal provides for the possibility to obtain more privileges.

#### **2.4.6 Impact on 'Better Regulation' and harmonisation**

- Option 0: the Agency has not yet fully complied with ICAO Annex 19.
- Option 1: the proposal transposes into Part-21 some standards from ICAO Annex 19, by providing a risk-based approach to compliance verification. Furthermore, it contributes to 'Better Regulation' by clarifying the rights and obligations of industry and CAs, as well as by removing inconsistencies from the existing rules.

#### **2.4.7 Conclusion**

Option 1 is the preferred one. This documented risk-based approach will improve the effectiveness, efficiency, transparency and predictability of the certification process, allowing for better planning of the certification process with fewer delays and better allocation of both the Agency's and the applicant's certification staff resources. In addition, it already transposes standards to ensure compliance with ICAO Annex 19.



## 2.5. Overview of the proposed amendments to Part-21

Amendments are proposed to Section A, Subparts B, D, E, J, M and O, and Section B, Subparts B, D, E, M, and O as follows.

### 2.5.1 Lol

**21.B.100 Level of involvement** contains the core requirements for the risk-based compliance verification in a certification project. The underlying Lol principle is that the Agency's determination of its Lol in a certification project results from assessment of the proposed compliance demonstration items in respect of the likelihood of an unidentified non-compliance with the certification basis and the potential impact of this non-compliance on product safety or environmental protection, using the criteria of 21.B.100(a)(1)–(4).

The Lol concept under the new 21.B.100 requirement is generally applicable to all Part-21 processes for issuing by the Agency of certificates for products, parts and appliances, as well as for changes and repairs thereto. It covers certification projects for a TC, RTC, (major and minor) changes to a TC (or STC), STCs, (major and minor) repair designs and the European technical standard order authorisations (ETSO(As)) (see 21.B.103(a)(2), 21.B.107(a)(3), 21.B.110(a)(2), 21.B.115(a)(3) and (b), and 21.B.117(b)). Apart from the airworthiness considerations, the Lol concept is applicable to the OSD and environmental protection certification processes. Lol applies to applicants holding or applying for a DOA, as well as to applicants demonstrating or having demonstrated their capability by derogation from the DOA requirement, either by approved alternative procedures to DOA (AP DOA) or by providing an acceptable certification programme only.

#### 21.B.100(a)

In certification projects for a TC or RTC, a major change to a TC (or to an STC), and for an STC, the Agency's Lol will be determined per *compliance demonstration item* (CDI). The proposal does not contain any definition of a CDI, but for the purpose of this Chapter, they are to be understood as stand-alone meaningful groupings of compliance demonstration activities, taken out from the certification programme for compliance demonstration, that can be considered in isolation from the others. The size of a CDI may differ depending on the size of the certification project and the technical discipline(s) involved. Detailed guidance will be established by the Agency in Phase II of the Lol project on the basis of the proposals which have been already consulted through NPA 2015-03 (see GM1 and GM2 to 21.B.100(a)).

Applicants will propose to the Agency appropriate CDIs together with the proposed Agency's involvement in their compliance verification. The Agency will then establish its Lol at the level of CDIs, including the *depth of the investigation*, i.e. the level of detail of the verification activities for that CDI (e.g. reviewing a compliance document, carrying out an inspection, witnessing a test etc.). The Agency takes into account the *risk* that the design organisation may unknowingly fail to ensure compliance with an item of the certification basis (i.e. non-compliance may not be identified by the design organisation). This process risk will be considered together with the severity of potential consequences of such non-compliance on product safety or environmental protection. The combination of both will drive the Agency's Lol determinations for each CDI.

The likelihood of non-compliance with the certification basis is to be assessed as a combination of the *novelty* and *complexity* of the design and/or compliance demonstration per CDI, and the predicted



*performance of the design organisation* in their task to ensure and demonstrate compliance of that CDI, i.e. to identify and eliminate any potential non-compliance. In this context, safety and environmental risks identified in products, parts or appliances of similar design, if any, should be taken into account. These risks to product safety may occur in similar designs in service, under production or under certification, or in a parallel certification project of the Agency or other certification authorities. They may indicate an increased likelihood of non-compliance or point to one or more imperfect items of the certification basis that were not identified in the course of the corresponding certification process for that similar design.

The impact of non-compliance on product safety or environmental protection varies with the severity of consequences that each, potentially non-complying, item of the certification basis mitigates. Such a risk severity differs per item and also per discipline.

Therefore, 21.B.100 was drafted to allow the Agency to take into account other criteria. The requirement has been intentionally left open for use of supplementary, e.g. discipline-specific, criteria to tailor the risk assessments to each technical domain or discipline of the certification project (e.g. the CS.X.1309 approach fits equipment and systems, but other similar approaches will need to be developed for other domains. The requirement has been left open also for the use of other supplementary criteria as a recognition of the differences that exist between the various sectors of civil aviation and the different risks involved, in particular the lower risk linked with operations of simple products used in light and sport aviation.

**21.B.100(b)** provides requirements for a proportionate approach to Lol determinations in smaller certification projects for minor changes to a TC, minor repair designs and ETSO(A)s. While the main principles of 21.B.100(a) and its assessment criteria equally apply, some of its elements do not fit the specific nature of these, relatively simpler certification processes. For example, the certification programme and/or its breakdown into CDIs, as requested for TC projects, major changes to a TC and STCs, is not required here and the Agency's Lol may be determined at the level of the whole certification project.

**21.B.100(c)** requires the Agency *to notify* the applicant of its initial Lol determination and allows the Agency to update this initial Lol when justified by receipt of information that has an appreciable impact on the risk assessment on which the previous Lol determination was based.

**21.A.15 Application** has been amended to require applicants for a TC or RTC to submit, either with their initial application or afterwards as its supplement, a *certification programme* for compliance demonstrations. The current 21.A.20(b) already requires applicants to provide a certification programme for compliance demonstrations, however, with the introduction of the Lol concept, the importance of the certification programme is becoming even higher because the certification programme will be the basis on which the Agency's Lol will be determined. Therefore, the Agency must review and *accept* the certification programme proposed by the applicant (see 21.A.20(a)) before it can make any Lol determination. The acceptability of the certification programme will mainly depend on the composition of the CDIs and on the level of insight into the means that the applicant is going to use for compliance demonstration.

The risk assessment required under 21.A.15(b)(6) is the same as the one required from the Agency under 21.B.100(a). It is just for the purpose of the Lol determination and should not be mistaken for a CS.X.1309 safety assessment.



**21.A.20 Compliance with the type-certification basis, operational suitability data certification basis and environmental protection requirements** has been amended, also with respect to the introduction of the Lol concept, in order to:

- (a) Indicate that the certification programme to be followed in the compliance demonstration phase is the one *accepted* by the Agency (see 21.A.20(a)).
- (b) Indicate that the applicable TC and OSD certification basis and EP requirements will be those *established and notified* to them *by the Agency* (see 21.A.20(a)). The applicants, however, shall submit their proposal in accordance with 21.A.15(b)(4).
- (c) Report to the Agency any difficulty or event encountered during compliance demonstration that may have an appreciable impact on the applicant's own risk assessment required under 21.A.15(b)(6) or on the certification programme (e.g. changed means of compliance (MoC)) or that could otherwise trigger a change to the previously notified Agency's Lol (e.g. a failed certification test not witnessed by the Agency) in order to allow the Agency to update its Lol accordingly (see 21.A.20(b)).
- (d) Refer to 21.A.33 and 21.A.35 to keep requirements of these points applicable not only to the applicants for a TC or RTC but also (by cross references) to the applicants for major changes to a TC or STCs as well as those DOA holders self-certifying these changes under their privileges.
- (e) Require those who have demonstrated compliance under 21.A.20 to declare in addition that *no feature or characteristic has been identified that would make the product unsafe for the uses for which certification is requested* (see 21.A.20(d)(2)). This is a new requirement for the stakeholders (for the Agency, it already exists in 21.A.21(c)(3), 21.A.103(a)(2)(iii) and 21.A.115(b)(3) applied to all Part-21 certification processes and is intended to ensure that the stakeholders who have demonstrated compliance with the certification basis, as well as the Agency during its investigations, have not identified, on top of compliance with the certification basis, any other risk to safety or environmental protection not captured in the certification basis. Reported safety occurrences (design-related) prove that such risks occasionally exist although every effort is made to capture during certification all the risks in the certification basis. In accordance with the ICAO Annex 19 standards, all parties involved shall be made responsible for identification of all the risks that relate to their activities.

Note that the amended 21.A.20 contains all the compliance demonstration requirements for TCs, RTCs, major changes and STCs, including major changes to STCs.

Note also that 21.A.20 is, by cross reference to Subparts D (21.A.97(b)(3)) and E (21.A.115(b)(4)), applicable also to certification of major changes to TCs and STCs both by the Agency and the DOA holders (self-)certifying these changes under their new DOA privileges (see below).

## 2.5.2 New DOA privileges

### *Principles*

The proposal introduces a possibility for DOA holders to obtain from the Agency, under strictly specified conditions, new privileges to certify certain major changes to a TC (or to an STC), issue STCs, and approve major repair designs within the scope established by the Agency.



These new DOA privileges follow the main principles of the Lol concept. The hazard is that a design organisation does not ensure compliance of a major change, STC or a major repair design, i.e. when the changed product after embodiment of these design changes is not compliant with its certification basis, this is not identified by the DOA holder, and the Agency is not aware because of not being involved. The resulting risk to product safety or environmental protection in the above scenario is also calculated the same way as under 21.A.15/21.B.100.

Therefore, before granting a privilege, a risk assessment needs to be made using the basic assessment criteria below:

- *novelty* of the change/repair design;
- *complexity* of the change/repair design;
- *criticality* of the change/repair design; and
- *performance and experience of the design organisations* in the given technical domain or discipline relevant to the requested privilege.

The assessment criteria for granting a new DOA privilege, which in this case means reducing the Agency's Lol to zero, remain the same — the risk assessments must conclude that the risk that the new privilege holder will not ensure compliance is mitigated by their proven satisfactory performance and experience as well as the limited severity of the consequences of non-compliance.

The new privileges are not to be granted automatically. The interested DOA holder will need to apply for each new privilege to include it into their terms of approval (see the introductory sentence in 21.A.263(c) as amended: *...within the scope of its terms of approval as established by the Agency...*). They will only be granted the new privilege when their *performance and experience* in the given technical domain or discipline relevant to the requested privilege will be found adequate.

*Part-21 points directly related to the new DOA privileges*

**21A.263(c)(5)** has been amended to extend the scope of this privilege to permit other interested DOA holders, not being the TC/STC/APU ETSO(A) holders but meeting the conditions for obtaining the privilege, to approve *certain* major repair designs within the scope as established by the Agency.

**21A.263(c)(8)** has been added as a new privilege in Part-21 to allow DOA holders, meeting the conditions for obtaining the privilege, to approve *certain* major changes to a TC within the scope as established by the Agency.

**21A.263(c)(9)** has been added as a new privilege in Part-21 to allow DOA holders, meeting the conditions for obtaining the privilege, to issue *certain* STCs and approve major changes to those STCs within the scope as established by the Agency.

Comprehensive guidance material will be developed in Phase II of the Lol project to explain in detail what 'certain' means, what is the intended scope of the new privileges as well as their conditions and limitations.



### 2.5.3 Alignment with the Basic Regulation as regards the type-certification basis

#### *ESFs*

**21.A.17A Type-certification basis** defining the content of the type-certification basis, has been moved to Section B as **21.B.80**, its structure has been revisited and it has been complemented to accept as an option for the type-certification basis any alternative proposed by the applicant to a CS, originally designated for the type-certification basis by the Agency, on condition that this alternative provides a safety level equivalent to that of the designated CS (see new 21.B.80(a)(2)).

#### *Deviations*

**21.A.17A Type-certification basis**, moved to Section B as **21.B.80**, has been further complemented by provisions in 21.B.80(a)(3) to allow the Agency to use other means (alternatives to the Agency's CSs issued in accordance with Article 19 of the Basic Regulation) to ensure a level of safety:

- when a TC is requested, as defined in the essential requirements of Annex I to the Basic Regulation; or
- when a restricted TC is requested, adequate with regard to the intended use.

(see also Section 2.1.2 above).

#### *Notification of the type-certification basis*

**21.B.80, 21.B.82, 21.B.85, 21.B.105, 21.B.109** and **21.B.113**, that have been newly created in Section B (as a consequence of the decision to move there the requirements applicable to the Agency), now require to notify the applicants for individual certificates and approvals of the established type-certification basis and, where applicable, OSD certification basis and designated EP requirements except that the applicants for repair design approvals are only notified of any amendments to the existing certification basis incorporated by reference in the TC, which otherwise remains applicable to the certification of repair designs.

### 2.5.4 Other significant changes

#### *Conformity inspections and access to data, tests and inspections*

##### **21.A.33 Inspections and tests**

Among the variety of the kinds of involvement, the Agency may be involved in compliance verification by witnessing or carrying out tests or inspections conducted for the purpose of compliance demonstration. 21.A.33(a) has been however deleted because tests and inspections are not to be required; it is up to the applicant to propose them as a means of compliance with the applicable certification basis and as such they might be accepted by the Agency.

21.A.33(e) currently requires the applicants to issue a *statement of compliance* with the requirements of 21.A.33(b). Practice shows that this wording may lead to a confusion. What is at stake is conformity of the test specimen together with conformity of the test and measuring equipment. Since the current 21.A.33 will be followed also by those DOAs self-certifying certain major changes to a TC and/or STCs under their new DOA privileges, it is considered necessary to amend 21.A.33 to require consistently all those who will follow 21.A.33 to issue a *statement of conformity* (see amended 21.A.33(c)). The



*statement of conformity* must include any potential nonconformity, together with a justification that this nonconformity may remain since it does not affect the test results.

21.A.33(d)(1) has been amended to extend the scope of access to data to all kinds of *data and information* related to compliance demonstration (instead of the currently required *reports*). *Data* is generally defined as not interpreted information and includes computer-stored data, whereas *information* as interpreted data, includes reports, calculations, safety analyses etc. The applicant must make this data available to the Agency on request, irrespective of whether the data is within an area selected for the Agency's Lol or not (note that there is no link between 21.A.33 and 21.B.100 in Section B). The request may be made by the Agency for various reasons, e.g. the Agency may obtain information that affects the previously made risk assessment on the basis of which the Agency's Lol was previously determined. Having received new information, the Agency may need to access more data and information in order to update its Lol. Data and information may be required by the Agency also for knowledge management reasons.

21.A.33(d)(2) has also been amended to clarify the time frame within which the Agency can request access to tests and inspections. The time frame must certainly include the time period before the final declaration of compliance in accordance with 21.A.20(d) is made (contrary to the potentially misleading current wording).

#### *Information requested with an application for a change*

**21.A.93 Application** has been amended to require submission, either with the application or later as a supplement thereto, of a certification programme for compliance demonstration. The programme requires to provide data (descriptions and identifications) on the change(s) (both for major and minor) approximately to the same extent as under the current 21.A.93.

However, for certification of major changes to a TC (and by cross reference to Subpart E, also for certification of an STC), the proposed 21.A.93 requires in addition (see in particular 21.A.93(b)(3)) similar information as required for a TC in a certification programme (see 21.A.15(b)(4)–(7)). This information is necessary for the Agency as a basis to determine its Lol in a certification project for a major change which can be of a size similar to a TC project (e.g. for significant changes).

#### *Minor changes to a TC*

**21.A.95 Requirements for approval of a minor change** has been amended to specify all the necessary requirements for approval of a minor change to a TC (currently addressed by 21.A.103(b), to be deleted). In that context, the following should be noted:

- (a) Minor changes are no longer (after deletion of 21.A.103) within the scope of 21.A.101.
- (b) The applicable type-certification basis and EP requirements for minor changes are those incorporated by reference in the TC unless specifications of later effective amendments are elected by the applicant. However, only those specifications elected that do not affect the compliance demonstration will be accepted by the Agency (see 21.A.95(b)(1)).
- (c) The rule text of 21.A.95(b)(2) provides for the (rare) possibility e.g. in the case of a master minimum equipment list (MMEL), that even a minor change may sometimes affect OSD, and the same approach towards the conditions for the issuance of an approval certificate (i.e. optionally



before compliance with the OSD certification basis has been demonstrated) is taken as applied in other certification processes (for a TC or major change to a TC/STC) for consistency.

- (d) A minor change will only be approved (see 21.A.95(b)(3)) when compliance has been declared and all justifications of compliance have been recorded in the compliance documents. This is added for consistency with the requirements of the current 21.A.433(a)(3) for repairs (taken over by the amended 21.A.433(a)(2)), as well as with similar requirements of 21.A.20 that apply to TCs, RTCs, major changes to a TC, and STCs.
- (e) A minor change will only be approved when *no feature or characteristic has been identified that may make the product unsafe for the uses for which certification is requested* (see 21.A.95(b)(4)). For more details, see information under (e) in 21.A.20 above.
- (f) To remove the existing inconsistency, a requirement has been added for the applicants to submit to the Agency a *statement of compliance* together with the *substantiation data* from each compliance demonstration for a minor change.
- (g) The wording of 21.A.95 has been amended such to accommodate its application by both the applicants to the Agency and those DOA holders self-certifying minor changes under their 21.A.263(c)(1) and (2) privileges. Where the amended 21.A.95(d) reads ... *the applicant* ..., it means that it does not apply to DOA holders self-certifying minor changes under their privileges (they are not applicants to the Agency).

#### *Major changes to a TC*

**21.A.97 Requirements for approval of a major change** has been amended to specify all the necessary requirements for approval of a major change to a TC (currently addressed by 21.A.103(a), to be deleted). In that context, the following should be noted:

- (a) 21.A.101 applies for establishment of the TC and OSD certification bases as well as EP requirements for a major change to a TC;
- (b) 21.A.20 has been cross-referenced (see 21.A.97(b)(3)) to apply for the compliance demonstration process to be followed *as applicable to the change*. GM will be developed to clarify how exactly 21.A.20 is to be applied for compliance demonstration for a major change by both the applicants to the Agency and those DOA holders self-certifying certain major changes under their 21.A.263(c) privileges; and
- (c) the wording of 21.B.97 has been amended such to accommodate future application by both the applicants to the Agency and those DOA holders self-certifying major changes under their 21.A.263(c)(8) privilege.

**21.A.101 Type-certification basis, operational suitability data certification basis and environmental protection requirements for a major change to a type-certificate** has been amended to specify how the type-certification and OSD certification bases for a major change to a TC (and an STC by cross reference to 21.A.115(b)(2)) shall be established, as well as to specify in accordance with which point of Section B the applicable EP requirements shall be designated. In that context, the following should be noted:

- (a) Minor changes are excluded from the scope of 21.A.101, which is limited to major changes to a TC and, by cross reference, to STCs.



- (b) *Changed product* wording has been changed to *change and areas affected by the change*, in order to exclude from certification of a major change or STC the areas of the product not affected either physically or functionally by the change. These areas are not to be recertified since, being unaffected, they continue to be in compliance with the type-certification and OSD certification bases and EP requirements incorporated by reference in the TC.
- (c) The wording of 21.A.101 has been amended to remove all the requirements for the applicant to demonstrate compliance because such requirements are now fully covered by 21.A.20 (cross-referenced in 21.A.97(b)(3)).
- (d) The current content of 21.A.101(e) is moved to 21.A.93(b) Application, where it belongs, and 21.A.101(e) itself is used to introduce a possibility for applicants to propose alternatives to CSs designated by the Agency on condition that it provides a level of safety equivalent to that provided:
- (1) either by the CS(s) designated by the Agency (*ESFs*); or
  - (2) by the essential requirements of Annex I to Regulation (EC) No 216/2008 (*deviations*).

For an RTC not meeting the essential requirements, the *deviations* must ensure a level of safety adequate with regard to the intended use.

#### STCs

**21.A.115 Requirements for issuance of a supplemental type-certificate** has been amended so that it contains requirements equivalent to the amended 21.A.97 requirements (see above) for major changes to TC (except for 21.A.115(b)(1) requiring the applicants to demonstrate capability). This means that the 21.A.101 and 21.A.20 requirements (as applicable to a major change to a TC) apply for STC projects as well.

#### Repairs

**21.A.432C Application for a repair design approval** has been added to include a (missing) requirement for submission of the application for approval of a repair design as well as requirements for the content of such an application. For major repairs, it requires submission to the Agency of a certification programme, but not necessarily with the application. It can be provided later as a supplement and submitted together with the substantiation data and the declaration, required under 21.A.433(b), after completion of the compliance demonstration.

However, the requirement for the need to prepare a certification programme for a major repair is considered appropriate because the applicant themselves should have such a programme for a project above a certain size irrespective of the Agency's need to obtain this document, and also because the certification programme is the only basis for the Agency to determine its LoI in a certification project for a major repair design of a bigger size. No certification programme is required for approval of minor repair designs because of the limited size of these projects. The complexity of the certification programme should be always proportionate to the complexity of the certification projects. For a simple major repair, it can be just simple. Guidance on this issue will be developed in Phase II of the LoI project to provide more clarity in that respect.



**21.A.433 Requirements for approval of a repair design** has been amended to specify all the necessary requirements for approval of a major and/or minor repair design. In that context, the following should be noted:

- (a) The applicable type-certification basis is that incorporated by reference in the TC unless any amendment proposed by the applicant is accepted or required by the Agency. The option for applicants to select those CSs in effect on the date of application is no longer available since this was found to be inadequate for use by the DOA self-certifying their repair designs under their privileges, without appropriate control by the Agency. The possibility for the applicants to apply amendments provides sufficient flexibility. The requirements for demonstration of compliance with EP requirements have been removed since the certification practice showed that environmental protection levels are not affected by repairs.
- (b) Those applicants demonstrating compliance for a major repair design should follow a certification programme established under 21.A.432C.
- (c) Where an arrangement with the TC/STC/APU ETSO(A) holder is in place, the holder must advise that they have no technical objection to the information submitted and agreed to collaborate with the repair design approval holder to ensure discharge of all obligations for continued airworthiness of the changed product.
- (d) The wording of 21.A.433 has been amended such to accommodate future application by both the applicants to the Agency and those DOA holders self-certifying repair designs under their privileges. 21.A.433(b)) requirement reads ... *the applicant* ..., which means that it does not apply to DOA holders self-certifying repair designs under their privilege (they do not submit an application to the Agency).

### 2.5.5 Concise review of all affected Part-21 points

Section A has been reviewed to identify the points and requirements applicable to the Agency. Based on the results of this review, some points applicable to the Agency have been completely removed from Section A and their content, adapted as necessary, moved to Section B — Procedures for competent authorities under a new designation. Some other Section A points, currently containing a mixture of requirements for applicants and for the Agency, have been revisited and the specific requirements applicable to the Agency have been extracted and moved to the new Section B points.

Some points in Section A have been streamlined and/or reworded since some of them will be applied by both the applicants to the Agency and those DOA holders self-certifying under their 21.A.263(c) privileges. The text of some points (e.g. 21.A.95, 21.A.97, 21.A.115, 21.A.433) has been neutralised to some extent to accommodate application by both the above entities. In cases where this is not possible, phrases like 'as applicable', 'where applicable' etc. have been used. Detailed guidance will be developed in Phase II of the Lol project to provide more clarity in that respect.

It is to be noted that the scope of the review and the resulting changes have been limited to those Section A parts that are directly or indirectly affected by the embodiment of the Lol concept. Further amendments will be proposed in Agency's Opinion under RMT.0251 (which will embody the SMS requirements into Part-21).

In addition, this rulemaking task has been used as an opportunity to improve the consistency of the current rule text and correct some errors in the Subparts affected by the proposal.



Table B below provides concise information on all points affected by this proposal.

**Table B — Detailed review of changes to the affected Part-21 points**

Point	Type of change	Description
21.A.14	amended	<ul style="list-style-type: none"> <li>— In (a), <i>Any organisation</i> has been replaced with <i>An applicant</i>. An applicant can be per 21.A.113 a natural person not representing an organisation.</li> <li>— In (c), besides editorial changes to improve its wording and to revise the cross reference, changes are made to indicate that the applicant demonstrates its capability not just through providing the Agency with a certification programme but through the <u>acceptance</u> of this programme by the Agency.</li> </ul>
21.A.15	amended	<p>In addition to the information on this point provided in Section 2.5.1 above:</p> <ul style="list-style-type: none"> <li>— In (a), the word <i>aircraft</i> in front of <i>restricted type-certificate</i> has been deleted. While RTC is indeed applicable only to aircraft, this is clear from 21.A.11 Scope and does not need to be repeated in every occurrence.</li> <li>— In (b), the amended wording for descriptive data to be provided supports the use of modern means to draw, store and display graphics. (b) is now applicable to all products.</li> <li>— (d) has been amended to improve the wording of the introductory sentence and align it with (b).</li> <li>— New (e) and (f) have been added containing the text (as amended to improve its wording) that originates from (b) and (c) of the current 21.A.17 Type-certification basis. The text of both (b) and (c) applies to applicants and their applications, therefore it must remain in Section A (21.A.17 itself has been moved to Section B as 21.B.80, as it is only applicable to the Agency). Note that the scope of 21.A.15(e) and (f) was extended to also cover RTCs.</li> <li>— In (f)(1) and (f)(2), note that the specifications and requirements for certification are the ones established by the Agency and notified to the applicant. The applicant only submits a proposal.</li> </ul>
21.A.16A	amended, renumbered and	21.A.16A is applicable to the Agency, so it has been moved, as amended, to Section B as 21.B.70



Point	Type of change	Description
	moved	
21.A.16B	amended, renumbered and moved	21.A.16B is applicable to the Agency, so it has been moved, as amended, to Section B as 21.B.75.
21.A.17A	renumbered and moved	21.A.17A is applicable to the Agency, so it has been moved, as amended, to Section B as 21.B.80.
21.A.17B	renumbered and moved	21.A.17B is applicable to the Agency, so it has been moved, as amended, to Section B as 21.B.82.
21.A.18	renumbered and moved	21.A.18 is applicable to the Agency, so it has been moved, as amended, to Section B as 21.B.85.
21.A.20	amended	In addition to the information on this point in Section 2.5.1 above, the title has been amended by adding <i>demonstration</i> .  The amended (d) also adds the missing reference in (d)(1) to the OSD certification basis <i>where applicable</i> .
21.A.21	amended	21.A.21 has been simplified by removing some requirements that are now covered by other points (21.A.20, 21.B.80, as amended). The reference to 21.A.44 has been deleted since it was found redundant. Some of the 21.A.23 text has been moved here to extend the scope to cover RTCs (and 21.A.23 has been consequently deleted). The issuance of both certificates by the Agency is now covered by the new 21.B.103 in Section B.
21.A.23	deleted	The requirements of this point are now covered by the amended 21.A.21.
21.A.33	amended	See Section 2.5.4 above.
21.A.41	amended	The text has been corrected to specify that <i>any other conditions or limitations prescribed for the product</i> are those prescribed <u>by the Agency</u> after it has recorded compliance with the applicable type-certification basis and EP requirements.
21.A.91	amended	<i>data after operational suitability</i> has been deleted. The effect to be assessed is on the series of characteristics of the product including operational suitability, so that the <i>data</i> is inconsistent.
21.A.93	amended	In addition to the information on this point in Section 2.5.4 above: — (a)(1) (now (b)(1)(i)) has been amended to require from the



Point	Type of change	Description
		<p>applicant to identify the baseline configuration(s) of the product upon which the change is made.</p> <ul style="list-style-type: none"> <li>— (a)(2) (now (b)(1)(ii)) has been amended to include the related text of the current (a)(1) as amended.</li> <li>— (b)(1)(iii) is added with the text of the current (c).</li> <li>— (b) (now (b)(2)) has been amended for the reasons explained under 21.A.101 below.</li> <li>— new (b)(3) has been added to request similar information as required in a certification programme for a TC (see also 21.A.15(b)(4)–(7))</li> <li>— new (c) has its origin in the current 21.A.101(e), the text of which (as amended) has been moved to (c) since it relates to the application for a change; the changes made relate to the wording of and references to the applicable specifications and requirements but do not affect the substance of this point.</li> </ul>
21.A.95	amended	<p>In addition to the information on this point in Section 2.5.4 above:</p> <ul style="list-style-type: none"> <li>— (b) (now (a)(2)) has been amended to stress that minor changes, when (self-)approved by a DOA holder, are approved within the scope of their privileges as recorded in the terms of approval.</li> <li>— new (b) and (c) include self-contained compliance demonstration requirements for approval of a minor change (the amended 21.A.20 is not applicable to minor changes).</li> <li>— new (d) has been added to require the applicants to submit the substantiation data and a statement of compliance.</li> <li>— new (e) specifies that also for minor changes (as currently for major changes), the approval is limited to that or those specific configuration(s) of the type design based on which the change is made.</li> </ul>
21.A.97	amended	<p>In addition to the information on this point in Section 2.5.4 above:</p> <ul style="list-style-type: none"> <li>— Current (a) has been deleted because its requirements are now covered by the amended 21.A.20, cross-referenced in the new (b)(3). The amended 21.A.20 ensures that 21.A.33 and 21.A.35 (currently in 21.A.97(a)(5)) remain applicable to major changes.</li> </ul>



Point	Type of change	Description
		<ul style="list-style-type: none"> <li>— New (a) reflects the fact that some major changes will be (self-)approved by some DOAs holding the 21.A.263(c)(8) privilege.</li> <li>— New (b) contains conditions for approval of a major change.</li> <li>— New (b)(3) contains cross references to 21.A.20, which shall be applied <i>as applicable to the change</i>. This wording indicates that some requirements of 21.A.20 may not be applicable, in particular to DOA holders (self-) approving a major change under their privilege. Detailed guidance will be developed in Phase II of the Lol project to provide more clarity in that respect.</li> </ul>
21.A.101	amended	In addition to the information on this point in Section 2.5.4 above, (c) has been amended to highlight that its requirements indeed derogate from those of (a). Instead of the top-down, a bottom-up approach has been taken in (c).
21.A.103	deleted	The existing requirements of 21.A.103 are now covered by 21.A.20, 21.A.95, 21.A.97 and 21.A.107.
21.A.111	amended	After replacement of the <i>major change to type design</i> wording by the <i>major change to a type-certificate</i> through the OSD amendment (Regulation (EU) No 69/2014 <sup>8</sup> ), it is necessary to complement 21.A.111 by a sentence making the TCs requirements of Subpart E also applicable to RTCs.
21.A.112A	amended	The word <i>organisation</i> has been deleted. A natural person (an eligible applicant) may not represent an organisation.
21.A.112B	amended	<ul style="list-style-type: none"> <li>— In (a), <i>organisation</i> has been replaced by <i>applicant</i>, which includes also a natural person eligible as per 21.A.112A.</li> <li>— (c) has been amended to introduce a requirement to demonstrate capability through <u>the acceptance</u> of a certification programme by the Agency.</li> <li>— The incorrect reference to (b) has been removed and the wording has been improved.</li> </ul>

<sup>8</sup> 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).



Point	Type of change	Description
21.A.113	amended	<ul style="list-style-type: none"> <li>— (b) has been amended to ensure that the same information required with an application for a change to a TC will also be provided with an application for an STC.</li> <li>— New (c) has been added to make the requirements of 21.A.93(c) for the time limits of the application validity and the conditions for the updates of the type-certification basis, OSD certification basis and EP requirements, if it is evident that the approval process will not be completed before the date on which the specified time limit expires, applicable also to applications for an STC.</li> </ul>
21.A.114	deleted	21.A.114 has been covered by the amended 21.A.115(b).
21.A.115	amended	<p>In addition to the information on this point in Section 2.5.4 above:</p> <ul style="list-style-type: none"> <li>— The current text of (a) has been deleted because its requirements are now covered by the amended (b) and the amended 21.A.20 (which is cross-referenced in 21.A.115(b)(4)).</li> <li>— The new text of (a) reflects the fact that STCs may now be also issued by some DOA holders under their 21.A.263(c)(9) privilege.</li> <li>— New (b) has been worded so as to be applicable not only to the applicants to the Agency but also to those DOA holders issuing STCs under their 21.A.263(c)(9) privilege. Note that in the case of DOA holders certifying under their 21.A.263(c)(9) privilege: <ul style="list-style-type: none"> <li>• 21.A.112A Eligibility;</li> <li>• 21.A.112B Demonstration of capability;</li> <li>• 21.A.113 Application; and</li> <li>• 21.B.110 Issue of a supplemental type-certificate</li> </ul> are not applicable.</li> <li>— New (b)(4) cross-references 21.A.20, which shall be applied <i>as applicable to <u>the</u> change</i>. This wording indicates that some requirements of 21.A.20 may not be applicable, in particular to DOA holders (self-) approving an STC under their privilege. Detailed guidance will be developed in Phase II of the LoI project to provide more clarity in that respect.</li> </ul>



Point	Type of change	Description
21.A.231	amended	After replacement of <i>major change to type design</i> by <i>major change to a type-certificate</i> through the OSD amendment (Regulation (EU) No 69/2014), it is necessary to complement this point by a sentence making the TCs requirements of Subpart J also applicable to RTCs.
21.A.258	amended	<ul style="list-style-type: none"> <li>— (a) has been amended to indicate that findings from both the investigation of the DOA holder in accordance with 21.A.257 and from the product compliance verification process in accordance with 21.B.100 are within the scope of 21.A.258.</li> <li>— Editorial changes have been made.</li> </ul>
21.A.263	amended	<p>In addition to the information on this point in Section 2.5.2 above:</p> <ul style="list-style-type: none"> <li>— The text of (a) has been deleted (but the point has been kept as <i>Reserved</i>) since the <u>right to design</u> aeronautical products, parts or appliances (even under Part-21) should not be regulated. In a state of law, what is not forbidden is allowed, and the aeronautical design activity is not forbidden since it does not present any risk to society.</li> <li>— The text of (b) has been deleted (but kept as <i>Reserved</i>) because it has become inapplicable with the introduction of the Lol concept.</li> <li>— (c) has been amended as follows: <ul style="list-style-type: none"> <li>• the wording of the introductory sentence has been improved to clarify that each privilege for which the DOA holder demonstrated their capability has its scope established by the Agency;</li> <li>• (1) and (2) have been amended to capture under the scope the classification and approval of <i>changes to an STC</i> and to add <i>design</i> after repair;</li> <li>• (3) has been deleted since it is in fact not a privilege but an obligation; therefore, it has been moved to 21.A.265(h);</li> <li>• (4) has been deleted (but the point has been kept as <i>Reserved</i>) because after replacement of <i>major change to type design</i> by <i>major change to a type-certificate</i> through the OSD amendment (Regulation (EU) No 69/2014), minor revisions to the aircraft flight</li> </ul> </li> </ul>



Point	Type of change	Description
		<p>manual (AFM) have fallen within the scope of the 21.A.263(c)(2) privilege;</p> <ul style="list-style-type: none"> <li>• (5) has been amended to extend the scope of the privilege to approve major repair designs (currently available only to the TC/STC/APU ETSO(A) holders) to other appropriately approved DOA holders who will be able to demonstrate capability for this privilege;</li> <li>• in (6), the wording has been slightly amended;</li> <li>• in (7), the wording has been improved;</li> <li>• new (8) has been added to introduce a new privilege for TC holders to approve certain major changes to their TC; and</li> <li>• new (9) has been added to introduce a new privilege to allow appropriately approved DOA holders to issue certain STCs and to allow STC holders to approve major changes to their STCs.</li> </ul>
21.A.265	amended	<p>Apart from changes in wording:</p> <ul style="list-style-type: none"> <li>— (d) has been amended to exclude those DOA holders self-approving under their (now extended) privileges without involvement of the Agency from the obligation to submit statements and associated documentation;</li> <li>— new (h) has been added with the text of current 21.A.263(c)(3).</li> </ul>
21.A.431A	amended	<ul style="list-style-type: none"> <li>— Editorial changes have been made.</li> <li>— In addition, new (f) has been added to indicate that the TCs requirements of Subpart M are also applicable to RTCs.</li> </ul>
21.A.432B	amended	<ul style="list-style-type: none"> <li>— Editorial change have been made to (a).</li> <li>— (c) has been amended (besides deleting the incorrect reference to (b) and making some wording changes) by referring to the new 21.A.432C requiring demonstration of capability via acceptance by the Agency of a certification programme specified in that point.</li> </ul>
21.A.432C	new	<ul style="list-style-type: none"> <li>— It has been added to have also in Subpart M a point specifying that an application needs to be submitted for approval of all repair designs (except those self-approved by</li> </ul>



Point	Type of change	Description
		DOA holders under their privileges). — (b) requires submission of a certification programme for major repair designs and specifies the content of such a programme.
21.A.433	amended	See information on this point in Section 2.4.5 above.
21.A.435	amended	— (a) has been amended through editorial changes only. — (b) has been amended such to specify who can <i>classify and approve</i> a repair design. The text incorporates now the information currently contained in 21.A.437.
21.A.437	deleted	In consequence of changes made to 21A.435, 21.A.437 has become redundant and has therefore been deleted.
21.A.604	amended	— Cross references have been amended and editorial changes made. — 21.A.17B (OSD certification basis) has not transposed into its successor 21.B.82 because potential impacts on OSD (relevant mainly for APU certification) will be dealt with at aircraft level.
21.A.605	amended	— The introductory sentence has been designated as (a). — New (a)(1) has been inserted to require applicants to submit a <i>certification programme</i> for certification of an ETSO(A) article. — (a) has been renumbered as (a)(2). — (b) (renumbered as (a)(3)) has been amended to specify that a statement of compliance is part of the declaration of design and performance (DDP). — (c)–(f) have been renumbered as (a)(4)–(a)(7). — A new (b) has been added for consistency with other certification processes to require the applicants to report to the Agency any difficulty or event encountered during the approval process that may significantly impact the ETSO(A).
21.A.606	amended	Apart from editorial and wording changes, the text has been amended as follows: — the current (c) has been deleted (the requirement was found redundant) and replaced with the requirement to



Point	Type of change	Description
		<p>comply with Subpart O as a condition for obtaining the ETSO(A); and</p> <ul style="list-style-type: none"> <li>— a new (d) has been added with a standard requirement, coming on top of compliance with the certification basis (to declare that no feature or characteristic has been identified that would make the article unsafe for the uses for which certification is requested), as a condition for the issuance of an ETSO(A).</li> </ul>
21.B.70	deleted	The current 21.B.70 in <u>Section B, Subpart D</u> is deleted. Its content is accommodated by 21.B.107(c).
21.B.70	new	New 21.B.70 is created in <u>Section B, Subpart B</u> , based on the text of the current 21.A.16A Certification specifications. In addition to editorial and wording changes, its scope has been extended to cover the issuance by the Agency of the ‘environmental’ CSs for noise and emissions.
21.B.75	new	21.B.75 is based on the text of the current 21.A.16B Special conditions. In addition to editorial changes, it incorporates, as a novelty, the term <i>newly-identified hazards</i> to introduce an additional reason for prescribing a special condition when a safety risk is identified even prior to the product entry into service that could lead to an unsafe condition and the need to issue an airworthiness directive (AD) (e.g. on the production line or in other parallel certification processes).
21.B.80	new	<p>21.B.80 is based on the text of the current 21.A.17A, as amended:</p> <ul style="list-style-type: none"> <li>— the introductory sentence contains an <i>obligation</i> for the Agency to establish and notify the applicant of the applicable type-certification basis;</li> <li>— (a) specifies what is the default option for the type-certification basis: applicable <i>certification specifications</i> (CSs) designated by the Agency for the product to be certified from those effective on the date of application;</li> <li>— (b) supports the use of SCs when the CSs do not contain adequate or appropriate safety standards for the product to be certified (see 21.B.75(a));</li> <li>— (a)(1) supports the use of <i>elects to comply</i> (CSs at a later amendment issued after submitting the application that is voluntary elected by the applicant for compliance);</li> </ul>



Point	Type of change	Description
		<ul style="list-style-type: none"> <li>— (a)(2) supports the use of <i>ESFs</i>;</li> <li>— (a)(3) supports the use of <i>deviations</i> (see <a href="#">EASA MB Decision 12-2007</a>); and</li> <li>— the current 21.A.17(b) and (c) have been retained in Section A (see the new 21.A.15(e) and (f)) because they are applicable to the applicants and their applications.</li> </ul>
21.B.82	new	<p>21.B.82 is based on the current 21.A.17B, as amended:</p> <ul style="list-style-type: none"> <li>— to extend the applicability to RTCs;</li> <li>— to clarify (by adding <i>whatever comes later</i>) that when the OSD is submitted after the initial application for a TC as its supplement, the date of submission of this application supplement is the effective date for the establishment of the OSD certification basis; and</li> <li>— to align the structure and wording with that of 21.B.80 as regards <i>elects to comply</i> and <i>deviations</i>.</li> </ul>
21.B.85	new	<p>21.B.85 is based on the current 21.A.18 as amended:</p> <ul style="list-style-type: none"> <li>— to extend in the introductory parts the applicability to RTCs, STCs and major changes to a TC (or STC);</li> <li>— to reflect Regulation (EU) 2016/5<sup>9</sup> which has transposed the new ICAO Annex 16 SARPS for noise (2014);</li> <li>— the current content of (c) has been transferred, as amended, to 21.B.70 to join the requirements for the issuance of the CSs for airworthiness; and</li> <li>— new text in (c) specifies that CSs for environmental protection provide AMC to demonstrate compliance with EP requirements.</li> </ul>
21.B.100	new	21.B.100 introduces the new Lol concept, explained in detail in Section 2.5.1 above.
21.B.103	new	21.B.103 contains the requirements and conditions for the Agency to issue a TC or an RTC.
21.B.70	deleted	The current 21.B.70 has been deleted. Its content has been

<sup>9</sup> Commission Regulation (EU) 2016/5 of 5 January 2016 amending Regulation (EU) No 748/2012 as regards the implementation of essential requirements for environmental protection (OJ L 3, 6.1.2016, p. 3).



Point	Type of change	Description
		incorporated into 21.B.107(c).
21.B.105	new	21.B.105 contains the requirements for the Agency to establish and notify applicants for a major change to a TC or STC of the applicable type-certification basis, OSD certification basis and EP requirements.
21.B.107	new	21.B.107 contains the requirements and conditions for the Agency to issue an approval of a minor or major change to a TC.
21.B.109	new	21.B.109 contains the requirements for the Agency to establish and notify the applicable type-certification basis, EP requirements and OSD certification basis to the applicants for an STC.
21.B.110	new	21.B.110 contains the requirements and conditions for the Agency to issue an STC.
21.B.113	new	21.B.113 contains the requirements and conditions for the Agency to designate, and notify to the applicant for a repair design, any amendments to the type-certification basis referenced in the TC, RTC, STC or APU ETSO(A).
21.B.115	new	21.B.115 contains the requirements and conditions for the Agency to issue an approval of a major or minor repair design.
21.B.117	new	21.B.117 contains the requirements and conditions for the Agency to issue an ETSO(A).

Done at Cologne, on 23 May 2016

Patrick Ky  
Executive Director



### 3. References

#### 3.1. Affected 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 30<sup>th</sup> 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') repealing Decision No 2003/01/RM of the Executive Director of the Agency of 17 October 2003

#### 3.3. Reference documents

- [ToR and Concept Paper MDM.060 \(RMT.0262 & RMT.0611 and RMT.0550 & RMT.0612\), Issue 1 — Embodiment of Level of Involvement \(LoI\) and Safety Management System \(SMS\) requirements into Part-21, 27 August 2013](#)
- ICAO Annex 19 to the Convention on International Civil Aviation — Safety Management, International Standards and Recommended Practices, first Edition, July 2013
- ICAO Doc 9859 — Safety Management Manual (SMM), third Edition, 2013
- ICAO Doc 9734 — Safety Oversight Manual, third Edition, 2013
- Safety Management International Collaboration Group (SM ICG) — Safety Management Terminology paper, 25 July 2012

