



Notice of Proposed Amendment 2015-03

Embodiment of Level of Involvement (LOI) requirements into Part-21

RMT.0262 (MDM.060) — 2.3.2015

EXECUTIVE SUMMARY

This Notice of Proposed Amendment (NPA) addresses the risks in the process of certification of aircraft and related products, parts or appliances, as well as changes and repairs thereto.

The Part-21 certification process is based on the principle of assurance of compliance of the certified product, part or appliance with the applicable requirements. The applicant demonstrates compliance and the Agency verifies the applicant's demonstrations on a non-exhaustive basis. This proposal does not change the principle of compliance assurance but it introduces into the process a risk-based approach to compliance verification to better mitigate the risks linked to the non-exhaustiveness of the process.

The concept of level of involvement (LOI) of the Agency in compliance verification will help to identify, using defined criteria, the certification areas where a possible non-compliance may pose a higher risk to product safety than other areas and, therefore, deserve thorough investigation by the Agency. The LOI concept will help the Agency to determine its level of involvement in each technical discipline of a certification project. Higher involvement in most safety-relevant areas of the compliance verification process has the potential to bring safety benefits.

The design organisation of the applicant may be permitted, if its performance has been assessed to be satisfactory, to ensure compliance in those areas where the safety risks are assessed to be lower. Such design organisations, Design Organisation Approval (DOA) holders, may also be granted new privileges to approve in the future certain major changes to a type-certificate or to issue supplemental type-certificates, when they have shown their capability in the certification process for previous change(s) approved with the involvement of the Agency.

It has to be noted that this proposal is in no case intended to lower the overall level of involvement of the Agency in certification projects but rather to focus its involvement on the areas of certification projects where it brings the most added value for safety.

This task completes the action [SYS 1.3a 'Incorporation of SSP in all domains of aviation' of the European Aviation Safety plan \(EASp\)](#).

Applicability		Process map	
Affected regulations and decisions:	Regulation (EU) No 748/2012 (Part-21); ED Decision 2012/020/R.	Concept Paper:	Yes
Affected stakeholders:	Applicants for Part-21 design approvals; design organisations; and the Agency.	Terms of Reference:	27.8.2013
Driver/origin:	Safety; legal obligation (ICAO alignment).	Rulemaking group:	No
Reference:	EASp.	RIA type:	Light
		Technical consultation during NPA drafting:	Yes
		Duration of NPA consultation:	3 months
		Review group:	No
		Focussed consultation:	Yes
		Publication date of the Opinion:	2016/Q1
		Publication date of the Decision:	2017/Q1



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1. Procedural information

1.1. The rule development procedure

The European Aviation Safety Agency (hereinafter referred to as the 'Agency') developed this Notice of Proposed Amendment (NPA) in line with Regulation (EC) No 216/2008¹ (hereinafter referred to as the 'Basic Regulation') and the Rulemaking Procedure².

This rulemaking activity is included in the [Agency's Rulemaking Programme](#) under RMT.0262 (MDM.060). The ToR, together with the concept paper for this task which had been classified as 'complex', was published on 27 August 2013³.

The text of this NPA has been developed by the Agency after a focused consultation of with selected Design & Manufacturing industry stakeholders, members of the LOI Steering Group. It is hereby submitted for consultation of all interested parties⁴.

The process map on the title page contains the major milestones of this rulemaking activity to date and provides an outlook of the timescale of the next steps.

1.2. The structure of this NPA and related documents

Chapter 1 of this NPA contains the procedural information related to this task. Chapter 2 (Explanatory Note) explains the core technical content. Chapter 3 contains the proposed text for the new requirements. Chapter 4 contains a light Regulatory Impact Assessment showing which options were considered and what impacts were identified, thereby providing the justification for this NPA.

1.3. How to comment on this NPA

Please submit your comments using the automated Comment-Response Tool (CRT) available at <http://hub.easa.europa.eu/crt/>⁵.

The deadline for submission of comments is **2 June 2015**.

1.4. The next steps in the procedure

Following the end of the NPA public consultation period, the Agency will review all comments and perform a focussed consultation with selected Design & Manufacturing industry stakeholders. The Agency will then publish the CRD with the Opinion.

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

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

³ <http://easa.europa.eu/rulemaking/docs/tor/mdm/ToR%20&%20CP%20RMT.0262%20&%20RMT.0611%20and%20RMT.0550%20&%20RMT.0612%20Issue%201.pdf>

⁴ In accordance with Article 52 of the Basic Regulation and Articles 5(3) and 6 of the Rulemaking Procedure.

⁵ In case of technical problems, please contact the CRT webmaster (crt@easa.europa.eu).



The Opinion will contain proposed amendments to Regulation (EU) No 748/2012 and its Annex (Part-21) and it is addressed to the European Commission, which uses it as a technical basis to prepare a legislative proposal.

The draft Acceptable Means of Compliance (AMC) and Guidance Material (GM) prepared under this NPA will be an input to the separate rulemaking task RMT.0611 aimed to develop, based on results of a number of pilot projects set up to test the implementation of the LOI concept, a full set of AMC and GM to support the amendments proposed by this NPA. The Decision containing the full set of the developed AMC and GM will be published by the Agency when the amendments to the related Regulation (EU) No 748/2012 will be adopted by the Commission.



2. Explanatory Note

Background

In line with the Agency's Decision to implement the MDM.060 project step by step, divided in several rulemaking tasks, this NPA for RMT.0262 'Embodiment of Level of Involvement (LOI) requirements into Part-21' contains only a proposal for changes to Part-21, accompanied by a limited amount of related AMC and GM, which are generic in nature, to support a basic understanding of the LOI concept.

A complete set of the AMC and GM (on the basis of domain-specific criteria) will be developed later in the context of RMT.0611, based on the results of certification pilot projects, and will be presented for public consultation in a separate LOI NPA (No 2), which is expected to be launched in Q1/2016.

In order to provide a sound understanding of the LOI concept, without a complete set of related AMC and GM yet available, as well as an understanding of the other proposed amendments to the rules, this Explanatory Note is rather more detailed.

Readers interested in learning more about the origins and history of the LOI issue, as well as the closely related issue of the Safety Management System (SMS) for Design and Manufacturing (D & M) organisations, can consult the detailed background information in the Concept Paper attached to the ToRs for RMT.0262, RMT.0611, RMT.0550 and RMT.0612 (sub-tasks of the MDM.060 project)⁶.

2.1. Overview of the issues to be addressed

This NPA addresses the following issues:

2.1.1. Level of involvement (LOI)

(a) Safety considerations:

- (1) The provisions of the current Part-21 (Annex to Regulation (EU) No 748/2012⁷) have proven to ensure a high level of safety by ensuring the compliance of certificated products, parts and appliances, including changes/repairs thereto, with all the applicable requirements (hereinafter referred to as the '*product certification process*'), established by the Agency to guarantee the safe and environmentally-friendly operation of aircraft. However, two external conditions can be observed that, when considered together, are likely to produce a hazard that may adversely affect the so far good safety records, if no measures are taken.
- (2) During the last few decades, the civil aviation industry has, despite several occasional crises, been growing in all sectors, including the D & M industry sector. Due to the growth in the aviation transport sector and the scientific and technological advances of recent years, the D & M industry is today producing products with increasingly sophisticated and complex designs. The designs of aircraft, engines, propellers and their parts or appliances incorporate novel and advanced concepts, complex aircraft systems, automated systems,

⁶ <http://easa.europa.eu/rulemaking/docs/tor/mdm/ToR%20&%20CP%20RMT.0262%20&%20RMT.0611%20and%20RMT.0550%20&%20RMT.0612%20Issue%201.pdf>

⁷ 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).



novel technologies and materials, etc. As a result, the number and complexity of the certification projects of the industry stakeholders in cooperation with the Agency is increasing. The demand from industry stakeholders for the Agency's certification services is expected to grow in the future, especially considering the ICAO estimate that the volume of traffic will double by 2030.

- (3) The current economic situation in the EU and the economic perspectives for the near future, that may result in certain budgetary restrictions for the Agency (which are already projected into the '*Multi-Annual Staff Policy Plan (MSPP) 2016-2018*', create a concern that cannot be ignored. There is no guarantee that the expected growth in demand for Agency certification services will be compensated by a commensurate increase in its certification workforce.
- (4) Aviation throughout the world, and in particular in the EU, has enjoyed a steadily improving standard of safety over the last few decades. This trend should not be allowed to stop or, more significantly, should not be allowed to reverse. We are now in a situation where '*common-cause*' accidents are diminishing in number. As the activity and complexity of global aviation continue to grow, the traditional methods for managing safety risks become less efficient and effective. We need to take measures to increase the power of current approaches to controlling risk, complemented by improved risk-based management strategies. This also applies to the compliance verification activities of the Agency in product certification. If no measures are taken, there is a risk that even product safety could be compromised, considering the worst-case scenario of a large imbalance between the demand for certification services and the limited certification staff available (see also Chapter 4.5 on how the situation could evolve).
- (5) According to Part-21, it is the applicant who has the exclusive responsibility to demonstrate full compliance of the product (part, appliance) and changes/repairs thereto with the applicable requirements (type-certification (TC) basis, operational suitability data (OSD) certification basis and environmental protection (EP) requirements). The compliance demonstration obligation of the applicant will remain intact whatever changes this proposal may bring.
- (6) The Agency has its own compliance verification role, using in each discipline the expertise of its certification staff. It is implicit in today's Part-21 that the verification activities of the Agency are non-exhaustive. This non-exhaustiveness is a result of the existing imbalance between the overall volume of certification work and the available human resources of the Agency for compliance verification. However, this situation is not new, it persists for decades. This imbalance does not allow the Agency to perform an exhaustive in-depth investigation of every compliance demonstration detail in every certification project. There is a risk that some safety issues embedded in the product design may not be identified through the compliance verification process (see also Chapter 4.3).
- (7) Consequently, as an inevitable result of the non-exhaustiveness of the process, the Agency's verification tasks are already today prioritised by the staff. They use their expertise and engineering judgment, taking into account the varying importance of different verification tasks with respect to product safety, to identify hazards and assess



the associated risks in their domain. The results of their assessment direct their involvement to verification of specifically those areas that pose a higher risk to product safety than others.

- (8) The problem is that the non-exhaustiveness issue is not recognised in Part-21. There is no recognition of a risk-based approach to compliance verification by the Agency's staff either in Part-21 or the related 'AMC and GM to Part-21' document. No support is, therefore, provided to the staff as to how and based on which criteria they should conduct their risk assessments and determine their involvement in certification projects.
 - (9) Applied individually and without clearly defined criteria, the process is not transparent. The effectiveness and efficiency of this non-transparent process cannot be guaranteed. This is the main issue intended to be addressed by this proposal.
- (b) Legal considerations:
- (1) ICAO Annex 19 'Safety Management' was adopted on 25 February 2013 and became applicable on 14 November 2013. It clearly requires the Contracting States to mandate '*organisations responsible for the type design or manufacture of aircraft*' (D & M organisations) to implement SMS, but there is no apparent link between Annex 19 and the type-certification tasks performed in States by a State's aviation authority or agency. In addition, the ICAO Annexes contain Standards and Recommended Practices (SARPs), but SARPs are not directly legally binding in the States.
 - (2) However, Annex 19 requires that the States shall establish a '*State safety programme*' (SSP) to manage safety in the State and, as a part of it, establish and implement '*State safety oversight*' over the State's aviation activities and functions. One of the States' functions is to '*issue a type-certificate which defines the design of an aircraft type and certifies that this design meets the appropriate airworthiness requirements of that State*'. Therefore, the aircraft type-certification function is subject to the State's safety oversight (see ICAO Doc 9734 — Safety Oversight Manual, Chapter 2.3.3).
 - (3) The framework for a State's SSP guides the States to establish such a safety oversight system that uses a '*Safety-data-driven targeting of oversight of areas of greater concern or need*', containing '*procedures to prioritize inspections, audits and surveys towards those areas of greater safety concern or need, as identified by the analysis of data on hazards, their consequences in operations, and the assessed safety risks.*' (see ICAO Annex 19, Attachment A, page ATT A-3, Chapter 3.3).
 - (4) The Agency, as the executive body of the EU in the domain of aviation safety, carrying out on behalf of the EU Member States the functions and tasks of the State of Design (and also the State of Manufacture or Registry) when related to design approval, shall perform these tasks as specified in the Chicago Convention and its Annexes (see Article 20(1)(a) of the Basic Regulation). The EU is, therefore, obliged to introduce the Safety Management (SM) principles of Annex 19 into the implementing rules of Part-21. As in other aviation domains, the Agency's scope of implementation of Annex 19 SM principles is wider than ICAO requires and also covers organisations designing and producing engines and propellers (NOTE: ICAO is also proposing to extend the applicability of Annex 19 to engines and propellers) as well as parts and appliances, including changes/repairs thereto.



- (c) Interface considerations:
- (1) Proposing the introduction of the LOI concept into the Part-21 product certification processes is the Agency's first step into responding to the above challenges and obligations in the domain of initial airworthiness. This first step will be followed by a number of others. The next one will be the rulemaking task to develop a complete set of Acceptable Means of Compliance (AMC) and Guidance Material (GM) to support the LOI rules proposed by this NPA (This step will be addressed by the separate rulemaking task RMT.0611).
 - (2) Through the implementation of the LOI concept, safety risk management in product certification will be addressed. However, this is just one of four components of the full (SSP) system. For full deployment of the Agency's SSP, it will be necessary to develop or complete the remaining components for product certification, including components for a safety policy, safety objectives, safety assurance and safety promotion. It will be necessary to develop robust safety-related databases, and to build a system for safety data collection and exchange between the certification teams of the applicants, the certification teams of the Agency, and the design organisation surveillance teams of the Agency. As a part of the safety promotion component, training courses will have to be developed based on the ICAO SM principles and the LOI concept, and be delivered to the Agency's certification staff.
 - (3) Even when the above tasks are completed, the MDM.060 project, as addressed by its Concept Paper, will not be complete. Both Annex 19 and the Basic Regulation require that SMSs have to be implemented by the EASA-approved D & M organisations. This will be the subject of the dedicated EASA rulemaking task RMT.0550.
 - (4) The management of civil aviation safety is an activity in which all the players involved in ensuring safety of civil aviation have to participate. Safety Management is a system of systems in which the safety of the systems is only efficiently ensured when all the systems are in place and speak the same language. The SSP framework (of the States & EASA) and the SMS framework (of the service providers) *'must be viewed as complementary, yet distinct, frameworks'* (see Annex 19. Attachment A, Framework for SSP). They do, however, apply, although differently (since they perform different safety functions), the same Safety Management principles.
 - (5) The MDM.060 project addresses action SYS 1.3a 'Incorporation of SSP in all domains of aviation' and action SYS 2.2a 'Incorporation of SMS in all domains of aviation' of the ongoing EASp.

2.1.2. Relocation of Part-21 points and requirements

Part-21 consists of Section A and Section B. Section A should only contain provisions governing the rights and obligations of the applicants for, and holders of, Part-21 certificates and approvals (see point 21.A.1), whereas provisions applicable to competent authorities, including the Agency, should be located in Section B. When embodying the LOI concept, it was identified that Section A still contains a number of provisions applicable to the Agency. These provisions, at least in those parts of Part-21 affected by the LOI proposal, should be re-located to Section B.



2.1.3. Alignment with the Basic Regulation as regards the TC basis

(a) *'Equivalent Safety Findings' (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 TC basis. However, these elements are not listed under the current point 21.A.17 'Type-certification basis'. (They are only addressed in the current point 21.A.21(c)(2), as if they were only taken into account right before the issuance of the TC). This is not considered to be consistent with the Basic Regulation and needs to be corrected.

(b) *'Deviations'*

In the Management Board's (MB) 'Products Certification Procedures' (EASA MB Decision 12-2007), which are the basis for the Agency's internal certification working procedures, the term *'deviations from the applicable airworthiness codes'* is used. From the context of the (MB) procedures, it appears that these elements are distinct from the *'Equivalent Safety Findings'* (ESFs) and *'Special Conditions'* (SCs) and are used as separate elements of the TC basis (see Article 3.2(b) of the (MB) procedures).

In addition, existing separately from ESFs and SCs, these *'deviations'* may be understood as not providing conformity with the essential requirements for airworthiness of Annex I to the Basic Regulation. However, this would be contradictory to this Regulation. To conclude, the possibility of deviation from the applicable certification specifications (not qualifying for an ESF) needs clearer support and a legal basis in Part-21.

(c) *Notification of the TC basis.*

Another inconsistency of Part-21 with the Basic Regulation is that Part-21 does not explicitly require the Agency to establish and notify applicants of the applicable certification bases for certification of products and changes/repairs thereto as it is required by the Basic Regulation (see Article 5(5)). This inconsistency needs to be removed.

2.1.4. Improvements, streamlining, corrections, consistency issues

The history of Part-21 goes back well into the past. Regulation (EU) No 748/2012 was not developed for EASA as a brand-new certification code but it was based on the previous certification code 'JAR-21' of JAA, which itself has its origins in FAA FAR Part 21. EASA Part-21 took over from these 'basic codes' their structure and to a large extent also their content, sometimes based on fifty-year-old certification concepts.

Part-21 is, nevertheless, a living document because certification activities are evolving with technology and need to be regulated by a state-of-the-art procedural code. For that reason, Part 21 needs to be regularly revised and improved to meet the high demands of the EU stakeholders for a good procedural code for product certification activities.

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 of this NPA.



The specific objectives of this proposal are the following:

2.2.1. Level of involvement

(see 2.1.1 above)

(a) Safety considerations:

- (1) The primary objective of this proposal is to recognise the hazard in Part-21 caused by the non-exhaustiveness of the Agency's compliance verification process, and address this hazard by a formal and transparent method. This method needs to ensure that the risks to product safety are mitigated effectively and efficiently.
- (2) There is, therefore, a need to improve the effectiveness and efficiency of the verification process by making more efficient use of the available certification workforce in order to focus their attention and involvement onto the areas of certification projects where a deeper investigation may bring the most added value for safety.
- (3) To achieve the above objective, this proposal provides a concept for the determination of the level of involvement of the Agency in compliance verification (i.e. the LOI concept). The LOI concept will enable the Agency to make its risk-based decisions and LOI determinations effectively and efficiently, based on explicit, common and safety-relevant criteria.
- (4) The LOI concept specifies the typical hazardous areas common to every certification project, i.e. areas with a greater potential to contain risks to product safety than others. This concept will require the Agency to conduct a formal risk assessment of the product and the whole certification project, using the typical generic hazardous areas as general criteria.
- (5) The specific goal of the risk assessment is to identify those items of the applicant's certification programme for compliance demonstration that will require the direct involvement of the Agency. The assessment will also define, for each compliance demonstration item (CDI) or groups of items, the depth of investigation. Based on these assessments, the Agency will determine its level of involvement in each area separately, discipline by discipline (or Air Transport Association (ATA) chapter), across all items of the applicant's certification programme.
- (6) Measures must be taken to control the risks in areas not selected by the Agency for its direct involvement. As the certification process is a two-party exercise, it is apparent that it will be the applicant's design organisation that will alone have the responsibility for ensuring compliance in those areas. However, this can only happen when the Agency finds the performance and experience of the organisation (in a specific domain/discipline of delegation) to be satisfactory enough in order to be comfortable with the transfer of responsibility to the applicant. Means must be determined for measuring of the performance of the design organisation and ensuring its continued monitoring. Moreover, only low-risk areas will be eligible for the transfer of responsibility to the applicant.
- (7) Logically, the high performing and experienced design organisations that have demonstrated their design and certification capabilities in several certification projects



with the Agency will require a lower level of the Agency's involvement. On the other hand, certification projects carried out by newcomers, inexperienced or poorly-performing design organisations will need to be subject to deeper Agency scrutiny and a higher level of involvement.

- (8) The LOI concept also includes the possibility of granting new privileges to high performing and experienced DOA holders in order for them to approve alone, under procedures agreed with the Agency, certain major changes to TCs and/or to issue supplemental type-certificates (STCs) without any involvement of the Agency. These privileges will not be granted automatically; each DOA holder will need to qualify for them, based on positive results of evaluation of their performance. The scope of these privileges will be defined and recorded by the Agency in the DOA terms of reference, and the applicant will need to apply for their change to obtain a new privilege.
- (9) By the LOI concept, the role of the Agency's oversight and the continued surveillance of design organisations will need to be strengthened. The oversight will need to implement the principles of the risk-based approach, in which more attention and a higher level of involvement of the Agency's DOA staff will be devoted to poorly performing and/or inexperienced design organisations (and vice versa). Performance-based oversight will affect the Agency's system for planning of DOA audits, i.e. their frequency and depth.
- (10) These audits will also need to become more technical, focussing not just on the quality of the DOA procedures but specifically on the quality of their implementation in on-going certification projects. For that purpose, the DOA department will need to enjoy more support from the product certification staff through their higher involvement in audits and by providing feedback to the DOA staff on the performance of design organisations in certification projects. A technical finding by the certification staff from their compliance verification activity in a certification project may result in a DOA finding.
- (11) On the other hand, the product certification staff will need to receive more information from the DOA staff about their findings. This will be taken into account in on-going certification projects and, if the nature of the finding may potentially affect product safety, such findings may change the level of involvement of the Agency's certification team in the related project and potentially even prevent the issuance of the related approval. The two oversight activities of the Agency, product certification and DOA holders oversight, will remain separate, but the staff involved will need to exchange information to a much larger extent than today.
- (12) The intent is to make a better use of the EU/EASA concept of approved design organisations. When it is justified and when the associated risks are well-managed, the Agency will rely more on approved design organisations to verify compliance themselves on its behalf. Certainly, the Agency needs to identify and keep for itself the verification of those parts of certification projects where the risks are higher and they necessitate the expertise and the direct involvement of the Agency's certification staff.
- (13) It should be noted that in no case does the Agency intend to lower the overall level of its involvement in certification projects. Considering the fact that the current practice of the Agency's staff already tackles the issue of verification non-exhaustiveness, the



implementation of the LOI concept will not substantially change the way the staff is working. It will merely formalise the process and provide better support and means to render the process more efficient and effective. The overall level of involvement is expected to remain the same.

- (14) NOTE: For better readability of the Explanatory Note text, we address safety issues only. However, the LOI concept is equally applicable to the certification of environmental protection. Only the risks and assessment criteria will be defined differently. The LOI concept may, therefore, also bring similar benefits in this domain. The LOI concept was drafted so as to cover both safety and environmental protection.

(b) Legal considerations:

The introduction of the LOI concept into Part-21 will render the Part-21 processes for the certification of products, parts and appliances, including changes/repairs thereto, compliant with the ICAO Annex 19 SM principles to be applied by the States in their safety oversight function. The Agency, carrying out on behalf of the EU Member States the function and tasks of the State of Design, by incorporating the LOI concept, will be ICAO compliant and will meet the requirement of Article 20(1)(a) of the Basic Regulation (see also 2.1.1(b) above).

(c) Interface considerations:

- (1) The intent of this rulemaking task (RMT.0262) is to propose changes to the Part-21 implementing rule. The development of a complete set of AMCs and GM to support the LOI rules is subject to the separate task RMT.0611, which is going to build on the results of several certification pilot projects launched to test the LOI concept. While the pilot projects have not yet been completed and final results are still pending, several basic AMCs and GM have been developed for this NPA to support the understanding of the LOI rules. They may be subject to changes based on the results of the pilot project and the output of RMT.0611.
- (2) The work on RMT.0262 and RMT.0611 on LOI will be closely coordinated with activities under RMT.0550 on the embodiment into Part-21 of SMS requirements for D & M organisations.

(d) Certification process effectiveness, efficiency and transparency

The additional objectives of the LOI proposal are to improve the effectiveness, efficiency as well as the transparency of the certification process by:

- (1) making better use of the Agency's certification staff by directing their involvement in verification to the areas where it brings added value for safety;
- (2) improving internal communication and strengthening support between the Agency departments involved (the product certification teams and the DOA staff);
- (3) improving the system for the collection, storing and sharing of relevant safety data to support the Agency's certification staff in making decisions;
- (4) improving external communication between the Agency and applicants to better the exchange of safety-related data;



- (5) uniform application of the LOI concept across all disciplines of certification projects and across various certification projects to improve consistency; and
- (6) recording the decisions of the Agency's certification staff.

Better transparency of the certification process will support its predictability and facilitate better planning, both on the side of the applicants and of the Agency. This should contribute to avoiding the accumulation of certification tasks towards the end of a project.

2.2.2. Relocation of Part-21 requirements applicable to the Agency

(see 2.1.2 above)

The second objective of this proposal is to relocate some Part-21 requirements that are applicable to the Agency. These are currently incorrectly located in Section A of Part-21, reserved for the applicants for and holders of Part-21 certificates. This proposal suggests relocation of those requirements, adapted as necessary, to Section B.

2.2.3. Alignment with the Basic Regulation regarding the TC basis

(see 2.1.3 above)

The third objective of this proposal is to:

- (a) recognise the ESFs as elements of the TC basis;
- (b) provide better support and a legal basis for enabling deviations from the applicable certification specifications (not qualifying for an ESF); and
- (c) require the Agency to establish and notify to the applicants for Part-21 design approvals the TC basis, the OSD certification basis, and EP requirements (except where the applicable specifications or requirements have already been published (e.g. ETSO specifications)).

2.2.4. Improvements, streamlining, corrections, consistency issues

(see 2.1.4 above)

The Agency wants to use this rulemaking task as an opportunity to review Part-21 and to introduce improvements in (at least) those parts of Part-21 that are directly or indirectly affected by the embodiment of the LOI concept. The objective is to remove some existing errors, inconsistencies and imperfections, as well as to streamline some points. This exercise will be completed later in the course of the rulemaking task RMT.0550 'Embodiment of SMS requirements into Part-21' intended to support the implementation of SMS by D & M organisations.

2.3. Summary of the Regulatory Impact Assessment (RIA)

Two options have been identified in the RIA:

- (1) **Option 0:** no change to rules (a reference option)
- (2) **Option 1:** taking rulemaking action to implement the LOI concept in Part-21 and meet the other specific objectives as defined above.

One of the main drivers of this rulemaking task is the legal obligation, prescribed in the Basic Regulation, for the Agency to take due account of the ICAO provisions in its implementing rules. This



also includes the provisions of Annex 19 related to the State Safety Programme. These provisions are applicable to ICAO Contracting States. However, the Basic Regulation (in Article 20(1)) requires the Agency to ‘carry out on behalf of Member States the functions and tasks of the state of design, manufacture or registry when related to design approval’. This means that there is a need to implement the safety management principles by the Agency acting in this domain. This obligation is already reflected in the EASA policy decision to implement safety management principles in all domains under the Basic Regulation (see action SYS 1.3a ‘Incorporation of SSP in all domains of aviation’ of EASp), and, therefore, needs to be fulfilled.

The other driver relates to product safety. If the LOI concept is implemented and the new risk-based approach to certification is applied, it will allow the Agency to focus more on safety critical areas of certification projects. Therefore, Option 1 has a potential to improve the overall level of safety of certified products, parts and appliances through improved effectiveness and efficiency of the certification process.

In addition, the implementation of the LOI concept will improve the transparency and predictability of the certification process, which, together with the improved effectiveness and efficiency of the certification procedures, will allow the Agency to make better use of its available product certification staff and the staff involved in the oversight of design organisations.

Based on the RIA considerations, Option 1 to amend Regulation (EU) No 748/2012 and its Annex (Part-21) per this proposal is preferred.

2.4. Overview of the proposed amendments

2.4.1. Level of involvement

(a) Determination and criteria of the level of involvement

The core requirement for the determination of the level of involvement is provided in the new point 21.B.100 in Section B.

Point 21.B.100(a) provides a definition of the LOI, consisting of two core elements that specify two key tasks for the determination of the LOI:

- (1) to identify and select those items of the applicant’s certification programme for compliance demonstration that need to be investigated directly by the Agency (see GM1 to 21.B.100 ‘Compliance Demonstration Items (CDIs)’ in Chapter 3.2 of this NPA); and
- (2) to determine the depth of the investigation that is adequate for each selected CDI (see GM2 to 21.B.100 ‘Depth of the Investigation’ in Chapter 3.2 of this NPA).

The level of involvement is determined by the Agency at the level of the certification programme, broken down into compliance demonstration items or groups thereof.

Point 21.B.100(b) requires an assessment of the safety and environmental risks while using specified ‘hazardous’ areas of the certification projects, common to all projects, where the probability and severity of the risks is estimated to be higher than in other areas.



The approach in point 21.B.100(c) for the determination of the level of involvement of the Agency in the certification of repairs and ETSO articles is similar, but a lighter approach is suggested.

Point 21.B.100(d) requires the applicant to be notified of the determined level of the Agency's involvement. There will be an initial notification, provided to the applicant at the stage of the acceptance of the certification programme. The initial LOI determination can be updated later, whenever the Agency obtains a new piece of information that appreciably changes the previously assessed safety or environmental risk. The level of involvement may be lowered, e.g. after the applicant has presented more specific design or compliance documents of good quality as a part of their compliance demonstration (e.g. a drawing, a design review, a calculation, a test plan and/or other means of compliance). That may satisfy the Agency to the extent that it agrees to reassess the risk and to lower the level of involvement in the next phases of the project.

On the other hand, the level of involvement may be elevated by the Agency if difficulties or safety-related events are encountered by the applicant and reported during the compliance demonstration process, or such a difficulty or event is identified by the Agency during the product certification process or a design organisation audit, or an occurrence is reported from the field, suggesting that a potentially unsafe condition or event was identified on an in-service product of a similar design.

Point 21.B.100(b) requires that the LOI shall be determined on the basis of a safety (and environmental) risk assessment. To support the understanding of the meaning and intent of safety risk assessments and related safety management principles, please find below several definitions and terms. They were taken from the 'Safety Management Terminology'⁸ document (published by the Safety Management International Collaboration Group (SM ICG) on 25 July 2012) as the most comprehensive current source for the given purpose. Please consult this document for more terminology, definitions and guidance material on the subject:

Safety: *The state in which risks associated with aviation activities, related to, or in direct support of the operation of aircraft, are reduced and controlled to an acceptable level.*

Risk: *The assessed predicted likelihood and severity of the consequence(s) or outcome(s) of a hazard.*

Hazard: *A condition that could cause or contribute to an aircraft incident or accident.*

Likelihood: *The frequency, in quantitative or qualitative terms, with which an unsafe event may occur.*

Severity: *The extent of loss or harm associated with the consequence(s) of a hazard. (NOTE: For airworthiness, 'Criticality' is defined in CS 25.1309, among others).*

Consequence: *Actual or potential impact of a hazard that can be expressed qualitatively and/or quantitatively. More than one consequence may evolve from an event.*

Risk Analysis: *Process whereby possible consequences of hazards are objectively characterised for their severity and probability. The process can be qualitative and/or quantitative.*

⁸ <http://www.skybrary.aero/bookshelf/books/1882.pdf>



Risk Assessment: *The identification, evaluation and estimation of the level of risk.*

In the specific case of the risk assessment for the purpose of determining the LOI, the risks will have to be assessed separately in each discipline by each expert in his/her field of expertise. This will be performed by each expert for those items (or group of items) of the certification programme assigned to them, taking into account the risks, their likelihood and the severity of their impact on the safety of the product or on environmental protection.

A qualitative analysis of the areas, generic to all certification projects, with a greater likelihood of containing higher risks to the safety of the product or environmental protection showed three main 'hazardous' areas:

- (1) the novel or unusual features of the certification project, including operational, organisational and knowledge management aspects;
- (2) the criticality of the design or technology and the related safety and environmental risks, including those identified in similar designs; and
- (3) the performance and experience of the design organisation of the applicant in the domain concerned.

However, the above criteria are not the only ones that can be used as inputs to the safety analysis. The wording of the introductory sentence in point 21.B.100(b) clearly indicates their non-exhaustiveness. These are the main criteria that should never be omitted from an expert's assessment. The experts may consider other criteria, e.g. the completeness and quality of the presented design or compliance documents, previous experience with the applicant's staff in a given discipline etc. As indicated in point 21.B.100(d), these inputs may change, one way or another, as the project matures and more information becomes available, so the LOI may be adapted accordingly.

Novel or unusual features of a certification project: These may be identified in:

- the proposed design (see current point 21.A.16B(a)(1)),
- the proposed operating characteristics and limitations,
- the intended use of the product and the kind of operations (see point 21.A.16B(a)(2)),
- the applicable certification specifications, AMC, GM, and EASA policy statements,
- the proposed means of compliance (incl. test methods, test set-ups, replacement of a test by a calculation or simulation etc.), or
- any other novel or unusual feature of the certification project identified by the applicant or by the Agency.

The hazard due to unusual or novel features should be understood in the broader meaning of the term. In particular, the novelty may be for the applicant, for the Agency, or for both. The Agency also needs to manage its knowledge across projects, applicants and disciplines in order to guarantee over time an up-to-date risk management capability to all applicants, and to ensure a consistent level of safety. A novelty is, therefore, not always assessed in the absolute, but also in relative terms, by the applicant and the Agency itself.



Safety risks identified in similar designs: These can exist in designs in service, under production or under certification and in parallel projects of the Agency or of foreign certification authorities.

Performance of the design organisation of the applicant: This may depend on the functioning of the organisation's design assurance system, i.e. the accuracy of relevant procedures, their practical application in certification projects, the accuracy and completeness of their design/compliance assurance work, the commitment to safety of the design organisation's management and technical staff, the level of co-ordination between relevant departments, the number, qualifications and experience of the technical staff involved, the allocation of responsibilities and the authority to make decisions affecting airworthiness, the availability of all the necessary resources (facilities, equipment) including financial ones, the overall experience of the organisation (the length of time in business) etc.

The evaluation of the performance of a design organisation will become substantially more complete when the organisation is SMS compliant and has integrated mature SM methodologies to address the organisational hazards that may indirectly adversely impact the safety of the products. This includes having in place systems for safety performance monitoring and measurement with Safety Performance Indicators (SPIs), management support for 'just culture' environments etc.

To respond to the need to introduce the Annex 19 Safety Management principles into the system of oversight over design organisations and their continued surveillance, the Agency needs to develop, by adapting its current system, a 'DOA performance measurement system' to incorporate the risk-based safety management features (see AMC 21.B.100(b)(3) 'DOA performance measurement system' in Chapter 3.2 of this NPA).

The inputs to the system of performance measurement and ranking of a design organisation in the context of the LOI concept will be:

- (1) the results of assessments of the functioning of the design organisation (per discipline) by the Agency's certification team in the previous and/or current certification project(s), and
- (2) the findings from investigations/audits of the design organisation by the applicable EASA DOA Team in charge.

The performance of a design organisation, particularly for large companies, can be advantageously assessed domain by domain, i.e. avionics, flight, structures etc. This will enable the Agency to optimise its LOI for each of the domains concerned.

(b) *Certification programme or plan*

- (1) Type-certificates and restricted type-certificates

NOTE: Unless otherwise stated, the references to type-certificates (TCs) include type-certificates and restricted type-certificates (RTCs).

Part-21 already requires applicants in the current point 21.A.20(b) to provide a '*certification programme*' for compliance demonstrations. With the introduction of the LOI concept, the role of the certification programme is becoming even more important because the LOI determination will be performed by the Agency at the level of the certification programme as broken down into the compliance demonstration items. The



certification programme is now required in the amended point 21.A.15(b) which also defines its content. The certification programme contains an important requirement relevant to the LOI determination, which is to assess safety aspects of the certification programme, in particular of any novel or unusual features of the project.

(2) Major changes to a TC and STCs

Note that the requirement for establishing the certification programme and keeping it updated, as defined in point 21.A.15(b), is also applicable to the approval of major changes to a TC by cross-reference in point 21.A.97 and to the issuance of STCs by cross-reference in point 21.A.115.

NOTE: A certification programme or plan is not required from applicants for minor changes to TC.

(3) Repairs

Applicants for approval of a major repair design are required in point 21.A.433(a)(2) to submit a '*certification plan*' to be followed to demonstrate compliance with the applicable TC basis for a major repair design.

NOTE: A certification programme or plan is not required from applicants for a minor repair design.

(4) ETSO authorisation (ETSOA)

Applicants for an ETSO authorisation are now required in the amended point 21.A.605(a) to submit a '*certification plan*' to demonstrate compliance with point 21.A.606(b). The content of the plan is specified in the new AMC 21.A.605 (see Chapter 3.2 of this NPA).

(c) *Compliance demonstration process with the TC basis, OSD certification basis and EP requirements*

Point 21.A.20, as amended, is now a core point for performing the compliance demonstration process for:

- TCs,
- RTCs,
- major changes, and
- STCs.

Minor changes, repairs and ETSOAs have their own, slightly lighter, compliance demonstrations requirements.

The amended point 21.A.20(a) cross-refers to those points in Section B that require the Agency to '*establish and notify*' to the applicants the applicable TC and OSD certification bases and EP requirements to be complied with.

By default, the applicant does not establish the applicable certification specifications and requirements without involvement of the Agency. Applicants are required to propose the applicable TC and OSD certification bases and EP requirements to the Agency but they must



demonstrate compliance with those certification bases and EP requirements as established and notified to them by the Agency.

The revised point 21.A.20 includes an important new obligation for the applicant's design organisation, that is to report to the Agency any difficulty or event encountered during the compliance demonstration process that may have a significant effect on the certification programme or that may appreciably change the assessed risk on the basis of which the level of involvement of the Agency was established. This obligation will be an important mitigating factor for managing the risks in areas of the certification project that were not selected for the Agency's direct involvement and that are, therefore, under the exclusive control of the applicant's design organisation (except for DOA audits by the Agency i.a.w. Subpart J).

Finally, the new point 21.A.20(d)(ii) is added to require applicants to declare that '*no known feature or characteristic makes the product unsafe for the uses for which certification is requested*'. This provision, currently contained, in another form, in points 21.A.21(c)(3) and 21.A.33(d)(2), has been moved to 21.A.20(d)(ii) to become applicable to applicants in order to require them to identify any new hazards including those that may have not been captured by the applicable TC basis, OSD certification basis and EP requirements.

(d) *New DOA privileges*

In addition to the current DOA holder's privileges to classify changes to type design and repairs as '*major*' or '*minor*' and approve the minor ones, this proposal brings new privileges that may be granted to those DOA holders with satisfactory performance and experience. The DOA holders that are found to be eligible may be granted privileges to approve, under defined conditions, major changes to TCs under Subpart D or to issue STCs under Subpart E (see new points 21.A.263(c)(8) and (9)).

These new privileges may only be granted when a DOA holder has demonstrated its capability to certify major changes or issue STCs in one or more previous certification projects in which the Agency was involved. The scope of the privilege will be limited to subsequent, assumingly repetitive major changes or STCs that are '*equivalent*' to a change previously approved by the Agency to the same DOA holder with the involvement of the Agency (see new AMC1 21.A.263(c)(8) and (9) 'Scope and Criteria' in Chapter 3.2 of this NPA).

It is important to note that, as with any other DOA privilege, the new privileges are not automatically granted to DOA holders. They may only be granted following an application by a DOA holder for a change to their DOA terms of approval. Granting of the privileges will be conditional upon satisfactory results of an assessment by the Agency of the experience and performance of a DOA holder in (a) previous/current project(s). The exact scope of the privileges will be detailed in the DOA terms of approval, including the specification of the exact conditions and limitations. The conditions and limitations may include items such as a fixed TC basis, means of compliance and guidance material, EASA certification policy, an approved Aircraft Flight Manual (AFM), noise and/or emission levels of the changed product etc.

Furthermore, the exercising of the privilege(s) will be subject to the procedures agreed between the Agency and the DOA holder. The exercising of the privileges will be monitored by the Agency as a part of the DOA holder surveillance activities.



2.4.2. Relocation to Section B of the Part-21 points applicable to the Agency

(see Chapters 2.1.2 and 2.2.2 above)

Section A has been reviewed to identify the points and requirements applicable to the Agency. Based on the results of this review, some points have been deleted in full from Section A and relocated, adapted as necessary, to Section B ('Procedures for competent authorities') under a new designation. Some other points of Section A currently contain a mixture of requirements for applicants and for the Agency. From these points, the requirements for the Agency have been extracted and relocated to Section B.

However, it is to be noted that the scope of the above review and the resulting relocations have been limited to those parts of Section A that are directly or indirectly affected by the embodiment of the LOI concept. Full consistency of Part-21 in this context will only be achieved when the next phase of the MDM.060 project (RMT.0550 'Embodiment of SMS requirements into Part-21') is completed.

Table A below provides detailed information on the relocated points and/or requirements.

2.4.3. Alignment with the Basic Regulation as regards the TC basis

(see Chapters 2.1.3 and 2.2.3 above)

Equivalent Safety Findings (ESFs)

Point 21.A.17 'Type-certification basis', defining the content of the TC basis, has been relocated to Section B under the new designation 21.B.80. Furthermore, it has been complemented by point 21.B.80(c) to introduce (in a modified form) into the TC basis the clause that '*airworthiness provisions not complied with are compensated for by factors that provide an equivalent level of safety*' (see current point 21.A.21(c)(2)), a.k.a. *Equivalent Safety Findings (ESFs)* (see Article 3(2) of [EASA Management Board Decision 12-2007 amending the products certification procedure](#)).

Deviations

For the case of a type-certificate, a new point 21.B.80(a)(1)(i) has been added to point 21.B.80 to formally introduce into the TC basis the possibility of deviations from the applicable certification specifications. This is conditional on finding mitigating features that ensure a level of safety as defined in the essential requirements of Annex I to the Basic Regulation. This point of Part-21, therefore, supports the use of the '*deviations*', as specified in Article 3 (2) of the EASA Management Board Decision 12-2007, which do not qualify for an *ESF*. The mitigating features in this case can be found e.g. in a specific design configuration, or specific operating conditions and limitations of the product.

For the case of a restricted type-certificate, a new point 21.B.80(a)(1)(ii) has been added to point 21.B.80 in order to formally introduce into the TC basis the possibility of deviation (while not qualifying for an *ESF*) from the applicable certification specifications when the level of safety as defined in the essential requirements cannot be ensured. Mitigating features must, however, be identified to ensure at least a level of safety that is '*adequate with regard to the intended use of the product*'.

2.4.4. Improvements, streamlining, corrections, consistency issues

(see Chapters 2.1.4 and 2.2.4 above)



A number of points have been amended to simplify their structure, streamline the points and remove the existing imperfections and inconsistencies.

For detailed descriptions of the affected points, see Table A below.



Table A: Detailed review of changes in the affected Part-21 points

Point	Type of change	Description
21.A.14	amended	Editorial changes have been made to paragraph (c) to improve its wording and revise the cross-reference to the requirement for a certification programme.
21.A.15	amended	<ul style="list-style-type: none"> — Point (b) is amended to require from the applicant a certification programme provided either directly with the application or later as a supplement to the application. The content of the certification programme is specified. Point (b) also specifies the minimum information (jointly for aircraft, engines and propellers) that must be provided in every case directly with each application. The amended wording for descriptive data to be provided supports the use of modern means to draw, store and display graphics. — The current content of point (c) (merged now with the content of point (b)) is deleted and point (c) is used to require applicants to keep the certification programme updated. — Point (d) contains minor editorial changes — The text of new points (e) and (f) (as amended) originates from points (b) and (c) of the current point 21.A.17 ‘Type certification basis’. The text of both (b) and (c) applies to applicants and their applications, so it must, therefore, stay in Section A (point 21.A.17 itself is relocated to Section B under the 21.B.80 designation, as it is applicable to the Agency). Note that the scope of points 21.A.15(e) and (f) was extended to also cover RTCs. — In points (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.
21.A.16A	amended, renumbered and relocated	This point is applicable to the Agency so it is relocated, as amended, to Section B under point 21.B.70
21.A.16B	amended, renumbered and relocated	This point is applicable to the Agency so it is relocated, as amended, to Section B under point 21.B.75.
21.A.17A	renumbered and	This point is applicable to the Agency so it is relocated, as amended, to



Point	Type of change	Description
	relocated	Section B under point 21.B.80.
21.A.17B	renumbered and relocated	This point is applicable to the Agency so it is relocated, as amended, to Section B under point 21.B.82.
21.A.18	renumbered and relocated	This point is applicable to the Agency so it is relocated, as amended, to Section B under point 21.B.85.
21.A.20	amended	<ul style="list-style-type: none"> — Point (a) is amended to require applicants to follow the certification programme established under the amended point 21.A.15(b) and to demonstrate compliance with those specifications and requirements for certification <u>as established and notified by the Agency</u>. — Point (b) is amended to remove the requirements related to the certification programme, now located in point 21.A.15(b), and is supplemented with the requirement for applicants to report to the Agency significant, safety-related difficulties or events encountered during the certification process. — In the amended point (c), the reference to point (b) is changed to refer to point 21.A.15(b). — The amended point (d) now makes a reference to points 21.A.33 and 21.A.35 in order to keep their applicability to certification of major changes and STCs (the cross-reference in point 21.A.97(a)(5) is now deleted, see the explanation for point 21.A.97 below). — The amended point (d)(1) adds the missing reference to the operational suitability data certification basis. — The amended point (d)(2) requires applicants to address any potentially unsafe features or characteristics of the product they are aware of, and that may exist even outside the type-certification basis requirements (see also current points 21.A.21(c)(3) and 21.A.115(b)(3)). <p>The amended point 21.A.20 is, by cross references in the amended points 21.A.97(b)(3) and 21.A.115(b)(4), also applicable to applicants for major changes under Subpart D or STCs under Subpart E, as well as to DOA holders (self-)approving some major changes or STCs under the privileges of points 21.A.263(c)(8) and (9) without any involvement of the Agency.</p> <p>The amended point 21.A.20 is a core point for compliance demonstration that contains all the compliance demonstration</p>



Point	Type of change	Description
		requirements for TCs, RTCs, major changes and STCs.
21.A.21	amended	<ul style="list-style-type: none"> Point 21.A.21 is simplified by the removal of some requirements that are covered now, as amended, by other points (21.A.20, 21.B.80). The reference to point 21.A.44 was deleted since it was found redundant. The scope is extended to cover RTCs (and point 21.A.23 can be, therefore, deleted). The issuance of both certificates by the Agency is covered now by the new point 21.B.103 in Section B.
21.A.23	deleted	The requirements of this point are now covered by the amended point 21.A.21.
21.A.33	amended	<ul style="list-style-type: none"> The current point (a) is deleted because it is covered by the amended point 21.A.20(d). The tests and inspections are identified and specified as means of compliance of the approved certification programme. The scope of the proposed (c)(1) (currently d((1)) is extended to allow the Agency to review <i>'any data (instead of 'reports' only) related to design and compliance demonstration'</i>. The applicant shall always make these data available to the Agency on request, irrespective of whether the data is within the LOI area or not (note that there is no link to the LOI point 21.A.100 in Section B). The request may be made by the Agency for various reasons, e.g. the Agency obtains new information that affects the previous assessment of the safety risks on which the level of involvement was previously determined, and needs to review additional design or compliance data, and possibly update its LOI. The scope of the proposed (c)(2) (current (d)(2)) is extended to allow the Agency to make an inspection, or to witness or perform a test, at any time and not only after the declaration i.a.w. point 21.A.20(d) was made, as the current (d)(2) suggests.
21.A.91	amended	<ul style="list-style-type: none"> Editorial change is made.
21.A.93	amended	<ul style="list-style-type: none"> The current Point (a)(1) (now point (a)(1)(i)) is amended to require from the applicant a description of the change, identifying the configuration(s) of the baseline type design upon which the change is made. The current Point (a)(2) (now point (a)(1)(ii)) is amended to require from the applicant the identification and description of areas physically changed and also the areas that are functionally



Point	Type of change	Description
		<p>affected by the physical change, including approved manuals. The designation of the applicable certification specifications and EP requirements to be complied with is no longer for the applicant to determine. In the case of certification of a major change to a TC or certification of an STC, they will be established by the Agency i.a.w. point 21.A.101 and notified to the applicant i.a.w. point 21.B.105. The applicant is only required to propose the applicable specifications and requirements with the draft certification programme established under the amended point 21.A.15(b), cross-referred from the amended point 21.A.20(a) (which is itself cross-referred from the amended point 21.A.97(b)(3)).</p> <ul style="list-style-type: none"> — The current point (b) (now (a)(2)) is amended for reasons explained under information on point 21.A.101 below. — The text of the new point (b) has its origin in the current point 21.A.101(e). The text (as amended) is moved here since it relates to the application for a change. The changes made relate to the wording and references to the applicable specifications and requirements but do not change the substance of this point.
21.A.95	amended	<ul style="list-style-type: none"> — The current point (b) (now (a)(2)) is amended to stress that minor changes, when (self-)approved by a DOA holder, are approved <u>within their terms of approval</u>. — The new points (b) and (c) comprise of self-contained requirements for the approval of a minor change (i.e. the amended point 21.A.20 is not applicable, in contrary to major changes). The original specifications and requirements as referenced in the TC (Type-Certificate Data Sheet (TCDS)) apply, unless later ones are elected by the applicant or required by the Agency. The absence of a cross reference to point 21.A.101 implies that minor changes are now excluded from the scope and the top-down approach of point 21.A.101. — Note that the new point (b) refers to the '<i>operational suitability data certification basis</i>', so that the OSD concept is also made applicable to minor changes, including the possibility to approve a minor change before compliance with the '<i>operational suitability data certification basis</i>' has been demonstrated (see new point (c)). — The new point (d) specifies that also for minor changes (as for major changes) the approval is limited to that or those specific



Point	Type of change	Description
		configuration(s) of the type design upon which the change is made.
21.A.97	amended	<ul style="list-style-type: none"> <li data-bbox="584 389 1447 667">— The current text of point (a) is deleted because its requirements are now covered by the new point (b)(1) and in the amended point 21.A.20 (which is cross-referred in point 21.A.97(b)(3)). The cross-reference to points 21.A.33 and 21.A.35, currently in point 21.A.97(a)(5), is moved to point 21.A.20(d) (cross-referred from the amended point 21.A.97(b)(3)) and, therefore, this requirement remains applicable to major changes. <li data-bbox="584 689 1447 801">— The new text of point (a) reflects the fact that some major changes may now be (self-)approved by a DOA holder, under their 21.A.263(c)(8) privilege. <li data-bbox="584 824 1447 1149">— The new point (b) is worded so as to be applicable not only to <u>applicants</u> for a major change but also to <u>DOA holders</u> (self-) approving some major changes under their privilege without an application. The point covers both cases. In the case of a DOA holder (self-)approving under their 21.A.263(c)(8) privilege, points 21.A.92 'Eligibility', 21.A.93 'Application' and 21.B.107 'Issue of an approval of a change to a type-certificate' are not applicable. <li data-bbox="584 1171 1447 1541">— The new point (b)(1) indicates that an applicant for a major change or a DOA holder (self-)approving a major change under the 21.A.263(c)(8) privilege must comply with the applicable TC basis and EP requirements <u>as established and notified by the Agency</u>. In the case of an applicant to the Agency, the applicant is notified i.a.w. point 21.B.105. In the case of a DOA holder (self-)approving a major change under their privilege, the DOA holder will be notified of the applicable TC basis and EP requirements when the Agency is granting the privilege. <li data-bbox="584 1563 1447 1798">— The new Point (b)(2) contains the OSD text (as amended) of the current point 21.A.103 (a)(3) (note that point 21.A.103 is now completely covered by other points (21.A.20 and 21.A.97) and can, therefore, be deleted). A similar text is also added in point 21.B.107 as a condition for the Agency to issue a major change approval. <li data-bbox="584 1821 1447 1980">— The new point (b)(3) cross-refers to point 21.A.20, which shall be applied '<i>as applicable to <u>the change</u></i>'. This wording is to indicate that some requirements of point 21.A.20 may not be applicable, more specifically to DOA holders (self-)



Point	Type of change	Description
		<p>approving a major change under their privilege. For them, there is no application to the Agency, so there is no applicant per point 21.A.20(a). The certification programme is determined by the Agency and recorded in the terms of approval when granting the privilege. The certification program is based on the approved certification programme(s) from previous certification project(s) on the 'root' change approved with the involvement of the Agency.</p> <ul style="list-style-type: none"> — Point (c) contains the OSD text (as amended) of the current point 21.A.103(a)(4) (note that point 21.A.103 is now completely covered by other points (21.A.20 and 21.A.97) and can, therefore, be deleted). A similar text is also added in point 21.B.107 as a condition for the Agency to issue a major change approval.
21.A.101	amended	<ul style="list-style-type: none"> — Point 21.A.101 is now only applicable to <u>major</u> changes to a TC and STCs (the reference to point 21.A.101 in the current point 21.A.93(a)(2) (now (a)(1)(ii)) is removed). For minor changes refer to point 21.A.95. — The wording of point 21.A.101 is amended to remove all the compliance demonstration requirements for the applicant because they are now fully covered by point 21.A.20 (cross-referenced in point 21.A.97(b)(3)). — The purpose of this point, as amended, is to support the Agency in establishing the applicable TC and OSD certification bases and EP requirements. For applicants, it only provides visibility to the process of designation of the applicable specifications and requirements. — The wording of point 21.A.101 is amended to depart, for the airworthiness part, from the '<i>changed product</i>' to the '<i>change and areas affected by the change</i>'. The reason is that the <u>areas unaffected</u> by the change continue to be compliant with the existing TC basis and are not to be re-certified. Only the areas physically changed or functionally affected by the physical change are to be certified. The applicant for a major change cannot be made responsible for possible (theoretical) non-compliances in the unaffected areas. However, regarding environmental protection, the whole '<i>changed product</i>' must be considered when ensuring compliance with the noise and emission characteristics prescribed for the change.



Point	Type of change	Description
		— Point (c) is amended to correct a mistake. The requirements of point (c) are indeed in derogation from point (a).
21.A.103	deleted	The existing requirements of this point are now covered by other points (21.A.20, 21.A.95 and 21.A.97) and it can therefore be deleted.
21.A.111	amended	After replacement of the ' <i>major change to <u>type design</u></i> ' wording by the ' <i>major change to a <u>type-certificate</u></i> ' wording done in the OSD amendment (Regulation (EU) No 69/2014 ⁹), it is necessary to complement the point by a sentence making the requirements of Subpart E applicable to TCs also applicable to RTCs.
21.A.112B	amended	Point (c) is amended to remove the incorrect reference to point (b), to improve its wording and to add a cross reference to point 21.A.15(b) requiring a certification programme.
21.A.114	deleted	Point 21.A.114 is covered by the amended point 21.A.115(b).
21.A.115	amended	<ul style="list-style-type: none"> — The current text of point (a) is deleted because its requirements are now covered by the amended point (b) and the amended point 21.A.20 (which is cross-referred from (b)(4)). — The new text of point (a) reflects the fact that some STCs may now be issued by a DOA holder under their 21.A.263(c)(9) privilege and within its terms of approval. — The new point (b) is worded so as to be applicable not only to <u>the applicants</u> to the Agency for an STC but also to those <u>DOA holders</u> (self-)approving some STCs under their 21.A.263(c)(9) privilege without an application to the Agency. The point covers both cases. In the case of DOA holders self-approving under their 21.A.263(c)(9) privilege, points: <ul style="list-style-type: none"> 21.A.112A Eligibility, 21.A.112B Demonstration of capability, 21.A.113 Application, and 21.B.110 Issue of a supplemental type-certificate are not applicable. — The new point (b)(2) indicates that an applicant for an STC or a

⁹ 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
		<p>DOA holder self-approving an STC under their 21.A.263(c)(9) privilege must comply with the applicable TC basis and EP requirements <u>as established and notified by the Agency</u>. In the case of an applicant to the Agency, the applicant is notified i.a.w. point 21.B.105. In the case of a DOA holder (self-)approving under their privilege the DOA holder is notified of the applicable TC basis and EP requirements when the Agency is granting the privilege.</p> <ul style="list-style-type: none"> — The new points (b)(3) and (c) contain the OSD text (similar to the text of the amended points 21.A.97(b)(2) and (c) for major changes) omitted by mistake from the OSD amendment (Regulation (EU) No 69/2014). A similar text is also added in point 21.B.110 as a condition for the Agency to issue an STC. — The new point (b)(4) cross-refers to point 21.A.20, which shall be applied <i>'as applicable to <u>the</u> change'</i>. This wording is to indicate that some requirements of point 21.A.20 may not be applicable, more specifically to DOA holders (self-) approving STCs under their privilege. For them, there is no application, so there is no applicant per point 21.A.20(a). The certification programme is determined by the Agency and recorded in the terms of approval when granting the privilege. The certification program is based on the approved certification programme(s) from previous certification project(s) on the 'root' change, that was approved with the involvement of the Agency. The cross-reference in 21.A.115(b) to point 21.A.20 renders the requirements of point 21.A.33 (Inspections and tests) and of point 21.A.35 (Flight tests) applicable to STCs.
21.A.231	amended	<p>After replacement of the <i>'major change to <u>type design</u>'</i> wording by the <i>'major change to a <u>type-certificate</u>'</i> wording, done in the OSD amendment (Regulation (EU) No 69/2014), it is necessary to complement the point by a sentence making the requirements of Subpart J applicable to TCs also applicable to RTCs.</p>
21.A.258	amended	<ul style="list-style-type: none"> — Point (a) has been amended in order to indicate that findings from both the investigation of the DOA holder i.a.w point 21.A.257 and from the product compliance verification process i.a.w point 21.B.100 are within the scope of point 21.A.258. — The wording <i>'holder of design organisation approval'</i> is replaced by <i>'DOA holder'</i> to align with Subpart G (<i>holder of Production Organisation Approval = POA holder</i>) and the <i>'AMC and GM to</i>



Point	Type of change	Description
		Part-21' document.
21.A.263	amended	<ul style="list-style-type: none"> — The content of the current points (a) and (b) is deleted (but the points are kept as 'Reserved') because they become inapplicable with the introduction of the LOI concept. — Point (c) is amended to: <ul style="list-style-type: none"> • extend the privilege to classify and approve <u>minor changes to STCs</u> (omitted by mistake from the OSD amendment (Regulation (EU) No 69/2014); • extend the current privilege under (c)(5) to approve major repairs by the TC/STC holders to also cover other appropriately approved DOA holders who are not the TC/STC holders; • to add a new privilege under (c)(8) to allow TC/STC holders to approve certain 'equivalent' major changes to a type-certificate within the scope as established by the Agency. The scope is explained in the new AMC1 21.A.263(c)(8) and (9); and • to add a new privilege under (c)(9) to allow appropriately approved DOA holders (including the TC/STC holders) to issue certain 'equivalent' STCs within the scope as established by the Agency. The scope is explained in the new AMC1 21.A.263(c)(8) and (9).
21.A.265	amended	The scope of point (d) is extended to cover major repairs, major changes to a TC and STCs. DOA holders (self-) approving these items under their privilege do not need to submit to the Agency the required statements and documentation.
21.A.431A	amended	Point (a) is amended (editorial changes). Besides, point (f) is added to indicate that the requirements of Subpart M applicable to TCs are also applicable to RTCs.
21.A.432B	amended	<ul style="list-style-type: none"> — Point (a) contains editorial changes. — Point (c) is amended by deleting the incorrect reference to point (b). Some editorial changes are also introduced. Note that the 'certification program' wording is replaced by the 'certification plan' wording to avoid a misunderstanding. The 'certification program' i.a.w. point 21.A.15(b) is not applicable to repairs. Furthermore, note that point 21.A.20 is also not applicable to



Point	Type of change	Description
		repairs (Subpart M has self-contained requirements). In general, the approach to repairs is lighter compared to that for changes and STCs.
21.A.433	amended	<ul style="list-style-type: none"> — Point (a) is amended to extend its scope to appropriately approved design organisations classifying and (self-) approving repairs under their 21.A.263(c)(1), (2) and (5) privileges. — Point (a)(1) is amended to indicate that the Agency may designate and notify applicants of <u>amendments</u> to specifications/requirements incorporated by reference in the TC, RTC, STC or APU ETSO authorisation applicable to the repair.
21.A.435	amended	<ul style="list-style-type: none"> — The text of the current point (a) is amended by editorial changes only. — The text of the current point (b) on who can classify repairs is deleted from point 21.A.435 to be merged with the requirements of point 21.A.437 on who can approve them.
21.A.437	amended	<ul style="list-style-type: none"> — The scope of this point, as amended, is extended to indicate who can both classify and approve repairs. The issuance of approval of a repair design by the Agency is covered by point 21.B.115 in Section B. — The introductory sentence is amended by editorial changes. — Point (b) is amended to extend its scope to cover appropriately approved design organisations (self-) approving repairs under their 21.A.263(c)(1), (2) and (5) privileges. — Point (c) is covered by point (a) and can, therefore, be deleted.
21.A.604	amended	Cross-references are amended and editorial changes are made.
21.A.605	amended	<ul style="list-style-type: none"> — A new point (a)(1) is added to require applicants to submit a 'certification plan' for certification of an ETSOA article. — The current point (a) (re-numbered to (a)(2)) is amended to specify the required declarations in a Declaration of Design and Performance (DDP). — Point 21.A.605 is completed by the new point (b) to require applicants to report to the Agency any difficulty or event encountered during the approval process that may significantly impact the ETSO authorisation.



Point	Type of change	Description
21.A.606	amended	Point 21.606 is amended by editorial changes only
21.B.70	new	This point is based on the text of the current point 21.A.16A 'Airworthiness codes'. In addition to editorial changes, the scope of the point is extended to cover the issuance by the Agency of the ' <i>environmental</i> ' certification specifications for noise and emissions.
21.B.75	new	This point is based on the text of the current point 21.A.16B 'Special conditions'. In addition to editorial changes, it incorporates the term ' <i>newly identified hazards</i> ' to introduce an additional reason for prescribing a special condition.
21.B.80	new	<p>This point is based on the text of the current point 21.A.17A, as amended.</p> <ul style="list-style-type: none"> — The first sentence introduces a new requirement for the Agency to <u>establish and notify</u> the applicant of the applicable TC basis. — Point (a)(1)(i) introduces into the TC basis for <u>(normal) TCs</u> the possibility of deviations from the applicable certification specifications when mitigating features exist. The mitigating features may be identified e.g. in the operational conditions and limitations while ensuring compliance with the essential requirements for airworthiness Annex I to the Basic Regulation. — Point (a)(1)(ii) introduces into the TC basis for <u>RTCs</u> the possibility of deviation from the applicable certification specifications when mitigating features exist. The mitigating features may be identified e.g. in the operational conditions and limitations. The essential requirements of the Basic Regulation need not be met but at least an <u>adequate level of safety with regard to the intended use</u> must be ensured. — Point (c) introduces into the TC basis the possibility of using an alternative to a certification specification that provides an <u>equivalent level of safety</u> (to support use of the ESFs per EASA Management Board Decision 12-2007 'Products Certification Procedures'). — Points (b) and (c) of the current point 21.A.17 are kept in Section A (see new points 21.A.15(e) and (f)) because they are applicable to the applicants and their applications.
21.B.82	new	Point 21.B.82 is based on the current point 21.A.17B, as amended by adding the requirement for the Agency to <u>establish</u> the OSD basis and



Point	Type of change	Description
		by editorial changes, including changes to the structure of paragraphs.
21.B.85	new	Point 21.B.85 is based on the current point 21.A.18. Its scope has been extended to cover RTCs. In addition to the existing requirements: <ul style="list-style-type: none"> — point (a) introduces a requirement for the Agency to <u>establish and notify</u> the applicant for a TC or RTC for aircraft of the applicable noise requirements; — point (b) introduces a requirement for the Agency to <u>designate and notify</u> the applicant for a TC or RTC for aircraft, or a TC for an engine, of the applicable emission requirements; and — The content of point (c) has been transferred ,as amended, to point 21.B.70 to join the requirements for the issue of the certification specifications for airworthiness.
21.B.100	new	This point introduces the new LOI concept. It is explained in detail under Chapter 2.4.1 above.
21.B.103	new	This point contains the requirements and conditions for the Agency to issue a TC or an RTC.
21.B.70	deleted	The current point 21.B.70 is deleted. Its content is incorporated into point 21.B.107(c).
21.B.105	new	This point contains the requirements for the Agency to establish and notify applicants for a major change to a TC of the applicable TC basis, the OSD certification basis and the EP requirements. The technical conditions for establishing the applicable TC and OSD bases and the EP requirements are defined in point 21.A.101.
21.B.107	new	This point contains the requirements and conditions for the Agency to issue an approval of a minor or a major change to a TC.
21.B.109	new	This point contains the requirements for the Agency to establish and notify the applicable TC basis, EP requirements and OSD certification basis to the applicants for an STC. The technical conditions for establishing the applicable TC and OSD certification bases and the EP requirements are defined in point 21.A.101.
21.B.110	new	This point contains the requirements and conditions for the Agency to issue an STC.
21.B.113	new	This point contains the requirements and conditions for the Agency to



Point	Type of change	Description
		designate and notify the applicant for a repair design of any amendments to the TC basis and EP requirements incorporated by reference in the TC, RTC, STC or APU ETSO authorisation.
21.B.115	new	This point contains the requirements and conditions for the Agency to issue an approval of a major or minor repair design.
21.B.117	new	This point contains the requirements and conditions for the Agency to issue an ETSO authorisation.



Table B: List of new AMC/GM material

AMC/GM	Type of change	Description
AMC1 21.A.263(c)(8) and (9)	new	Contains acceptable means of compliance defining the scope and criteria for the new privileges of points 21.A.263(c)(8) and (9). Explains the term ' <i>equivalent change</i> '.
AMC 21.A.605	new	Defines the content of the ' <i>certification plan</i> ' for an ETSOA.
GM1 21.B.100	new	Provides guidance for interpretation of the term ' <i>compliance demonstration item</i> ' (CDI).
GM2 21.B.100(a)	new	Provides guidance for interpretation of the term ' <i>Depth of the investigation</i> '.
AMC 21.B.100(b)(3)	new	Contains AMC for the Agency to establish the DOA performance and experience measurement system.



3. Proposed amendments

The text of the amendment is arranged to show deleted text, new or amended text as shown below:

- (a) deleted text is marked with ~~strike through~~;
- (b) new or amended text is highlighted in grey;
- (c) an ellipsis (...) indicates that the remaining text is unchanged in front of or following the reflected amendment.

3.1. Draft Regulation (Draft EASA Opinion)

3.2. Part-21

SECTION A

TECHNICAL REQUIREMENTS

(...)

SUBPART B — TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATE

(...)

21.A.14 Demonstration of capability

- (a) Any organisation applying for a type-certificate or restricted type-certificate shall demonstrate its capability by holding a design organisation approval, issued by the Agency in accordance with Subpart J.
- (b) By way of derogation from point (a), as an alternative procedure to demonstrate its capability, an applicant may seek the agreement of the Agency for the use of procedures setting out the specific design practices, resources and sequence of activities necessary to comply with this Annex I (Part 21), when the product is one of the following:
 - 1. an ELA2 aircraft;
 - 2. an engine or propeller installed in ELA2 aircraft;
 - 3. a piston engine;
 - 4. a fixed or adjustable pitch propeller.
- (c) By way of derogation from point (a), an applicant may choose ~~for demonstration of capability~~ to demonstrate its capability by providing the Agency with the certification programme required by point ~~21.A.20(b)~~ 21.A.15(b) when the product is one of the following:
 - 1. an ELA1 aircraft;
 - 2. an engine or propeller installed in an ELA1 aircraft.

21.A.15 Application

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



(b) An application for an aircraft a type-certificate or restricted type-certificate shall be accompanied by three view drawing of that aircraft and preliminary basic data including the proposed operating characteristics and limitations include, or be supplemented after the initial application to include, a certification programme for compliance demonstrations in accordance with point 21.A.20, consisting of, as applicable:

1. a detailed description of the type design, including all of its configurations to be certified;
2. the proposed operating characteristics and limitations;
3. the intended use of the product and the kind of operations for which certification is requested;
4. a proposal for the initial type-certification basis, operational suitability data certification basis and environmental protection requirements;
5. the proposed means of compliance with references to related compliance documents;
6. an assessment of safety aspects related to points (1) to (5), in particular for any novel or unusual features;
7. a proposal for the Agency's level of involvement to support its decision to be made in accordance with point 21.B.100.

In all cases, the application shall always include, as a minimum, descriptive data of the product, the intended use of the product and the kind of operations for which certification is requested, as applicable.

(c) ~~An application for an engine or propeller type certificate shall be accompanied by a general arrangement drawing, a description of the design features, the operating characteristics, and the proposed operating limitations, of the engine, or propeller.~~ During the compliance demonstration process performed in accordance with point 21.A.20, the certification programme shall be kept updated, as necessary.

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

1. the minimum syllabus of pilot type rating training, including determination of type rating;
2. the definition of scope of the aircraft validation source data to support the objective qualification of simulator(s) associated to the pilot type rating training, or provisional data to support their interim qualification;
3. the minimum syllabus of maintenance certifying staff type rating training, including determination of type rating;
4. determination of type or variant for cabin crew and type specific data for cabin crew;
5. the master minimum equipment list; and
6. other type-related operational suitability elements.

(e) An application for a type-certificate or restricted type-certificate of a large aeroplane or a large rotorcraft shall be effective for five years and an application for any other type-certificate shall be



effective for three years, unless an applicant shows at the time of application that their product requires a longer period of time for design, development, and testing, and the Agency agrees to a longer period.

- (f) In the case where a type-certificate or restricted type-certificate has not been issued, or it is clear that it will not be issued, within the time limit established under point (e), the applicant may:
1. file a new application for a type-certificate or restricted type-certificate and comply with the type-certification basis, operational suitability data certification basis and environmental protection requirements, established and notified by the Agency in accordance with points 21.B.80, 21.B.82 and 21.B.85 to be applicable to the new application; or
 2. file for an extension of the original application and comply with the type-certification basis, operational suitability data certification basis and environmental protection requirements, established and notified by the Agency in accordance with points 21.B.80, 21.B.82 and 21.B.85 for an effective date to be selected by the applicant, but not earlier than the date which precedes the date of issue of the type-certificate or restricted type-certificate by the time limit established under point (e) for the original application.

~~21.A.16A — Airworthiness codes~~

~~21.A.16B — Special conditions~~

~~21.A.17A — Type certification basis~~

~~21.A.17B — Operational suitability data certification basis~~

~~21.A.18 — Designation of applicable environmental protection requirements and certification specifications¹⁰~~

(...)

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

- (a) The applicant for a type-certificate or a restricted type-certificate shall demonstrate, following the certification programme established under point 21.A.15(b), compliance with the applicable type-certification basis, the applicable operational suitability data certification basis and environmental protection requirements, as established and notified by the Agency in accordance with points 21.B.80, 21.B.82, 21.B.85, 21.B.105 or 21.B.109, as applicable, and shall provide the Agency with the means by which such compliance has been demonstrated.
- (b) The applicant shall provide the Agency with a certification programme detailing the means for compliance demonstration. This document shall be updated as necessary during the certification process report to the Agency any difficulty or event encountered during the compliance demonstration process that may have a significant effect on the certification programme or on the level of involvement (LOI) of the Agency, that is notified to the applicant in accordance with point 21.B.100(d).
- (c) The applicant shall record justifications of compliance within compliance documents according to the certification programme established under point 21.A.15(b).

¹⁰ These points are moved, as amended, to Section B under new designations: 21.B.70, 21.B.75, 21.B.80, 21.B.82 and 21.B.85.



- (d) After completion of all compliance demonstrations in accordance with the certification programme, including the inspections and tests in accordance with point 21.A.33 and, where applicable, point 21.A.35, the applicant shall declare that:
1. it has demonstrated compliance with the applicable type-certification basis, the operational suitability data certification basis and environmental protection requirements, according to the certification programme established under point (b); and
 2. no known feature or characteristic makes the product unsafe for the uses for which certification is requested.
- (e) Where the applicant holds an appropriate design organisation approval, the declaration of point (d) shall be made according to the provisions of Subpart J.

21.A.21 Requirements for issue of a type-certificate or restricted type-certificate

The applicant shall To be entitled to have obtain a product type-certificate or, when an aircraft does not meet the essential requirements of Annex I to Regulation (EC) No 216/2008, an aircraft restricted type-certificate issued by the Agency after, the applicant shall:

- (a) demonstrating demonstrate its capability in accordance with point 21.A.14;
- (b) submitting the declaration referred to in demonstrate compliance with point 21.A.20(d); and
- (c) it is shown that:
 1. the product to be certificated meets the applicable type certification basis and environmental protection requirements designated in accordance with points 21.A.17A and 21.A.18;
 2. any airworthiness provisions not complied with are compensated for by factors that provide an equivalent level of safety;
 3. no feature or characteristic makes it unsafe for the uses for which certification is requested; and
 4. the type certificate applicant has expressly stated that it is prepared to comply with point 21.A.44.
- (d) demonstrate that:
 1. in the case of an aircraft type-certificate, the engine or and propeller, or both, if installed in the aircraft, have a type-certificate issued or determined in accordance with this Regulation; or
 2. in the case of an aircraft restricted type-certificate, the engine and propeller, if installed in the aircraft,
 - (i) have a type-certificate issued or determined in accordance with this Regulation; or
 - (ii) have been shown to be in compliance with the certification specifications necessary to ensure the safe flight of the aircraft;
- (ed) In the case of an aircraft type-certificate or restricted type-certificate, it is demonstrated the applicant shall demonstrate that the operational suitability data meets the applicable operational suitability data certification basis designated established in accordance with 21.A.17B point 21.B.82.
- (fe) By derogation from point (ed), and at the request of the applicant included the applicant may request in the declaration referred to in point 21.A.20(d), that an the aircraft type-certificate may be is issued before the applicant has demonstrated compliance with the applicable operational suitability data



certification basis ~~has been demonstrated~~, subject to the applicant demonstrating compliance with the operational suitability data certification basis before the operational suitability data must actually be used.

~~21.A.23 Issue of a restricted type certificate~~¹¹

(...)

21.A.33 Inspections and tests

- (a) ~~The applicant shall perform all inspections and tests necessary to demonstrate compliance with the applicable type certification basis and environmental protection requirements.~~
- (ba) Before each test required by point (a) is undertaken during the compliance demonstrations required by point 21.A.20, the applicant it shall have be determined:
1. for the test specimen:
 - (i) that the materials and processes adequately conform to the specifications for the proposed type design;
 - (ii) that the parts of the products adequately conform to the drawings in the proposed type design;
 - (iii) that the manufacturing processes, construction and assembly adequately conform to those specified in the proposed type design; and
 2. that the test equipment and all the measuring equipment used for tests are adequate for the test and are appropriately calibrated.
- (cb) The applicant shall allow the Agency to make any inspection considered necessary to check compliance with point (ba).
- (dc) The applicant shall allow the Agency to:
1. review any report data related to design and compliance demonstration; and
 2. make any inspection and to perform or witness any test necessary to check the validity of the declaration of compliance submitted by the applicant under point 21.A.20(d) and to determine that no feature or characteristic makes the product unsafe for the uses for which certification is requested.
- (ed) For tests performed or witnessed by the Agency under point (dc):
1. the applicant shall submit to the Agency a statement of compliance with point (ba); and
 2. no change relating to the test that would affect the statement of compliance may be made to a product, part or appliance between the time compliance with point (ba) is shown and the time it is presented to the Agency for test.

(...)

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

¹¹ This point has been incorporated into 21.A.21 'Requirements for issue of a type-certificate or restricted type-certificate'.



(...)

21.A.91 Classification of changes to a type-certificate

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

(...)

21.A.93 Application

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

- (a) — 1. A description of the change identifying:
- 1.(i) all parts of the type design and the approved manuals affected by the change the configuration(s) of the type design upon which the change is made; and
 - 2.(ii) the certification specifications and environmental protection requirements with which the change has been designed to comply in accordance with 21.A.101 all areas of the type design and the approved manuals that are changed or affected by the change.
- (b) — 2. An identification of any re-investigations necessary to show demonstrate compliance of the changed product change and areas affected by the change with the applicable certification specifications and environmental protection requirements.
- (c) — 3. When the change affects the operational suitability data, the application shall include, or be supplemented after the initial application to include, any necessary changes to the operational suitability data.

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

1. file a new application for a change to the type-certificate and comply with the type-certification basis, operational suitability data certification basis and environmental protection requirements, established by the Agency in accordance with point 21.A.101 and notified in accordance with point 21.B.105 to be applicable to the new application for a change; or
2. file for an extension of the original application and comply with the type-certification basis, operational suitability data certification basis and environmental protection requirements, established by the Agency in accordance with point 21.A.101 and notified in accordance with point 21.B.105 for an effective date to be selected by the applicant, but not earlier than the date which precedes the selected date of approval by the time period established under this point for the original application.



21.A.95 Requirements for approval of a Mminor changes

- (a) Minor changes to a type-certificate shall be classified and approved either by:
- ~~(a)~~ 1. ~~by~~ the Agency; or
 - ~~(b)~~ 2. ~~by~~ an appropriately approved design organisation within its terms of approval and privileges of point 21.A.263(c)(1) and (2) under a procedure agreed with the Agency.
- (b) A minor change to a type-certificate shall only be approved when it has been demonstrated that the change and areas affected by the change comply with the type-certification basis, the operational suitability data certification basis and the environmental protection requirements incorporated by reference in the type-certificate, unless specifications of later effective amendments are elected by the applicant or required by the Agency.
- (c) By derogation from point (b), a minor change to an aircraft type-certificate may be approved before compliance with the applicable operational suitability data certification basis has been demonstrated, subject to demonstrating compliance before the operational suitability data must actually be used.
- (d) An approval of a minor change to a type-certificate is limited to that or those specific configuration(s) of the type design upon which the change is made.

21.A.97 Requirements for approval of a Mmajor changes

- ~~(a) — An applicant for approval of a major change shall:~~
- ~~1. — submit to the Agency substantiating data together with any necessary descriptive data for inclusion in the type design;~~
 - ~~2. — demonstrate that the changed product complies with applicable certification specifications and environmental protection requirements, as specified in point 21.A.101;~~
 - ~~3. — comply with points 21A.20 (b), (c) and (d); and~~
 - ~~4. — where the applicant holds an appropriate design organisation approval, make the declaration referred to in point 21A.20(d) according to the provisions of Subpart J;~~
 - ~~5. — comply with point 21.A.33 and, where applicable, point 21.A.35.~~
- (a) Major changes to a type-certificate shall be classified and approved either by:
1. the Agency; or
 2. an appropriately approved design organisation within its terms of approval and privileges of points 21.A.263(c)(1) and (8) under a procedure agreed with the Agency.
- (b) A major change to a type-certificate shall only be approved when:
1. it has been demonstrated that the change and areas affected by the change comply with the applicable type-certification basis and the environmental protection requirements established by the Agency in accordance with point 21.A.101;
 2. in the case of a change affecting the operational suitability data, it has been demonstrated that the necessary changes to the operational suitability data meet the applicable operational suitability data certification basis established in accordance with point 21.A.101(g); and



3. compliance with points (1) and (2) has been demonstrated in accordance with point 21.A.20, as applicable to the change.

(c) By derogation from points (b)(2) and (3), a major change to an aircraft type-certificate may be approved before compliance with the applicable operational suitability data certification basis has been demonstrated, subject to demonstrating compliance before the operational suitability data must actually be used.

(bd) An approval of a major change to a type-certificate is limited to that or those specific configuration(s) in the type-certificate upon which the change is made.

(...)

21.A.101 ~~Designation of applicable certification specifications~~ Type-certification basis, operational suitability data certification basis and environmental protection requirements for a major change to a type-certificate

(a) ~~An applicant for a change to a type-certificate shall demonstrate that the changed product complies the certification specifications that are~~ A major change to a type-certificate and areas affected by the change shall comply with the certification specifications that are applicable to the changed product and that are in effect at the date of the application for the change, unless compliance with certification specifications of later effective amendments is chosen~~selected~~ by the applicant or required under points (e) and (f),~~and with the applicable environmental protection requirements laid down in point 21.A.18.~~ The changed product shall comply with the applicable environmental protection requirements laid down in point 21.B.85.

(b) By derogation from point (a), ~~an applicant may show that the changed product~~ the change and areas affected by the change ~~complies~~ may comply with an earlier amendment of the certification specifications referred to in point (a), and of any other certification specification the Agency finds is directly related. However, the earlier amended certification specifications may not precede the corresponding certification specifications incorporated by reference in the type-certificate. ~~The applicant may show compliance with an~~ An earlier amendment of the certification specifications may be used for any of the following:

1. A change that the Agency finds not to be significant. In determining whether a specific change is significant, the Agency considers the change in context with all previous relevant design changes and all related revisions to the applicable certification specifications incorporated by reference in the type-certificate for the product. Changes that meet one of the following criteria are automatically considered significant:

- (i) the general configuration or the principles of construction are not retained;
- (ii) the assumptions used for certification of the product to be changed do not remain valid.

2. Each area, system, part or appliance that the Agency finds is not affected by the change.

3. Each area, system, part or appliance that is affected by the change, for which the Agency finds that compliance with the certification specifications referred to in point (a) would not contribute materially to the level of safety of the changed product or would be impractical.

(c) By derogation from point (a), ~~An applicant for a change to~~ in the case of a change to an aircraft (other than a rotorcraft) of 2 722 kg (6 000 lbs) or less maximum weight or to a non-turbine rotorcraft of 1 361



kg (3 000 lbs) or less maximum weight may show that the changed product complies, the change and areas affected by the change shall comply with the type-certification basis incorporated by reference in the type-certificate. However, if the Agency finds that the change is significant in an area, the Agency may designate compliance with an amendment to the type-certification basis incorporated by reference in the type-certificate in effect at the date of the application, and any certification specification that the Agency finds is directly related, unless the Agency also finds that compliance with that amendment or certification specification would not contribute materially to the level of safety of the changed product or would be impractical.

- (d) If the Agency finds that the certification specifications in effect at the date of the application for the change do not provide adequate standards with respect to the proposed change, the applicant change and areas affected by the change shall also comply with any special conditions, and amendments to those special conditions, prescribed under the provisions of point 21.A.16B 21.B.75, to provide a level of safety equivalent to that established in by the certification specifications in effect at the date of the application for the change.
- (e) ~~An application for a change to a type-certificate for large aeroplanes and large rotorcraft is effective for five years, and an application for a change to any other type-certificate is effective for three years. In a case where the change has not been approved, or it is clear that it will not be approved under the time limit established under this point, the applicant may:~~
1. ~~file a new application for a change to the type-certificate and comply with all the provisions of point (a) applicable to an original application for a change; or~~
 2. ~~file for an extension of the original application and comply with the provisions of point (a) for an effective date of application, to be selected by the applicant, not earlier than the date which precedes the date of approval of the change by the time period established under this point for the original application for the change.~~
- (fe) If an applicant chooses elects to comply with a certification specification of an amendment to the designated certification specifications that is becomes effective after the filing of the application for a change to a type-certificate, the applicant change and areas affected by the change shall also comply with any other certification specification that the Agency finds is directly related.
- (gf) When the application for a change to a type-certificate for an aircraft includes, or is supplemented after the initial application to include, changes to the operational suitability data, the operational suitability data certification basis shall be designated in accordance with points (a), (b), (c), (d) and (fe) above.

21.A.103 Issue of approval

(...)

SUBPART E — SUPPLEMENTAL TYPE-CERTIFICATES

(...)

21.A.111 Scope

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



holders of, those certificates. In this Subpart, the references to type-certificates include type-certificates and restricted type-certificates.

(...)

21.A.112B Demonstration of capability

- (a) Any organisation applying for a supplemental type-certificate shall demonstrate its capability by holding a design organisation approval, issued by the Agency in accordance with Subpart J.
- (b) By way of derogation from point (a), as an alternative procedure to demonstrate its capability, an applicant may seek Agency agreement for the use of procedures setting out the specific design practices, resources and sequence of activities necessary to comply with this Subpart.
- (c) By way of derogation from points (a) and (b), in the case of products defined in point 21.A.14(c), an applicant may choose to demonstrate for demonstration of its capability through Agency approval of a certification programme detailing the means for compliance demonstration on an aircraft, engine and propeller defined in point 21.A.14(c) established in accordance with point 21.A.15(b).

(...)

~~21.A.114 Showing of compliance~~

21.A.115 Requirements for issue of a supplemental type-certificate

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

- ~~(a) submitting the declaration referred to in point 21A.20(d); and~~
- ~~(b) it is demonstrated that:
 - 1. the changed product meets the applicable certification specifications and environmental protection requirements, as specified in point 21A.101;
 - 2. any airworthiness provisions not complied with are compensated for by factors that provide an equivalent level of safety; and
 - 3. no feature or characteristic makes the product unsafe for the uses for which certification is requested.~~
- ~~(c) demonstrating its capability in accordance with point 21.A.112B;~~

(a) Supplemental type-certificates shall be issued either by:

- 1. the Agency; or
- 2. an appropriately approved design organisation within its terms of approval and privileges of points 21.A.263(c)(1) and (9) under a procedure agreed with the Agency.

(b) A supplemental type-certificate shall only be issued when:

- 1. the applicant has demonstrated its capability in accordance with point 21.A.112B;
- 2. it has been demonstrated that the change to a type-certificate and areas affected by the change comply with the applicable type-certification basis and the environmental protection requirements established by the Agency in accordance with point 21.A.101;



3. in the case of a supplemental type-certificate affecting the operational suitability data, it has been demonstrated that the necessary changes to the operational suitability data meet the applicable operational suitability data certification basis established by the Agency in accordance with point 21.A.101(g);
4. compliance with points (b)(2) and (3) has been demonstrated in accordance with point 21.A.20, as applicable to the change; and

- (d) 5. where, under point 21.A.113(b), the applicant has entered into an arrangement with the type-certificate holder,
1. (i) the type-certificate holder has advised that it has no technical objection to the information submitted under point 21.A.93; and
 2. (ii) the type-certificate holder has agreed to collaborate with the supplemental type-certificate holder to ensure discharge of all obligations for continued airworthiness of the changed product through compliance with points 21.A.44 and 21.A.118A.

(c) By derogation from points (b)(3) and (4), a supplemental type-certificate for an aircraft may be issued before compliance with the applicable operational suitability data certification basis has been demonstrated, subject to demonstrating compliance before the operational suitability data must actually be used.

(d) A supplemental type-certificate is limited to that or those specific configuration(s) in the type-certificate upon which the related major change is made.

(...)

SUBPART J — DESIGN ORGANISATION APPROVAL

(...)

21.A.231 Scope

This Subpart establishes the procedure for the approval of design organisations and rules governing the rights and obligations of applicants for, and holders of, such approvals. In this Subpart, the references to type-certificates include type-certificates and restricted type-certificates.

21.A.258 Findings

- (a) When, during the investigations referred to in points 21.A.257 and 21.B.100, objective evidence is found showing non-compliance of the holder of a design organisation approval (DOA holder) with the applicable requirements of this Annex I (Part 21), the finding shall be classified as follows:
1. a level one finding is any non-compliance with this Annex I (Part 21) which that could lead to uncontrolled non-compliances with applicable requirements and which could affect the safety of the aircraft;
 2. a level two finding is any non-compliance with this Annex I (Part 21) which that is not classified as level one.
- (b) A level three finding is any item where it has been identified, by objective evidence, to contain potential problems that could lead to a non-compliance under point (a).



- (c) After receipt of notification of findings under the applicable administrative procedures established by the Agency,
1. in the case of a level one finding, the DOA holder of the design organisation approval shall demonstrate corrective action to the satisfaction of the Agency within a period of no more than 21 working days after written confirmation of the finding;
 2. in the case of level two findings, the corrective action period granted by the Agency shall be appropriate to the nature of the finding but in any case initially shall not be more than three months. In certain circumstances and subject to the nature of the finding the Agency may extend the three months period subject to the provision of a satisfactory corrective action plan agreed by the Agency;
 3. a level three finding shall not require immediate action by the DOA holder of the design organisation approval.
- (d) In cases of level one or level two findings, the design organisation approval may be subject to a partial or full suspension or revocation under the applicable administrative procedures established by the Agency. The DOA holder of the design organisation approval shall provide confirmation of receipt of the notice of suspension or revocation of the design organisation approval in a timely manner.

21.A.263 Privileges

- (a) ~~Reserved.~~ The holder of a design organisation approval shall be entitled to perform design activities under this Annex I (Part 21) and within its scope of approval.
- (b) ~~Reserved.~~ Subject to point 21.A.257(b), the Agency shall accept without further verification the following compliance documents submitted by the applicant for the purpose of obtaining:
1. ~~the approval of flight conditions required for a permit to fly; or~~
 2. ~~a type certificate or approval of a major change to a type certificate; or~~
 3. ~~a supplemental type certificate; or~~
 4. ~~an ETSO authorisation under point 21.A.602B(b)(1); or~~
 5. ~~a major repair design approval.~~
- (c) The A DOA holder of a design organisation approval shall be entitled, within its terms of approval as established by the Agency and under the relevant procedures of the design assurance system:
1. to classify changes to the a type-certificate or to a supplemental type-certificate and or repairs as 'major' or 'minor';
 2. to approve minor changes to a type-certificate or to a supplemental type-certificate and or minor repairs;
 3. to issue information or instructions containing the following statement: 'The technical content of this document is approved under the authority of DOA ref. EASA. 21J. [XXXX].';
 4. ~~reserved to approve minor revisions to the aircraft flight manual and supplements, and issue such revisions containing the following statement: 'Revision No [YY] to AFM (or supplement) ref. [ZZ] is approved under the authority of DOA ref. EASA. 21J. [XXXX].';~~



5. to approve the design of major repairs under Subpart M to products or Auxiliary Power Units for which it holds the type certificate or the supplemental type certificate or ETSO authorisation;
6. to approve the conditions under which a permit to fly can be issued in accordance with point 21.A.710(a)(2), except for permits to fly to be issued for the purpose of point 21.A.701(a)(15);
7. to issue a permit to fly in accordance with point 21.A.710(b) for an aircraft it has designed or modified, or for which it has approved under point 21.A.263(b)(6) the conditions under which the permit to fly can be issued, and when the design organisation itself is controlling controls under its Design Organisation Approval the configuration of the aircraft and is attesting attests conformity with the design conditions approved for the flight;
8. to approve major changes to a type-certificate under Subpart D within the scope as established by the Agency; and
9. to issue supplemental type-certificates under Subpart E for major changes to a type-certificate within the scope as established by the Agency.

21.A.265 Obligations of the holder

The holder of a design organisation approval shall:

- (a) maintain the handbook in conformity with the design assurance system;
- (b) ensure that this handbook is used as a basic working document within the organisation;
- (c) determine that the design of products, or changes or repairs thereof, as applicable, comply with the applicable requirements and have no unsafe features;
- (d) provide the Agency with statements and associated documentation confirming compliance with point (c), except for minor changes or repairs approved under the privilege of point 21.A.263(c)(2), major repairs approved under the privilege of (c)(5), major changes to a type-certificate approved under the privilege of (c)(8) or supplemental type-certificates issued under the privilege of (c)(9), provide to the Agency statements and associated documentation confirming compliance with point (c);
- (e) provide to the Agency information or instructions related to required the actions required under point 21.A.3B;
- (f) where applicable, under the privilege of point 21.A.263(c)(6), determine the conditions under which a permit to fly can be issued;
- (g) where applicable, under the privilege of point 21.A.263(c)(7), establish compliance with points 21.A.711(b) and (e) before issuing a permit to fly to an aircraft.

(...)

SUBPART M — REPAIRS

(...)

21.A.431A Scope



- (a) This Subpart establishes the procedure for the approval of a repair design of a product, part or appliance, and establishes the rights and obligations of the applicants for, and holders of, those approvals.
 - (b) This Subpart defines standard repairs that are not subject to an approval process under this Subpart.
 - (c) A 'repair' means the elimination of damage and/or restoration to an airworthy condition following the initial release into service by the manufacturer of any product, part or appliance.
 - (d) The elimination of damage by replacement of parts or appliances without the necessity for design activity shall be considered as a maintenance task and shall therefore require no approval under this Annex I (Part 21).
 - (e) A repair to an ETSO article other than an Auxiliary Power Unit (APU) shall be treated as a change to the ETSO design and shall be processed in accordance with point 21.A.611.
 - (f) In this Subpart, the references to type-certificates include type-certificates and restricted type-certificates.
- (...)

21.A.432B Demonstration of capability

- (a) An applicant for approval of a major repair design approval shall demonstrate its capability by holding a design organisation approval, issued by the Agency in accordance with Subpart J.
- (b) By way of derogation from point (a), as an alternative procedure to demonstrate its capability, an applicant may seek Agency agreement for the use of procedures setting out the specific design practices, resources and sequence of activities necessary to comply with this Subpart.
- (c) By way of derogation from point (a) and (b), in the case of products defined in point 21.A.14(c), an applicant may seek the agreement of the Agency for the approval of a certification programme setting out the specific design practices, resources and sequence of activities necessary to comply with this Annex I (Part 21) for a repair on a product defined in point 21.A.14(c) choose to demonstrate its capability through the submission of a certification plan describing the means and process followed to establish compliance with the applicable type-certification basis of a major repair design.

21.A.433 Requirements for approval of a Repair design

- (a) The An applicant for approval of a repair design, or an appropriately approved design organisation using its privilege to classify and approve repairs under point 21.A.263(c)(1)(2) and (5), shall:
 1. demonstrate compliance with the type-certification basis and environmental protection requirements incorporated by reference in the type-certificate or supplemental type-certificate or APU ETSO authorisation, as applicable or those in effect on the date of application (for repair design approval), plus any of its amendments to those certification specifications or special conditions the Agency finds necessary to establish a level of safety equal to that established by the type-certification basis incorporated by reference in the type-certificate, supplemental type-certificate or APU ETSO authorisation established and notified, when applicable, by the Agency in accordance with point 21.B.113;



2. submit, for a major repair, a certification plan describing the means and process followed to demonstrate compliance with point (a)(1), and submit all necessary substantiation data, when requested by the Agency;
 3. declare compliance with the ~~certification specifications~~ applicable type-certification basis and environmental protection requirements of point (a)(1).
- (b) Where the applicant is not the type-certificate or supplemental type-certificate or APU ETSO authorisation holder, as applicable, the applicant may comply with the requirements of point (a) through the use of its own resources or through an arrangement with the type-certificate or supplemental type-certificate or APU ETSO authorisation holder as applicable.

21.A.435 Classification of repairs

- (a) A repair may be 'major' or 'minor'. The major/minor classification shall be made in accordance with the criteria of point 21.A.91 for a change in to the type-certificate.
- (b) A repair shall be classified 'major' or 'minor' under point (a) either:
1. by the Agency; or
 2. by an appropriately approved design organisation under a procedure agreed with the Agency.

21.A.437 Issue Approval of a repair design

~~When it has been declared and has been shown that the repair design meets the applicable certification specifications and environmental protection requirements of point 21.A.433(a)(1), it~~ A repair design shall be classified and approved by:

- (a) the Agency; or
 - (b) an appropriately approved design organisation ~~that is also the type-certificate, the supplemental type-certificate or APU ETSO authorisation holder,~~ within its terms of approval and privileges of point 21.A.263(c)(1)(2) and (5) under a procedure agreed with the Agency; ~~or~~
 - (c) ~~for minor repairs only, by an appropriately approved design organisation under a procedure agreed with the Agency.~~
- (...)

SUBPART O — EUROPEAN TECHNICAL STANDARD ORDER AUTHORISATIONS

(...)

21.A.604 ETSO Authorisation for an Auxiliary Power Unit (APU)

With regard to ETSO authorisation for an Auxiliary Power Unit:

- (a) ~~Points 21.A.15, 21.A.16B, 21.B.75, 21.A.17A, 21.A.17B, 21.B.80, 21.B.82,~~ 21.A.20, 21.A.21, 21.A.31, 21.A.33, 21.A.44 shall apply by way of derogation from points 21.A.603, 21.A.606(c), 21.A.610 and 21.A.615, except that an ETSO Authorisation shall be issued in accordance with point 21.A.606 instead of the type-certificate.



- (b) Subpart D or Subpart E is applicable for the approval of design changes by way of derogation from point 21.A.611. When Subpart E is used, a separate ETSO authorisation shall be issued instead of a supplemental type-certificate.
- (c) Subpart M is applicable to the approval of repair designs.

21.A.605 Data requirements

- (a) The applicant shall submit the following documents, to the Agency:
 1. a certification plan for the ETSO authorisation, defining the means to demonstrate compliance with point 21.A.606(b);
 - ~~(a.2.) a statement of compliance certifying that the applicant has met the requirements of this Subpart~~ a Declaration of Design and Performance (DDP) declaring that:
 - (i) the article has been designed in compliance with the requirements of this Subpart;
 - (ii) the applicant has demonstrated that the article complies with the applicable CS-ETSO in accordance with the certification plan; and
 - (iii) no known characteristic makes the article unsafe for the uses for which certification is requested;
- ~~(b) a Declaration of Design and Performance (DDP);~~
 - (e3) one copy of the technical data required in the applicable ETSO;
 - ~~(d4)~~ the exposition (or a reference to the exposition) referred to in point 21.A.143 for the purpose of obtaining an appropriate production organisation approval under Subpart G or the manual (or a reference to the manual) referred to in point 21.A.125A(b) for the purpose of manufacturing under Subpart F without production organisation approval;
 - (e5) for an APU, the handbook (or a reference to the handbook) referred to in point 21.A.243 for the purpose of obtaining an appropriate design organisation approval under Subpart J; and
 - (f6) for all other articles, the procedures referred to in point 21.A.602B(b)(2), (or a reference to these procedures).
- (b) The applicant shall report to the Agency any difficulty or event encountered during the approval process that may significantly impact the ETSO authorisation.
- (...)

21.A.606 Requirements for issue of an ETSO authorisation

~~The applicant shall~~ To be entitled to have obtain an ETSO authorisation issued by the Agency, after the applicant shall:

- (a) ~~demonstrating~~ demonstrate its capability in accordance with point 21.A.602B; and
- (b) ~~demonstrating~~ demonstrate that the article complies with the technical conditions of the applicable ETSO; and
- (c) ~~expressly stating that it is prepared to comply with point 21.A.609~~ submit the corresponding statement of compliance.



SECTION B**PROCEDURES FOR COMPETENT AUTHORITIES**

(...)

SUBPART B — TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES

~~Administrative procedures established by the Agency shall apply.~~

21.B.70 Certification specifications

The Agency shall issue certification specifications in accordance with Article 19 of Regulation (EC) No 216/2008, including certification specifications for operational suitability data and environmental protection, as the standard means to demonstrate compliance of products, parts and appliances with the relevant essential requirements of Annexes I, III and IV to Regulation (EC) No 216/2008 and the essential requirements for environmental protection of Article 6 of that Regulation. Such specifications shall be sufficiently detailed and specific to indicate to applicants the conditions under which certificates will be issued, amended or supplemented.

(...)

21.B.75 Special conditions

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

1. the product has novel or unusual design features relative to the design practices on which the applicable certification specifications are based; or
2. the intended use of the product is unconventional; or
3. experience from other similar products in service or products having similar design features, or newly identified hazards, have shown that unsafe conditions may develop.

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

(...)

21.B.80 Type-certification basis for a type-certificate or restricted type-certificate

The Agency shall establish and notify the applicant for a type-certificate or restricted type-certificate of the applicable type-certification basis, which shall consist of:

(a) the applicable certification specifications designated by the Agency that are effective on the date of application for that certificate, unless:

1. otherwise specified by the Agency, when it finds that compliance with specific certification specifications is not appropriate considering the intended use of the product; and
 - (i) in the case of a type-certificate, there are mitigating features that provide a level of safety as defined in the essential requirements of Annex I to Regulation (EC) No 216/2008; or
 - (ii) in the case of a restricted type-certificate, there are mitigating features that provide a level of safety adequate with regard to the intended use; or



2. compliance with certification specifications of later effective amendments is elected by the applicant or is required under point 21.A.15 (f).

If an applicant elects to comply with a certification specification of an amendment to the designated certification specifications that is effective after the filing of the application for a type-certificate or restricted type-certificate, the Agency shall include in the type-certification basis any other certification specification that it finds is directly related;

- (b) any special condition prescribed in accordance with point 21.B.75(a); and
- (c) any alternative to a certification specification under (a)(1) that provides an equivalent level of safety.

(...)

21.B.82 Operational suitability data certification basis for an aircraft type-certificate or restricted type-certificate

The Agency shall establish and notify the applicant for an aircraft type-certificate or restricted type-certificate of the operational suitability data certification basis. It shall consist of:

- (a) the applicable certification specifications for operational suitability data issued in accordance with point 21.B.70 that are effective on the date of application or application supplement, unless:
 1. the Agency accepts other means to demonstrate compliance with the relevant essential requirements of Annexes I, III and IV to Regulation (EC) No 216/2008; or
 2. compliance with certification specifications of later effective amendments is elected by the applicant.

If an applicant elects to comply with a certification specification of an amendment to the designated certification specifications that becomes effective after the filing of the application for a type-certificate or a restricted type-certificate, the Agency shall include in the type-certification basis any other certification specification that it finds is directly related; and

- (b) any special condition prescribed in accordance with point 21.B.75(a).

(...)

21.B.85 Designation of applicable environmental protection requirements and certification specifications for a type-certificate and restricted type-certificate

- (a) The Agency shall designate and notify the applicant for a type-certificate or restricted type-certificate for an aircraft of the applicable noise requirements according to the provisions of Chapter 1, Part II, Volume I of Annex 16, to the Chicago Convention and:
 1. for subsonic jet aeroplanes, in Chapters 2, 3 and 4, Part II, Volume I, as applicable;
 2. for propeller-driven aeroplanes, in Chapters 3, 4, 5, 6 and 10, Part II, Volume I, as applicable;
 3. for helicopters, in Chapters 8 and 11, Part II, Volume I, as applicable; and
 4. for supersonic aeroplanes, in Chapter 12, Part II, Volume I, as applicable.

- (b) The Agency shall designate and notify to the applicant for a type-certificate or restricted type-certificate for an aircraft, or a type-certificate for an engine, the applicable emission requirements according to the provisions of Annex 16 to the Chicago Convention:
 1. for prevention of intentional fuel venting, in Chapter 2, Part II, Volume II;

1. for prevention of intentional fuel venting, in Chapter 2, Part II, Volume II;



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

(c) The certification specifications for environmental protection issued in accordance with point 21.A.70 provide for acceptable means to demonstrate compliance with the noise and emission requirements laid down in points (a) and (b) respectively.

(...)

21.B.100 Level of Involvement

(a) The level of involvement of the Agency in a certification project is the selection of the compliance demonstration items that the Agency will investigate and the depth of those investigations.

(b) The Agency shall establish its level of involvement at the level of compliance demonstration items, or groups thereof, following a safety and environmental risk assessment, taking into account but not limited to:

1. the novel or unusual features of the certification project, including operational, organisational and knowledge management aspects;
2. the criticality of the design or technology and the related safety and environmental risks, including those identified on similar designs; and
3. the performance and experience of the design organisation of the applicant in the domain concerned.

(c) By derogation from point (b), for a major repair design or an ETSO authorisation, the Agency shall establish its level of involvement based on an assessment of the safety risk associated with the characteristics of the repair or the ETSO article design and/or compliance demonstration, as well as on the performance of the design organisation of the applicant.

(d) The Agency shall notify the applicant of the Agency's level of involvement. The Agency shall update its level of involvement when this is warranted by changes in the certification programme or in the safety or environmental risk assessed under (b) or (c) and notify the applicant accordingly.

(...)

21.B.103 Issue of a type-certificate or restricted type-certificate

(a) The Agency shall issue a type-certificate to an aircraft, engine or propeller, or a restricted type-certificate to an aircraft, provided that :

1. the applicant has complied with point 21.A.21; and
2. the Agency, through its investigations in accordance with point 21.B.100, has not found any non-compliance with the applicable type-certification basis, the operational suitability data certification basis and the environmental protection requirements.

(b) By derogation from points (a) and (b), and at the request of the applicant included in the declaration referred to in point 21.A.20(d), an aircraft type-certificate may be issued before compliance with the applicable operational suitability data certification basis has been demonstrated, subject to the



applicant demonstrating compliance with the operational suitability data certification basis before the operational suitability data must actually be used.

(...)

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

~~Administrative procedures established by the Agency shall apply.~~

~~21.B.70 — Approval of changes to type certificates~~

~~The approval of the changes to the operational suitability data is included in the approval of the change to the type certificate. However, the Agency shall use a separate classification and approval process for administering changes to operational suitability data.~~

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

21.B.105 Type-certification basis, environmental protection requirements and operational suitability data certification basis for a major change to a type-certificate

The Agency shall establish and notify the applicant for a major change to a type-certificate of the applicable type-certification basis and environmental protection requirements designated in accordance with point 21.A.101 and, in the case of a change affecting the operational suitability data, the operational suitability data certification basis designated in accordance with point 21.A.101(g).

21.B.107 Issue of an approval of a change to a type-certificate

(a) The Agency shall issue an approval of a change to a type-certificate provided that:

1. the applicant for a minor change has complied with point 21.A.95; or
2. the applicant for a major change has complied with point 21.A.97; and
3. the Agency, through its investigations in accordance with point 21.B.100, has not found any non-compliance with the applicable type-certification basis, the operational suitability data certification basis and the environmental protection requirements.

(b) In the case of a major change affecting the operational suitability data, by derogation from point (a)(2) and (3), and at the request of the applicant included in the declaration referred to in point 21.A.20(d), a major change to an aircraft type-certificate may be approved before compliance with the applicable operational suitability data certification basis has been demonstrated, subject to the applicant demonstrating compliance before the operational suitability data must actually be used.

(c) The approval of the changes to the operational suitability data is included in the approval of the change to the type-certificate. However, the Agency shall use a separate classification and approval process for administering changes to operational suitability data.

(d) The approval of a change to a type-certificate is limited to that or those specific configuration(s) in the type-certificate upon which the related change is made.

SUBPART E — SUPPLEMENTAL TYPE-CERTIFICATES



~~Administrative procedures established by the Agency shall apply.~~

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

21.B.109 Type-certification basis, environmental protection requirements and operational suitability data certification basis for a supplemental type-certificate

The Agency shall establish and notify the applicant for a supplemental type-certificate of the applicable type-certification basis and the environmental protection requirements designated in accordance with point 21.A.101 and, in the case of a change affecting the operational suitability data, the operational suitability data certification basis designated in accordance with point 21.A.101(g).

21.B.110 Issue of a supplemental type-certificate

(a) The Agency shall issue a supplemental type-certificate provided that:

1. the applicant has complied with point 21.A.115(b); and
2. the Agency, through its investigations in accordance with point 21.B.100, has not found any non-compliance with the applicable type-certification basis, the operational suitability data basis and the environmental protection requirements.

(b) In the case of a supplemental type-certificate affecting the operational suitability data, by derogation from point (a)(1) and (2), and at the request of the applicant included in the declaration referred to in point 21.A.20(d), a supplemental type-certificate may be issued before compliance with the applicable operational suitability data certification basis has been demonstrated, subject to the applicant demonstrating compliance with the operational suitability data certification basis before the operational suitability data must actually be used.

(c) The approval of the changes to the operational suitability data is included in the supplemental type-certificate. However, the Agency shall use a separate classification and approval process for administering changes to operational suitability data.

(d) The supplemental type-certificate is limited to that or those specific configuration(s) in the type-certificate upon which the related major change is made.

SUBPART M — REPAIRS

~~Administrative procedures established by the Agency shall apply.~~

21.B.113 Type-certification basis for a major repair design approval

The Agency shall designate and notify the applicant for a major repair design of any amendments to the type-certification basis or to the environmental protection requirements incorporated by reference in the type-certificate or supplemental type-certificate or APU ETSO authorisation, as applicable, that the Agency finds necessary to maintain a level of safety equal to that previously established.

21.B.115 Issue of a repair design approval

(a) The Agency shall issue approval of a major repair design provided that:

1. the applicant has demonstrated its capability in accordance with point 21.A.432B;
2. the applicant has complied with point 21.A.433; and



3. the Agency, through its investigations in accordance with point 21.B.100, has not found any non-compliance with the applicable type-certification basis and environmental protection requirements.

(b) The Agency shall issue an approval of minor repair design provided that the applicant has complied with points (a)(2) and (3) above.

SUBPART O — EUROPEAN TECHNICAL STANDARD ORDER AUTHORISATIONS

~~Administrative procedures established by the Agency shall apply.~~

21.B.117 Issue of an ETSO authorisation

The Agency shall issue an ETSO authorisation provided that :

- (a) the applicant has complied with point 21.A.606; and
- (b) the Agency, through its investigations in accordance with point 21.B.100, has not found any non-compliance with the technical conditions of the applicable ETSO or deviations approved in accordance with point 21.A.610, if any.



3.3. Draft Acceptable Means of Compliance and Guidance Material (AMC and GM to Part-21) (Draft EASA Decision)

SECTION A

(...)

Subpart J — Design organisation approval

(...)

AMC1 21.A.263(c)(8) and (9) Scope and Criteria

The scope of privileges under points 21.A.263(c)(8) and (9) granted to a DOA holder will be limited to subsequent repetitive changes that are 'equivalent' to a previous major change or supplemental type-certificate approved by the Agency to the DOA holder. The previous change or supplemental type-certificate was approved to the DOA holder in one or more certification projects with the involvement of the Agency, while the DOA holder demonstrated to the satisfaction of the Agency its capability to approve 'equivalent' changes in the future, without any involvement of the Agency.

Definition and criteria for an 'Equivalent Change':

An 'Equivalent Change' is a change that is qualitatively similar to a change already approved by the Agency in terms of design, technology, requirements, justifications and operational features, considering both:

- the change itself, and
- the product to which the change is applied.

In particular, with respect to the previous changes already approved by the Agency:

- the technical domain of the change is the same, e.g. a cabin interior change, avionics change etc.;
- the technologies of the change and of the underlying product are the same, e.g. a glass cockpit, integrated modular avionics, metallic structure, composite structure etc.;
- the certification and operational requirements applicable to the new change are equivalent or less stringent;
- the specific design and operational aspects of the change and of the product upon which it is intended to be applied do not require a different type of justifications;
- the change is classified as not significant according to point 21.A.101(b)(1);
- the change does not require a change to the existing type-certification basis;
- the change does not affect the noise and/or emissions characteristics of the changed product;
- the means of compliance that will be used for the new change are the same or are already agreed as equivalent to the ones previously accepted; and
- the Guidance Material (GM) and the interpretative material that will be used for the new change are the same.

(...)

Subpart O — European Technical Standard Order

(...)



AMC 21.A.605 Certification plan

- (a) For the purpose of the compliance demonstration in accordance with point 21.A.606(b), the applicant should:
- (1) establish a certification plan;
 - (2) submit the plan to the Agency; and
 - (3) keep the plan updated during the approval process.
- (b) The certification plan should contain the following information:
- (1) a detailed description of the article, including all of its configurations to be certified, identification of non-ETSO functions and safety means (if applicable);
 - (2) the operating characteristics and limitations or deviations from ETSO requirements;
 - (3) the intended use of the article and kind of operations for which the approval is requested;
 - (4) the applicable CS-ETSO requirements and optional aspects (DO-160 version, demonstration of compliance to certification memoranda);
 - (5) the proposed means of compliance including the list of documents and deliverables to the Agency;
 - (6) an assessment of the safety aspects related to points (1) to (5) and the main failure conditions, in particular for any novel or unusual features;
 - (7) how the applicant will record its justifications of compliance; and
 - (8) a project schedule, including major milestones.



SECTION B

Subpart A — General provisions

GM1 21.B.100(a) Compliance Demonstration Item (CDI)

A compliance demonstration item (CDI) is a meaningful group of compliance demonstration activities taken from the certification programme that can be considered in isolation for the purpose of demonstrating compliance with a group of specifications, a certain specification, or even a part of a specification. A CDI may comprise compliance statements, design reviews, calculations, analyses, safety assessments, laboratory, ground or flight tests, simulations, inspections or equipment qualifications.

A CDI should be the largest element of the certification programme that can practically be assessed in isolation. On simple projects, a CDI may be as global as a discipline, e.g. avionics, flight, structure, hydromechanical system etc.

A CDI defines the level of granularity at which the Agency will establish its level of involvement.

To that purpose, to assist the Agency in the determination of its level of involvement, applicants are invited to break down their certification programme into CDIs and to identify within a discipline:

- novel CDIs, where the technology or the certification specifications, or their interpretation or the means of compliance present a novelty with respect to the applicant's experience; and
- critical CDIs, as defined e.g. by the classification in CS 25.1309.

GM2 21.B.100(a) Depth of the investigation

The depth of the investigation is the extent and level of detail of the verification activities that the Agency plans to perform in order to investigate the item. These activities may include:

- a review of the applicant's compliance statements;
- a review of design and compliance documents, engineering evaluation and acceptance of the applicant's compliance documents (type design definition documents, calculations/analyses, safety assessments, manuals, test plans (laboratory/ground/flight) and test reports, inspection reports/records etc.);
- a review and engineering evaluation of the applicant's conformity documents, including an evaluation of non-conformances of test articles/specimens;
- participating in reviews, inspections of products, auditing processes and procedures;
- witnessing or participating in the applicant's tests or inspections; and
- performing the Agency's own inspections/tests, including flight tests.

AMC 21.B.100(b)(3) DOA performance and experience measurement system

The Agency will establish a DOA performance and experience measurement system. This system should contain a set of indicators that captures the maturity of the DOA holder's organisation and their performance. The indicators may include the level of activity of the organisation, the scope and management of subcontractors, feedback from the current and previous projects, and feedback from DOA holder surveillance. The performance and experience measurements should be subject to trend analysis.



4. Regulatory Impact Assessment (RIA)

NOTE: This RIA is a qualitative 'light' RIA, as indicated in the process map of the related ToR. Safety and economic data are not available at this stage to make a quantitative assessment. In addition, the actual impacts of the LOI concept implementation will depend on the final and complete set of AMC/GM which is not part of this NPA and will be developed later.

A more thorough 'full' RIA will be developed when the AMC/GM are available.

4.1. Issues to be addressed

See Chapter 2.1 'Issues to be addressed' in the Explanatory Note *above*.

4.2. Objectives

See Chapter 2.2 'Objectives' in the Explanatory Note *above*.

4.3. Safety risk assessment

It is implicit in today's Part-21 that the verification activities of the Agency are non-exhaustive. This non-exhaustiveness is a result of the existing imbalance between the overall volume of the certification work and the available human resources of the Agency for compliance verification. This imbalance does not allow the Agency to perform an exhaustive investigation of every compliance demonstration detail to the very depth in every certification project. This is identified as a hazard.

Despite all the measures taken in the current certification process, safety issues and unsafe conditions occur from time to time on aircraft in service, which may endanger their safe operation. Such unsafe conditions are normally addressed a posteriori by issuance of Airworthiness Directives (ADs). They often address a problem embedded in the certified type design. The existence of ADs as well as the occurrence of other safety issues shows that the certification process does not always capture all hazards and related risks for the safety of the product and that there is still room for improvement.

The potential risks embedded in the certification process are of two types as follows:

- (a) Imperfect establishment of the correct TC basis due to:
 - (1) imperfect identification and composition of the set of the certification specifications applicable to a product, or a change/repair thereto, being certified;
 - (2) an unidentified need for a special condition (SC) e.g. owing to an obsolete airworthiness standard or missed safety issues reported through the occurrence reporting system;
 - (3) acceptance of an alternative to (a) certification specification(s) that does not provide an equivalent level of safety;
 - (4) acceptance of a deviation not compensated by mitigating features with regard to the intended use; or
 - (5) failure to identify any other latent hazard or safety risk not captured by the cases listed above.
- (b) A non-compliance with the correct certification basis.



In the light of a high-level assessment of the probability/frequency and the severity of issued ADs, and the risk that the current certification process will not capture a safety issue in the TC basis or a non-compliance with the correct certification basis (which may lead to an 'unsafe condition' in the product and related need to address it by means of an 'average' AD), the following classification is proposed:

Probability of occurrence		Severity of occurrence				
		Negligible	Minor	Major	Hazardous	Catastrophic
		1	2	3	4	5
Extremely improbable	1					
Improbable	2					
Remote	3				12	
Occasional	4					
Frequent	5					

4.4. Who is affected?

Implementation of the LOI concept will affect:

- the Agency's product certification staff;
- the staff of the Agency's design organisations department; and
- the applicants for and holders of Part-21 design approvals and their design organisations demonstrating to the Agency compliance of their products, parts and appliances with the established TC basis, OSD certification basis and EP requirements.

4.5. How could the issue/problem evolve?

It is difficult to predict how the issue could evolve since it will depend on future external conditions, such as the growth of the global aviation activities, new technological advances, increased complexity of product designs, system complexity, automation, etc. These developments would lead to an increased demand for certification services by the Agency. There may be several possible responses to these challenges. The straightforward one is to ask for and obtain more resources, including an increased budget and additional certification staff in the product certification domain. Another response would be to introduce the risk-based LOI concept to increase the effectiveness and efficiency of the applicable certification processes and procedures.

The worst-case scenario would be that the demand by the industry stakeholders for the certification services of the Agency will, indeed, continue to grow (causing a greater number of more complex certification projects) and the economic situation of the EU will not allow the Agency to obtain enough additional financial/human resources to fully compensate for the resulting increased demand.

If this threat materialises, and the Agency takes no measures now, the current level of product safety could be difficult to maintain or could be even compromised. In anticipation of such a situation, the option to improve the effectiveness and efficiency of the product certification processes may be the



only way to mitigate this threat, to maintain sufficient control over product safety and to keep the risks at an acceptable level.

If this threat does not materialise, the improved effectiveness and efficiency of the product certification processes and procedures could bring product safety benefits.

4.6. Policy options

Table 1: Selected policy options

Option No	Short title	Description
0	No rule change	Baseline option (no change in rules; risks remain as outlined in the issue analysis).
1	Rulemaking action	Rulemaking action to implement the LOI concept into Part-21 and meet the other specific objectives of this proposal.



4.7. Analysis of impacts

4.7.1. Safety impact

Option 0 (no change in rules)

This option may potentially have an adverse impact on product safety if the threat described in Chapter 4.5 above materialises. Besides, the legal obligation of the Agency to take due account of the ICAO provisions in its implementing rules, including the provisions of Annex 19, would not be accomplished (see also Chapter 2.1.1(b)).

Option 1

Regarding the legal considerations (see also Chapter 2.1.1(b) and 2.2.1(b)), the legal obligation of the Agency to take due account of the ICAO provisions in its implementing rules, including the provisions of Annex 19, would be accomplished.

Regarding the safety considerations (see also Chapter 2.1.1(a) and 2.2.1(a)), if the threat described in Chapter 4.5 above does not materialise, the implementation of the risk-based LOI concept has a potential to reduce the certification process risks as specified in 4.3. The implementation of the LOI concept would help to further reduce occurrences of unsafe conditions embedded in certified designs and/or lower their severity, consequently improving the level of product safety.

If the threat described in Chapter 4.5 above does materialise, the implementation of the LOI concept may, due to more effective and efficient certification procedures, serve as a mitigating measure to control the risk specified in 4.3. It will be possible to maintain the product safety risk at an acceptable level.

The new LOI approach will also 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.

4.7.2. Environmental impact

While the LOI concept is primarily focused on product safety, its principles are equally applicable to the certification of environmental protection. However, a different set of environmental risks and assessment criteria will be applied to identify compliance demonstration items with a higher risk to the environment. On the basis of that environmental risk assessment, the Agency will determine its LOI. Therefore, the implementation of the LOI concept is exactly the same, with similar impacts and a similar potential to bring benefits for environmental protection as for safety.

4.7.3. Social impact

The Agency wants to stress that there is no intent to lower the overall LOI of the Agency's staff in certification projects through the implementation of the LOI concept. Certification procedures will change, and the Agency's certification staff will be differently involved with varying levels of involvement in verification of different areas of certification projects and, in particular, the related applicant's compliance demonstrations. For those who are already practising the LOI principles on voluntary basis, there will be no change of principle in their way of working.



There will be new tasks for the Agency's certification staff related to the need to exchange more safety-related information both internally, between the product certification staff and the design organisation's surveillance staff, and externally with the applicants and their design organisations. It will be necessary to identify data sources and to collect safety data to build up an appropriate database, in order to conduct the safety risk assessments in a more formal way, to improve and formalise the evaluations of DOA holders' performance etc. There will also be a few new administrative tasks, such as recording and updating the records of the LOI determinations, and sending corresponding notifications to the applicants.

However, making for this purpose a hypothetical assumption that the external conditions in industry and the external demand by the stakeholders for the Agency's certification resources do not change, the introduction of the LOI concept will change neither the internal demand for the Agency for human resources in product certification and design organisation oversight nor the overall workload of the existing staff in place. From this point of view, the introduction of the LOI concept is neutral. No impact on employment, workload and working hours, or internal transfers of personnel are envisaged. The certification experts are, however, expected to be more involved in technical audits of design organisations. On the stakeholders' side, similar impacts are envisaged.

4.7.4. Economic impact

From an economic perspective, the more structured and traceable decision-making process with the LOI concept, using enhanced involvement criteria (risk-based and performance-based), bears a potential in terms of gains, both in efficiency and effectiveness of the certification process.

On the industry's side, the increased predictability of the Agency's involvement will contribute to more efficient project planning processes. In addition, design organisations that demonstrate mature and reliable performance may enjoy new privileges, enabling them to gain time, thus enhancing their competitiveness.

On the Agency's side, the existing limited resources will be used more effectively without fundamentally changing any well-established working methods. The extension of DOA holders' privileges will, in principle, not negatively impact the Agency's budget due to the fact that a reduced number of applications and a correspondingly reduced income will be counter-balanced by equally reduced costs for the Agency. However, reducing the number of applications for projects requiring only limited (or even no) technical involvement entails reduced administrative burden. This will free some of the Agency's limited resources for the benefit of projects that require a greater degree of technical involvement, ultimately increasing the Agency's efficiency.

The introduction of improved involvement criteria and the traceability of decision-making will also allow for a more focused and tailor-made approach towards the identification of safety-critical areas and a LOI in each project. Ultimately, this will increase the effectiveness of the Agency's limited resources invested per project.

4.7.5. General aviation, SMEs and proportionality issues

The impact of the LOI implementation on General Aviation and/or Small and Medium Enterprises (SMEs) is not expected to be disproportionate. There will be an impact since SMEs, including those working under alternative procedures to DOA, will also be required to assess and manage safety risks in their certification projects with the Agency, but the required safety assessments will be simpler,



commensurate with the complexity of their products, parts, appliances or changes and repairs thereto. On the other side, SMEs will also benefit from the increased predictability and transparency of the certification process. Those designing major changes to TCs under alternative procedures to DOA, or only under certification programmes, will not enjoy the new privileges granted through the LOI implementation to DOA holders, but this will not change their current status.

4.7.6. Impact on 'Better Regulation' and harmonisation

It should be noted that the FAA and other authorities are seriously contemplating the implementation of safety management principles similar to the Agency's LOI concept.

4.8. Comparison and conclusion

The main driver of this rulemaking task is the legal one and, indeed, it needs to be addressed. In addition, the implementation of the LOI concept may bring safety benefits. It will also improve the effectiveness and efficiency of the Agency's certification procedures and will allow to make better use of the available certification staff resources of the Agency.

Based on the above considerations, Option 1 is preferred in order to achieve the objectives of this proposal as specified under 4.2 above.



5. References

5.1. *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.

5.2. *Affected CS, AMC and GM*

AMC and GM to Part-21 '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', Issue 2, 30 October 2012 .

5.3. *Reference documents*

- ToR and Concept Paper MDM.060 (RMT.0262 & RMT.0611 and RMT.0550 & RMT.0612) — 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 ; and
- Safety Management International Collaboration Group (SM ICG) — Safety Management Terminology paper, 25 July 2012.

