European Aviation Safety Agency

Comment-Response Document 2015-03

Embodiment of level of involvement requirements into Part-21

CRD TO NPA 2015-03 — RMT.0262 (MDM.060) — 23.5.2016
Related Opinion No 07/2016

EXECUTIVE SUMMARY

This Comment-Response Document (CRD) contains the comments received on Notice of Proposed Amendment (NPA) 2015-03 published on 2 March 2015 and the responses provided thereto by the European Aviation Safety Agency.

Based on the comments and responses, Opinion No 07/2016 was developed.

Based on the comments and responses, the Agency developed the revised draft Regulation amending Part-21 (Annex I to Regulation (EU) No 748/2012).

Applicability		Process map	
Affected regulations and decisions:	— Annex I to Regulation (EU) No 748/2012 (Part-21) — ED Decision 2012/020/R	Terms of reference (ToR), Issue 1:	27.8.2013
		Concept paper (CP):	Yes
		Rulemaking group (RMG):	No
		Regulatory impact assessment (RIA) type:	Full
Affected stakeholders:	Design organisations, the Agency and accredited MS NAAs contracted by the Agency.	Technical consultation during NPA drafting:	Yes
		NPA publication date:	2.3.2015
Driver/origin:	Safety, Efficiency/Proportionallity, Level playing field	NPA consultation duration:	3 months
		Review group (RG):	No
		Focused consultation:	Yes
Reference:		Opinion publication date:	23.5.2016
		Decision expected publication date:	2017//Q2

Table of contents

1. Procedural information

1.1 The rule development procedure

The European Aviation Safety Agency (hereinafter referred to as the 'Agency') developed this CRD in line with Regulation (EC) No 216/2008[1] (hereinafter referred to as the 'Basic Regulation') and the Rulemaking Procedure[2].

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

The draft Regulation has been developed by the Agency based on the input of the LoI Steering Group (SG) with representatives of design and manufacturing industry. During the NPA 2015-03[3] public consultation, 347 comments by 38 commentators were received from interested parties, including industry, European Union (EU) national aviation authorities (NAAs) and the Federal Aviation Administration (FAA).

The text of this CRD has been developed by the Agency and will be published concurrently with the Opinion.

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

1.2 The structure of this CRD and related documents

This CRD provides a summary of comments and responses as well as the full set of individual comments (and responses thereto) received on NPA 2015-03.

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 (MB) and is referred to as the 'Rulemaking Procedure'. See MB Decision No 18-2015 of 15 December 2015 replacing Decision 01/2012concerning the procedure to be applied by the Agency for the issuing of opinions, certification specifications and guidance material.

3 https://www.easa.europa.eu/document-library/notices-of-proposed-amendment?search=2015-03&date_filter%5Bvalue%5D%5Byear%5D=&=Apply

2. Summary of comments and responses

Commentators

6 EU NAAs and the FAA responded. The feedback from industry stakeholders represents opinions of design and production associations, large companies designing aircraft and engines, as well as small and medium enterprises (SMEs) involved in the lower range of the General Aviation (GA) sector, aviation industry (designers of sailplanes, aircraft modifiers and designers and producers of ETSO articles).

Comments on the LoI concept

As regards general comments on the LoI concept itself, the majority of the NAAs either support the concept or have no comments at all. One NAA is strongly opposed to the concept of a risk-based approach to compliance verification and is concerned about a number of potentially adverse impacts (for details see Comments 166, 167,169, 178, 180-185 in Chapter 3 below).

The industry stakeholders welcome in general the introduction of the LoI concept and, in particular, the new design organisation approval (DOA) privileges. Some SMEs expressed concerns about the new DOA privileges, especially in respect of a level playing field.

Special concerns

Special concerns were expressed about the following:

— The minimum number of draft acceptable means of compliance (AMC) and guidance material (GM) provided in NPA 2015-03 made it very difficult for the commentators to comprehend how exactly the LoI concept would be implemented in the certification practice and how it would affect them. Without this understanding, they cannot fully assess the actual impacts of the proposal on their businesses. Some further concerns (see below) have resulted from an incorrect interpretation of the proposed rule text as well as from of understanding of the Agency's intentions.

— Fairness issues, i.e. how a level playing field will be ensured for all actors competing on the internal aviation market, in particular as regards fairness when granting the new DOA privileges.

— Transparency issues, i.e. access to information, in particular with respect to the LoI determinations, DOA experience and performance evaluations as well as ranking by the Agency.

— Particular concerns were expressed about the individual LoI determinations by the Agency in the certification process, and the possibility to challenge those determinations.

— Impact of the proposal on validation projects, and the need for changes to bilateral agreements with third countries.

3. Individual comments (and responses)

In responding to comments, a standard terminology has been applied to attest the Agency's position. This terminology is as follows:

(a) **Accepted** — The Agency agrees with the comment and any proposed amendment is wholly transferred to the revised text.

(b) **Partially accepted** — The Agency either agrees partially with the comment, or agrees with it but the proposed amendment is only partially transferred to the revised text.

(c) **Noted** — The Agency acknowledges the comment but no change to the existing text is considered necessary.

(d) **Not accepted** — The comment or proposed amendment is not shared by the Agency.

(General Comments)	-

comment	*31*	comment by: *CAA-NL*
	General Comments 1. Introduction of this NPA could have an effect upon the DOA terms of approval and/or the Expositions and procedures of several DOA's. Therefore it is suggested to think about a proper implementation period. 2. Both the wordings "Certification Programme" and "Certification Program" are used throughout the document. Please choose to use only one spelling.	
response	*1. Noted.* *2. Noted and corrected.*	

comment	*118*	comment by: *Austro Control*
	Page 47, Paragraph 21.A.263 **Comment:** As the privilege for the Minor revisions to the AFM has been cancelled (because it ts a change and therefore covered by c2), the question arises why the points c1 and c3 are still in the remaining text. C1 is a basic privilege, where we cannot imagne issuing a DOA Approval without this. Hence it is inherent to the DAO Approval and a necessity and covered also by c2. The same is true for C3. Proposed text: Delete C1 and C3	

Page 58, Point 3.3, AMC1.21.A.263(c)(8)and (9)

Comment:

The wording of the condition for the equivalence:

- the change does not require a change to the existing TC Basis
can be read in a misleading way.

Justification: This is usually the wording used to classify a change as minor. In this context it could be interpreted in a way that the similar change may not later the TC basis of the product instead of it may not alter the TC basis of the change used as reference. It should be made clear, that the TC Basis used as reference is the one from the reference change.

Proposed text:

- the change does not necessitate to alter the TC Basis of the previous approved change

Page No.65, Paragraph No.4.7.5

Comment:
The new rule (as with the old) does not make clear that an organisation undergoing initial DOA certification, or operating under an alternative procedure issued iaw 21.A.14b / 21.A.112b or 21.A.432b has no privilege for finding of compliance, and therefore 100% authority involvement should be applied.

Justification:
Increase transparency – Stating this allows an organisation to better understand/ assess the cost/benefit of DOA certification.

Increase safety - ADOA currently receive minimal, possibly inadequate oversight. Clarifying the authority requirement for 100% involvement should lead to more effective oversight, with the same Level of Involvement being systematically applied to all organisations lacking the privilege of finding compliance.

Ensure a level playing field – There is currently a strong mismatch between the limited advantage of a DOA vrs ADOA, and the oversight, with it's associated cost. Even applying effective LOI principles to a good functioning DOA, still leaves a massive cost disadvantage verses an ADOA, which in practice has no cost and no oversight.

Proposal (new proposed text, etc.):

21.B.100 (e) The level of involvement of the agency in a certification project by the holder of an alternate procedure to DOA, approved in accordance with 21.A.14 (b), 21.A.112 (b) or 21.A.432 (b), or a new design organisation undergoing the initial approval is 100%.

AMC to 21.B.100 (e) – 100% level of involvement is ensured through:

- the agency reviewing of all MOC lists,

	- prior agency approval of all test plans, - the agency witnessing all tests, - the agency reviewing all certification reports for compliance, - and any other activities deemed necessary by the agency.
response	*For 21.A.263 (c)(1) and (2): Partially accepted.* For (c)(1): *Not accepted.* The privilege to classify is not inherent to the privilege to approve It can exist separately and must be spelled out explicitly. It could be *combined* with (c)(2) (*to classify and approve*) but for practical reasons is kept as a separate privilege. The issue may be revisited in the next rulemaking task RMT.0251 (Phase II) For (c)(3): *Accepted.* The 'privilege' is deleted and the same text added to 21.A.265 as an obligation of the holder. *For AMC1.21.A.263(c)(8)and (9): Deferred.* The intent of the comment is understood and the need for amendments to the text is recognised. The issue will be revisited in Phase II of this LoI rulemaking task to develop AMC/GM material. *For 21.B.100(e) and RIA 4.7.5: Not accepted*. While the substance of the comment is understood and your concerns partially recognized the proposal is not carried on. *Justification:* The LoI concept per 21.B.100 is based on risk and is made fully applicable to all certification processes and all kinds of applicants – DOA holders, APDOA holders or the 'certification programme only' applicants, both experienced and newcomers, under various level of oversight. Consistent application of maximum risk and resulting 100% involvement of the Agency to all who does not have a DOA is not substantiated. For APDOA holders or the 'certification programme only' applicants, all criteria of 21.B.100(a)(1)-(4) (or (b) in the case of smaller certification projects) are still applicable to establish the risk driving the Agency LoI. The only difference is there are no inputs from continues surveillance of these applicants which are not under the Agency's organisational oversight. However, their performance can be assessed based on their certification projects with the Agency. The criteria in 21.B.100 are not exhaustive. Another criteria that are going to be taken into account is the risk linked to the complexity of the product and the kind of its operation. Note please that the proposal for the new Basic Regulation (still under development) contains a declaration concept where for certain aircraft to be used in certain kind of operation in the lowest end of aviation the level of involvement of the Agency will be zero.

comment	*119* comment by: *THALES AVIONICS* THALES support the introduction in Part 21 of the Level of Involvement Concept based on a risk based approach. Nevetheless, some changes proposed by the NPA for ETSO projects would have an impact on ETSO applicants without any safety benefit, neither providing any additional benefit to AP-DOA Holders (no extension of privileges as for DOA holders). For these reasons THALES strongly recommend to limit the changes proposed in the Part 21 for ETSO to the introduction of the Certification Plan and the determination of LoI. Moreover, THALES consider that in the hypothesis of a ETSO/TSO mutual acceptance provision introduced in the TIP of the EU/US bilateral agreement, the differences between EU and US process shall be minimized. In addition, THALES would be grateful if EASA can initiate discussions with EU industry in order to identify what Part 21 changes could facilitate ETSO execution as it is done in US by the Part 21 ARC task. Consequently, THALES propose in its comments hereafter to reduce and simplify the number of changes made in Part 21 to prevent any unnecessary burden on industry and divergence with US Part 21.
response	*Noted.* As regards your general comments: The Agency agrees that unnecessary differences between EU and US process shall be minimized. However, according to the principles of mutual recognition of certificates differences between both systems may exists when it is concluded that both systems guarantee comparable levels of safety despite using alternative means. For the Agency's responses to THALES's specific comments, see the corresponding comments below.

comment	*133* comment by: *UK CAA* Thank you for the opportunity to comment on NPA 2015-03, 'Embodiment of Level of Involvement (LOI) Requirements into Part-21'. Please be advised there are no comments from the UK Civil Aviation Authority.
response	*Noted.*

comment	*145* comment by: *EUROCONTROL* The EUROCONTROL Agency does not make any comment on NPA 2015-03.
response	*Noted*.

comment	*159* comment by: *Rolls-Royce* Comment: Multiple occurrences throughout the document where it refers to Chapter 3.2 when it looks like it should be Chapter 3.3
response	*Accepted and corrected. Thanks.*

comment	*166* comment by: *CAA CZ* From the point of view of the CAA-CZ, the proposed system is not acceptable. The introduction of the LOI concept will, in our opinion, lead to decrease of technical level of certification experts and decrease of number of EASA and NAA certification specialists. Simultaneously, the implementation of the concept in question may lead to a loss of EASA/NAA´s overview on DOA activities and their progressive and irreversible releasing from strict adherence to the set of current certification processes. Granting DOA privileges to approve major changes of the type design and issue STC relies on high knowledge and maximum accountability of the organization. DOA organizations cannot be judged only by the number of certification projects carried out, but also on the composition of the certification personnel, experience, expertise, financial background and corporate culture. Additionally, the proposed LOI system assumes that there is long-term stability of DOA organizations, which is a fiction in reality. Especially for smaller entities, the standard of work is very variable, dependent on many internal and external factors, and generally, it is completely unpredictable. The LOI concept introduces a decision-making process within certification, which depends on the subjective opinion of several people (agency staff) on the DOA standard, which is irregular, and may favour a particular entity against another and lead to disputes between applicants and the Agency. In current EASA practice, their standard is in most cases detected only on the basis of audits, held once a year. DOA standard assessment is, in our opinion, completely inadequate and in particular does not cover its true capabilities in the technical domain. Therefore, we would like to propose: - To carry out continuous surveillance within individual projects. If EASA is not in the position to ensure this by its own means and own resources, or the supervision is inefficient, to transfer the surveillance of technical level of projects to accredited national authorities. - To give the industry a real support, especially where it is needed and where it is

	basically expected by industry. Thus, it is, according to our experience, a case of smaller companies, which is the area from COMMUTER aircraft category. - To provide support by continuous contact of the entity with the supervisory authority, and especially for non-complex aircraft, to develop such an advisory circulars system which would lead the applicant step by step, and especially it would completely provide him a form, how to prove eligibility requirements. The presented proposal of the LOI system emphasizes the administrative part of the initial approval process of aircraft and products, instead of transferring the essence of the eligibility approval system to the technical domain. In case that the projects will be solved just from a technical standpoint, it is possible, for simplifying their process, to use an "engineering judgement", based on the experience of the applicant in the technical field, without relying on results obtained during audits of organizations. Based on the supervision experience of our authority in certification, acquired in 45 years of activity in this area (of which 12 years were in the EASA system), we believe that the LOI proposal would, in the longer term, completely subvert the established system, which today provides an acceptable level of safety.
Response	a) As to your particular concerns: *Decrease of technical level of certification experts* The LoI rule itself will not result in a reduction of the Agency's overall LoI. The Agency may rather re-focus its resources to those parts of the project, where the risks are higher. Certification experts will only not retain verifications of compliance demonstrations that they are already familiar with from the previous certification project(s). Saved resources from these 'not retained' areas will allow the Agency experts to more deeply investigate those areas of design and related compliance demonstration that are novel or complex. This addresses your concern related to a decrease of technical level of certification experts. *Decrease of number of EASA and NAA certification specialists* The proposal itself is totally neutral in terms of the requested Agency's certification workforce. If the external conditions do not change, namely the certification demand from the industry, the proposal will lead to no increase or decrease of the staff. Rather will the certification staff's focus change to certification areas where deeper involvement may bring more safety benefits? Currently, there is excess of the certification demand for the human resources available, so fears about redundancy of the Agency staff are not really substantiated. *Loss of EASA/NAA´s overview on DOA activities'/'DOA assessment and oversight* The LoI concept, in contrary, requires to strengthen the DOA oversight, namely because of the new DOA privileges. Implementation of the LoI proposal will indeed lead to increased DOA oversight by higher involvement of PCMs and Experts in sample checks, technical discipline per discipline, how the DOA performs, in particular in those certification areas with no Agency's involvement in the product certification process (e.g. due to the new DOA privileges, which will provide at the same time some additional time to the staff). This also addresses your concerns about the threat of decrease of the numbers of EASA specialists

because of redundancy.

Subjectivity of decision-making introduced by the LOI concept

The current status, when LoI is applied on purely individual level, is more prone to subjective decisions. The LOI concept will introduce objective criteria for deciding about the Agency's LoI and bring also some standardisation aspects.

b) As regards to your general proposal:

Thank you for your kind offer to help. However, this proposal, in particular putting the majority of the resources to *individual (product certification) projects,* is not in line with the overall risk-based concept the Agency (as well as other worldwide Authorities, including the FAA) is taking. The EASA system is built on trust into approved (and overseen) organisations. Furthermore, the Agency's risk-based approach needs to be implemented into Part 21 in view of the ICAO SARPs, namely those contained in Annex 19.

comment *173* comment by: *Luftfahrt-Bundesamt*

The LBA has no comments on NPA 2015-03.

response *Noted.*

comment *187* comment by: *AeroSpace and Defences Industries Association of Europe (ASD)*

ASD General Comment:
ASD appreciates the open approach taken by the Agency in preparing this rule in consultation with industry via the Industry/EASA LOI Steering Group. This is a model that should be followed for future rulemaking activities.

ASD supports the introduction of Level of Involvement Concept based on a risk based approach to compliance verification into the Part 21 for TC and STC projects in conjunction with an extension of the DOA Holders privileges. This will allow the Agency to efficiently use its resources by focusing on novel and higher risk areas of certification and make fuller use of the privileges granted to Design Organisation Approval (DOA) holders, where such organisations have proven high performance and experience.

For ETSO projects, some changes proposed by the NPA for ETSO projects would have an impact on ETSO applicants without any safety benefit, neither any additional benefit to AP-DOA Holders (no extension of privileges as for DOA holders). For these reasons, ASD requires further review by the Agency.

ASD believes that some adjustments and clarifications are still needed both to the text proposed in this NPA and the text of the AMC/GM being developed under RMT0611 to ensure the full benefit of this approach is realised by both industry and EASA.

ASD will finalise comments on the AMC/GM in NPA2 (RMT0611) when it is made available for public comment.

response *Noted.*

See also the Agency's responses to the ETSO specific (Thales's) comments below.

comment *209* comment by: *SIRIUM AEROTECH*

The concept "experience" should be revised in this NPA.
Experience should not be a driver itself to rely on a company. It is indeed a circumstance which will likely help for a good performance, but it is the good performance itself the final goal, not the experience. The experience is a simple mean to get the real objective.
Experience of the staff working for a company should be taken into account apart from the experience of the own company. New companies hiring skilled and experienced personnel which demonstrated being able to reach and maintain a good performance should not be penalized because they just didn't accumulate a large amount of years. Also, old companies which performed poorly during several years should not be benefitted towards others.

response *Noted.*

The concept of 'experience' contains a bit more than just assessing the experience of the involved applicant's staff's qualification. It also covers the issue of the Agency's accumulated experience with the applicant. The LoI determination in a nutshell reflects a level of confidence the Agency has in a given moment that the applicant, demonstrating and determining the compliance alone without involvement of the Agency, will secure full compliance for a particular compliance demonstration.

Building a confidence, in general, is a process that may need certain time and accumulation of positive 'experience' with the applicant's performance(s). Normally a satisfactory performance needs to be repeated to increase the confidence. The first one is just a good start. However, confidence can be also increased (and the LoI updated down) within a single project (of certain timeframe).

comment *217* comment by: *SIRIUM AEROTECH*

Sirium Aerotech supports the NPA in regards with the LOI in certification projects, but we fully disagree with the privilege to approve STCs for the following reasons:

- It is unsafe
The definition of "equivalent STC" is ambiguous and subjective. It exists a real risk of misunderstundings or abuses wich would lead to STCs wich are not equivalent indeed being approved without control. The surveillance of EASA may detect these cases or not, but in any

	case, the STC would be already installed and creating a safety risk. The fact that a DOA approved in the past a similar STC doesn't ensure its future performance, even in the case that the STCs are indeed equivalent. The staff could have been renovated and the new personnel may have not experience at this field. Also, new requirements of Part 21 as EWIS ICA, OSD or flight testing policy may not be correctly implemented because they didn't exist at the time of approval of the original STC. - It is unfair New privilege is based on equivalent STCs previously approved. Therefore, the DOAs more benefitted are not the best performers, but those big and old with a large portfolio of STCs already approved. This will create an unfair gap between old/big companies and new/small companies which will have nothing to do with skills or performance, but mainly with size and age. DOAs without large collections of STC would be forced to go through a normal process which involves high costs and time. It will be, therefore, impossible to make competitive offers against old and big DOAs with similar STCs approved. The competitivity advantage to approve directly STCs is so big, that this alone fact is enough to prevent new/small DOAs from participating in the STC market regardless its performance and commitment to safety, leaving it in few hands. This would lead to unfair distortion of the market and the closure of DOAs for this reason. Many DOAs will be banned in fact from STCs market or will be forced to stop business despite they might be excellent performers. The criteria to decide whether an STC is equivalent or not are very ambiguous. This introduces a new source of subjetivity and will lead to different interpretations by different TLs/experts as currently happen with other ambiguous parts of the rule. Some DOAs will be randomly benefitted or disadvantaged depending of the TL criterion. In the case of approving STCs, the competitive advantage is so important that small differences could mean hughe injustices. - It is unnecessary. The general provisions of LOI in certification projects already can handle with situations of "equivalent" STCs. PCM could decide, following a normal application, a minimal involvement after evaluating the proposed STC and previous STCs already done by that company/staff. The workload from the Agency's side would be minimal, but it would keep the control of STC approval process and would solve most problems mentioned before.
response	*Noted.* For *It is unsafe*: In Phase II of this rulemaking project AMC/GM will be developed to explain the concept of *equivalent change.* You will see that mitigating measures will be put in place that will control the related risk to an acceptable level. For *It is unfair:* Your assumption that *size and age* of the applicants will matter the most is not substantiated. Size does not matter at all. Age, translated to experience, may matter but what will matter is not how big this experience is but how positive or negative it will be. This criteria is fair to all applicants, big and small. For *It is unnecessary*: The intent is also to minimise the administrative burden. When the

	technical workload is minimal what remains is just the administrative burden for the Agency and fees for the applicant. You will see that the AMC/GM will provide the Agency sufficient control.

comment	*218* comment by: *Bombardier* Bombardier supports the intent of this rulemaking, a more efficient and targeted use of resources during certification programs with no adverse effect on safety. No mention however is made of foreign validation in the NPA. Is it the intent of EASA to apply these same LOI principles to foreign validation programs, and would it be necessary to amend existing bilateral agreements (e.g. EU-USA, EU-Canada) or the agency-specific (e.g. EASA-FAA, EASA-TCCA) implementation procedures to do so?
response	*Noted*. Part-21 code, which is subject to this rulemaking, does not have validation issues in its scope. The issue of LoI application in validation projects will need to be addressed separately from this rulemaking by the staff in charge of the respective bilateral agreements and technical implementation procedures and implement it with full consultation of our bilateral partners. EU bilateral agreements prevail over EU regulations, incl. Part-21, so that what will be adopted for Part-21 is not necessarily binding or constraining the future changes to BASA's.

comment	*219* comment by: *Hugues LE CARDINAL (Chairman of VELICA SAS)* VELICA agrees with the objective of this NPA 2015-03.
response	*Noted.*

comment	*221* comment by: *Dassault Aviation* Dassault-Aviation support ASD comments and propose some additionnal remarks
response	*Noted.*

comment	*232* comment by: *Airbus Helicopters* Please find hereafter the comments on behalf of Airbus Helicopters and Airbus Helicopters Deutschland, who also support the comments posted by the AeroSpace and Defence

	Industries Association of Europe (ASD).
response	*Noted.*

comment	*233* comment by: *Airbus Helicopters* Some paragraphs or parts of paragraphs dealing with requirements applicable to the Agency have been relocated to section B. Such a rearrangement has the following drawbacks: • More difficult to understand the process, split between stakeholders, • Some duplication, especially in the conditions. Also, Subpart B does not give a full visibility on the Agency's part of the process, because some Subparts simply refer to the Agency's procedures. At last, such a rearrangement is prone to mistakes, as revealed by some of the comments below. The RIA does not consider an option where the LOI would be introduced, without the dispatch between sections A and B, and even does not address the advantages and drawbacks of such a dispatch. **Suggestion** The suggestion is to reconsider this position and, at least, to justify it in the RIA.
response	*Note accepted.* One reason of the relocation of requirements of Part-21 is to bring it into consistency with the similar structure of implementing rules in other aviation domains (Parts AR/OR) under the Basic Regulation. Another reason is to clearly identify the provisions applicable to the applicants and/or holders and the provisions applicable to the Agency – who is responsible for what. The message will be clearer not blurred as of today. Both the stakeholders and the Agency wants to have the implementing rules consistent and therefore Part-21 must align with the other implementing rules that all took the 'split way'.

comment	*248* comment by: *Pilatus* Pilatus supports the initiative by EASA to amend Part 21 and welcomes the introduction of additional privileges. The LOI concept however requires clear criteria definition i.e. risk based approach, for technical involvement as well as organisational involvement to avoid different interpretation and application by National Authorities.
response	*Noted.*

comment	*256* comment by: *DAHER* DAHER supports the need of improvement of part 21 to define more precisely the implication of the Agency in the GA aircraft certification and, as such, fully agrees with the objective of this NPA 2015-03.
response	*Noted.*

comment	*278* comment by: *Airbus Helicopters* Due to the introduction of new paragraphs in Section B, paragraph numbering in no more in a strictly increasing order. For example, Subpart B ends with 21.B.110, whereas Subpart D starts with 21.B.105. **Suggestion** Reconsider the numbering of Subpart B paragraphs to have a strictly increasing order.
response	*Noted*. Subpart B of Section B ends with 21.B.103 (not 21.B.110 as you state). All points are in strictly increasing order.

comment	*283* comment by: *European Sailplane Manufacturers* The NPA in several ways explains that the LOI issue is mainly motivated by the lacl of resources of EASA to fully cover the compliance verification role. Of course it is now a possibility to find ways to optimize use of EASA resources and lowering the level of involvement (LOI) is exactly such an approach. Nevertheless two main questions need to be answered beside the more technical disussion about what to change in Part-21: 1. Are the products where the society (the public, the EU system, the member states) still want to see a certain involvement of organisations like EASA and the NAAs? 2. If the first answer is yes then the second question should be: Should the society (the public, the EU system, the member states) then agree to invest certain resources (aka financial budget and manpower) to such involvement? The reason for these two questions is self-evident: With the introduction of EASA and the associated fees and charges system it was imposed to “the industry” (the applicants, which in this context are the manufacturers) to finance the level of oversight by direct fees.

This has increased the financial burden in many cases and in only a few cases a more streamlined certification process has been the result.
(To be honest, the creation of a pan-European TC has been a real benefit, but perhaps this is also the only sizeable one.)

If now the whole concept needs optimization like the LOI issue discussed here, it should be asked if the really needed optimization is a better financial basis for the certification process / compliance verification role of EASA.

This is not the place to discuss the different possible funding schemes already discussed again and again, but the observation is that the LOI proposal is merely a tweaking of processes to optimize the use of limited resources.
We – the sailplane manufacturers – doubt that even for the DOA identified to get a lower LOI the total workload will become less.
We also doubt that this complication in Part-21 will make it easier for applicants or authorities.

Therefore:

- First identify where a high level of supervision is really needed.
- Then create a system which is well equipped to conduct such supervision.
- Everything else will not be productive and hurting safety as well as economy.

response *Noted.*

We are aware that there are new regulatory developments in process. In these regulatory developments new approaches can be taken, particularly for the lower end of aviation as proposed by *GA Roadmap* projected into draft new Basic Regulation. The new draft Basic Regulation, where you can see some of your recommendations partly in, can take the holistic approach you recommend. However, for this rulemaking task we have no other way than to respect the existing regulatory framework, namely the Regulation (EU) 216/2008 Nevertheless, optimisation of the use of the Agency's resources within the existing framework make sense and can be utilised even under the new framework.

comment *326* comment by: *DGAC France*

DGAC France agrees on the fact that the resources of the Authority are reduced and therefore it is essential to focus on issues that increase safety. The development of the LOI concept can be a solution to this issue.

response *Noted.*

comment *327* comment by: *DGAC France*

The concept of Level of Involvement (LOI) was previously developed in NPA 2006-16 and received globally disagreement from DGAC France and other entities. On the concept, this new NPA resolves many of the issues that were raised at that time and EASA's efforts are appreciated. In particular it is not anymore to the Agency to substantiate its involvement in proving the reasons for reviewing certain issues.

response

Noted.

This understanding is the correct one. The Agency and also the accredited NAAs are owners of the verification process and verification of compliance is their core task. Therefore, the decisions on what to verify and what not are purely remit of the Agency and those NAAs. While, for transparency reasons, the applicant shall be notified of the Agency's LoI decision and briefed on the reasoning there is no need to reach a consensus with the applicant on this matter. Long decisions should be prevented otherwise the LoI would become a burden that could potential negate its expected benefits.

comment *328* comment by: *DGAC France*

DGAC deeply regrets that all the complete set of AMC/GM will only be developed in a second NPA. The complete set of IR and AMC/GM would have enabled to define more accurate comments.
Moreover, it is indicated that certification pilot projects are forecast, especially to determine this complete set of AMC/GM. These pilot projects could have also been used in order to define if the NPA is correctly fitted to the reality. It seems as the present stage that it remains theoretical.

response

Noted.

The Agency plans advance implementation of the LoI concept with selected companies (and NAAs involved), still before the amending Regulation is adopted, based on new draft certification memoranda (CMs) being finalised, to get experience. This should provide an early input into rulemaking for AMC/GM material. You will have possibility to comment on the CMs sent to public consultation and then on draft AMC/GM material subject to a dedicated NPA.

comment *329* comment by: *DGAC France*

This NPA also introduces a new privilege for DOAs to approve certain major changes or STCs. This issue could represent a safety problem for three main reasons:

- The criteria to define which DOA would be considered as high performing and experienced to be granted such a privilege are not detailed sufficiently; AMC 21.B.100(b)(3) criteria must be developed.

	- Should such a privilege be introduced, DGAC considers that it should really be limited to modifications completely similar to those already EASA approved, by introducing this criteria in the regulation itself (21A.263 c) 8 and 9) and by amending the related proposed AMC which we consider too « permissive » as written. For example: o the terms « same technologies » or « same means of compliance » are too general and may be interpreted in various ways. o A criteria could be introduced in the AMC to provide that when the modification impacts the AFM, the limitations should be similar. - The risk with such a privilege is for the Authority specialists to loose expertise and knowledge on specific designs. It is important that EASA experts/PCMs remain involved in sufficient variety of projects in order to maintain their expertise. DGAC concurs with EASA on the need to have technical experts and/or PCMs involved in the approval and surveillance of such a privilege if granted. Therefore, this new privilege should be considered further very cautiously and maybe some pilot projects could allow defining if it is practically acceptable. Note: If such a privilege is granted, it should be required that STCs approved accordingly by a DOA shall be notified to the Agency in order to update the list of the approved STCs in the website.
response	*Noted.* On your individual concerns: - AMC 21.B.100(b)(3) was included in the NPA to provide minimal understanding of the task. The Agency is finalizing the work on a DOA assessment model (Scoreboard) based on several criteria (key performance indicators). - Note that, apart from general guidance per AMC, each requested privilege will be assessed on its own merits and considering the applicants capabilities for it. Limitation and conditions specifying the exact scope (including e.g. AFM limitations, fixed TC basis, certification programme with means of compliance etc.) will be defined for each privilege as its unique parameters and recorded in the Terms of Approval. - The mentioned risk of the Authority specialists of losing their expertise is going to be mitigated by: o full involvement of the specialists in the previous certification project(s) and the process leading to granting the privilege; o attendance of specialists in dedicated ad-hoc technical DOA audits (sampling); and o conducting the continued airworthiness monitoring tasks (safety data monitoring); - A system for numbering, notifying and registering the issued STCs and major changes to TC will be developed. - Advance implementation of LoI project is going to test also 'simulated' privileges.

comment	*330* comment by: *DGAC France* DGAC France appreciates the work performed in this NPA as concerns the relocation of Part 21 points and requirements between Section A and Section B and the Alignment with the Basic Regulation as regards the TC basis.
response	*Noted.*

comment	*331* comment by: *DGAC France* According to the explanatory note, it seems that the LOI concept has been developed only for DOA organisations. Can EASA confirm that it will be also applicable for applicants that demonstrate their capability by other means (alternative procedures for ELA 2 aircraft or only providing the certification programme for ELA 1 aircraft) as it seems to be according to the IR proposal?
response	*Noted.* Yes, we can confirm the LoI concept is applicable to all Part-21 certification processes by all applicants for an EASA design approval, including those that demonstrate their capability by other means than DOA (alternative procedures or certification programme only). See also the Explanatory Note in the Opinion.

comment	*332* comment by: *DGAC France* As this NPA also addresses improvement issues through Part 21, DGAC France suggests incorporating a modification in 21.A.95 linked to minor changes. For a (restricted) Type Certificate (see 21.A.20), a major change (see 21.A.97), an STC (see 21.A.114 & 21.A.115) or a repair (either minor or major, see 21.A.437), the applicant shall demonstrate compliance with the applicable TC basis and environmental protection requirements and shall declare that it has made this demonstration (see 21.A.20). DGAC France considers that such requirements should also apply to minor changes. Therefore, we suggest adding in 21.A.95 the following sentence: “An applicant for approval of a minor change shall declare that it has demonstrated compliance with the applicable type-certification basis and environmental protection requirements.” DGAC France also considers that 21.A.33 Inspection and tests should apply to changes and repairs, included the minor ones and therefore modify the paragraphs linked to all approvals accordingly.
response	*Partially accepted.*

- The proposal for requirement on declaration of compliance for minor changes is carried in a modified form (see proposed 21.A.95(b)(3)).
- 21.A.33 and 21.A.35 (when applicable) is by a cross-reference applicable also to major changes and STCs. For minor changes and repairs was considered too 'heavy'.

comment *333* comment by: *DGAC France*

DGAC France wonders if EASA has estimated that such a concept will have implications on fees and charges.

response *Noted.*

Possible changes to fees and charges due to implementation of LoI concept (namely the deeper oversight of DOA holders with the new privileges) will be considered in the next suitable amendment of the applicable Regulation.

comment *337* comment by: *Robert Kremnitzer / Diamond Aircraft Industries GmbH*

Combining the LOI concept with the possibility of extenden DOA previliges and the clarification of RTCs is highly appreciated.

response *Noted.*

comment *339* comment by: *DGAC France*

General comment related to the formalism associated with LOI determination and notification (§2.4.1 and 21B.100) , defined as follows:

"DGAC is concerned that for the less complex projects, the administrative burden associated to the determination and the notification of the LOI might be disproportionate with the complexity of the project, which would be counterproductive. "

response *Noted.*

The Agency is very well aware of the danger that the LoI concept implementation will slip into an administrative burden. Every effort will be developed to avoid this trap. Communication means must fast and not formalistic.

Executive Summary p. 1

comment	*134* comment by: *Ultramagic, S.A.* In behalf of Ultramagic DOA 21J.351, we support this Proposed Amendment to Part-21.
response	*Noted.*

comment	*136* comment by: *FAA* PAGE 1: The Executive Summary states Part 21 is based on "the principle of assurance of compliance". Later in 2.1.1 it references Part 21 "ensuring compliance" and the Agency "guarantee" of safety. This could lead to confusion as to the Agency role and put too much emphasis on the certifying authority rather than the applicant. We recommend that the principle of LOI relies on the applicant to properly address the safety of the product, not the certifying authority to guarantee it.
response	*Accepted.* The wording of the Explanatory Note of the Opinion reflects the comment by avoiding any wording that would suggest that the Authority's obligation is to 'guarantee' safety of the product. In opposite, it stresses that the verification of compliance is non-exhaustive and the applicants/stakeholders are fully responsible to ensure compliance.

1. Procedural information p. 3-4

comment	*163* comment by: *LMI Aerospace* 1. From the NPA, Section 1.4: **"Next steps in the procedure"** This DOA would like to volunteer to become one of the selected Design and Manufacturing Industry stakeholders as we are one of the few stakeholders with Major Repair and have significant practical experience in repair and modification Fatigue and Damage Tolerance, without being an OEM. The experience is based on implementation of the FAA Aging Aircraft regulations in 2010 and the associated impact to industry and the regulators. This DOA is concerned that this NPA 2015-03 in conjunction with the Aging Aircraft NPA 2013-07 will create a potentially significant workload for EASA and industry.
response	*Noted.*

2. Explanatory Note — 2.1 Overview of the issues to be addressed — 2.1.1. Level of involvement (LOI) — (a) Safety considerations p. 5-7

comment *67* comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 6/67, paragraph 2.1.1(a)

2. PROPOSED TEXT / COMMENT:
The subparagraph (3) indicates:

"(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 […] 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."

How does this statement fit with the Opinion No 01/2015?

3. RATIONALE / REASON / JUSTIFICATION for the Comment:
The Opinion No 01/2015 refers in its paragraphs 2.4. and 2.5. to "Optimising the use of available resources" and "Ensuring adequate and stable EASA funding", respectively.

The voluntary and temporary (i.e. reversible) transfer of responsibilities and tasks is contemplated horizontally, i.e. between Member State Competent Authorities, but also vertically from Competent Authorities to EASA.

The Agency expresses the possibility to dedicate a part of its workforce to additional responsibilities and tasks. Would not this be in contradiction with the uncertainties explained in this NPA?

The further expansion of the concept of Qualified Entities is also considered in the Opinion No 01/2015. In the same Opinion, it is proposed to amend the Regulation (EC) No 216/2008 in order to include additional sources for the EASA's revenues. These may range from route charges over passenger contributions to other external grants (e.g. from specific EU funds), either to finance specific and clearly defined activities, or to be included in the EASA's general budget and to be used as deemed most appropriate by EASA.

response *Noted.*

The LoI RMT task is performed within the framework of the existing Basic Regulation and the current system of the Agency's staff establishment plan is quite rigid. Therefore, we took in the NPA/RIA a conservative approach (the wort scenario) which we recognize may not in the end materialize. It is quite possible that the LoI concept, as adopted, may later go through adaptations when the new Basic Regulation is adopted to align with the new regulatory

framework.

comment *167* comment by: *CAA CZ*

To fulfil the requirements of ICAO Annex 19, an introduction of risk assessment (and management) on the principle of "safety-data-driven targeting" is required. In connection with this, the proposal demands to develop:
a. "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
b. "This concept will require the Agency to conduct a formal risk assessment of the product and the whole certification project".
From the proposal it is not clear how these requirements will be met in practice (ad point a. above), or what methodology will be used for their provision (ad point b. above). For effective implementation of elements of risk management we deem necessary completion of specific implementation practices and providing accurate methodology (Risk Management Manual) for risk management in a certification project, on both parts – of the applicant and of the Agency.

response *Noted.*

The NPA explains in 2.1.1 (c) that introduction of the LoI concept (risk-based approach to verification by the Agency) into Part-21 is the first step that will be followed by other SMS related steps to implement the full potential of the framework for SSP for initial airworthiness. Specific risk/performance assessments models and methodologies will be brought in the Phase II of the project subject to dedicated NPA with AMC/GM material.

comment *169* comment by: *CAA CZ*

2.1.1(a)(2)
The argument that the certification of products continues to grow is not true for the Czech Republic.

response *Noted.*

comment *178* comment by: *CAA CZ*

2.1.1(a)(3)
The argument of the economic situation of the EU (and of the financial situation at EASA) is on principle a very dangerous in connection with the issue of aviation safety. From our point of view, EASA decision-making should not be based on economic factors.

response | *Noted.*

In the real world the economic factors and available budgets will inevitably play their role and must be taken into account. See also our response to comment 67.

comment | *284* comment by: *European Sailplane Manufacturers*

page 6 para (6) ff

We understand from the explanations in para (6) to (9) that obviously the main motivation of this LOI initiative comes from the fact that EASA has too limited resources to fully cover the compliance verification role.
Whereas this is understandable when seeing the current developments this opens up a really new question:

Is society (aka the European Union and the member states) really interested in the safety of aircraft design and manufacturing exceeding the ever-remaining fact that the manufacturer is always responsible for his products (see para (5)) ?

We suppose that in the case of aircraft as used for public transport the answer is certainly YES.
We also suppose that in case of small aircraft used for sport and recreational purposes the society does not care as much.
As a consequence: should it therefore be proposed that the LOI may also be lower for certain products (e.g. ELA1 aircraft and products) – we believe that this should be the case.

response | *Noted.*

We agree with principles of your proposal. However, this is going beyond the limits of this rulemaking task that must stay within the limits of the current regulatory framework. Your concerns may be addressed under the regulatory framework being prepared under the new draft Basic Regulation proposing a declaration concept which will mean zero LoI of the Agency.

2. Explanatory Note — 2.2. Objectives — 2.2.1. Level of involvement — (a) Safety considerations p. 10-12

comment | *32* comment by: *CAA-NL*

The non-exhaustiveness of the Agency's compliance verification process is recognized as a hazard and therefore a risk-based approach is introduced. However the execution of a risk analysis is done with the knowledge that is available today, by both the applicant as the Agency. Knowledge that is evolving time after time, when due to accidents, incidents and

occurrences new blind spots and weak areas are discovered. Therefore, having recognized the above-mentioned hazard, also the relation to the continued airworthiness process should be explained, such as:
a. In a timely manner authorities and independent safety investigation organisations should make easily available the outcome of their safety analysis.
b. DOA's and certification staff of the Agency (part. 2.2.1(9) only mentions 'the Agency's oversight and the continued surveillance of design organisations') should pro-actively study the reports of a. and determine the strengthening of their knowledge regarding the assessment of safety aspects.
c. Apply this when necessary for running certification programmes.

response

Noted.

Your recommendations are fully shared. The LoI concept touches this issue in 21.B.100(a)(3) by referring to '*including those (risks) identified on similar designs'*. It relates to a wider issue of a system for gathering, exchange and analysis of data and information. This is another component of the full SMS system in the initial airworthiness certification next to the 'hazard identification and safety risk management (addressed by the LoI concept). Some of the elements of the data system are already addressed by Regulation 376/2014 on the reporting, analysis and follow-up of occurrences in civil aviation ('Occurrence Reporting') together with the Agency Internal Occurrence Reporting System (IORS). However, the issue is going to be further expended with the adoption of the new Basic Regulation tasking the Agency with the creation and management of 'a Union repository of information relevant for certification, oversight and enforcement'. The task to analyse the gathered data, including those gathered from independent accident investigation bodies is surely an important part of the safety assurance task.

comment

68 comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 10/67, paragraph 2.2.1(a)

2. PROPOSED TEXT / COMMENT:
The subparagraph (2) indicates:
"(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."

How is it demonstrated that making more efficient use of the available certification workforce will be sufficient to:

- Address the concern of the non-exhaustiveness of the Agency's compliance verification process,
- Ensure equal treatment amongst applicants, and

- Ensure on-time delivery of approvals (particularly in case of AOG).

Proposed change: N/A

3. RATIONALE / REASON / JUSTIFICATION for the Comment:
It is not disputed and fully shared that the concept for the determination of the level of involvement of the Agency in compliance verification will contribute to improve the effectiveness and efficiency of the process.
However, some further explanations/figures should be provided in the RIA in order to better evidence the expected benefit of the LOI proposed concept.

response *Noted.*

See the enhanced RIA in the Opinion.

comment *69* comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 10/67, paragraph 2.2.1(a)

2. PROPOSED TEXT / COMMENT:
The subparagraph (4) indicates:

"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."

"Hazardous" is a wording dedicated to safety (refer 25.1309) and implicitly provides a limitation of scope. If this is the intent then it should be clearly mentioned, if not an alternative wording should be defined. In any case, a risk assessment methodology linked to the certification project (including a risk assessment matrix) should be further described within the AMC/GM to 21.A.15(b) and to 21.B.100. The risk assessment matrix used by EASA for pre RIA and RIA (refer to chapter 4.3 within the NPA) could be used as a benchmark.

The wording “areas” deserves further definition since the current definition within GM to 21.A.101 §4 does not provide the expected level of information on what is an “area”.

3. RATIONALE / REASON / JUSTIFICATION for the Comment:
Need to further define the risk assessment methodology and the product “areas”

response *Accepted.*

The Explanatory Note for the Opinion and, more importantly, the rule proposal itself (see 21.A.100(a) and 21.A.15(b)(6)) now clearly specifies the type of risk assessment needed for

	LoI determination and differentiates from the xx.1309 type of assessment. The wording 'area' was used in his general, dictionary meaning (similarly as in 21.A.101/GM 21.A.101). In Phase II of this rulemaking project the issue risk assessment methodology will be addressed by one or more AMCs.
comment	*70* comment by: *Airbus* **1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:** Page 11/67, paragraph 2.2.1(a) **2. PROPOSED TEXT / COMMENT:** The subparagraph (8) indicates: *"(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. …"* The statement should also indicate that the LOI concept covers the extension of the privilege to approve major repairs to organisations not being the TC or STC or APU ETSO holders. Proposed change: *"(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, major repair designs when not being the TC, STC or APU ETSO holder and/or to issue supplemental type-certificates (STCs) or without any involvement of the Agency. …"* **3. RATIONALE / REASON / JUSTIFICATION for the Comment:** Major repair approval privilege to non TC, STC or APU ETSO holders is part of the LOI concept and should be highlighted in the explanatory note.
response	*Noted.* The substance of your comment is fully agreed and the Explanatory Note to the Opinion describes it in 2.5.2.
comment	*71* comment by: *Airbus* **1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:** Page 11/67, paragraph 2.2.1(a) **2. PROPOSED TEXT / COMMENT:** The subparagraph (10) indicates:

"(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. […]."

There is broad support for the idea of audits taking also into account the importance of technical aspects.

Proposed change:
"(10) These audits will also need to become more technical, focussing not just on the quality of the DOA procedures but as well ~~specifically~~ on the quality of their implementation in on-going certification projects. […]."

3. RATIONALE / REASON / JUSTIFICATION:
The risk-based approach should address both (and equally) technical and process-related hazards over the whole product life cycle. The impression is that audits may have been more focus- sing on processes in the past.

response

Partially accepted.

We agree with the substance of your comment (the wording in the EN to Opinion has been amended. However, we aim to highlight that the already existing, mainly procedural DOA audits, needs to be complement with dedicated technical audits and documentation reviews serving as a posteriori sampling and in-depth investigation of a certain percentage of certification files to verify that the DOA holder's performance in the conduct of the new privileges is adequate.

comment

72 comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 11/67, paragraph 2.2.1(a)

2. PROPOSED TEXT / COMMENT:
The subparagraph (11) indicates:

"(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."

Proposed change:
"(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 **aspects of the** oversight ~~activities of~~ **by** 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."*

3. RATIONALE / REASON / JUSTIFICATION:
There are not two oversights of TC/DOA applicants/holders of the Agency but only one covering certification through the DOA.

response

Not accepted.

In practise, there are two EASA oversight processes – 1. Product safety oversight (certification process by EASA certification team working i.a.w. product related internal certification working procedures) and 2. Organisation oversight (EASA DOA team working i.a.w. DOA oversight procedures). The requirements, the process, the staff, and the certificates are different. However, if the intent of you comment was that these two processes should become closer and the level of co-operation of the relevant staff higher then this would be fully agreed. The LoI concept implementation is to make indeed these two processes closer requesting more intensive exchange of information and higher participation of the relevant staff of both EASA teams in each other activities.

comment

73 comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 11/67, paragraph 2.2.1(a)

2. PROPOSED TEXT / COMMENT:
The subparagraph (12) indicates:

"(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."

The verifications of compliance made by the approved design organisations via the CVE function are not made on behalf of the Agency but as part of the duties/obligations of the DOA holder.

Proposed change:
"(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."

3. RATIONALE / REASON / JUSTIFICATION:
To clarify that verification of compliance is made by DOA holders as an obligation but not on behalf of the Agency.

response

Noted.

The substance of your comment is agreed which lead to amendments to the Explanatory Note to express this more clearly.

comment

74 comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 11-12/67, paragraph 2.2.1(a)

2. PROPOSED TEXT / COMMENT:
The subparagraph (13) indicates:

"(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."

These statements seem being contradictory to the intent of the NPA LOI contents.
Could the Agency clarify the meaning of "overall level"? Is reference made to quantitative, qualitative, or to both aspects?
Eventually, the term overall level of involvement should be replaced by another wording.
Therefore it is proposed to rewrite this paragraph 13, representing better the future way of working and the real impact on the way of working.

3. RATIONALE / REASON / JUSTIFICATION:
The term 'overall level' may give the impression that the number (quantitative) of compliance verifications performed by the Agency's staff will not significantly evolve. It may at the same time give the impression that the level of risks (qualitative) requiring the involvement of the Agency's staff in certification projects will not significantly evolve.

With the introduction of the LOI concept and the uniform application of rules by the Agency's staff, it may be anticipated that a certain volume (quantitative) of compliance verifications previously carried out by the Agency will be transferred to the Industry or vice versa, due to qualitative criteria.

EASA will select the LOI needed based on a risk assessment. This will focus EASA to activities that have the most added value to the safety. Therefore LOI will be less in certain cases and more in other cases depending on the experience with the applicant, the criticality and novelty criteria.
To state that the LOI concept will not substantially change the way the staff is working seem not correct, as today the selection of documents and activities retained is based on a personal judgement without clear criteria. With this NPA, the criteria will be more formalised and this will consequently influence the way of working.

response

Noted.

Again, the substance of your comment is agreed. Certainly, some things will change with implementation of the LoI concept. The risk-based approach to verification process will be explicit, the process itself formalised and applied uniformly by EASA staff under common assessment criteria. However, the main principles will not change because there are already existing today (non-exhaustiveness of verifications by the Agency, the risk-based approach to verification with safety in mind). The Agency staff are already 'prioritising' their verification work today, using naturally the criteria like novelty, criticality and knowledge of the DOA performance. There will be changes but the intent of the quoted text was to say that the LoI introduction will not be (as some other comments on the NPA suggest) a dramatic, revolutionary change to the current way of working.

The sentence *'The overall level of involvement is expected to remain the same"* intended to express that if there are no changes to the conditions external to the LoI concept then the relative ratio that can be expressed as percentage of the items verified to the items demonstrated may remain approximately the same. By the external conditions we mean the certification demand from the industry, the number of the Agency's certification staff, their work assignment, working hours etc. These external conditions may certainly evolve but not because of the LoI concept. The LoI concept is neutral in terms of these conditions and for the purpose of the impact assessment assumes they remain constant. Then, indeed, the overall level of involvement may remain approximately the same. However, if, for example, the certification demand goes down then with the Agency's workforce/capacity remaining constant the level of involvement would go up…and opposite. But this does not depend on the LoI concept. It must be recognized that the LoI concept will bring with the formalisation of the process certain administrative burden which will consume certain resources of the staff. The aim is to keep this burden and resources consumed as limited as possible.

comment

137 comment by: *FAA*

Page 10: The discussion for 2.2.1 item (6) states only low risk areas will be eligible for transfer of responsibility to the applicant. It is important to know how risk is determined in order to fully evaluate this position. Risk is defined in this document as the assessed predicted likelihood and severity of the consequence(s) or outcome(s) of a hazard. Recommend that guidance provides information on what goes into determining low risk. The guidance should also emphasize that risk based decisions are significantly different than performance based decisions.

Page 11: The discussion for 2.2.1 item (8) talks of a DOA able to "approve alone" and "without any Agency involvement". This would imply that the holder has approval authority. It is hard to determine the impact to our validation programs of such a system without knowledge of the details around how this would work.

Page 11: The discussion for 2.2.1 item (9) talks of "performance based oversight". Performance based oversight is not the same as a risk based oversight. A poor performing manufacturer of a widget that has no impact on safety should not be reviewed more frequently. Elsewhere it is mentioned that good performing organizations could be granted certain privileges. Recommend that performance alone should not be a determining factor when granting such privileges. Rather a full risk assessment should be completed.

response

Noted.

1. 2.2.1 item (6) : A guidance material will bring a risk assessment model or models to define, in relative terms, what is low, medium or high risk.

2. 2.2.1 item (8): This situation exists already today. DOA holders have *approval authority* given by EU law to approve minor changes and repair design or even major repair designs (TC/STC/APU ETSOA holders only). Consequences of the LoI introduction into Part-21 will certainly need to be addressed by possible changes to the BASA (TIP) if this LoI concept is to be applied in some form to validation projects.

3. 2.2.1 item (9. Your comment and example on a difference between performance based oversight and a risk based oversight risk is understood and shared. From the LoI determinations point of view, the risk related to the function of an article in the product is taken account under 'criticality'. For organisation oversight, EASA has decided to apply the performance based model but we may consider the product/part/appliance risk parameter for the set of key performance indicators to take it into account to determine the level of oversight.

comment

179 comment by: *CAA CZ*

2.2.1(a)(6)
"Low risk areas" is, from our point of view, a very precarious term in the field of aircraft design and the LOI concept of the transfer of responsibility to DOA organizations is based on this.
The NPA requires from applicant´s DOA organization to control the risks in areas of the certification project not selected by the Agency for its direct involvement. From the proposal

	it is not clear according to what rules and using what tools the DOA will exercise this responsibility and how the Agency will carry out supervision of it. At the same time, in our view, this DOA´s responsibility should also cover areas of the certification project selected by the Agency for its direct involvement, which means the entire certification project. Further, the proposal requires continued monitoring and measuring of the performance and experience of the DOA organizations. From other provisions of the NPA it is clear that the role of the Agency ("Performance-based oversight") will need to be significantly strengthened (see current, for economy reasons limited, participation of national DOA consultants). What means for measuring and monitoring of the performance and experience of DOA organizations to be implemented and how it will differ from the current system of DOA organizations oversight.
response	*Noted.* The Explanatory Note of the Opinion reflects the comments on the NPA and addresses principles of these issues. It should be however noted that the implementation means (the *how)* will be only developed in Phase II of this rulemaking project.

comment	*180* comment by: *CAA CZ* 2.2.1(a)(10) Audits will solve problems afterwards – that is, from our point of view too late and therefore unacceptable. These will have to be more extensive and it will constitute another administrative burden. Improving cooperation between DOA certification teams and the Agency is expected – see section 2.2.1(d), but it is true that audits reveal only 1 % of what would be revealed during the normal certification process.
response	*Noted.* Your concerns seem to suggest that the LoI concept will introduce new hazards and risks to the certification processes but this is misapprehension of the current situation and the changes going to be brought by introduction of the LoI concept. The same risks exist already today – not enough staff to perform anything close to exhaustive verification. This is shared experience, among others, of all the members of the Safety Management International Coordination Group (SM ICG) composed of number of Civil Aviation Authorities of the world, including the leading Authorities like the FAA, TCCA, ANAC, FOCA, CAA UK …and many others. They all arrived to the same conclusion that rather than to insist on substantial increase of their resources it necessary to recognize that the hazard of non-exhaustivity of oversight is a standard situation and it is therefore necessary to identify and manage (assess and mitigate) the existing risks in a way a better then today. ICAO Annex 16 provides regulatory (SSP/SMS) frameworks for safety management and this proposal is the first step towards transposition of the Annex 16 standards into Part-21.

comment	*285* comment by: *European Sailplane Manufacturers* page 11 para (8) / (12) The sailplane manufacturers do not concur that a lower LOI should only be possible for the "high performing DOA". The limitation to DOA holders is not taking into account the fact that especially within manufacturers of ELA1 and ELA2 products the percentage of DOA is much lower as often these design organisations work under ADOA rules. This certainly does not mean that these organisations are not able to design (and build) safe aircraft, nor that they use procedures which are unsafe. It simply means that the procedures used by EASA today to grant a DOA to such manufacturers are by far much too onerous. The observation is that such small companies often fight for years to get DOA and afterwards struggle sometimes with the resulting additional workload. When assessing the working procedures within such small design organisations it easily becomes clear that the minimum requirements for becoming and holding the DOA simply are not tailored to a design organisation with sometimes much less than ten engineers. In summary: Yes, a lower LOI should be possible for the more experienced and good working design organisations. No, this should not be limited to DOA holders. If this is not possible in the current system, then adaption of the DOA approval process (and of the EASA fees and charges regulation) for DOA within small organisations should be improved.
Response	*Noted.* The quoted expression is highly imprecise and is not repeated in the Explanatory Note for the Opinion. All, including APDOA holders and certification-programme-only applicants have chance to lower the Agency's involvement by showing they are capable and credible in ensuring compliance. Except that the new privileges will only be available to DOA holders because only the DOA holders are on top subject to organisational oversight.

Comment	*290* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland* 2.2.1 Level of involvement (a) Safety considerations: 1) *Noted. Swiss FOCA recognizes and supports this objective.* (3) *Swiss FOCA could provide support in shaping such concept.* (4*) A formal risk assessment requires knowledge and resources at Agency and its service providers, Swiss FOCA could provide some support to establish crisp and efficient tools in risk assessment.*

(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." *Comment FOCA: This approach will require the Agency to provide more detailed guidance on how to establish a certification programme.*

"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". *Swiss FOCA is concerned if such extensive determination can be finalized until Phase 2 of a certification project in small projects. Again, it is essential for the Agency and SP staff to have adequate and efficient tools available.*

(6) …"Means must be determined for measuring of the performance of the design organisation and ensuring its continued monitoring". *Swiss FOCA could share its experience gained since 2011 in that respect.*

response

Noted.

For (3), (4) and (6):- Your support would be certainly appreciated. You will be contacted.

For (5): Detailed guidance is planned will be provided in Phase II of this rulemaking project.

comment

291 comment by: *Federal Office of Civil Aviation (FOCA), Switzerland*

(8) *Swiss FOCA: The results of the performance measurement must be transparent, if not unfair treatment can be easily claimed by applicants.*
In addition it must be very clear to the Agency that means must be provided to the public community to indicate which changes to products etc. are approved under the new privileges to enable the industry to identify the correct configuration before a change can be applied for. The responsibility to provide such information may not be compromised by IP rights.

(9) Swiss FOCA supports this activity to standardize a high level of oversight principles.

(11) … "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". *Swiss FOCA: It must be ensured efficient communication between EASA , NAAs and QEs.*

response

Noted.

(8) Agreed. A system for formal numbering and registering of approvals issued under the privileges will need to be established.

(*11) Noted and agreed.*

2. Explanatory Note — 2.2. Objectives — 2.2.1. Level of involvement — (c) Interface considerations p. 12

comment	*293* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland* (c) Interface considerations: (1) … " They may be subject to changes based on the results of the pilot project and the output of RMT.0611." *Swiss FOCA: It would be beneficial to support the pilot projects with existing experience from STC and other projects.* (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". *Swiss FOCA: Abbreviation "D & M" may be misinterpreted as "design and maintenance" too, therefore "D & P" for design and production is considered more appropriate.*
Response	*Noted.* *(c)(1) – Noted.* *(c)(2)* - The 'D & M' is already deep in use (e.g. D & M Sub-SSCC).

2. Explanatory Note — 2.2. Objectives — 2.2.1. Level of involvement — (d) Certification process effectiveness, efficiency and transparency p. 12-13

comment	*11* comment by: *Franz Redak* (4) EASA is indicating that the external communication is to be improved. We believe that statement needs somehow addressing the fact that once a DOA is in place, it cannot just left alone with their certification task. Pro-Active information of DOAs about changes in certification policies and interpretation of technical and administrative topics is absolute essential. In other words making DOAs partner and not enemies. Hiding information within EASA essential for certificatin tasks is contra-productive and I believe against the spirit of the BR and certainly of DOA interest.
response	*Noted.* EASA web has been recently amended and the Agency is already contemplating further web

based means to support a better communication with the stakeholders.

comment

54 comment by: *DOA EASA.21J.041 Aero-Dienst GmbH & Co. KG*

(4):
I suggest to emphasize the importance of a timely communication and to make the experts project time schedule transparent to the applicant. Last minute feedbacks are not helpful at all and at the end increase Agency workload.

response

Noted

We are aware of the issue of responsiveness. It is a resources issue.

comment

75 comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 13/67, paragraph 2.2.1(d)

2. PROPOSED TEXT / COMMENT:
The paragraph indicates:

"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."

To which extent will it be possible for the applicant to access, and challenge if necessary, the data used by the Agency to establish the risk assessment?

3. RATIONALE / REASON / JUSTIFICATION:
Some clarifications are requested to establish the level of transparency claimed in this NPA, including the records of the rationale for EASA decision on its own involvement.

response

Noted.

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment

181 comment by: *CAA CZ*

	2.2.1(d) At the end of this paragraph it is stated that the introduction of LOI will improve planning (of certification tasks) – but, at least in our environment, it is expected not to work. The certification tasks of our aviation companies are usually heavily dependent on the national/EU grants/subsidies or on the customer order itself.
response	*Noted.* Such external factors like the applicant's project financing problems cannot be certainly solved by the LoI concept.

comment	*182* comment by: *CAA CZ* 2.2.1(d)(4) An incomplete sentence: "... to better (...? ...) the exchange of safety-related data." In this regard we would like to ask for explanation what is idea of the practical implementation of this requirement. From the proposal it is not clear how the exchange of safety-related data will be practically implemented, and whether, and if so, what implementing procedures, including the possible implementation of appropriate IT systems, will exist.
Response	*Noted.* Within the LoI context and also out of the LoI context (EASA will become owner of the European Central Repository (ECR) of safety data) various software including web based solutions are under development. It relates to the 'big data' project.

comment	*294* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland* (d) Certification process effectiveness, efficiency and transparency (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"; *Swiss FOCA: It should be continously monitored that added value for safety is achieved by the proper definition of LOI.* (2) "improving internal communication and strengthening support between the Agency departments involved (the product certification teams and the DOA staff)"; *Swiss FOCA: Please clarify what is to be understood under "internal" communication! Does this include communication to accredited NAA or QE staff too?*
response	*Noted.* (d)(1) – The Agency is aware it will need to complement the LoI implementation by adding the other SSP components of safety management to build a full 'EASA SMS'. Key performance indicators will need to be established to measure performance of the product

certification process. Very difficult tasks.

(d)(2) –Certainly, it is necessary to involve those contracted NAA performing certification tasks on behalf of EASA. In the future QE too.

2. Explanatory Note — 2.3. Summary of the Regulatory Impact Assessment (RIA) p. 13-14

comment *12* comment by: *Franz Redak*

We believe it is worthwhile to mention that over and above the safety concerns, it is also an obligation of EASA to respond timely to an application for a design change. We would even say the industry has a right to get timely response in order to support operation in europe.
Response times of 4-8 weeks should belong to the past.
The implementation might (if properly managed) improve overall turnaround times of STCs and/or Minor changes.

response *Noted.*

2. Explanatory Note — 2.4. Overview of the proposed amendments — 2.4.1. Level of involvement — (a) Determination and criteria of the level of involvement p. 14-17

comment *1* comment by: *Prof. Filippo Tomasello*

Article 13 of Basic Regulation legitimates Qualified Entities (QEs). The existence of a QE involved in the process and a report or statement produced by said QE, independent from the designer, should be taken into consideration to determine the LOI of the Agency.

response *Not accepted.*

Out of scope. QE are not yet introduced in Part-21 and this issue was not included in the adopted ToR. The issue is however going to be addressed by the draft new Basic Regulation based on EASA Opinion 2015/1:

***'Article 58**: The provisions on accreditation of qualified entities have been clarified. It is proposed that qualified entities may be granted a privilege to issue, revoke, and suspend certificates on behalf of the Agency or national competent authority. The principle of recognition of accreditations of qualified entities is introduced. This is without prejudice to the rights of Member States to decide to which qualified entity they wish to allocate certification and oversight tasks. It is also proposed that Member States may accredit a*

qualified entity jointly.'

comment *13* comment by: *Franz Redak*

Gaining experience with an applicant may be very hard for applicants typically working on multiple types of aircrafts. They will have to deal with multiple PCMs in an infrequent manner and therefore may have a disadvantage position.
Still we believe they have the same right to be evaluated similar to their fellow DOAs.

response *Noted.*

Yes, they have the same right to be evaluated similar to their fellow DOA holders. The LoI concept is applicable to all (not the privileges). The disadvantages of the 'business model' of small companies is difficult to be circumvented under the LoI concept. The LoI is about the Agency's confidence, trust in the applicant and to build the trust may take time. But the possibility is there. One

comment *14* comment by: *Franz Redak*

to (1)
The wording ... in the previous.... certification projects seems to indicate that EASA is evaluating DOAs on a standard which is not approved because done prior to the implementation of the LOI principle. On which basis can this be done?

response *Noted.*

In the previous means conducted before the upcoming project. There are two sources, two inputs to applicants performance evaluation: evaluation of the applicant in their certification projects with the Agency and, for DOA holders, DOA oversight evaluation.

comment *76* comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 14/67, paragraph 2.4.1(a)

2. PROPOSED TEXT / COMMENT:
The subparagraph (a) indicates:

"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."

Can the Agency clarify to what risks reference is made (i.e. risks to the product safety, risks to the
compliance demonstration, etc…)?

3. RATIONALE / REASON / JUSTIFICATION:
For sake of clarity.

response

Noted.

The amended rule proposal and the Explanatory Note explains better explains the nature of the risk - there is compliance demonstration process risk (i.e. a non-compliance) together with severity of its consequences on product safety.

comment

77 comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 15/67, paragraph 2.4.1(a)

2. PROPOSED TEXT / COMMENT:
The subparagraph (a) indicates:
"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."

Note: The point 21.B.100(c) refers to major repairs.

This subparagraph gives the impression there is the intent to introduce some proportionality in the LOI.

Can the Agency further explain the reasons justifying a different approach for ETSO articles and (major) repairs only?

3. RATIONALE / REASON / JUSTIFICATION:
For sake of understanding. Although the concept of proportionality is not disputed, the full (proportionality) scale should be detailed.

As stated later in the subject subparagraph, novel or unusual features of a certification project may be identified in:

- the proposed design,
- the proposed operating characteristics and limitations,

· the intended use of the product and the kind of operations,
· 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.

Can any of these, be found in certification projects for ETSO articles and (major) repairs?

Noted.

The Explanatory Note to the Opinion addresses these issue (see info for 21.A.100(b) in 2.5.1).

comment *78* comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 16/67, paragraph 2.4.1(a)

2. PROPOSED TEXT / COMMENT:
The subparagraph (a) indicates:
"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.

[…]

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.

[…]

The hazard […] 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."

Could the Agency clarify how equal treatment between applicants will be ensured with transparency if all specific and measurable criteria are not published?

3. RATIONALE / REASON / JUSTIFICATION:
The publication of specific and measurable criteria is a prerequisite for the uniform application of rules by the Agency's staff.

response

Noted.

The LoI discipline specific criteria as well as more details on the generic criteria will be published, first as a Certification Memoranda and then in AMC/GM material to be developed in Phase II of this rulemaking tasks, including an NPA to be consulted upon, and a related comment-response document (CRD) leading to an ED Decision.

comment

79 comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 16/67, paragraph 2.4.1(a)

2. PROPOSED TEXT / COMMENT:

This paragraph states: *"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.(…)"*

Does it mean that a subject agreed for long time as "not novel" with an experienced expert may be qualified as "novel" for a less experienced expert assigned to a project?
Such situation should be avoided as it would be a practice not in line with the overall objective of the NPA for implementation of the LOI concept, and the acquisition of knowledge by a new Agency expert should be de-correlated from projects' schedules (e.g.: through DOA audit)

Proposed change:
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, taking into consideration that acquisition of knowledge by Agency experts can be de-correlated from projects' schedules and performed during DOA investigations/surveillance activities.

3. RATIONALE / REASON / JUSTIFICATION for the Comment:
Novelty concept should be less dependent on the experience of Agency experts assigned to a project

response

Partial accepted.

The substance of the comment is agreed. These implementation issues will be addressed by a dedicated AMC/GM material to support the legislative proposal of the corresponding Opinion. It will be developed during Phase II of this rulemaking activity and the draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment

80 comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 17/67, paragraph 2.4.1(a)

2. PROPOSED TEXT / COMMENT:
The subparagraph (a) indicates:
*"**Performance of the design organisation of the applicant:** […].*

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 […].

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.

[…]."

Could the Agency clarify how the performance of design organisations will be assessed and ranked before the implementation of the SMS within such organisations?

3. RATIONALE / REASON / JUSTIFICATION:
The publication of specific and measurable criteria is a prerequisite for the uniform and transparent application of rules by the Agency's staff to ensure equal treatment between applicants.

response *Noted.*

How the performance of design organisations will be assessed is subject to an internal working procedure being developed. It will be made publically available.

comment *160* comment by: *Rolls-Royce*

Comment:
Performance of the Design Organisation of the Applicant (page 17): The basic principle behind Level of Involvement is to allow a Design Organisation to be permitted to make findings of compliance, in those areas where the safety risks are assessed to be lower, based on the assessed "performance" of the Design Organisation. The EASA assessment of the "performance" of the Design Organisation should therefore focus on its ability to make satisfactory findings of compliance, rather than consider the broad scope of DOA approval

Suggested Resolution:
'Clarify the Design Organisation "performance" assessment will focus on its demonstrated ability to make satisfactory findings of compliance, rather than the consider all activities within the scope of DOA approval.

Please note: this comment applies throughout the NPA where the performance of the design organisation is discussed (such as Table B, Page 54, Page 60 and others) - any change in response to this comment will therefore require all occurrences to be reviewed to ensure consistency

response *Partially accepted.*

The NPA already stated that the performance will not be measured for the broad scope of a DOA approval but separately in each technical domain or discipline and it is implicit that it relates to their main obligation to determine and demonstrate compliance. But the substance of the comment is agreed and proposal is, in a modified form, carried into the Explanatory Note of the Opinion to make it more explicit (see Chapter 2.5.1).

comment *162* comment by: *sabena technics BOD*

The concept of certification plan was not existing in (EC) No 748/2012. Definitions should be given to explain differences between certification plan and certification programme.

response	*Noted.* The terminology has been unified to abandon the *plan* in favour of *the programme.*

comment	*183* comment by: *CAA CZ* 2.4.1(a) Compliance Demonstration Items – this is a new element that brings more administration. The proposal of 21.B.100 stipulates that EASA notifies the applicant of Agency´s level of involvement in the certification project. If we understand it correctly, EASA will have no opportunity to decide ad-hoc on its involvement in certification projects in cases where applicants, on the basis of their privileges, have assessed the change as "an Equivalent Change" and approved the change themselves. In these cases, EASA will evidently not know of such a certification project prior to its implementation, and will not be able to decide about its possible involvement. It can bring a considerable risk to the whole certification system.
response	*Noted.* 21.B.100 is applicable to the certification projects with the applicants to Agency. The determined LoI is notified to the applicant. This is not the case of the new DOA privileges where there is no application and no applicant (except for the privilege itself) for the individual application of the privilege. The Agency's LoI in the case is by definition zero. However, the risk assessment will have to be performed before granting the privilege and mitigation means must be put in place to reduce the risk. The scope of each granted privilege will be therefore limited, strictly established and recorded in the DOA Term of Approval.

comment	*205* comment by: *SIRIUM AEROTECH* LOI provisions will impact largely in competitivity of companies. For this reason, it is important to apply homogeneously the new rules and to make an effort to standarize criteria. Drivers to choose different LOI are quite subjective and it is not acceptable to leave its evaluation in hands of one only person or a reduced group of experts/TLs. This would lead to an unfair handicap for DOAs surveilled by more strict TLs, as already happens with the rest of Part 21. EASA should create or improve an effective mechanism to standarize criteria and create a fair playfield before implementing more rules based on subjective elements like "commitment to safety". For example, a closer surveillance over TLs' work (including NCAAs) and a systematic rotation of TLs by different companies.
response	*Noted.* The criteria, generic and discipline specific, will be common to all stakeholders and published. Standardisation of the LoI concept application will be secured by training to the

staff and also within the individual panels of experts.

comment

216 comment by: *British Airways*

Please describe the process of DOA discipline assessment. How and when do the Agency propose to conduct these assessments and when will we be notified of our ranking.

response

Noted.

These implementation issues will be addressed by a dedicated AMC/GM material to support the legislative proposal of the corresponding Opinion. It will be developed during Phase II of this rulemaking activity and the draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment

298 comment by: *Federal Office of Civil Aviation (FOCA), Switzerland*

Point 21.B.100(d) ... "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". *Swiss FOCA: Definition of "new piece of information" should be clarified.*
"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". *Swiss FOCA: This is inconsistent as the review of compliance data starts only phase 3, directly followed by the issuance of the expert statements in phase 4 and the issuance of the Agency's design approval in phase 5.*

"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". *Swiss FOCA: definition of "difficulties" should be clarified.*

Point 21.B.100(b) *Swiss FOCA: Why to adopt SMS principles rather than 1309 principles for projects to define Agency's LOI?*

response

Noted.

For point 21.B.100(d):

1. Example: The initial LoI includes review of a test plan when available and requests the test witnessing by the Agency on site. After a review of the test plan and after interactions with the applicant's staff in charge the Agency concludes that the test witnessing is not needed and the test report suffices.
2. Example: A reported failed ground or flight test that put in question the proposed design and/or the means of compliance or the certification assumptions previously made. This has led to design changes and need for additional testing with higher LoI of the Agency.

For point 21.B.100(b) per the NPA (now (a)): The updated proposal is more explicit on the nature of the risk assessment and clarifies that it is not the xx.1309 type of safety assessment (See 21.A.100(a)and 21.A.15(b)(6))

comment

299 comment by: *Federal Office of Civil Aviation (FOCA), Switzerland*

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". *Swiss FOCA: Noted. It must be highlighted that such assessment per discipline will require additional efforts and resources.*

"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". *Swiss FOCA: Efficient flow of information and knowledge must be ensured by the Agency in order to achieve standardization among experts.*

response

Noted.

1. Yes, the Agency experts are working on their discipline specific criteria to support the future assessments Noted for Phase II.
2. All the criteria will be subject to consultation though Certification Memoranda and, when adopted, will be made publically available. Standardisation means within a domain, panel or discipline will include PCM/Experts meetings, training to all the staff involved, including those from contacted NAAs

comment

300 comment by: *Federal Office of Civil Aviation (FOCA), Switzerland*

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. *Swiss FOCA: Communication on similar risks must be ensured between Agency and its service providers.*

"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".
Swiss FOCA: Based on the fact that across Europe there are two dozens of DOAHs employing staff above 50 engineers this may be feasible for those DOAHs, but not for the majority of DOAHs having less engineers.

response

Noted.

1. *Agreed*. Relates to the Agency 'big data' project.
2. If the design organisation is involved in design and compliance demonstration activity in a specific domain/discipline than their performance in this domain/discipline must be assessed irrespective of the number of engineers.

2. Explanatory Note — 2.4. Overview of the proposed amendments — 2.4.1. Level of involvement — (b) Certification programme or plan p. 17-18

comment

33 comment by: *CAA-NL*

EN 2.4.1(b)(3)/(4) blz 18.
Part 21 currently does not clearly require a certification plan for repairs and ETSOs. What is suggested in these two items means new requirements are implied to (A)DOA's. It is not substantiated why this is required.

response

Noted.

The amended proposal requests a certification *programme* (the final wording) for every certification process except for a minor change or minor repair design. The reason is twofold:

1. The applicant should always have, irrespective from the Agency needs, a data summary/planning document for every project above certain size. This is considered natural requirement for every serious activity of certain complexity. This includes also projects for major repair designs and ETSO articles.
2. The Agency needs this documents because it provides necessary information and insight into a certification project for which an EASA approval/certificate is requested. With introduction of LoI, the document becomes even more important because the documents provides a necessary information on the basis of which the Agency's LoI can only be determined.

comment	*164* comment by: *sabena technics BOD* 2.4.1 (b)(2) NOTE: suggest to add "and STCs". Indead, by nature the impact of a minor change to a STC should not require to reissue a certification programme, reason for revision given in Form FO.CERT.00032 should be sufficient.
response	*Noted.* These implementation issues will be addressed by a dedicated AMC/GM material to support the legislative proposal of the corresponding Opinion. It will be developed during Phase II of this rulemaking activity and the draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	*165* comment by: *LMI Aerospace* Please see comments against 21.A.433 (a) 2.
response	*Noted.* See our response to these comments.

comment	*301* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland* *(b) Certification programme or plan* *Swiss FOCA: Minimum content of CP must be clearly defined in related guidance material.*
response	*Noted.* For ETSO articles, the NPA already provided draft guidance on the content of the *plan* (see AMC 21.A.605 in Chapter 3.3). The draft guidance may be revisited in Phase II of this rulemaking project.

2. Explanatory Note — 2.4. Overview of the proposed amendments — 2.4.1. Level of involvement — (c) Compliance demonstration process with the TC basis, OSD certification basis and EP requirements p. 18-19

comment	*15* comment by: *Franz Redak*

	The reporting of a difficulty or event that may have a significant effect on certification requires that EASA pro-actively informs the applicant of their criterias for such decision.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	*81* comment by: *Airbus* **1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:** Page 19/67, paragraph 2.4.1(c) **2. PROPOSED TEXT / COMMENT:** 21.A.20(d)(ii) should read 21.A.20(d)2 Proposed change: Finally, the new point 21.A.20(d)(~~ii~~)2 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)~~ 2 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. Comment: Typo: **3. RATIONALE / REASON / JUSTIFICATION for the Comment:** To correct Typo.
response	*Accepted.* Thanks.

comment	*184* comment by: *CAA CZ* 2.4.1(c) The LOI generally causes that DOA organizations will greatly push on their LOI, ultimately leading to the fact that they will have another reason not to report (any) difficulties in their internal certification. The obligation to report difficulties (see 21.A.20) will not probably be an adequate tool.
response	*Noted.*

	The possibility of intentional underreporting is not a justification for not requiring the reporting. This applies for occurrence reporting in general. We are not going to delete 21.A.3A(b) from Part-21 because design approval holders may decide not to comply with it.
comment	*302* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland* *(c) Compliance demonstration process with the TC basis, OSD certification basis and EP requirements* *Swiss FOCA: Minimum knowledge of the Agency's certification process must be ensured for DOATLs -normally not having extensive experience in type-certification activities - to enable them in the course of initial investigations to settle a common standard. Longterm experience from certification activities has already shown differences between EASA DOAHs standards*
response	*Noted.* One of the objectives of the LoI concept implementation is to improve collaboration between the Agency's product certification team and DOA staff in charge of the applicant's DOA. This includes a higher involvement of the DOATL in product certification projects.
comment	*303* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland* "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." *Swiss FOCA: A more precise definition of the required activities for applicants would be helpful.* "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." *Swiss FOCA: How should the industry cope with the new requirement to identify any new hazards? Explanation: For this approach it would be required to have available relevant information on hazard already identified in the past, as an applicant normally may not have sufficient information on hazards that may not have been captured by the initial TC, OSD basis and/or EP requirements.*
response	*Noted.* *For 21.A.20:* These implementation issues will be addressed during Phase II of this rulemaking

task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

For 21.A.20(d)(2): This requirement (as amended) on the industry stakeholders is already in preparation of the upcoming implementation of SMS by D & M organisations . Until then the industry stakeholders can relatively comfortably declare they have not identified any hazard. After Part-21 is amended with SMS standards they will be required to establish the whole system for identification of hazards related to their activities, including those that may exist for their new product, part or appliance to be certified on top of the hazards captured (by the Agency) in the established certification basis. They will have to have a system for hazard identification and risk management based on a system for collection, analysis and exchange of safety data. According to Annex 19 hazard identification shall be based on a combination of reactive, proactive and predictive methods of safety data collection.

2. Explanatory Note — 2.4. Overview of the proposed amendments — 2.4.1. Level of involvement — (d) New DOA privileges p. 19

comment

16 comment by: *Franz Redak*

We would like to highlight that it would be beneficial to the system if EASA grants privileges (after review of the DOA) automatically if the respective DOA performs well.

response

Not accepted.

The risks to product safety linked to the new DOA privileges needs to be reduced to under an acceptable safety level for each and every privilege granted and therefore must be assessed for each and every privilege separately case by case.

comment

82 Improved wording comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 19/67, paragraph 2.4.1(d)

2. PROPOSED TEXT / COMMENT:
The subparagraph (a) indicates:

"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."

Should it read the following?

"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~~ changes to type design and the minor and major repairs, this proposal brings new privileges that may be granted to those DOA holders with satisfactory performance and experience."

3. RATIONALE / REASON / JUSTIFICATION for the Comment:
For sake of consistency with the current point 21.A.263.

response

Noted.

Also note that the privilege to approve major repairs is currently available only for the TC (STC or APU ETSOA) holders and the quoted sentence referred to all DOA holders. The text of the Explanatory Note has been amended for the Opinion anyway.

comment

215 Request for Clarification comment by: *British Airways*

If a DOA is granted the privilege to issue an STC will they issue the Tech Visa to the Agency or will they issue the STC directly ? In the case of a programme where the DOA does not have this privilege and the Agency still retain the issuing of the STC, how does the DOA signify to the Agency compliance has been shown if there are no final documents to be reviewed by the Agency.

response

Noted.

1. When a DOA holder has been granted with a privilege of appropriate scope: STC will be issued *directly* by the holder, without submitting any data to the Agency (unless requested to do so by the Agency's DOA audit).
2. When a DOA holder does not have this privilege it proceeds as usual, starting with an application to the Agency and submitting all the necessary descriptive and identification data (for an STC, see amended 21.A.113(b) and amended 21.A.93(b)) providing at the end the declaration of compliance (for STC per 21.A.20(e) and means by which such compliance has been demonstrated (see 21.A20(a)).

comment

304 comment by: *Federal Office of Civil Aviation (FOCA), Switzerland*

(d) New DOA privileges

"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)." *Swiss FOCA: Full transparency in the results of the DOAH performance across the entire community is necessary to avoid unfair treatment of individual approval holders or applicants. As an alternative an excellence concept (known in the QM domain) should be considered by the Agency.*
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

2. Explanatory Note — 2.4. Overview of the proposed amendments — Table A: Detailed review of changes in the affected Part-21 points p. 22-34

comment	*17* comment by: *Franz Redak* 21.A.16B Isn't an ESF also a special condition (listed under SC in a TC). If so, the applicant must have some obligations here to identify them.
response	*Noted*. ESF is not a special condition. In contrary to SC, the ESF is normally proposed by the applicant to be used as an alternative to an existing and adequate certification specification. Special conditions are prescribed by the Agency when the applicable certification specifications do not contain adequate or appropriate safety standards for the product.

comment	*18* comment by: *Franz Redak* 21.A.20b) It requires to specify clear conditions and criterias to allow the applicant to identify conditions which have a significant effect on the Level of involvement. EASA is requested to identify them. Also the conditions for "signficant effects on the certification program" must be identified.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA

and a related comment-response document (CRD) leading to an ED decision.

comment *22* comment by: *Franz Redak*

EN missing text + missing justification of an amendment

21.A.263c4) The deletion of this privilege (minor AFM changes) is not indicated here. What is the purpose?
This privilege is needed by DOAs even without the privilege of approving major changes.

response *Noted.*

The 21.A.263(c)(4) privilege is now covered by the (c)(2) privilege. AFM is not considered part of the *type design* but is considered part of the *type certificate* (see 21.A.31 and 21.A.41) After the change in wording from *a change to type design* to *a change to type-certificate* introduced by the amending Regulation (EU) 69/2014 (OSD) the (c)(4) privilege have fallen into the scope of the (c)(2) privilege.

comment *34* comment by: *CAA-NL*

Tabel A:
On page 29 of 67, top paragraph, it is stated that "*the DOA holder is notified of the applicable TC basis and EP requirements when the Agency is granting the privilege*".
· If an appropriately approved Design Organisation is granted the privilege to issue an STC, what system will be in place to coordinate the numbering system of those STC's? Will an STC-number be assigned at the time of granting of the privilege?
· Will these STC's that are approved by an appropriately approved DOA be mentioned in the list as published on the EASA website (http://easa.europa.eu/document-library/type-certificates/supplemental-type-certificates)? Should then the DOA contact EASA again to inform that the STC has been approved?

response *Noted.*

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment *55* comment by: *DOA EASA.21J.041 Aero-Dienst GmbH & Co. KG*

Missing justification

	21.A.263: The privilege to approve minor revisions to the AFM and Supplement (21.A.263(c)(4)) is deleted and no explanation mentioned. Please clarify.
response	*Accepted.* The 21.A.263(c)(4) privilege is now covered by the (c)(2) privilege. AFM is not considered part of the *type design* but is considered part of the *type certificate* (see 21.A.31 and 21.A.41) After the change in wording from *a change to type design* to *a change to type-certificate* introduced by the amending Regulation (EU) 69/2014 (OSD) the (c)(4) privilege have fallen into the scope of the (c)(2) privilege. The explanation for the deletion of the 21.A.263(c)(4) privilege is now provided in the Table B in the Explanatory Note for the LoI Opinion. See info for the applicable point 21.A.263

comment	*171* comment by: *sabena technics BOD* *Text - correction* 21.A.115 last dash: certification programmes of previous STC certification projects have never been formally approved by the Agency. There was only indirect approval whan the certification program was called in the STC certificate.
response	*Accepted*. The *formal approval* wording was inappropriate. There is no formal approval of the certification programme. The programme is *accepted.*

comment	*269* comment by: *Airbus Helicopters* Table A, 21.A.97 It is stated that, for DOA holders approving a major change under their privilege, there is no application to the Agency, consequently “there is no applicant per point 21.A.20(a)”. However: • The explanatory note for 21.A.20, page 23, states that 21.A.20 is also applicable to applicants for major changes or STCs under the privileges of points 21.A.263(c)(8) and (9), • All subparagraphs of 21.A.20 use the word “applicant” This is inconsistent. It is also stated that, in the case of approval under delegation, the certification programme is determined by the Agency and recorded in the terms of approval when granting the privilege. However, this does not appear in any paragraph of sections A or B.

Suggestions
The inconsistency about "applicant" should be resolved.

Also, the proposal should be completed with information about how the new privileges are exercised (determination of certification basis and programme, materialisation of major change approval).

response *Noted.*

For 21.A.20, page 23: the text on page 23 is correct. It states:

> *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*

For 'the applicant' wording: Note that the wording of 21.A.97(b)(3) and 21.A.115(b)(4) is *'as applicable for the change'* . This shall be understood the way that when a DOA holder is self-certificating some major change or an STC under their privilege it applies 21.A.20 not literally, to the word . It will be explained by an AMC.

For the other issues related to implementation of the new privileges: These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment *270* comment by: *Airbus Helicopters*

Table A, 21.A.115

It is stated that, for DOA holders approving a STC under their privilege, there is no application, consequently "there is no applicant per point 21.A.20(a)".
However:

- The explanatory note for 21.A.20, page 23, states that 21.A.20 is also applicable to applicants for major changes or STCs under the privileges of points 21.A.263(c)(8) and (9),
- All subparagraphs of 21.A.20 use the word "applicant"

This is inconsistent. (Text – correction)

It is also stated that, in the case of STC approval under delegation, the certification basis and programme are established by the Agency when granting the privilege and there is no issue of a STC according to 21.B.110. However, this does not appear in any paragraph of sections A or B. LOI implementation - request for clarification

Suggestions
The inconsistency about "applicant" should be resolved.

Also, the proposal should be completed with information about how the new privileges are exercised (determination of certification basis and programme, materialisation of STC approval).

response

Noted.

See our response to your comment 269.

comment

271 comment by: *Airbus Helicopters*

Point (b) is not "*supplemented with*" but "*replaced by*" the requirement to report to the Agency.

Suggestion
Should be corrected in the explanatory note of the opinion.

response

Noted and corrected.

comment

272 comment by: *Airbus Helicopters*

Table A, 21.A.20

"*see also current points 21.A.21(c)(3) and 21.A.115(b)(3)*" fails to indicate that point (d)(2) is replacing current points 21.A.21(c)(3) and 21.A.115(b)(3)".
Also, point (d)(2) is not amended but new.

Suggestion
Should be corrected in the explanatory note of the opinion.

response

Noted.

Note that in the amended proposal (d)(2) is now not replacing the current points 21.A.21(c)(3) and 21.A.115(b)(3) but complementing the equivalent requirements kept applicable to the Agency that populate all the point in Section B related to issuance of the certificates by the Agency.

comment	*273* comment by: *Airbus Helicopters* Table A, 21.A.20 (amended point (d)(2)) "*see also current points 21.A.21(c)(3) and 21.A.115(b)(3)*" fails to indicate that point (d)(2) is the direct transposition of current points 21.A.21(c)(3) and 21.A.115(b)(3). **Suggestion** Should be corrected in the explanatory note of the opinion.
response	*Noted.* Note that in the amended proposal (d)(2) is now not replacing the current points 21.A.21(c)(3) and 21.A.115(b)(3) but complementing the equivalent requirements kept applicable to the Agency that populate all the point in Section B related to issuance of the certificates by the Agency..

comment	*274* comment by: *Airbus Helicopters* Table A, 21.A.103 This deleted point is not only covered by points 21.A.20, 21.A.95 and 21.A.97, but also by 21.B.107. **Suggestion** Should be corrected in the explanatory note of the opinion.
response	*Accepted.*

comment	*275* comment by: *Airbus Helicopters* Table A, 21.A.606 Unlike stated, changes are not editorial only. **Suggestion** Should be corrected in the explanatory note of the opinion.
response	*Accepted.*

comment	*306* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland* 21.A.15 - The current content of point (c) (merged now with the content of point (b)) is deleted and point (c) is used to required applicants to keep the certification programme updated. *Swiss FOCA: Submittal of updated CP to Agency is missing.*
response	*Noted.* This procedural/implementation issue will be covered by an AMC/GM.

comment	*307* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland* 21.A.97 "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". *Swiss FOCA: Agency to indicate in GM/AMC which means for issuing a design approval under §§ 21.A.263(c)8) and/or (c)(9) are acceptable to the Agency and how the information of such approvals will be available to the public. As of today neither EASA STCs nor Major or minor change approvals are visible to the European Public, but all STCs issued by the FAA can be found publicly.*
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	*308* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland* 21.A.263 "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." *Swiss FOCA: Requires the re-issuance of all DOA approval certificates. Need existing approval certificates to be revised and how such shall be handled?*
response	*Noted*. The DOA certificates and in particular the Terms of Approval will need to be changed anyway for other reasons. EASA DOA department will handle the issue.

comment	*309* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland* 21.B.80 "The first sentence introduces a new requirement for the Agency to establish and notify the applicant of the applicable TC basis." *Swiss FOCA: By which formal means such notification shall be given to the applicant?*
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

3. Proposed amendments — Draft Opinion p. 36

comment	*222* comment by: *Dassault Aviation* Section A Subpart B: Dassault Aviation will not comment AMCs more than preliminarily. Full AMC comments will be issued when NPA2 is released for public consultation.
response	*Noted.*

3. Proposed amendments — Draft Opinion — 21.A.14 — Demonstration of capability p. 36

comment	*287* comment by: *Sell GmbH* 21.A.20(d)2: the term "known feature or characteristic" is not clear (when, by whom and under which conditions is it "known") and should be replaced by "no feature or characetristic was identified during the compliance demonstrations ...".

response | *Accepted.*

The wording of 21.A.20(d)2 has been amended in the proposal. See also our response to comment 303

3. Proposed amendments — Draft Opinion — 21.A.15 Application p. 36-38

comment | *35* comment by: *CAA-NL*

21.A.15(b)
21.A.15(b) The here specified certification programme is suggested by the applicant. Further in the rule it is revered to as the established programme. Will there be a formal acceptance of the certification programme as well as the compliance demonstration by the Agency? How will this be visible and where is this described in this rule?
(Text and LOI Implementation - Request for clarification)

21.A.15(c)
21.A.15(c): We support the principle that the certification programme (CP) shall be updated if during the certification process there are significant changes to the proposed design or the used means of compliance. However, in the past we have seen that EASA required applicants to revise a CP close to the end of the certification process to address small changes in the proposed design or means of compliance. We see no added benefit in keeping a CP up to date with all small changes that are likely to occur during a certification process.
Guidance material is needed to explain in more detail the meaning of the words "as necessary" at the end of the proposed 21.A.15(c). LOI Implementation - Request for clarification

21.A.15(e)
In proposed 21.A.15(e) the phrase 'design, development, and testing' should be replaced by 'establishing compliance with the certification requirements', because only that is relevant in case of an application for certification and not design, development or testing.

response | *Noted.*

For 21.A.15(b): The certification programme will not be *formally approved* by the Agency but will be just accepted as a step in the certification process. Individual detailed procedural steps of the certification process, including their acceptance, should not be addressed on the rule level. These are issues for AMC/GM material and/or certification procedures.
For 21.A.15(c): These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED

decision.

For 21.A.15(e): Accepted. The proposal is carried in a modified form.

comment *83* comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 37/67, paragraph 21.A.15(b).

2. PROPOSED TEXT / COMMENT:

The paragraph should better clarify what is systematically mandatory from the other information needed as applicable.

Proposed change:

"An application for an aircraft a type-certificate or restricted type-certificate shall 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~~:

(i) On a mandatory basis:

1. a detailed description of the type design, including all of its configurations to be certified;
~~2. the proposed operating characteristics and limitations;~~
2.~~3.~~ the intended use of the product and the kind of operations for which certification is requested;

(ii) As applicable

3.~~2~~. the proposed operating characteristics and limitations;
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."~~

3. RATIONALE / REASON / JUSTIFICATION:
For sake of clarity

response *Partially accepted.*

The intent of the proposal is agreed but the proposal is carried in a modified form.

comment *84* comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 37/67, paragraph 21.A.15 (c)

2. PROPOSED TEXT / COMMENT:
"During the compliance demonstration process performed in accordance with point 21.A.20, the certification programme shall be kept updated, as necessary."

The wording "as necessary" deserves further clarification within a guidance material.
Such AMC/GM should provide, for instance examples where certification programme should be updated:
- o Design evolution vs previous issue requiring new MoC or new agency involvement
- o Introduction of alternative compliance methodology, not previously used in other project
- o Change of supplier
- o Increase of Agency LOI

And where it may not need to be updated:
- o Project planning adjustment
- o Design update not invalidating the compliance methodology expressed in previous issue
- o Change of MoC to new compliance methodology previously used in other project or other area within the same project
- o Decrease of Agency LOI, if agreed with the Agency…

3. RATIONALE / REASON / JUSTIFICATION for the Comment:
Cases where the certification programme needs to be updated should be clarified in a GM/AMC to 21.A.15(c)

response Noted.

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment *138* comment by: *FAA*

Page 37:21.A.15 (c) The regulation states that the programme plan needs to be updated "as necessary". Recommend that all changes to the plan be reported. An alternative would be to provide guidance on what changes are necessary to report. Similarly, 21.A.20 includes the obligation for the applicant's design organization 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. However the applicant may not know what is significant to the Agency or what went into the Agency LOI decision Recommend that "all" events encountered that are inconsistent with the programme plan be reported. An alternative is to develop guidance for what changes need to be reported to the Agency.

Page 37: 21.A.15 (b) now implies that a detailed description of the type design (rather than preliminary basic data) is submitted with the application. At the time of application some applicants may not have the design completely defined. However, it is understandable that the Agency needs more than preliminary data and that the applicant should have a good idea of their proposed design. Recommend providing guidance for the minimum level of design that the Agency requires at the time of application.

response

Noted.

For 21.A.15(c) We prefer not to require in the rule every and each amendment to CP but rather clarify what kinds of changes to CP should be reported by means of AMC/GM material

For 21.A.15(b): The text was amended to indicate what basic information must be submitted with the initial application and what can be included later as a supplement.

comment

146 comment by: *Rolls-Royce*

Comment/Suggested Resolution 1:
Section (b): For restricted type-certificates, the word 'aircraft' should be added to be consistent with 21.A.21 (Text correction/improvement)

Comment 2:
Section (b): Sub-bullets 1-7 defining supplemental material to accompany an application is seen as guidance material (distribution between rules and AMC/GM)
Suggested Resolution 1: Move to AMC/GM section

response

For comment 1: Not accepted. We have decided to rely on readers' awareness of information provided in 21.A.11 'Scope' and we have removed the word *aircraft* from all subject occurrences linked to *restricted type-certificates*, except in 21.A.21 where it is really necessary.

For comment 2: Not accepted. This information is a necessary condition and basis for the Agency's LoI determination. We have however indicated in the introductory of point (b) that information under (1) – (7) may be submitted later, after the initial application as its supplement.

comment	*175* comment by: *sabena technics BOD* 21.A.15 (b): Suggest to add a new item 8: "a project schedule including major milestones", as previously mentionned in AMC 21.A.20(b) § 1.2. This will help the Agency to plan its ressources in accordance with its involvement per 21.A.15 (b)(7).
response	*Accepted* See the corresponding text in the amended proposal.

comment	*176* comment by: *sabena technics BOD* 21.A.15 (f)(2): There is no form currently available on EASA web site to apply for an extension of a TC or STC project when the application effectivity is reached.
response	*Noted.* The issue of an application form for an extension of a TC/STC projects will be considered in Phase II of this rulemaking tasks..

comment	*188* comment by: *AeroSpace and Defences Industries Association of Europe (ASD)* 21.A.15(b) It has been found during the LOI pilot projects that the discussion about LOI has the potential to become a burdensome process similar to the CPR process: lengthy discussions, recurring requests by the Agency for more details prior any decision. For some pilot projects, the discussions about LOI were seen more time-consuming that the usual way of working (discussions at a low level of detail in the certification plan about which compliance demonstrations activities are retained or not by the EASA experts). Therefore, guidance material and Agency work instructions should make clear that the discussion on LOI is done at the CDI level (compliance demonstration item = meaningful grouping of activities) and not at the level of each single compliance demonstration activity (usually a means of compliance MC0 to MC9 as per AMC 21.A.20.b). For allowing the applicant to propose a level of involvement, the Agency has to keep it periodically aware of the DOA performance level assessed by the DOA Team. The 'better / less regulations' principles should drive the transfer into an AMC 21,A,15,b of the items 1 to 7.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed

	to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	*189* comment by: *AeroSpace and Defences Industries Association of Europe (ASD)* 21.A.15(c) The wording "as necessary" deserves further clarification within a guidance material. Such AMC/GM should provide, for instance examples where certification programme should be updated: o Design evolution vs previous issue requiring new MoC or new agency involvement o Introduction of alternative compliance methodology, not previously used in other project o Change of supplier o Increase of Agency LOI And where it may not need to be updated: o Project planning adjustment o Design update not invalidating the compliance methodology expressed in previous issue o Change of MoC to new compliance methodology previously used in other project or other area within the same project o Decrease of Agency LOI, if agreed with the Agency…
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	*214* comment by: *British Airways* Please provide an explanation as to what guidance will be provided for an applicant to determine the Agencies LOI as in point 21.A.15 (b) 7
response	Noted. These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	*223* comment by: *Dassault Aviation*

21.A.15 c : Add a guidance for determination of "as necessary".

response *Noted.*

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment *257* comment by: *DAHER*

§ 21.A.15 (c)
The wording “as necessary” shall be explained in AMC/GM to be used without mistake by the applicant and the Agency.
The guidance should explain in which case the certification programme must be updated.

response *Noted.*

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment *341* comment by: *LHT DO*

21.A.15 (b) (5) requires the references of related compliance documents already to be defined and provided to EASA with the application. The definition of the document numbers for the substantiation data as well as the structure of the compliance documentation is highly dependent upon the progress of the project. The time constraints related to STC-projects require to finalize and publish the compliance data as soon as they become available to support the design assurance functions of the design organization. All necessary data to identify the affected requirement, the design document (description of change) and the means of compliance are provided within the certification program. The reference to the compliance document itself would establish the structure of compliance documents and prevent the flexible and timely provision of the documents to support the independent checking and the release of compliance data.

2. 21.A.15 (b) (6) requires the assessment of safety aspects related to details of the design. At the early stage of an STC project the detailed design is not sufficiently completed to support a safety assessment with respect to items (b) (1) to (b) (5) of this requirement. However, an assessment of safety aspects will be established with the compliance data at a later stage in the project.

21.A.15 (c) (6) requires that the certification programme to be kept updated as necessary.

There is no definition what the threshold for a necessary update of the certification programme may be and if the term “updated” also indicates the requirement to publish the revised certification programme. This may lead to several updates e.g. for editorial changes which are not relevant for the definition of the level of involvement, but would hinder the type investigation process and increase the workload unnecessarily. This has to be clarified in more detail within AMC/GM

response

Noted.

For 21.A.15 (b) (5): Note that the proposed rule does not require this information to arrive in the *initial application.* It can be provided later as a supplement.

For 21.A.15 (b) (6): The wording has changed in the amended proposal to clarify which kind of risk assessment is required not to be mistaken for the xx.1309 type of safety assessment.

For 21.A.15 (c): This will be clarified in more detail within AMC/GM material.

3. Proposed amendments — Draft Opinion — 21.A.20 Compliance with the TC basis,OSD cert basis and EP reqs p. 38-39

comment *36* comment by: *CAA-NL*

21.A.20(b)/(d)
We suggest to include reverences to 21.A.15(b) with the certification programme as is done elsewhere in the text (21.A.20(c)) for consistency.
Further we suggest to relocate the text in 21.A.20(d) “including the inspections and tests in accordance with point 21.A.33 and, where applicable, point 21.A.35” to be moved to 21.A20(a). When required, ground and flight testing is part of the compliance demonstration and should therefore be mentioned in 21.A.20(a).
New text:
21.A.20
(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), including the inspections and tests in accordance with point 21.A.33 and, where applicable, point 21.A.35, 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 established under point 21.A.15(b) 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).
(d) After completion of all compliance demonstrations in accordance with the certification programme established under point 21.A.15(b)~~, including the inspections and tests in accordance with point 21.A.33 and, where applicable, point 21.A.35,~~ t~~T~~he 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 21.A.15(b) ~~established under point (b)~~.; and

response

Not accepted.

1. *Not accepted:* We consider the *certification programme under point 21.A.15(b) as accepted by the Agency* occurrence in 21.A.20(a) sufficient. Repetition of the cross-reference is not considered necessary. The definite article *'the'* defines the document and this solution shorten and simplifies the text.

2. *Not accepted*. We do not want to distract the reader's attention in 21.A.20 by referring to the means of compliance. Even if located in (d) the *inspections and tests* remain part of the compliance demonstration (note the word *including*) and location in (d) serves a specific objective to specify that the flight testing i.a.w 21.A.35(f) must be completed before the final declaration of compliance under (d) is made.

comment

56 comment by: *DOA EASA.21J.041 Aero-Dienst GmbH & Co. KG*

21.A.20(b):
There is a need to know how the Agency defines a "significant effect on the certification programme". Please extend existing Guidance Material.

response

Noted.

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment

139 comment by: *FAA*

Page 38 21.A.20 (a) states the applicant shall demonstrate compliance by following the certification programme plan. Recommend regulation or guidance that the applicant is expected to continually review the plan during the certification effort for additional hazards that were not identified at application or when the certification programme

plan was reviewed by the Agency.

response

Noted.

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment

147 comment by: *Rolls-Royce*

Comment1:
Section (b): The required reporting can only be done, if the Agency did provide to the applicant the reason for the final LOI level determined by the Agency. This may differ from the proposal submitted by the applicant under 21.A.15(b)

Suggested Resolution:
Introduce requirement for the Agency to submit their reasons for the final LOI decision.

Comment 2: Correction
Section (d)(1): OSD is not applicable to engine or propeller

Suggested Resoltion:
Add "where applicable" after OSD certification basis

response

For comment 1: Not accepted.

Introduction into Part-21 of an obligation by means of a legal requirement for the Agency to justify to the applicants its LoI decisions is considered improper. The determination of the Agency's LoI does not interfere with the applicant's rights. Legally wise, the LoI determination is not a EASA *Decision* subject to the applicant's appeal where a justification by the Agency may indeed need to be provided. It is a procedural decision made by the Agency on its own part of the certification process – verification of compliance.

To put it more generally, an entity 1 under oversight prescribed by the EU law claims from an entity 2 requested by the EU law to perform on behalf of EU and general public the oversight over the entity 2 to justify its decisions about the scope of its oversight. This is considered unacceptable.

To be on the safe side, we have checked the EU law in the other domains under the Basic Regulation (operations, licensing etc.) where oversight is performed and we have not identified, neither in the implementing rules nor in their oversight practise, anything similar to what is requested under this and other similar comments.

Notification about the Agency's LoI determinations will be required but no *justification* requirement will be put in Part-21 on the Agency or related certification procedures. The

	Agency's LoI determinations should not be subject to any lengthy negotiations or necessity to reach a consensus between the applicant and the Agency otherwise this could subvert the whole concept and destroy the benefits expected from the implementation of the LoI concept. *For comment 2:* Noted and corrected. Not in just this one but in all similar occurrences.
comment	*190* comment by: *AeroSpace and Defences Industries Association of Europe (ASD)* Concept improvements/alternative proposals AMC 21.A.20.b Certification programme should be amended to clarify that difficulty or event encountered having a significant effect on LOI are those which can impact the novelty or the criticality of CDI.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.
comment	*212* comment by: *British Airways* During product developement such as seat dyanamic testing, there may be multiple failures while the seat design is being finalised. Do the Agency really want all such data which may not be applicable to the final product design.
response	*Noted.* The requirement is only applicable to the certification tests for the purpose of compliance demonstration for the proposed Type Design. It is NOT applicable to the applicant's development tests. It will be clarified by means of AMC/GM material to be developed in phase II)
comment	*286* comment by: *Sell GmbH* 21.A.20(b): Criteria for "significant" effect have to be added to assure unambiguity and uniform application. AMC is needed to develop appropriate criteria and comprehensive example to classify difficulties and events having significant effects.

response	Noted. These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	*310* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland* (c) "The applicant shall record justifications of compliance within compliance documents according to the certification programme established under point 21.A.15(b)." *Swiss FOCA: Wording to be improved to provide more clarity to read: "...shall record justifications of compliance within compliance documents as referred in the certification program…*
response	Accepted. See the amended text.

comment	*338* comment by: *Robert Kremnitzer / Diamond Aircraft Industries GmbH* (b): please clearly define "[...] dificulty or event encountered during the compliance demonstration process [...]" within this rulemaking task (e. g. as additional AMC) or at the latest within the No. 2 LOI NPA.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	342 comment by: LHT DO AMC 21.A.20.b Certification programme should be amended to clarify that difficulty or event encountered having a significant effect on LOI are those which can impact the novelty or the criticality of CDI.
response	Noted. These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA

and a related comment-response document (CRD) leading to an ED decision.

3. Proposed amendments — Draft Opinion — 21.A.21 Reqs for issue of a TC or RTC p. 39-40

comment *37* comment by: *CAA-NL*

21.A.21
1. We suggest to change the reverence in point (b) from 21.A.20(d) into 21.A.20(a) as point (d) deals with the declaration only and point (a) deals with the demonstration of compliance itself. With the change of the text in our opinion a change of the content of the rule is made and thus the change in the reverence is needed.

2. If the above reasoning is correct then proposed point (d) is not needed as the compliance demonstration of 21.A.20(a) includes the compliance demonstration of the operational suitability data thru the reverence to the certification programme established under 21.A.15(b) which include the operational suitability data certification basis. We suggest to delete the proposed point (d) and to renumber the proposed point (e) into (d).

response *For 1: Partially accepted.* The reference has been made to full *21.A.20.*

For 2: Not accepted. Point (d) is need for several reasons: to require the applicant/self-certificating DOA to make the declaration, to require that the inspections and tests, including the ones under 21.A.35(f), must be completed before the declaration is made, and to comply with (d)(2) requirement.

comment *311* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland*

"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…"
Swiss FOCA: insufficient wording to provide clarity of the requirement, must read: "the engine and propeller...or are determined in accordance with...."

response *Not accepted.*

It is the *TC* that is issued or *determined* in accordance with this Regulation (refers to the TCs not issued by the Agency but determined (*grandfathered)* under Article 3 of Regulation 748/2012

comment	*312* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland* "By derogation from point…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…" *Swiss FOCA: Noted. Requires an update of the technical visa form for the PCM teams statement of technical satisfaction to include such a provision to indicate the applicants request to Agency.*
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

3. Proposed amendments — Draft Opinion — 21.A.33 Inspections and tests p. 40

comment	*38* comment by: *CAA-NL* Text improvements /corrections **21.A.33** We suggest to keep the words 'the applicant' included in the text of new point (a). The words 'it shall be determined' may raise the question by whom? When keeping the applicant in this point it will be clear it is a responsibility of the applicant. 21.A.33(b) and (c) both contain "make any inspection". CAA-NL advises to combine the text of 21.A.33(b) and (c). New text: (~~c~~b) The applicant shall allow the Agency to: 1. review any data related to design and compliance demonstration; and 2. make any inspection and to perform or witness any test ~~make any inspection~~ considered necessary to check compliance with point (~~b~~a). ~~(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.~~ Numbering of next points and references to these points needs to be amended accordingly.
response	*For 21.A.33 (a): Accepted.* For the self-certificating DOAs that are also required (by cross-reference from 21.A.20(d)) to follow 21.A.33 (this was the reason for removing *the applicant)*

a GM will be drafted to clarify.

For 21.A.33 (b) and (c): Not accepted). Note please that inspections under (c) (numbering per the final proposal) are conformity inspections. The test and inspections under (d) are for compliance demonstration.

comment *85* comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 40/67, paragraph 21.A.33

2. PROPOSED TEXT / COMMENT:
Requirement 21.A.33 should be deleted and content transferred to AMC to 21.A.20(a)
Furthermore:
- wording within 21.A.33(c)1 shall not refer to design data but only to compliance demonstration data
- wording in 21.A.33(c)2 shall not refer to test but only to compliance demonstration tests (or certification) tests.

Proposed change:
~~21.A.33 Inspections and tests~~

AMC to 21.A.20(a)
1. Before each compliance demonstration test required by point 21.A.20 is undertaken, ~~during the compliance demonstration required by point 21.A.20~~, it shall be determined:
1.1. 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
1.2. that the test equipment and all the measuring equipment used for tests are adequate for the test and are appropriately calibrated.
2. The applicant shall allow the Agency to make any inspection considered necessary to check compliance with point (1).
3. The applicant shall allow the Agency to:
(i) review any data related to ~~design and~~ compliance demonstration; and
(ii) make any inspection and perform or witness any compliance demonstration test.
4. For tests performed or witnessed by the Agency under point (3):
(i) the applicant shall submit to the Agency a statement of compliance with point (1); and
(ii) 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 (1) is shown and the time it is presented to the Agency for test.

3. RATIONALE / REASON / JUSTIFICATION for the Comment:
Tests, inspections and flight tests are means of compliance among other means of compliance . All means of compliance shall be subject of 21.A.20 and there is no imperious

reason to keep some provisions related to tests and inspections out of 21.A.20 requirement and associated AMC/GM

response

Partially accepted.

For the relocation to AMC: Not accepted. 21.A.33 contains not just means of compliance (tests and inspections) but in respect to the conduct of the compliance demonstrations also hard requirements, including meeting obligations towards the Agency (to allow the Agency to access data, inspections and tests related to compliance demonstration) . These obligations relate to the rights of the Agency and these cannot be moved to an AMC level. Right and obligations are always on the rule level.

For the other two proposals: Accepted.

comment *86* comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 40/67, paragraph 21.A.35

2. PROPOSED TEXT / COMMENT:
Requirement 21.A.35 should be deleted and content transferred to AMC to 21.A.20(a)

Proposed change:
No change proposed in the content of current 21.A.35 but the whole transferred to AMC to 21.A.20(a)

3. RATIONALE / REASON / JUSTIFICATION for the Comment:
Flight tests are means of compliance among other means of compliance. All means of compliance shall be subject of 21.A.20 and there is no imperious reason to keep some provisions related to flight tests out of 21.A.20 requirement and associated AMC/GM

response

Not accepted.

The same reasoning as for your comment 86 above.

comment *140* comment by: *FAA*

Page 40: 21.A.33 (a) was deleted with the expectation that 21.A.20(d) was adequate to cover the expectation that the applicant would complete all inspections and tests necessary to meet the applicable certification basis. However, 21.A.20(d) includes the term “according to the certification programme” which implies the applicant is only responsible for the inspections and tests in the programme plan. Recommend that 21.A.20(d) be revised to add “and any test or inspection necessary to show compliance to the applicable regulations.”

Page 40: 21.A.33(b)(2) states that test articles should conform to the type design. However, this is not always the case. Sometimes the parts represent the worst case or "damaged" type design. The test articles should be conformed to the drawings and specifications in the test plan. The applicant should be required to include in the test plan the rational for why the test articles are representative of the type design.

Page 40: 21.A.33 (c)(2) states the applicant shall allow the Agency to "make any inspection and perform or witness any test". The applicant should also allow the Agency to witness any inspection. Recommend (c)(2) be modified to state 1) Make any inspection 2)perform any test and 3) witness any test or inspection conducted by the applicant

response

Accepted.

For 21.A.20(d) Partially accepted. The proposal is carried in a modified form.

For 21.A.33(b)(2): Partially accepted. What is demonstrated by the test are the *drawings and specifications* presented to the Agency as a *part of the proposed type design* (it is the type design ('papers') that is certificated, not the test specimens/prototypes) .The test articles should adequately conform to these *drawings and specifications of the proposed type design*. The *adequately* means that non-conformities may exist but, to remain, they need to be justified that they will not affect the test results. See also our response to comment 234 and check the final proposal if we are on the same line.

For 21.A.33 (c)(2)(as renumbered to (d)(2)*): Accepted.*

comment

148 comment by: *Rolls-Royce*

Comment:
Section (c)2: Deleted text should be retained - it stipulated a reasonable limit to focus the scope on certification compliance. This is now gone and the option is now open ended.

Suggested Resolution:
The deleted text should be retained or the NPA state clearly why it is deemed necessary to not reasonably limit the scope of EASA to inspect/witness compliance demonstration tests

response

Not accepted.

The current text might be interpreted such that allows the Agency to make any inspection and perform or witness any test only *after* the 21.A.20(d) declaration was made …in order to check its validity. It might work deep in the past of certification of aircraft but not today. These tests and inspections are conducted well before the final declaration is made and the Agency may select these inspections and test for its LoI. .

comment	*191* comment by: *AeroSpace and Defences Industries Association of Europe (ASD)* 21.A.33(a), (b) & (d) The 'better/less regulations' principle should drive the deletion of 21.A.33.a and .b and the transfer of its content into an AMC 21.A.20.a
response	*Not accepted.* See our response to the comment 85.

comment	*192* comment by: *AeroSpace and Defences Industries Association of Europe (ASD)* 21.A.33(c) The applicant shall be required to allow the Agency to review data, make inspection and perform test only when related to compliance demonstration required by 21.A.20.a
response	*Accepted.* However, in the phase I – Familiarisation, design data must be made available as well under 21.A.15(b)(1). It is agreed that when they are subject to tests or inspections the have become *compliance data*.

comment	*193* comment by: *AeroSpace and Defences Industries Association of Europe (ASD)* 21.A.35: Flight Tests The 'better/less regulations' principle should drive the deletion of 21.A.35 and the transfert of its content into an AMC 21.A.20.a
response	*Not accepted.* See our response to comment 86.

comment	*224* comment by: *Dassault Aviation* 21.A.33 c : This is a regression compared to the existing 21.A.33.c as the review possibility is extended to any type of design data or tests, including development test. The former wording should be retained: "... 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".
response	*Not accepted.*

	See also our response to comment 148. But note that the amended proposal is only applicable to tests and inspection conducted for the purpose of compliance demonstration.
comment	*234* comment by: *Airbus Helicopters* 21.A.33(a) Usually, tests are performed on prototype parts not stamped as "proposed Type Design". Once the "proposed Type Design" is available, a representativeness analysis is performed so as to show that the tested part is representative of the Type Design. Therefore, compliance to 21.A.33(a) is shown indirectly. **Suggestion** Such an approach should be described in an AMC to 21.A.33(a)
response	*Partially agreed*. The tests and inspections under 21.A.33 are to be conducted for the purpose of compliance demonstration. Compliance demonstration of *THE proposed type design* (papers). What is presented for compliance demonstration are parts of the type design (papers) and the compliance is demonstrated …*through* testing of test articles/specimens *adequately* conforming to the currently proposed type design. If the type design later evolves (this happens), the applicant may still try to substantiate to the Agency that the past *certification* test remain valid. But the applicant will have to substantiate to the Agency that the *non-conformities* (the delta between the drawings of the evolved (final) type design and the drawings conforming to the test articles originally used for the test) do not invalidate the past *certification* test results. If the applicant is unable to properly substantiate the above *non-conformities* the test needs to be repeated. It is understood that in reality the type design evolves throughout the certification project and after the certification test …for various reasons. Changes to type design are reality. The Agency, however, does not need to be involved in some *trial* tests (in fact development tests).when the type design is immature. To call the Agency for the conformity inspections under 21.A.33(c) and witnessing the tests and inspections under 21.A.33(d)(2) would be otherwise just wasting of resources. See also our response to comment 140 Agreed that an AMC to address these issues needs to be developed.
comment	*235* comment by: *Airbus Helicopters* 21.A.33(d)

	The review, inspections, and witnessing should be in line with the definition of the LOI according to 21.B.100. **Suggestion** Refer to 21.B.100 in 21.A.33(c)
response	*Agreed.*

comment	*259* comment by: *DAHER* § 21.A.33 c) The sentence (2) is ambiguous concerning the tests which the Agency would follow. The applicant should understand that the Agency would participate to all tests, development and certification. That is in opposition with the principle of the LOI.
response	*Accepted.* The text was amended.

comment	*279* comment by: *CFM* 21.A.33(c) : Proposed text referes to data instead of report for investigaton. Therefore, investigation based on detailed design data, test data, including development data will be more detailed investigation than with the current regulation. We should keep the current text. In addition, it should be emphasised that the Agency will perform compliance demonstration investigation in accordance with the point 21.A.257 and with the agreed Agency Level of Involvement programme in accordance with the point 21.B.100(d).
response	*Accepted.* The text was amended.

comment	*313* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland* 21.A.33 “The applicant shall allow the Agency to make any inspection considered…” *Swiss FOCA: must read: "..considered necessary by the Agency..."*
response	*Accepted.* The text was amended.

comment	*344* comment by: *LHT DO* Please keep the original numbering of paragraphs. Various IT systems and documentation systems refer to 21.A.33(b) and would have to be changed. Proposal : 21.A.33 (a) - deleted; 21.A.33 (b) Before …
response	*Accepted.* The text was amended.

3. Proposed amendments — Draft Opinion — 21.A.91 Classification of changes to a TC p. 40-41

comment	*170* comment by: *LMI Aerospace* The criteria for a "major change or major repair" does not directly address damage tolerance. The current AMC / GM provide guidance that any repair that requires permanent additional inspections to the maintenance program is a major change. However, this means that most repairs to primary or fatigue critical structure will be major. The repair may be similar in inspections to another SRM repair or other inspection data from the TC holder. It is suggested that EASA consider additional criteria for damage tolerance in the definition of Major / Minor so that some repairs can be considered as minor deviations from existing data rather than becoming major on the basis of requiring damage tolerant inspections. This is now rare for repairs to primary structure hence most repairs will become major per this classification requirement.
response	*Noted.* Out of scope of this rulemaking tasks (RMT.0262). But recorded for future rulemaking for GM 21.A.91.

3. Proposed amendments — Draft Opinion — 21.A.93 Application p. 41

comment	*19* comment by: *Franz Redak* 21.A.93 a1i) EASA needs to specify what they understand as the configuration(s) of the type design. It is open for subjective requests to cover all kind of details in a Certification Program which may not be avaiable at the time of application and/or not needed to be defined in such a high level document.

21.A.93 a1ii) similar to a1i) ... areas of the type design. Specify what is understood.

21.A.93 a3) the wording seems to indicate that the OSD changes are applied with the TC, RTC, STC or major change. It was our understanding that this is a separate applicaiton.

response

Noted.

For 21.A.93 a1i): You will find the answer in GM 21.A.101 (Chapter 3, point 2. for Step 1 of Figure 1 (a)). To be able to assess and classify a change the baseline configuration must be defined.

For 21.A.93 a1ii): The term 'areas' has its normal dictionary meaning. It is used here with the same meaning as in 21.A.101 and related GM 21.A.101.

For 21.A.93 a3): It is an 'application supplement'. See amended 21.A.15(d) and new 21.B.82 in Section B.

comment

141 comment by: *FAA*

Page 41: 21.A.93 (a) does not distinguish between a major change and a minor change. Recommend the language is modified to clarify whether an application is expected for a minor change to design.

Page 41: 21.A.93 (a)(1)(i) Request that guidance be provided whether the "configuration" means the baseline aircraft (i.e. as delivered from the TC /PC holder) or the configurations that are in operation which may have previously installed design changes and alterations, or both.

Page 41: 21.A.93(a)(3) Recommend deleting "when the change affects…" The applicant should state whether or not the change affects the operational suitability data and if so how, similar to what is in (a)(2).

Page 41: 21.A.93(b) Recommend that the regulation be revised to clarify whether the time limits for a change in the design apply to "self-approved" DOA changes since there is no application in these cases.

response

Noted.

For Page 41: 21.A.93 (a): Application is requested for both. The content now differs for major and minor See the final proposal for 21.A.93

For Page 41: 21.A.93 (a)(1)(i): Confirmed, the type design of baseline aircraft to be changed is meant. See also GM 21.A.101 (Chapter 3, point 2. For Step 1 of Figure 1 (a)).

For Page 41: 21.A.93(a)(3): Not accepted to delete the subject clause .Some design changes clearly do not affect the OSD. If for some it later appears that the change, originally not considered to affect OSD, in reality does affect OSD, the application must be supplemented

with necessary changes to the operational suitability data.

For Page 41: 21.A.93(b): when there is no application then the approval process is fully in the hands of the self-approving DOA holder and no time limits apply. However, if you have in mind some derivative aircraft, a change classified significant or a major-major change, such would never meet the criteria for 'equivalent' change (only such can qualify for the 21.A.263(8) or (9) privilege).

comment

314 comment by: *Federal Office of Civil Aviation (FOCA), Switzerland*

21.A.93 Application

(i) "…the configuration(s) of the type design upon which the change is made; and" *Swiss FOCA interpretation: The configuration which the "to-be-changed product" etc. has, before it will be modified.* Agency to confirm this interpretation.

(ii) "… all areas of the type design and the approved manuals that are changed or affected by the change". *Swiss FOCA interpretation: 21.A.93 (a)1(ii) means the configurations and related designs and affected manual changes of the "to-be-certified type design", representing the change. Agency to confirm this interpretation.*

response

Noted.

For (i): Yes.

For (ii): Yes.

3. Proposed amendments — Draft Opinion — 21.A.95 Reqs for approval of a minor change p. 42

comment

8 comment by: *Swiss Air-Ambulance Ltd.*

21.A.95 requires a minor change to be compliant with the type-certification basis, the operational suitability data and the environmental protection requirements as incorporated by reference in the type-certificate.
21.A.115 (b)(2) requires an STC to be compliant with the type-certification basis and the environmental protection requirements as incorporated by reference in the type-certificate. Compliance with the operational suitability data must be demonstrated only if such data are affected (21.A.115 (b)(3)).
Comparing such requirements indicates a disadvantage for minor changes with regard to operational suitability data (OSD), although the probability of OSD being affected by a minor change is significantly lower than for an STC.
Therefore, Swiss Air-Ambulance suggests to align both wordings in such way that the

	requirement as stated in 21.A.115 (b)(3) is made applicable to minor changes as well (21.A.95). Suggested wording for 21.A.95 (new point): "In case of a minor change affecting the operational suitability data, it has been demonstrated that…"
response	*Accepted.* See the text of the final proposal.

comment	*87* comment by: *Airbus* **1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:** Page 42/67, paragraph 21.A.95(a)2. **2. PROPOSED TEXT / COMMENT:** Proposed change: *"2. by an ~~appropriately~~ approved design organisation within **the scope in** its terms of approval **including** ~~and~~ privileges of point 21.A.263(c)(1) and (2) under a procedure agreed with the Agency."* **3. RATIONALE / REASON / JUSTIFICATION:** Wording "appropriately" is meaningless. Either it is removed (as proposed) or further clarified. Privileges are part of the Terms of Approval.
response	*Partially accepted.* Your proposal is carried in a slightly modified form. See the text of the final proposal

comment	*142* comment by: *FAA* Page 42: 21.A.95 It is not clear if an applicant for a minor change needs to make a certifying statement under 21.A.20, which relies heavily on a programme plan that does not appear to be applicable to minor changes. Recommend that the applicant should always complete the certifying statement for any changes (major or minor) that are submitted to the Agency.
response	*Accepted.* See the text of the final proposal.

comment	*149* comment by: *Rolls-Royce* Comment: Section (b): OSD is not applicable for engine and propeller Suggested Resolution: Add "where applicable" after OSD certification basis
response	*Accepted.* Consistently applied in every applicable occurrence throughout the proposal.

3. Proposed amendments — Draft Opinion — 21.A.97 Requirements for approval of major changes p. 42-43

comment	*20* comment by: *Franz Redak* 21.A.97a2) We believe that not all of the referenced paragraphs are necessarily connected with a major change. E.g. c2 (minor changes), c5 (major repair), C6 (FC), c7 (PtF)
response	Noted. That is why the reference is made just to the points (c)(1) and (8).

comment	*39* comment by: *CAA-NL* **21.A.97** We suggest the following changes in the text to bring it more in line with the point 21.A.20(a) and 21.A.95(b). (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, the applicable operational suitability data 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 point~~s~~ (1) ~~and (2)~~ has been demonstrated in accordance with point 21.A.20, as applicable to the change. (c) By derogation from point~~s~~ (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.

response

Not accepted.

The point (b)(2) is needed since when the change does not affect the OSD then no compliance demonstration is required at all.

comment

88 comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 42/67, paragraph 21.A.97(a)2.

2. PROPOSED TEXT / COMMENT:

Proposed change:

*"2. by an ~~appropriately~~ approved design organisation within **the scope in** its terms of approval i**ncluding** ~~and~~ privileges of point 21.A.263(c)(1) and (8) under a procedure agreed with the Agency."*

3. RATIONALE / REASON / JUSTIFICATION:
Wording "appropriately" is meaningless. Either it is removed (as proposed) or further clarified.
Privileges are part of the Terms of Approval.

response

Partially accepted.

Your proposal is carried in a slightly modified form. See the corresponding text of the final proposal

comment

143 comment by: *FAA*

Page 26 and 42: 21.A.97 (b) Background for the new point (b) states 21.A.92 'Eligibility', 21.A.93 'Application' and 21.B.107 'Issue of an approval of a change to type-certificate' are not applicable to self-approving DOA organizations. Recommend that the regulations be revised to specifically address self-approval of design changes by an organization. The regulation should address the application requirements and how the certification basis under change product regulations is established when an organization is allowed to self-approve major design changes. The requirement for an application and the determination of the certification basis are regulations that have merit. We would recommend that an application be completed similar to an ODA project notification to allow the Agency to know what the DOA is doing and provide the Agency an opportunity to know what the DOA is doing and get

	involved, if necessary.
response	While the reasoning and concerns of your comment are understood, we believe that our DOA system, as amended by the LoI proposal, will addresses all you concerns. To reflect the higher risk (compared to minor changes) to product safety linked to these new privileges, additional risk mitigating measures will be introduced. - The scope of the subsequent changes to be certified by the DOA ,under their privileges and without any LoI of the Agency, is constrained to changes 'equivalent' to the baseline change already previously approved under an application to the same DOA. - The Agency will be in full control of the TC basis, means of compliance, changes to manuals etc. These limitations and conditions will be established by the Agency when granting the privilege to the DOA and these will build on documents prepared for the previously approved 'baseline' change, amended as necessary. Every privilege needs to be applied for as a change to the DOA terms of approval. - The subsequent equivalent changes certified by the DOA are of limited scope not expected to divert from this TC. When a change to TC basis is indeed necessary then the DOA must contact the Agency and obtain an acceptance. All the conditions and procedure will be clarified in AMC/GM material. These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	*172* comment by: *LMI Aerospace* 1. The wording here is for **changes** but the paragraph includes **Major Repairs**. 2. Should the wording in 21.A.97(a) 2. include reference to 21.A.263(c)(1), **(5),** (8) **and (9)**? 21.A.263(c)(9) allows approval of an STC which is discussed on NPA page 11 of 67, Section 2.2.1(a)(8).
response	*Not accepted.* Repairs and STCs are not in the scope of 21.A.97.

comment	*236* comment by: *Airbus Helicopters* 21.A.97(b) mentions that the applicable TC basis, environmental protection requirements and OSD certification basis are established i.a.w. 21.A.101, but does not mention how these requirements are notified by the Agency.

The explanatory note for 21.A.97 (page 26) states that, in the case of an applicant to the Agency, the applicant is notified i.a.w. 21.B.105, whereas in the case of a DOA holder self-approving a major change under its privilege, the DOA holder will be notified when the Agency is granting the privilege.

Suggestion
Suggestion is to clarify, at least in an AMC, how the TC basis and other requirements (environmental protection requirements, OSD certification basis) are notified for each case (applicant or DOA privilege).

response

Accepted.

AMC/GM will be developed to clarify this issue. See also our response to comment 143 above.

comment

237 comment by: *Airbus Helicopters*

21.A.97(b)(2)
The reference to 21.A.101(g) for the establishment of the operational suitability data certification basis is not in line with updated 21.A.101.

Suggestion
Change "*21.A.101(g)*" to "*21.A.101(f)*"

response

Partially accepted.

Finally, the cross-reference is made to full 21.A.101 because, after the new entry for (e), all of its paragraphs apply. See the text of the final proposal.

comment

315 comment by: *Federal Office of Civil Aviation (FOCA), Switzerland*

21.A.97

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;"
Swiss FOCA: Link to to 21.B.80 & 21.B.82 missing.

response

21.B.80 and 21.B. 82 are not directly applicable to a major change. 21.A.85 only by cross-reference from 21.A.101(a). Otherwise 21.A.101 is fully stand alone. It has the full instrumental inside, including Special Conditions, Elects to Comply, Equivalent Safety Findings and Deviations to establish the all certification bases for a major change. The Agency follows it by reference from 21.B.105.

3. Proposed amendments — Draft Opinion — 21.A.101 TC basis, OSD cert basis and EP reqs for a major change to a TC p. 43-44

comment *40* comment by: *CAA-NL*

21.A.101
1. Point 21.B.85 itself does not contain anything on an application for changes to the type certificate, it only deals with applications for a (restricted) type-certificate. Point 21.B.105 however does deal with the environmental protection requirements for major changes. Probably the reference needs to be changed into 21.B.105.
(a) ..... The changed product shall comply with the applicable environmental protection requirements laid down in point 21.B.~~85~~105.

2. As points (a), (b), (d) and (e) in itself contain the requirements for operational suitability as these are laid down in the applicable certification specifications or special conditions (ref 21.B.82(a)/(b) point (f) can be deleted when the operational suitability data certification basis is included in point (c). Therefore we suggest the following:
(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 and the operational suitability 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 or the operational suitability 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.
.....
~~(f) When the application for a change to a type-certificate for an aircraft includes, or is supplemented after the initial application to include, changes to the operational suitability data, the operational suitability data certification basis shall be designated in accordance with points (a), (b), (c), (d) and (e) above.~~

response *Partially accepted*

For 1: No environmental protection requirements are *'laid down'* in 21.B.105. They are to be designated under 21.B.85. Environmental protection requirements are not subject to 21.A.101(b)-(g) below (they are no longer mentioned). In addition, a reference in 21.A.101 to 21.B.105 would be circular one. However, your comment led to the refinement of the text in 21.A.101(a).

For 2: Note that your proposed solution would enforce a requirement to demonstrate compliance with OSD certification basis even in the case when a change does not affect the OSD. However, in those cases there is no need to demonstrated compliance.

comment	*89* comment by: *Airbus* **1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:** Page 44/67, paragraph 21.A.101(c). **2. PROPOSED TEXT / COMMENT:** Wording "may designate compliance with" is unclear. Should better read: "may require compliance with" Wording "in effect at the date of the application" deserve clarification. Does it mean "enforced at the date of the application? **3. RATIONALE / REASON / JUSTIFICATION:** For sake of clarity
response	*For 'designate': Not accepted* for the sake of having the wording harmonised with the FAA. *For 'in effect':* 'In effect' means *'effective'./ 'in force'*, simply those of the current valid amendment.

comment	*90* comment by: *Airbus* **1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:** Page 44/67, paragraph 21.A.101(d) **2. PROPOSED TEXT / COMMENT:** The requirement 21.A.101(d) does not emphasise enough that special conditions are relevant only when the product meets one or more of the three criteria mentioned within 21.B.75 (Former 21.A.16B) Proposed change: **21.A.101 Type-certification basis, operational suitability data certification basis and environmental protection requirements for a major change to a type-certificate** *(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 and criteria 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 .* **3. RATIONALE / REASON / JUSTIFICATION for the Comment:** As written, a possible interpretation could be that the purpose of Special Conditions is to provide a level of safety equivalent to that established by the certification specifications in effect at the date of the application for the change… whereas this is only the case for the

	specific subjects that meet the eligibility criteria of future 21.B.75 (former 21.A.16B).
response	*Not accepted.* Point (d) cross-refers to 21.B.75. The criteria are part of it.

comment	*91* comment by: *Airbus* **1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:** Page 44/67, paragraph 21.A.101(e). **2. PROPOSED TEXT / COMMENT:** Proposed change: *"If an applicant elects to comply with a certification specification or ~~of~~ an amendment to the designated certification specifications that becomes effective after the filing of the application for a major change to a type-certificate, the change and areas affected by the change shall also comply with any other certification specification that the Agency finds is directly related."* **3. RATIONALE / REASON / JUSTIFICATION:** For sake of clarity New title of 21.A.101 refers only to major changes
response	*Not accepted.* Indeed, the new title of 21.A.101 refers only to major changes. This also defines the scope of changes that are dealt with under this point. Therefore, there is no need to repeat 'major' in all the occurrences of the word 'change' in this point. You other proposal (*or ~~of~~)* would completely change the intended meaning of the requirement and would make it incorrect.

comment	*92* comment by: *Airbus* **1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:** Page 44/67, paragraph 21.A.101(f). **2. PROPOSED TEXT / COMMENT:** Proposed change: *When the application for a major 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 (e) above*

3. RATIONALE / REASON / JUSTIFICATION:
For sake of clarity
New title of 21.A.101 as proposed by the Agency refers only to major changes

response

Not accepted.

Indeed, the new title of 21.A.101 refers only to major changes. This also defines the scope of changes that are dealt with under this point. Therefore, there is no need to repeat 'major' in all the occurrences of the word 'change' in this point.

comment

150 comment by: *Rolls-Royce*

Comment:
Section (d): The current text is confusing mainly due to it being a paragraph with a single very long sentence

Suggested Resolution:
The text should be reworded to be provide clarity

response

Not accepted.

For the sake of the text harmonised with FAA/TCCA.

comment

161 comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:

Pages 43-44, point 21.A.101

2. PROPOSED TEXT / COMMENT:

Paragraphs (a) and (g) should be changed as follows:

(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, for its type-certification basis, 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~~elected 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.

(g) 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~~ remain the original operational suitability data certification basis of the aircraft, as established and notified by the Agency in accordance with point 21.B.82. **3. RATIONALE / REASON / JUSTIFICATION for the Comment:** Point 21.A.101 establishes the "Changed Product Rule" (CPR), which is harmonized, together with its guidance material, with the major certification Authorities worldwide. Its intent is to upgrade the design requirements (i.e. the type-certification basis) of changed products. As the validity of the CPR approach for the operational suitability data requirements (a unique EASA concept, involving procedural certification specifications for the development of these data) has not been established in terms of safety benefit versus implementation cost, we request that the CPR approach remain limited to the determination of the type-certification basis.
response	*Not accepted.* 1. (a): Demonstration of compliance is not performed *'for its type certification basis'* but as a condition for issuance of a certificate. 2. (g): This was subject of another rulemaking task (for Regulation (EU) 69/2014). This rulemaking task for LoI is not going to subvert its results.

comment	*194* comment by: *AeroSpace and Defences Industries Association of Europe (ASD)* 21.A.101(a) Only 21.A.101.e addresses volontary compliance with later amdts. Reference to point (f) should be removed. It should be clarified that 21.A.101.a applies to type-certification basis. [...] A major change to a type-certificate and areas affected by the change shall comply, for its type-certification basis, with the certification specifications that are [...]
response	*Partially accepted.* 1. The reference to point (g) is corrected to 21.A.93(b) where the applicable text was relocated from (f). Thank you for pointing at this error. 2. Not understood. The title of 21.A.101 sufficiently clarifies that the subject of this point is to establish the TC, OSD certification bases and EP requirements.

comment	*195* comment by: *AeroSpace and Defences Industries Association of Europe (ASD)*

	21.A.101(f) The CPR process has proven to be quite burdensome, costly and lengthy compared to the safety benefit. General safety issue on existing TC related to OSD should be addressed through retroactive requirement mechanisms such as Part 26. It is therefore proposed to remove 21.B.82.a. (g) 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 remain the original operational suitability data certification basis of the aircraft, as established and notified by the Agency in accordance with point 21.B.82.
response	*Not accepted.* This was subject of another rulemaking task (for Regulation (EU) 69/2014). This rulemaking task for LoI is not going to subvert its results.

comment	*225* comment by: *Dassault Aviation* 21.A. f : Add guidance to clarify that the reference date for the determination of the OSD certification basis is the same as the reference date of the change to the Type Certificate.
response	*Noted.* For the reference date relevant for the determination of the OSD certification basis consult 21.B.82(a) in section B. It does not apply directly to major changes but the approach taken there will be applied also for changes. It will be clarified by AMC/GM.

comment	*239* comment by: *Airbus Helicopters* 21.A.101(a) "*…elected by the applicant or required under points (e) and (f)*." Reference to point (f) looks inadequate in this context. **Suggestion** Remove reference to point (f)
response	*Accepted.* Corrected. See also our response to comment 194

comment	*316* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland*

	21.A.101 "…The changed product shall comply with the applicable environmental protection requirements laid down in point 21.B.85." *Swiss FOCA: Link to to 21.B.80 & 21.B.82 missing too.*
response	*Not accepted.* See our response to comment 315.

comment	*343* comment by: *LHT DO* A reference to Part B seems not to be helpful, since Part B is the requirement for the agency.
response	Noted. In fact, 21.A.101 is common for the applicants and the Agency. The applicants are required to follow it when making their proposal. The Agency is obliged to follow it by cross-reference from 21.B.105. 21.B.85 becomes applicable for both by the cross-reference from 21.A.101(a).

3. Proposed amendments — Draft Opinion — 21.A.112B Demonstration of capability p. 45

comment	*41* comment by: *CAA-NL* **21.A.112B** In point (c) the last past of the sentence is 'certification programme established in accordance with point 21.A.15(b)' while the similar requirement in 21.A.14(c) reads 'certification programme required by point 21.A.15(b)'. We think the wording used in 21.A.14(c) fits best for the purpose intended in this rule so we suggest to use these wording also in 21.A.112B(c).
response	*Not accepted.* We think that the wording *'established in accordance with'* fits better the purpose. That is why we have aligned all the occurrences in the proposal, including the one in 21.A.14, with this wording in order to be consistent.

3. Proposed amendments — Draft Opinion — 21.A.115 Reqs for issue of a STC p. 45-46

comment	*9* comment by: *Swiss Air-Ambulance Ltd.* In point. (b)(3) reference is made to point 21.A.101(g). Paragraph 21.A.101 has been altered in such way that point (g) does no longer exist. Therefore the reference should read 21.A.101**(f)**.
response	*Accepted.* See the corresponding text of the final proposal.

comment	*21* comment by: *Franz Redak* 21.A.115a2) not all the refered topics in 21.A.263c1 to 9 apply for major changes (STC) 21.A.115b1) I assume the limitation should be to 21.A.112B a) or c) only.
response	*Not accepted* *1.For 21.A.115a2) :* The text reads 21.A.263(c)(1) and (9) (and not '(c)(1) to (9)). *2. For 21.A.115b1):* (b) is a valid option.

comment	*42* comment by: *CAA-NL* **21.A.115** 1. We suggest the following changes in the text to bring it more in line with the point 21.A.20(a) and 21.A.95(b). This proposal mirrors the proposal we made for 21.A.97: (b) 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, the applicable operational suitability data 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 and (c) By derogation from point~~s~~ (b)(2~~3~~) and (34), 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.

response	*Not accepted.* See our response to comment 39.

comment	*93* comment by: *Airbus* **1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:** Page 45/67, paragraph 21.A.115(a)2. **2. PROPOSED TEXT / COMMENT:** Proposed change: *"2. by an ~~appropriately~~ approved design organisation within **the scope in** its terms of approval **including** ~~and~~ privileges of point 21.A.263(c)(1) and (9) under a procedure agreed with the Agency."* **3. RATIONALE / REASON / JUSTIFICATION:** Wording "appropriately" is meaningless. Either it is removed (as proposed) or further clarified. Privileges are part of the Terms of Approval.
response	*Partially accepted.* Your proposal is carried in a slightly modified form. See the text of the final proposal

comment	*114* comment by: *KLM Engineering & Maintenance* 21.A.115(b)(3): Typographical error. In the proposed 21.A.115(b)(3) reference is made to 21.A.101(g). However, in proposed 21.A.101, paragraph (g) will be renumbered to (f), hence reference should be made to 21.A.101(f).
response	*Accepted.* Thanks.

comment	*238* comment by: *Airbus Helicopters* 21.A.115(b)(2) mentions the applicable TC basis and environmental protection requirements established by the Agency i.a.w. 21.A.101, but does not mention how these requirements are notified by the Agency.

The explanatory note for 21.A.115 (page 20) states that, in the case of an STC applicant to the Agency, the applicant is notified i.a.w. 21.B.105 (should be 21.B.109), whereas in the case of a DOA holder self-approving the STC under its privilege, the DOA holder will be notified when the Agency is granting the privilege.

Suggestion
Suggestion is to clarify, at least in an AMC, how the TC basis and other requirements for the STC are notified for each case (applicant or DOA privilege).

response

Noted.

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

3. Proposed amendments — Draft Opinion — 21.A.258 Findings p. 46-47

comment *43* comment by: *CAA-NL*

21.A.258
21.A.258(a) and (b) handles the non-compliances found by the Agency during their investigations, both during compliance demonstration as well as during DOA-audits. Therefore 21.A.258(a) and (b) should be relocated to the Section B.

response

Noted.

Deferred for the rulemaking tasks RMT.0251 (SMS) in progress.

comment *94* comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 46-47/67, paragraph 21.A.258.

2. PROPOSED TEXT / COMMENT:
Level 3 findings are not non-compliances with the Part 21, thus the provisions for level 3 findings should be only documented in the GM (soft law) but not in the requirement itself (hard law).

Level 2 findings:
- provisions for corrective action period should be transferred to the guidance material to provide some flexibility which is actually already implemented within the current practises in

the oversight of DOAs by EASA.
- Only multiple not corrected level 2 findings should potentially lead to a DOA suspension or revocation but not a single level 2 finding

Proposed changes:

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) 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) 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)*~~ *(b) 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 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.*~~

~~*(d)(*~~*c) In cases of level one or multiple not corrected 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 shall provide confirmation of receipt of the notice of suspension or revocation of the design organisation approval in a timely manner.*

GM to 21.A.258
For a level two finding, the corrective action period granted by the Agency should not be more than three months. In certain circumstances and subject to the nature of the finding the Agency may grant a period beyond three months, subject to the provision of a satisfactory corrective action plan agreed by the Agency;

Any other Item than level 1 or level 2 finding where it has been identified, by objective evidence, to contain potential problems that could lead to a non-compliance with Part 21 should be classified as a level three finding.
A level three finding does not require immediate action by the DOA holder.

3. RATIONALE / REASON / JUSTIFICATION:
To better consider the actual practice implemented by EASA in the DOA oversight and not to link DOA suspension or revocation to a single level two finding not corrected.

response *Not accepted.*

Considered out of scope of this rulemaking task. Subpart J will need to be reviewed completely in the context of the RMT.0251 (SMS). We have therefore decided to defer resolution of this comment for the RMT.0251 currently in progress.

comment *345* comment by: *LHT DO*

We do not see an issue to retract a DOA if there are level 2 findings. Please clarify that a level 2 finding cannot cease the DOA.

response Noted.

Considered out of scope of this rulemaking task. Subpart J will need to be reviewed completely in the context of the RMT.0251 (SMS). We have therefore decided to defer resolution of this comment for the RMT.0251 currently in progress.

3. Proposed amendments — Draft Opinion — 21.A.263 Privileges p. 47-48

comment *6* comment by: *J.Bedriñana*

The wording of th new 21.A.263(c) 8. and 9. paragraphs must include "....for equivalent changes", because right now this concept is hidden in the new AMC

response *Not accepted.*

Note that the word *certain* has been used in the final proposal.

comment *10* comment by: *Swiss Air-Ambulance Ltd.*

It is observed that the privilege to approve minor revisions to the aircraft flight manual (as currently detailed in 21.A.263 (c)(4)) has been deleted from the list of privileges without further substitution. Swiss Air-Ambulance considers such deletion to be contradictory to the intent of this NPA to shift responsibilities from EASA to the DO's, since every revision to the AFM would have to be approved by EASA. Furthermore after considering the intent of this NPA, there is no obvious connection between the implementation of LOI and the withdrawal

of said privilege.
Ultimately such deletion would restrict currently privileged DO's in doing their business since the withdrawal of such privilege would limit the organisation's capabilities and flexibility.

Swiss Air-Ambulance suggest to **leave said privilege** (as currently detailed in 21.A.263 (c)(4)) as it is currently given, meaning **not to delete** it.

response

Not accepted

See our responses to comments 22 above and 44 below.

comment

44 comment by: *CAA-NL*

21.A.263
1. The privileges of 21.A.263(a) are deleted. The rationale for this proposal is not substantiated and this is not in line with other parts e.g. 145.A.75(a).

2. It is proposed to delete 21.A.263(c)4 related to the privilege a DOA may have to approve minor revisions to the aircraft flight manual (AFM).
The NPA provides no explanation on the background of this amendment but we understand that, as the approved part of the AFM is part of the type design, an organisation that has the privilege to approve minor changes to the type design automatically should have the privilege to approve minor changes to the approved part of the AFM. We fully agree with this principle but there are a number of side effects that the NPA does not address:
· There is a need for guidance on making the distinction between minor and major changes to the AFM. The only guidance that exists at present is in GM 21.A.263(c)(4) (even though it uses the term "revision" as opposed to "change"), but the basis for this GM disappears when 21.A.263(c)4 itself is deleted. There is no adequate guidance on this subject in GM 21.A.91. In our opinion GM 21.A.91 should be extended to provide specific guidance on making the distinction between minor and major changes to the AFM, in line with what is currently in GM 21.A.263(c)(4).
· Organisations that have at this time the privilege of 21.A.263(c)2 but not of 21.A.263(c)4 will automatically with this amendment of Part 21 have the privilege to approve minor changes to the AFM and supplements, but their processes and manuals will need to be amended for this. Organisations that currently have the privileges of both 21.A.263(c)2 and 21.A.263(c)4 will likely also have to amend their processes and manual. DOA organisations need to be made aware of this.
· Minor changes to an AFM may be of a purely administrative nature, as described in GM 21.A.263(c)(4) paragraph 2.1(c). Guidance needs to be provided to the effect that for such changes, no visible demonstration of compliance with the certification basis is likely to be required.
· The need for a separate Form 36 for "application for approval of stand-alone or minor change related revisions of flight manual" should be re-assessed: as the privilege under 21.A.263(c)2 now obviously includes the privilege to approve minor change related revisions to the AFM, and as stand-alone major changes to the AFM are considered equivalent to any other major change to a type design, the reason for a dedicated application form seems no longer to exist. Changes are also likely to be necessary for Form 31, Form 32 and Form 96.

	· The RIA of the NPA does not take into account the above effects. 3. In line with the new privileges for major changes and STC's we suggest to include also for repairs the possibility for the Agency to limit the scope of repairs a DOA holder can approve when it sees the need. Therefore we suggest to change point (c)5. As follows: (c)5. to approve the design of major repairs under Subpart M to products or Auxiliary Power Units within the scope as established by the Agency ~~for which it holds the type-certificate or the supplemental type-certificate or ETSO authorisation~~; If this suggestion is accepted, **AMC1 21.A.263 (c)(8)and (9)** also need some amendments. (c)(5) Need to be included in the title and the first sentence. as well as the word 'repair(s)' need to be incorporated in the text at various places next to the word 'change(s)'.
response	1. *Noted* The text of (a) has been deleted (but the point has been kept as *Reserved*) since the right to design aeronautical products, parts or appliances (even under Part-21) should not be regulated. In a state of law what is not forbidden is allowed and the aeronautical design activity is not forbidden since itself it does not present any risk to society. We apologise for not providing the above explanation in the NPA 2*. Noted* We again apologise for not providing the explanation in the NPA Your understanding of the reasons for the deletion of the 21.A.263(c)(4) is the correct one, with the exception that AFM is not considered part of the type design but part of TC. Your concerns related to necessary adaptation to the DOA Terms of Approval and applicable DOA procedures are fully recognised. However, these will need to be reviewed anyway also for other reasons triggered by this proposal. There is a time to complete this job before the amending Regulation for LoI is adopted. *3. Partially accepted* Your proposal is carried in a modified form. See the text of the final proposal.

comment	*57* comment by: *DOA EASA.21J.041 Aero-Dienst GmbH & Co. KG* 21.A.263(c)(4): The privilege to approve minor revisions to the AFM and Supplement is deleted. There is no explanation in this NPA why the privilege shall be removed. The removal of this privilege would increase Agencies workload and reduces the capabilities of DOAs. Please clarify. Retaining the privilege is suggested.
response	*Not accepted* See our responses to comments 22 and 44 above.

comment	*95* comment by: *Airbus* **1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:** Page 47-48/67, paragraph 21.A.263 (c) **2. PROPOSED TEXT / COMMENT:** It is proposed to amend the point 21.A.263(c) Proposed change: "(c) A DOA holder shall be entitled, within its terms of approval as established by the Agency and under the relevant procedures of the design assurance system: 1. […]; 2. to approve **the design of** minor changes to a type-certificate or to a supplemental type-certificate or **of** minor repairs; […] 5. to approve the design of major repairs under Subpart M to products or Auxiliary Power Units; […] 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 ~~controls~~ **manages** 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 **the design of** major changes to a type-certificate under Subpart D within the scope as established by the Agency; and **3. RATIONALE / REASON / JUSTIFICATION for the Comment:** For sake of clarity and consistency with the wording in Part 21 Subpart M which mentions "repair design" although, similar to the changes, not only the design data are covered by the approval but as well the potential other data impacting the Type certificate (e.g.: Operational limitations, airworthiness limitations). .
response	*Partially accepted* As you correctly pointed out, the scope of the privileges to classify and approve minor (major) change to TC is wider that just change to (type) design (see also our responses to

comments 22 and 44 above) so this part of your proposal is not carried. But your comment on repair design is carried, in a modified form.

comment *96* comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 47/67, paragraph 21.A.263 (c)4

2. PROPOSED TEXT / COMMENT:

Could EASA clarify why the DOA privilege 21.A.263(c)4, relevant to approval of minor revisions to AFM, is proposed to be removed within this NPA?

Proposed change:

To keep21.A.263(c)4 as it is currently:

"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].';

Or to explain/clarify within table A "detailed review of the changes in the affected part 21 points" in the NPA, the reason for this deletion together with the foreseen measures; to get it embodied in Part 21 in another way (e.g. : via current DOA privileges 21.A263(c)1 & (c) 2)).

3. RATIONALE / REASON / JUSTIFICATION for the Comment:

Reason for removal of the privilege is not understood. Furthermore nothing is mentioned in page 30 within the table A providing the details for the changes introduced through this NPA.

response *Not accepted*

See our responses to comments 22 and 44 above.

comment *97* comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 48/67, paragraph 21.A.263 (c)5

2. PROPOSED TEXT / COMMENT:

Could EASA clarify why eligibility conditions (i.e : reserved to TC , STC holders) for the DOA privilege 21.A.263(c) 5 relevant to approval of design of major repairs, are proposed to be removed within this NPA?

3. RATIONALE / REASON / JUSTIFICATION for the Comment:

Reason for removal of the eligibility conditions is not understood. Furthermore nothing is mentioned in page 30 within the table A providing the details for the changes introduced through this NPA.

response

Noted.

In view of introduction of the new privileges for major changes to a TC and STCs, it was concluded that the limitation, reserving this privilege for major repair designs just to the TC/STC/APU ETSOA holders, can be removed when the safety risk is controlled. The privilege related to major repair designs is seen of similar magnitude as the one for major changes to TC/STC. However, note that, compare to the NPA text, we have amended the introductory text for 21.A.263(c)): to read *within the scope of its terms of approval, as established by the Agency, and under the relevant procedures of the design assurance system.*

comment

115 comment by: *KLM Engineering & Maintenance*

21.A.263(c)(4) – Privileges
Under current 21.A.263(c)(4) a DOA holder shall be entitled, within its terms of approval as established by the Agency and under the relevant procedures of the design assurance system, 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]'."
In the NPA proposal, this privilege will be deleted. No rationale what so ever is given why this privilege will be deleted.
From an airline DOA point of view, this is unacceptable. Considerable cost savings can be obtained annually for an operator over Airport- and ATM fees by making use of this privilege (i.e. approval of reduced MTOW in the AFM). This DOA privilege should therefore not be deleted.

response

Not accepted

See our responses to comments 22 above and 44 below.

comment

135 comment by: *TURBOMECA Alain BARON*

The NPA 2015-03 proposes to delete the paragraph 21.A.263(b).

	This deletion will lead to also delete the associated AMC 21.A.263(b)(1). AMC 21.A.263(b)(1) defines the capability of the engine / propeller designer to define and to justify the Flight Conditions applicable to the engine / propeller under the authority of their DOA, applying an EASA agreed procedure. It is necessary to maintain this capability: • Either by granting an engine / propeller designer privilege • Either by an AMC linked to the paragraph 21.A.710(a)(2) related to the approval of the Flight Conditions by an approved organisation. The organisations responsible for the design of the aircraft do not participate to the engines / propellers Type Certification. They are not suitable for agreeing the engine / propeller compliance documents justifying the engine / propeller Flight Conditions.
Response	*Noted.* The issue of AMC 21.A.263(b)(1) will be clarified by means of AMC/GM material to be developed in Phase II. This AMC may be, with the text revised as necessary, relocated to AMC/GM for Subpart P. 21.A.263(b) needs to be deleted since it collides with the LoI concept (21.A.100)

comment	*151* comment by: *Rolls-Royce* Comment: Section (c)5: No reason to specifically mention Auxiliary Power Units Suggested resolution: Delete specific reference to Auxiliary Power Units, leaving just "Products"
response	*Not accepted.* Unlike other ETSOA articles, APUs have a special status in Part-21 and in particular Subpart M. They are treated like products, including approval of repair design.

comment	*177* comment by: *sabena technics BOD* 21.A.263 (c)(4): How a DOA without LOI privilege can approve minor changes to a AFM (add a new aircraft serial number, for example), as it is currently granted per 21.A.263 (c)(4)?
response	*Noted.*

	See our responses to comments 22 and 44 above.

comment	*196* comment by: *AeroSpace and Defences Industries Association of Europe (ASD)* 21.A.263(b) Current AMC/GM linked to 21.263.(b)(1) should be moved to AMC/GM for 21.A.710(a)(2) an AMC linked to the paragraph 21.A.710(a)(2) related to the approval of the Flight Conditions by an approved organisation shall clarify that an Engine or Propeller manufacturer can provide validated flight conditions substantiation documents to the aircraft manufacturer.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	*197* comment by: *AeroSpace and Defences Industries Association of Europe (ASD)* 21.A.263 (c)(2) The guidance material for 21.A.91 (Classifcation of Changes) should clarify that changes to type certificates include changes to approved manuals. Comments on AMC/GM will be provided in NPA2 (RMT.0611)
response	*Noted.* See our responses to comments 22 and 44 above.

comment	*210* comment by: *British Airways* AFM privilege
response	*Noted.* See our responses to comment 22 and 44 above.

comment	*211* comment by: *British Airways*

	Please provide an explanation why the AFM minor revision privilege has been removed from 21.A.263 as this is an extremely useful privilege. British Airways would respectfully request this privilege is re-instated. Will there be a new privilege added to allow DOA's to make changes to OSD, if required, as part of a change.
response	*Noted.* See our responses to comments 22 and 44 above.

comment	*220* comment by: *Hugues LE CARDINAL (Chairman of VELICA SAS)* VELICA thinks that the current wording is clearer than the proposed wording : 21.A.263(c)4 “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]."
response	*Noted.* See our responses to comments 22 and 44 above.

comment	*226* comment by: *Dassault Aviation* 21.A.263 c8: DASSAULT-AVIATION fully support the EASA approach to identify the conditions of use of a privilege in guidance rather than in a hard law.
response	*Noted.*

comment	*227* comment by: *Dassault Aviation* 21.A.263 c2: DASSAULT-AVIATION fully supports merging several privileges into one. A guidance should extend the idea of minor changes to approved manuals (may be also in guidance material to 21.A.97).
response	*Noted.* See our responses to comments 22 and 44 above.

comment	*249* comment by: *Pilatus* Point 21.A.263(c)4. the privilege to approve minor changes to the AFM has now been deleted by this proposed change, but Pilatus did not find any other pargragraph where it was reintroduced. EASA to clarify the intent of deleting this privilege as this is seen as an advantage to have especially in case where only a stand-alone change is introduced in the AFM. Point 21.A.263(c)8. Will the approval of Major Changes also inlcude the related AFM changes as well as AMM Chapter 4 (ALS) changes?
response	*Noted.* 1. *For 21.A.263(c)4:* See our responses to comments 22 and 44 above. 2. *For 21.A.263(c)8:* Currently under consideration (for both AFM and ALS)

comment	*260* comment by: *DAHER* § 21.A.263 c2) The guidance material shall clarify : - that changes to type certificates include changes to approved manuals - the definition of minor / major changes of approved manual as identified before in 21.A.263 c4 - the definition of the minor or major change of OSD. § 21.A.263 c4) DAHER proposes to keep21.A.263(c)4 as it is currently: “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]." This subparagraph could be used to identify and define the OSD changes.
response	*Noted.* *1. For 21.A.263 c2):* It will be clarified by means of AMC/GM material to be developed in Phase II. *2. For changes to OSD:* Consult NPA 2015-12 and ED Decision 2016/007/R on EASA website. *3. For 21.A.263 c4:* See our responses to comments 22 and 44 above.

comment	*280* comment by: *CFM* 21.A.263(b) : The delation of the regulation point 21.A.263(b) should not delate the AMC 21.A.263(b)(1). This AMC allows to provide engine flight test compliance data to the Airframers under EASA regulation or Airframer from third countries (e.g. FAA, AIC AR or CAAC). This AMC should be retained in the frame of the point 21.A.263(c).
response	*Noted.* The issue of AMC 21.A.263(b)(1) will be clarified by means of AMC/GM material to be developed in Phase II. This AMC may be, with the text revised as necessary, relocated to AMC/GM for Subpart P. 21.A.263(b) needs to be deleted since it collides with the LoI concept (21.A.100)

comment	*282* comment by: *CFM* 21.A.263(c)(7) : Typo error in the reference to 21.A.263(b)(6) as this paragrph is proposed to be delated. Should be 21.A.263(c)(6).
response	*Accepted.* Thanks.

comment	*296* comment by: *Sell GmbH* 21.A.263(c)5: Removal of existing DOA privilege to approve major repairs, e.g. for respective TC- and STC-holder, is unjustified and thus requiring grandfather ruling for DOAs having this privilege in their existing Terms of Approval.
response	*Noted.* The 21.A.263(c)(5)privilege is extended, not removed. The limitation is removed.

comment	*317* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland* **21.A.263** 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]~~ *Swiss FOCA: Agency to clarify in which context standalone minor revisions to manuals or*

	manual supplements shall be handled in the future.
response	*Noted* See our responses to comments 22 and 44 above.

comment	*318* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland* **21.A.263** 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;"~~ *Swiss FOCA: Repairs to "unknown" designs contain a certain risk of inappropriate application of common-practice repair design principles (i.e. FAA AC43-14...) being not in accordance with the design principles initially defined by the TC holder.*
response	*Noted*. See amended 21.A.432C(b)(7) and 21.A.433(a)4

comment	*346* comment by: *LHT DO* Thank you keeping the point as reserved and not deleting it. The reason for cancelling the privilege of approving minor revisions the the AFM(-S) is unclear. Please keep the approval of AFM changes under the DOA system valid. Please ammend OSD approval.
response	*Not accepted.* See our responses to comments 22 and 44 above.

3. Proposed amendments — Draft Opinion — 21.A.265 Obligations of the holder p. 48

comment	*98* comment by: *Airbus* **1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:** Page 48/67, paragraph 21.A.265.

2. PROPOSED TEXT / COMMENT:

It is proposed to amend the point 21.A.265.

Proposed change:
"The holder of a design organisation approval shall: […]
(c) determine that the design of products, or changes or repairs there~~of~~to, 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 **the design of** minor changes or repairs approved under the privilege of point 21.A.263(c)(2), **of** major repairs approved under the privilege of (c)(5), major changes to a type-certificate approved under the privilege of (c)(8) or **of** supplemental type- certificates issued under the privilege of (c)(9),

[…]"

3. RATIONALE / REASON / JUSTIFICATION for the Comment:

For sake of consistency in wordings used in this point, and consistency with the wording in Part 21 Subpart M which mentions "repair design" although, similar to the changes, not only the design data are covered by the approval but as well the potential other data impacting the Type certificate (e.g.: Operational limitations, airworthiness limitations).

response

Partially accepted.

A change to TC cannot be reduced to just a design change. The scope is wider and covers e.g. *operation limitations* See our response to comment 22 above.

The word *'design'* has been however added after *'repair'* .

3. Proposed amendments — Draft Opinion — 21.A.432B Demonstration of capability p. 49

comment

45 comment by: *CAA-NL*

21.A.432B
For consistency reasons to be in line with the wording of 21.A.14 and 21.A.112B, we suggest the following wording:
(a) An organisation applying ~~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.

response

Not accepted.

According to 21.A.432A 'Eligibility', 'any natural or legal person' may apply. A natural person

	can be a single human being with no 'organisation' behind. The term 'organisation' was intended to apply just to the 'legal person'. The term 'applicant' covers both the natural and legal person. Thanks to your comment the incorrect 21.A.14 and 21.A.112B have been amended to align with the preferred wording.

comment	*99* comment by: *Airbus* **1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:** Page 49/67, paragraph 21.A.432B(c) **2. PROPOSED TEXT / COMMENT:** Could EASA clarify the meaning and content of a "certification plan" versus a "certification programme" ? Special care should be taken in order not to confuse the stakeholders with the wordings "certification plan" and "certification programme" as per 21.A.15(b) **3. RATIONALE / REASON / JUSTIFICATION for the Comment:** For the sake of clarity. "Certification plan" needs to be further explained/detailed within the 21.A.432B or in associated AMC/GM.
response	*Noted.* The wording *certification plan* was abandoned in favour to *certification programme* since numerous comments suggest it is confusing. See also new 21.A.432C specifying the content of the *certification programme* requested for major repair designs only.

comment	*229* comment by: *Dassault Aviation* 21.A.432B and 21.A.433 : Why was certification programme changed to certification plan ?
response	*Noted.* The wording *certification plan* was abandoned in favour to *certification programme* since numerous comments suggest it is confusing. See also new 21.A.432C specifying the content of the *certification programme* requested for major repair designs only.

comment	*262* comment by: *DAHER*

§21.A.432B c)
DAHER supposes that there is a mistake in the wording " certification plan" versus "certification programme".

response

Noted.

The wording *certification plan* was abandoned in favour to *certification programme* since numerous comments suggest it is confusing. See also new 21.A.432C specifying the content of the *certification programme* requested for major repair designs only.

comment

319 comment by: *Federal Office of Civil Aviation (FOCA), Switzerland*

21.A.432B Demonstration of capability

(c) "By way of derogation… 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".
Swiss FOCA: inconsistent wording, must read certification program

response

Noted.

The wording *certification plan* was abandoned in favour to *certification programme* since numerous comments suggest it is confusing. See also new 21.A.432C specifying the content of the *certification programme* requested for major repair designs only.

3. Proposed amendments — Draft Opinion — 21.A.433 Reqs for approval of a repair design p. 49-50

comment

100 comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 49/67, paragraph 21.A.433(a) & (b)

2. PROPOSED TEXT / COMMENT:

Could EASA clarify the meaning and content of a "certification plan" versus a "certification programme" ?
Special care should be taken in order not to confuse the stakeholders with certification plan and certification programme as per 21.A15(b)

Wording "appropriately" is meaningless

Proposed change
(a) An applicant for approval of a repair design, or an ~~appropriately~~ approved design

	organisation using its privileges to classify and approve repairs under point 21.A.263(c)(1)(2) and (5), shall: Content of the arrangement in point (b) should be clarified **3. RATIONALE / REASON / JUSTIFICATION for the Comment:** For the sake of clarity. Wording "appropriately" is meaningless. Either it is removed (as proposed) or further clarified. Classify and approve are subject to two separate DOA privileges as stated in 21.A.263(c).
response	*Noted.* *For certification plan vs programme:* The wording *certification plan* was abandoned in favour to *certification programme* since numerous comments suggest it is confusing. See also new 21.A.432C specifying the content of the *certification programme* requested for major repair designs only. The *'appropriately'* indicates *For the 'appropriately': Partially accepted.* Proposal carried in a modified form and modified wording used in all similar occurrences. *For the 'arrangement':* See 21.A.433(a)(4) in the final proposal.

comment	*101* comment by: *Airbus* **1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:** Page 50/67, paragraph 21.A.433(b) **2. PROPOSED TEXT / COMMENT:** Arrangement between the major repair approval applicant and the TC or STC holder, when required by EASA, should be aligned on what is required from an STC applicant in Part 21.A.115 (d). **3. RATIONALE / REASON / JUSTIFICATION for the Comment:** Minimum content of the arrangement, when required by the Agency, shall be determined. Principle for the arrangement should be within the 21.A.433 requirement itself and all the details/conditions only within the associated AMC/GM.
response	*Accepted.* See 21.A.433(a)(4) in the final proposal. and also new point 21.A.432C(b)(7).

comment	*116* comment by: *KLM Engineering & Maintenance* 21.A.433(a) – Requirements for approval of a repair design In the NPA proposal it will be required for a major repair to submit a certification plan describing the means and process followed to demonstrate compliance, and submit all necessary substantiation data, when requested by the Agency. In only a few occasions a major repair can be planned for accomplishment and the approval of the major repair design can more or less be scheduled. However, a major repair is almost always when the aircraft is AOG. Waiting for the approval of the repair design will result in additional groundtime (no revenues). In case of a major repair almost always concurrence from the (S)TC-holder will have been sought. It is impractical in an AOG situation to prepare a Certification Programme, obtain concurrence from the Agency, demonstrate compliance with the applicable TC-basis en environmental protection requirements and submit any substantiation data that is requested by the Agency and then wait for approval of the major repair design. It should be sufficient for a DOA to demonstrate compliance and submit all substantiation data to obtain the approval from the Agency.
response	*Partially accepted.* The amended proposal requests for major repair designs the *certification programme* in new 21.A.432C. Such a documents is consistently under this proposal requested for every certification process except for a minor change or minor repair design. The reason is twofold: 1. The applicant should always have, irrespective from the Agency needs, a data summary/planning document for every project above certain size. This is considered natural requirement for every serious activity of certain complexity. This includes also projects for major repair designs. The task of compliance demonstration for a typical non-standard major repair design by an applicant (currently a DOA holder not eligible for the 21.A.263(c)(5) privilege) is a project of a certain size. Therefore, a *certification programme*, commensurate to the project complexity, should be produced to be used by the organisation itself anyway. 2. The Agency needs this documents because it provides necessary information and insight into a certification project for which an EASA approval/certificate is requested. However, note please that neither 21.A.433(a) per the NPA nor the amended proposal per new 21.A.432C require a prior approval/acceptance of the *certification programme* by the Agency as a condition for the applicant to start with the compliance demonstration activities. Under new 21.A.432C(b), the *certification programme* for a major repair design may be provide even after the application as its supplement. The issue will be clarified by means of AMC/GM material to be developed in Phase II.

comment	*152* comment by: *Rolls-Royce* Comment: Section (a)2: "submit, for major repair, a certification plan" only applies if seeking Agency approval - will not apply if repair is being approved under 21.A.263 privilege Suggested Resolution: Clarify requirement only applies if applicant is seeking Agency approval for a major repair
response	*Accepted.* See the corresponding text of 21.A.433(b) in the final proposal. '*The applicant'* wording suggests that the requirement is applicable only to applicants to the Agency. AMC/GM material may be considered in Phase II.

comment	*168* comment by: *LMI Aerospace* 1. Firstly the wording of this requirement is unclear. Does the need for documentation requested by the agency apply to a certification plan or substantiation data or both? 2. Is there always a requirement to submit a certification plan to the agency for every major repair? If a DOA has authorisation to approve major repairs do they need to submit a certification plan to the agency? Or can they approve the certification plan internally? 3. The requirement for a certification plan for every major repair is onerous and unnecessary. A major repair could be triggered simply because a repair requires permanent additional inspections to the maintenance program. As an example, if an operator applies an SRM repair with some minor deviations (e.g. fastener type, size or material thickness, temper) and the repair incorporates permanent additional inspections into the maintenance program as required by CS 25.571 then this repair will be major. Is it really intended that a simple set of deviations to an SRM repair requires a certification plan? Will EASA have the manpower to evaluate and respond to these certification plans in a timely fashion? 4. It is suggested that some thought be put into the development of criteria that would require a certification plan for a major repair to remove unnecessary workload from the regulatory authority. Also, the addition of an aging aircraft rule (NPA 2013-07) will add significantly increased volume to the current set of damage tolerant aircraft in service. As an example, a major repair that is determined to be Significant may require a certification plan. 5. It is also suggested that EASA consider adding language to this requirement that allow them to accept DOA procedures for determining the requirement for a certification plan in lieu of this as a blanket requirement.
response	Noted. *For 1: Accepted*. See new 21.A.432C(b) and amended 21.A.433(b). *For 2:* The text is amended to clarify that only the applicants to the Agency are required to submit a *certification programme* (with the application or later, see new 21.A.432C(b)). The applicants to the Agency shall provide a declaration/statement of compliance always and the

substantiation data only when requested by the Agency (see amended 21.A.433(b)). The submission requirements in general do not apply to the DOA holders using their privileges (see 21.A.265 (d)).

For 3: The *certification programme* can be proportionate. Even when a major repair design is the very simple case you mention above, there is no burden for an applicant (when not having an appropriate 21.A.263(c)(5) privilege) to draft and submit a very simple document summarizing the necessary descriptions and compliance demonstration of repair of such a small scope. For items that are not applicable you will put 'N/A'.

What is of upmost importance to notice is the fact that both the rule per the NPA and the final proposal do not require the applicant to wait for acceptance of the programme by the Agency to start with the compliance demonstration.

AMC/GM will explain the issue.

For 4: See the response for 3 above and our response to comment 116 above.

5. The best way for DOA holders wanting to reduce the Agency involvement is to obtain a 21.A.263(c)(5) privilege of a proper scope. However, to lower the Agency's LoI to zero the DOA must demonstrate that no Agency's involvement is needed because the DOA performance and experience is such that a risk of a non-compliance is reduced under an acceptable level. The Agency needs to build trust in that DOA. For this the Agency need to see how the design assurance system of the DOA works in individual certification projects for repairs under an application. Reviewing quality of the certification programme and substantiation data may exactly provide the Agency with that kind of information it needs to assess the risk of a non-compliance acceptably low and grant the DOA privilege of a defined scope. Therefore a certification programme can provide benefit to the Agency and to the DOA holders through obtaining the privilege that fits.

comment

198 comment by: *AeroSpace and Defences Industries Association of Europe (ASD)*

21.A.433
EASA should clarify the meaning and content of a "certification plan" versus a "certification programme".
Special care should be taken in order not to confuse the stakeholders with certification plan and certification programme as per 21.A15(b).
The text in 21.A433(a)(2) should make it clear that this requirement only applies if the applicant is seeking Agency approval for a major repair and would therefore not apply if repair is being approved under 21.A.263 privilege.

response

Noted.

The wording *certification plan* was abandoned in favour to *certification programme* since numerous comments suggest it is confusing. See also new 21.A.432C specifying the content

of the *certification programme* requested for major repair designs only.

For the 21.A.432(a)(2) issue, it is corrected by amendments to 21.A.433 (see 21.A.433(b)). When you read the applicant, it is only applicable to applicants to the Agency.

comment

213 comment by: *British Airways*

Ammendments to 21.A.433 appear to have removed the ability to demonstrate repairs to the latest applicable specifications. Please comment why this change has been made

response

Noted.

Because it was obsolete bottom-up requirement not specifying if the *latest option* is for all items of the certification basis or if a 'cherry picking' within the specifications is also possible. It was replaced by requiring compliance with the existing TC basis as a default with possibility of amendments.

comment

229 ❖ comment by: *Dassault Aviation*

21.A.432B and 21.A.433 : Why was certification programme changed to certification plan ?

response

Noted.

The wording *certification plan* was abandoned in favour to *certification programme* since numerous comments suggest it is confusing. See also new 21.A.432C specifying the content of the *certification programme* requested for major repair designs only.

comment

240 comment by: *Airbus Helicopters*

21.A.433(a)(1) states about amendments to the TC basis and environmental protection requirements "…*established and notified, <u>when applicable</u>, by the Agency in accordance with point 21.B.113*"

This is in line with the explanatory note to 21.A.433 (page 31), which states that point (a) has been amended to extend its scope to repairs approved under DOA privilege.

However, there is no mention how the DOA holder knows what amendments to the TC basis should be applied in the case of repair approved under the privilege of 21.A.263(c)(5).

Suggestion
Suggestion is to clarify, at least in an AMC, how the TC basis and other requirements for the repair are notified, in the case of repair approved under DOA privilege).

response	Noted. 21.B.113 is only applicable for projects under an application to the Agency. A DOA holder using their 21.A.263(c)(5) privilege will get the TC basis with the privilege to be recorded in their DOA Terms of Approval. These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	*241* comment by: *Airbus Helicopters* 21.A.433(a)(2) introduces a new requirement to "*submit, for a major repair, a certification plan describing the means and process followed to demonstrate compliance…*". Elaborating and submitting a Certification Plan for a repair would increase the complexity of the process and is not perceived as having a real added value. **Suggestion** Suggestion is to keep the present text for 21.A.433(a)(2), requesting the applicant to submit all necessary substantiation data, when requested by the Agency.
response	*Not accepted.* The text is amended to clarify that only <u>the applicants to the Agency</u> are required to submit a *certification programme* (with the application or later, see new 21.A.432C(b)). It can be submitted even after the application. The applicants to the Agency shall provide a declaration/statement of compliance always and the substantiation data only when requested by the Agency (see amended 21.A.433(b)). The submission requirements in general do not apply to the DOA holders using their privileges (see 21.A.265 (d)).

comment	*242* comment by: *Airbus Helicopters* 21.A.433 (a)(2) & (3) According to the proposed text, a DOA holder approving a major repair under the privilege of 21.A.263(c)(5) is also supposed to submit a certification plan and a statement of compliance. This is not consistent with the concept of approval under DOA. **Suggestion** 21.A.433 needs adaptation to handle both situations of approval by the Agency and approval under DOA.
response	*Accepted.*

	Corrected. See the amended text in the final proposal for 21.A.433(b) and new 21.432C(b

comment	*250* comment by: *Pilatus* In 21.A.433(a)2, it is not clear how this particular paragraph effects a DOA with the privilege to classify and approve major changes. In the Pilatus opinion such a DOA should be exempted from this requirement e.g. submit a certificaiton plan, especially if approved process are already in place, however the DO shall provide substantiation data when requested by the Agency.
response	*Accepted.* See the amended text of 21.A.433(b) and new 21.432C(b)

comment	*264* comment by: *DAHER* §21.A.433a2) DAHER supposes that there is a mistake in the wording " certification plan" versus "certification programme". Submission of the certification plan to the Agency should be applicable only if the privilege to classify and approve repairs is not used. The text should be clarified.
response	*Accepted.* See the amended text of 21.A.433(b) and new 21.432C(b)

comment	*288* comment by: *CFM* 21.A.243(a) : Point 21.A.433(a)(2) requests to an applicant for a major repair to submit a certification plan and substantiation data when requested by EASA. Need to clarify that it should not apply to Design Organisation with the major repair DOA privilege. Point 21.A.433(a) should includes, as for Sub-parts B, D & O, a statement for the no known characteristics that makes the article unsafe. Proposal for 21.A.433(a)(4): "no known characteristic makes the article unsafe for the uses for which certification is requested".
response	*Accepted.* *For point 21.A.433(a)(2): Accepted*. See the amended text of 21.A.433(b) and new 21.432C(b) *For 21.A.433(a)(4): Accepted*. See amended 21.A.433(a)(3).

comment	*320* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland* **21.A.432B Demonstration of capability** 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;" *Swiss FOCA: inconsistent wording, must read certification program*
response	*Accepted* See the amended text of 21.A.433(b) and new 21.432C(b)

comment	*347* comment by: *LHT DO* EASA should clarify the meaning and content of a "certification plan" versus a "certification programme". Special care should be taken in order not to confuse the stakeholders with certification plan and certification programme as per 21.A15(b). The text in 21.A433(a)(2) should make it clear that this requirement only applies if the applicant is seeking Agency approval for a major repair and would therefore not apply if repair is being approved under 21.A.263 privilege.
response	Noted. The wording *certification plan* was abandoned in favour to *certification programme* since numerous comments suggest it is confusing. See also new 21.A.432C specifying the content of the *certification programme* requested for major repair designs only. The text is amended to clarify that only the applicants to the Agency are required to submit a *certification programme* (with the application or later, see new 21.A.432C(b)). It can be submitted even after the application. The applicants to the Agency shall provide a declaration/statement of compliance always and the substantiation data only when requested by the Agency (see amended 21.A.433(b)). The submission requirements in general do not apply to the DOA holders using their privileges (see 21.A.265 (d)).

3. Proposed amendments — Draft Opinion — 21.A.435 Classification of repairs p. 50

comment	*102* comment by: *Airbus* **1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:** Page 50/67, paragraph 21.A.435 & 21.A.437 **2. PROPOSED TEXT / COMMENT:** Two paragraphs 21.A.435 & 21.A 437 should be merged Proposed change ***21.A.435 Classification and approval of repair~~s design~~*** *(a) A repair design 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.~~* *(b) A repair design shall be classified and approved by:* *1.~~(a)~~ the Agency; or* *2. ~~(b)~~ an ~~appropriately~~ approved design organisation ~~that is also the type certificate, the supplemental type certificate or APU ETSO authorisation holder~~, within the scope in its terms of approval including ~~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~~.* ***21.A.437 ~~Issue of a repair design~~ Reserved*** **3. RATIONALE / REASON / JUSTIFICATION for the Comment:** No need for two separate paragraphs, when considering the change to 21.A.437 proposed by EASA as follows: "a repair design shall be classified and approved by …". Otherwise, 21.A.435 shall cover classification approval and 21.A.437 shall cover only repair design approval.
response	*Accepted.* See amended 21.A.435 in the final proposal. GM. 21.A.437 and GM. 21.A.437 (a) and the cross-references in AMC & GM to Part-21 will be reviewed and renumbered in phase II (see 1.3 above).

3. Proposed amendments — Draft Opinion — 21.A.437 Approval of a repair design p. 50

comment *102* ❖ comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 50/67, paragraph 21.A.435 & 21.A.437

2. PROPOSED TEXT / COMMENT:

Two paragraphs 21.A.435 & 21.A 437 should be merged

Proposed change
21.A.435 Classification and approval of repair~~s design~~
(a) A repair design 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.~~
(b) A repair design shall be classified and approved by:
1.~~(a)~~ the Agency; or
2. ~~(b)~~ an ~~appropriately~~ approved design organisation ~~that is also the type-certificate, the supplemental type certificate or APU ETSO authorisation holder~~, within the scope in its terms of approval including ~~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~~.

21.A.437 ~~Issue of a repair design~~ Reserved

3. RATIONALE / REASON / JUSTIFICATION for the Comment:

No need for two separate paragraphs, when considering the change to 21.A.437 proposed by EASA as follows: "a repair design shall be classified and approved by …". Otherwise, 21.A.435 shall cover classification approval and 21.A.437 shall cover only repair design approval.

response *Accepted.*

See amended 21.A.435 in the final proposal.

GM. 21.A.437 and GM. 21.A.437 (a) and the cross-references in AMC & GM to Part-21 will be reviewed and renumbered in phase II (see 1.3 above).

comment *153* comment by: *Rolls-Royce*

Comment:
Section (b): Previously the approval of major repairs were limited to type-certificate, supplemental type-certificate or APU ETSO authorisation holders. The proposed text deletion

	means that all approved design organisations can approve major repairs without reference to the type-certificate, supplemental type-certificate or APU ETSO authorisation holder. It is not clear how the competence of these other Design Organisations can be assessed without reference to the type certificate holder? Suggested Resolution: Restore deleted text
response	*Restoration of the text not accepted but the substance agreed..* See new 21.A.432C(b)(7) and 21.A.433(a)(4).

comment	*243* comment by: *Airbus Helicopters* Comment is related to 21.A.435 and 21.A.437 In order to cope with the fact that repairs can be classified and approved by the Agency or a DOA holder, the text of old section 21.A.435(b) has been moved to 21.A.437. Consequently, titles of these paragraphs are no more in line with contents. **Suggestion** Suggestion is to rename: • 21.A.435 Classes of repairs • 21.A.437 Classification and approval of a repair design Another possibility is to redistribute the text between the two paragraphs.
response	*Partially accepted.* 21.A.435 and 21.A.437 has been merged. See amended 21.A.435.

3. Proposed amendments — Draft Opinion — 21.A.605 Data reqs p. 51

comment	*23* comment by: *Franz Redak* 21.A.605b) It requires to specify clear conditions and criterias to allow the applicant to identify conditions qualifying for "difficulty or event encountered that may significantly impact the ETSO authorisation".
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA

	and a related comment-response document (CRD) leading to an ED decision.

comment	*121* comment by: *THALES AVIONICS* ***(a) 1*** *a certification plan for the ETSO authorisation, defining the means to demonstrate compliance with point 21.A.606(b);* Even if this requirement represents an additional document to be provided in the certification file, THALES consider that the certification plan could be a good tool to facilitate the identification of potential issues at the beginning of the project rather than at the end.
response	*Noted.*

comment	*122* comment by: *THALES AVIONICS* ***(a21.A.605 (a) (2)*** *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;* THALES do not understand neither concur with the change proposed about the DDP content by introducing additional declarations such as Subpart O compliance (i) and a No known unsafe characteristics (iii) for the following reasons: • A DDP is a technical document associated with an equipment. The concept was created in order to declare that the equipment complies with its technical specifications. For ETSO, it means a declaration that the article complies with its technical specifications and with the applicable ETSOs. • All the suppliers use the DDP as is and the format used should remain the same for ETSO or non-ETSO articles. The introduction of the bullets (i) and (iii) as part of the DDP will provide an unnecessary burden and cost on industry because a specific DDP format will be required for ETSO article. Therefore THALES do request keeping the original spirit of the DDP. Consequently, for 21.A.605 (a) Thales propose the following bullet for DDP in the paragraph 21.A.605 (a):

(x) A Declaration of Design and Performance (DDP) declaring that the applicant has demonstrated that the article complies with the applicable CS-ETSO in accordance with the certification plan;

response

Partially accepted.

For 21.A.605 (a)(2)(i): The declaration of compliance with Subpart O in is not a new declaration. It already exists, currently in 21.605(a). However, we accept your proposal to remove it from the DDP and we have re-located it back under 21.605(a)(2).

For 21.A.605 (a)(2(iii): The requirements has been removed from the DDP but introduced, in a modified form, under 21.A.606(d).

comment

123 comment by: *THALES AVIONICS*

***21.A.605 (a)(2**) 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**;*

THALES do not concur in (iii) with the introduction of the notion of *"no known unsafe characteristics"* at article level. Indeed, the notion of safety cannot be assessed at article level, but only at A/C level. By nature, the ETSO certification process being made at article level independently of the A/C installations, it is not possible to assess the safety impact at A/C level that depends on the A/C system architecture.
Moreover, this proposed change is introducing a major difference with the US Part21 without any justification.

Consequently, THALES propose the following revised text for the 21.A.605 (a):
(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);
(2) A statement of compliance certifying that the applicant has met the requirements of this Subpart
(3) A Declaration of Design and Performance (DDP) declaring that the applicant has demonstrated that the article complies with the applicable CS-ETSO in accordance with the certification plan;
(4) one copy of the technical data required in the applicable ETSO;
(5) 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;
(6) 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

	(7) for all other articles, the procedures referred to in point 21.A.602B(b)(2), (or a reference to these procedures).
response	*Partially accepted.* *For 21.A.605(a)(2)(iii):* This requirement (as amended and moved to 21.A.606(d)) is already in preparation of the upcoming implementation of SMS by D & M organisations . Until then the industry stakeholders can relatively comfortably declare they have not identified any hazard. After Part-21 is amended with SMS standards they will be required to establish the whole system for identification of hazards related to their activities, including those that may exist for their new product, part or appliance to be certified on top of the hazards captured (by the Agency) in the established ETSO specification . They will have to have a system for hazard identification and risk management based on a system for collection, analysis and exchange of safety data. According to Annex 19 hazard identification shall be based on a combination of reactive, proactive and predictive methods of safety data collection Note that this requirement is consistently applied for in all certification processes under Part-21 and applicable to the industry stakeholders and the Agency (it populates all the point in Section B related to issuance of the certificates by the Agency)

comment	*124* comment by: *THALES AVIONICS* ***(a21.A.605(b)*** *The applicant shall report to the Agency any difficulty or event encountered during the approval process that may significantly impact the ETSO authorisation.* THALES consider this paragraph not clear regarding the impact on ETSO authorization and propose revision to be more consistent with TC/STC proposed change. For 21.A.605 (b) Thales propose the following revised text: (b) The applicant shall report to the Agency any difficulty or event encountered during the compliance demonstration process that may have a significant impact on the certification plan.
response	*Not accepted* The scope of the certification *programme* (final wording) is not wide enough. Everything that could compromise compliance of the article with the technical conditions of the applicable ETSO or compliance with Subpart O shall be reported. AMC/GM material will be developed in Phase II of this rulemaking tasks to clarify this issue.

comment	*199* comment by: *AeroSpace and Defences Industries Association of Europe (ASD)* 21.A.605 Comments on AMC/GM will be provided in NPA2 (RMT.0611) ASD do not concur with the change proposed for the DDP content in (a)(2) by introducing in the DDP a declaration of Subpart O compliance and a declaration of no known unsafe characteristics. Indeed, a DDP is a technical document associated with equipment. The concept was created in order to declare that the equipment complies with its technical specifications. For ETSO, it means a declaration that the article complies with its technical specifications and with the applicable ETSOs. Changing the DDP format only for ETSO articles will have an impact on industry (process change and cost impact) and will induce inconsistencies between ETSO and non-ETSO DDPs. Therefore ASD recommend to keep DDP concept as it is and to define it in 21.A.605 as follows: "A Declaration of Design and Performance (DDP) declaring that the applicant has demonstrated that the article complies with the applicable CS-ETSO in accordance with the certification plan".
response	See our response to comment 122 above.

comment	*244* comment by: *Airbus Helicopters* New subparagraph 21.A.605 (a)(2) gives some expected contents of the DDP. However, the contents of the DDP are currently specified in 21.A.608 and the information is therefore spread. **Suggestion** Suggestion is to complete expected DDP contents in section 21.A.608.
response	See our response to comments 122 and 123

comment	*246* comment by: *Airbus Helicopters* According to 21.A.605 (a)(2)(iii), the ETSOA applicant is supposed to declare that "*no known characteristic makes the article unsafe for <u>the uses for which certification is requested</u>*". However: • The ETSOA applicant is generally not aware of the future uses of the article, and especially on the installation conditions, • There is no explicit request (including in 21.A.608) that the DDP contains an indication of the uses for which certification has been requested.

Suggestion
Complete the expected contents of the DDP.

response *Partially accepted.*

The requirement was removed from DDP but was located under 21.A.606(d)

The applicant may be not aware of all the installation risks on aircraft level but is well aware of the article uses. The certification is requested to obtain ETSOA, so in isolation from installation issues/risks. The uses however must be considered when identifying the risks linked to ETSO functions to be certified.

See also our responses to comments 122 and 123

comment *292* comment by: *Sell GmbH*

21.A.605(b): Criteria for "significantly impact" have to be added to assure unambiguity and uniform application. AMC is needed to develop appropriate criteria and comprehensive example to classify difficulties and events having significant impact. in addition replace "approval process" with "compliance demonstration process" where usually such difficulties or events will be identified.

response *Noted.*

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment *321* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland*

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);”

Swiss FOCA: inconsistent wording, must read certification program.

response *Accepted.*

3. Proposed amendments — Draft Opinion — 21.A.606 Reqs for issue of an ETSO authorisation p. 51

comment	*46* comment by: *CAA-NL* **21.A.606** 21.A.606(c): '… statement of compliance' should be: '… a Declaration of Design and Performance', see 21.A 605(a)2.
response	*Partially accepted.* See amended 21.A.605(a)(3) and 21.A.606(c) and (d).

comment	*125* comment by: *THALES AVIONICS* **21.A.606 Requirements for issue of an ETSO authorisation** *To be entitled to obtain an ETSO authorisation issued by the Agency, the applicant shall:* *(a) demonstrate its capability in accordance with point 21.A.602B; and* *(b) demonstrate that the article complies with the technical conditions of the applicable ETSO; and* *(c) submit the corresponding statement of compliance.* THALES concur with the proposed editorial changes
response	Noted.

comment	*245* comment by: *Airbus Helicopters* According to 21.A.606 (c), the ETSOA applicant is supposed to "*submit the corresponding statement of compliance*" It is understood that this refers to the statement of compliance part of the DDP (item 21.A.605(a)(2)(i); however, this is not explicit. **Suggestions:** • Either "*submit the corresponding DDP, including the statement of compliance*", • Or "*submit the corresponding DDP*"
response	*Partially accepted.* The intent of the comment is understood and the proposal is carried in a modified form. See amended 21.A.605(a)(3) and 21.A.606(c) and (d).

comment	*295* comment by: *Sell GmbH* 21.A.606(c): To be in line with 21.A.605(a)2. where statement of compliance is replaced with Declaration of Design and Performance (DDP) replace in 21.A.606(c) statement of compliance likewise with Declaration of Design and Performance (DDP) to foster one clear statement and to prevent undue burden without additional safety benefit when adding additional documents.
response	*Partially accepted.* The intent of the comment is understood and the proposal is carried in a modified form. See amended 21.A.605(a)(3) and 21.A.606(c) and (d).

3. Proposed amendments — Draft Opinion — 21.B.75 Special conditions p. 52

comment	*60* comment by: *DOA EASA.21J.041 Aero-Dienst GmbH & Co. KG.* Please add obligation for the Agency to publish SCs. Reason: DOAs may not be aware of the details of such conditions when exercising their privileges of classification of changes or in determining the criticality of certain areas or technologies. It would reduce the agencies workload, if DOAs would be able to fully consider the content of SCs already in the Cert. Program, rather than preparing the CP with available knowledge and wait for the agency to ask for amendments of the CP later.
response	*Noted.* Special Conditions as well as other similar measures are currently published under *Public consultations* page of EASA website. They remain there after expiration of the deadline for comments. Further measures will be considered. See: http://www.easa.europa.eu/document-library/public-consultations

comment	*247* comment by: *Airbus Helicopters* 21.B.75 (a)(3) As compared to the current text in section 21.A.16B, "*newly identified hazards*" has been added as a potential source to raise a special condition. This opens the door to raising special conditions based on engineering judgment, with the risk of subjective addition of special conditions if not clearly communicated with the applicant.

Suggestion
Clarify who and how is performed the hazard identification and how it is shared with the applicant.

response

Noted.

This point allows to prescribe a special condition when a safety hazard has been identified prior to product entry into service (e.g. on the production line or in other parallel certification process). If not addressed during certification it is assumed that an *unsafe condition* could develop and the Agency would have to issue an AD immediately after entry into service of the first product.

Note that the requirement on *no feature or characteristic has been identified that may make the product/article unsafe for the uses for which certification is requested* is consistently applied in all certification process under Part-21 and made applicable to both the industry stakeholders and the Agency.

With introduction of SMS the requirement will gain even more weight. See also our response to comment 303.

3. Proposed amendments — Draft Opinion — 21.B.80 TC basis for a TC or RTC p. 52-53

comment

251 comment by: *Airbus Helicopters*

21.B.80(c)
"*a certification specification under (a)(1)*"
(a)(1) is a specific case of using a certification specification, as well as (a)(2). The general case of a certification specification is (a).

Suggestion
"*a certification specification under (a)*"

response

Partially accepted.

25.A.80 has been, however, completely redrafted. See the corresponding text of the final proposal.

3. Proposed amendments — Draft Opinion — 21.B.82 OSD cert basis for an aircraft TC or RTC p. 53

comment	*47* comment by: *CAA-NL* **21.B.82** 1. The first sentence in (a) is in its wording slightly different than the same sentence in 21.B.80 which has the same intent. We would like to suggest to align these sentences and use the wording of 21.B.80: '(a) the applicable certification specifications designated by the Agency that are effective....'. 2. In (a)(2) the only option described is when the elects to comply with a later applicable amendment. However point 21.A.15(f) is also applicable to OSD, so we suggest to include a reverence to this as is done in 21.B.80(a)(2): 'compliance with certification specifications of later effective amendments is elected by the applicant or is required under point 21.A.15 (f).'
response	*Accepted.* *For 1.: Accepted.* 21.A.80 and 21.A.82 were redrafted and aligned with each other. See the corresponding text of the final proposal. *For 2.: Accepted.* 21.A.80 and 21.A.82 were redrafted and aligned with each other. See the corresponding text of the final proposal.

3. Proposed amendments — Draft Opinion — 21.B.85 Designation of applicable EP reqs and CSs for a TC and RTC p. 53-54

comment	*154* comment by: *Rolls-Royce* Comment/Resolution: Section (c): 21.A.70 should be 21.B.70?
response	*Accepted.* Thanks.

comment	*252* comment by: *Airbus Helicopters* 21.B.85(a) and (b) Moving the applicable environmental protection requirements from 21.A.18 to 21.B.85 has an impact on CS-34 and CS-36, which reference 21.A.18. This impact has apparently not been identified. **Suggestion**

	Revise CS-34 and CS-36. NOTE: At long term, it should be examined whether the environmental protection requirements could be specified in another place than Part 21, which is process related.
response	*Noted.* The impact will only happen when the amending Regulation for LoI is adopted. In the meantime ED decision might be issued in time to correct CS-34 and CS-36.

comment	*253* comment by: *Airbus Helicopters* 21.B.85(a) and (b) Designating Chapter, then Part, then Volume of Annex 16 is strange. Also, as the volumes, parts and chapters are specified, adding "*as applicable*" is strange. **Suggestion** • Designate: "*Annex 16, Volume <X >, Part < Y>, Chapters < Z>*", • Remove "*as applicable*"
response	*Partially accepted.* *1.* The designations follow now your proposal 2. The *'as applicable'* must kept. Not all the standards within the Chapters are applicable to a particular product and certification project. They must be *designated'.*

comment	*254* comment by: *Airbus Helicopters* 21.B.85(a), (b) and (c) The following is strange: • points (a) and (b) indicate that the Agency shall "*designate and notify*" the certification requirements, whereas they are "hard coded" as specified in this paragraph, • point (c) does not to indicate that the Agency shall designate and notify the certification specifications, whereas they need to be specifically designated. **Suggestion** Make wording more consistent.
response	*Noted* • See our response to comment 253 above

- The certification specifications of CS-34 and 36 are not part of EP *'certification basis'* This is reserved just for EP requirements designated from Annex 16. Book 1 just provide a link to 21.A.18 (today) that calls for designation of the applicable standards from Annex 16. Book 2 provides the CSs as a means of compliance with the standards.

comment	*289* comment by: *CFM* 21.B.85(b) : Clarification to be added in the reference to the "Aircraft Engine Emissions" ICAO standards. Proposal : "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 "aircraft engine emissions" requirements according to the provisions of Volume II of Annex 16 to the Chicago Convention:
response	*Not accepted.* The *Aircraft Engine Emissions* are covered under *emissions* requirements for aircraft (TC)

3. Proposed amendments — Draft Opinion — 21.B.100 LOI p. 54

comment	*2* comment by: *Prof. Filippo Tomasello* An additional point 4. should be added to 21.b.100(b) as follows: 'any statement, report or assessment produced by an independent Qualified Entity (QE)'
response	*Not accepted* See our response to comment 1

comment	*3* comment by: *Prof. Filippo Tomasello* few more words should be added at the end of 21.B.100(c) as follows: .... of the applicant', or any report or statement issued by an independent QE'
response	*Not accepted* See our response to comment 1

comment	*24* comment by: *Franz Redak* 21.A.100c) and d) It woudl be appropriate to indicate a timeframe until when the agency should come back with a decision of its LOI and their safety risk assessment. It should be acceptable that applicants receive (at least on request) the applicable classifications to be able to challenge the decision if found against the interest of the applicant or found to be to restrictive. 21.A.100c) We believe that the safety risk should be available immediately and should be provided pro-active, since the ETSO is known. Deviations will have to be covered by processes known to applicants.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	*48* comment by: *CAA-NL* **21.B.100** 1. The text in proposed in Section B does not contain a requirement for the approval / acceptance of the proposed means of compliance. And this requirement should be added as a reference to the text in 21.A.20 “in accordance with points 21.B.??, etc.” 2. Section B does not mention the fact that the Agency investigates the compliance demonstrations sent by the applicant as well as the investigations of the ground tests and flight test that it has witnessed. In Part 21.A several times reference is made for this investigation to 21.B.100, but that point currently only describes the level of involvement. As a result it is not clear how the Agency carries out this investigation, how the results are communicated to the applicant, and what has to happen if the investigation resulted in a NO GO. These new texts could include the relocated points on Findings.
response	*Noted.* 1. The means of compliance are not to be explicitly *approved* under Part-21 rules but they are accepted with the certification programme. .They are not part of the type-certification basis. 2. Note the sentence *In addition, administrative procedures established by the Agency shall apply’* at the end of each affected Subpart in Section B. The EASA internal certification working procedures are publically available on EASA website. See the link: http://www.easa.europa.eu/document-library/internal-certification-working-procedures and consult e.g. the *Airworthiness of type design* procedures.

comment	*58* comment by: *DOA EASA.21J.041 Aero-Dienst GmbH & Co. KG* 21.B.100(b)(3): As a small DOA dealing with different kind of A/C, it is not clear, how the Agency wants to make sure, that the LOI is determined transparent with multiple PCMs. Please clarify.
response	*Noted.* The transparency and uniformity is going to be achieved through application of common generic and domain/discipline specific criteria publically available, the applicable (DOA and certification process) Working Instructions , by provision of training to the staff both from the Agency and contracted NAAs, by involving panel of experts and Chief Experts to take care of standardisation, also by PCM meetings etc.

comment	*61* comment by: *DOA EASA.21J.041 Aero-Dienst GmbH & Co. KG.* 21.B.100(d) It is not clear at which point in time the agency shall make this notification. Please clarify. I suggest: when accepting the Cert. Program. Please include this here or in the GM.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	*103* comment by: *Airbus* **1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:** Page 54/67, paragraph 21.B.100(d) **2. PROPOSED TEXT / COMMENT:** Maximum reasonable timeframe envelope for EASA to notify applicants of their level of involvement should be introduced in 21.B.100(d). Proposed change: 21.B.100 Level of Involvement (d) The Agency shall notify the applicant of the Agency's level of involvement ***within 4 weeks from submission of the certification programme by the applicant*****.** 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.

3. RATIONALE / REASON / JUSTIFICATION for the Comment:

The NPA states in Paragraph 2.4.1(a) , page 15:
Quote:
"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. (…) Point 21.B.100(b) requires that the LOI shall be determined on the basis of a safety (and environmental) risk assessment. 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."
Unquote:

One of the main difficulties during major changes projects (including STCs) is to rapidly reduce the industrial program risk, especially by securing as soon as possible that the applicable certification basis are determined and agreed by the Agency. A common practice in the Agency is however to leave general CRI for certification basis "open" all along a project, and only close it in very late project stages, even after EASA experts have issued their Statement of Satisfaction. This current EASA practice seems not in line with the overall objective of the NPA for implementation of the LOI concept, but is not really mitigated by the proposed text in the NPA since no reasonable timeframe envelope is prescribed for notification by EASA of their level of involvement.

response

Not accepted.

The LoI determination(s) does not depend purely on the Agency but on the quality and completeness of the data and information submitted by the applicant, by its responsiveness to questions raised by the Agency certification team and quality of the corresponding feedback etc Also, a fix timeframe is difficult for the Agency to commit for in the rule. It very much depends on the project size/novelty complexity. *One Size Does Not Fit All*. .

comment

104 comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 54/67, paragraph 21.B.100(d)

2. PROPOSED TEXT / COMMENT:
EASA shall justify within its notification, its level of involvement.

Proposed change:
21.B.100 Level of Involvement
"(d) The Agency shall notify the applicant of the Agency's level of involvement together with the relevant justifications…"

GM to 21.B.100(d)

Agency level of involvement justifications provided to the applicant should consist of the safety and environmental risk assessment required as per 21.B.100(b)

3. RATIONALE / REASON / JUSTIFICATION for the Comment
LOI shall be justified by EASA at least when not aligned on the proposal made by the applicant through the certification programme issued under 21.A.15(b).

response

Not accepted.

See our response to comment 147 (sub-comment 1)

comment

131 comment by: *THALES AVIONICS*

21.B.100 Level of Involvement
(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.

THALES concur with the proposal that reflects the current practice.
Nevertheless THALES would like that EASA review with industry its current assessment method that often provides a high "Level of Involvement" for avionics products. Indeed, the current assessment method called "risk register" is a global assessement over one year combining all the factors and may be not appropriate to define the LoI for individual application.

response

Noted.

The current practice for ETSO(A) might be slightly reviewed in respect of the LoI concept implementation.

Note that 21.B.100(c) (now (b) was amended.

comment

155 comment by: *Rolls-Royce*

Comment:
Section (d): The notification should not be limited to the determined LOI.

Suggested Resolution:
Introduce requirement for the Agency to submit their reason for the final LOI decision to allow compliance with 21.A.20(b). EASA reasons for LOI decision to be done in a timely manner.

response

Not accepted.

	See our response to comment 147 (sub-comment 1)
comment	*158* comment by: *Rolls-Royce* Comment 1: Section GM1 21.B.100(a): "applicants are invited to break down their certification programme into CDIs and to identify within a discipline:" - the term "discipline" is used repeatedly throughout the NPA - the document would benefit from a clear definition of what is meant by "discipline". Within the same section it gives examples of disciplines for simple projects but gives no examples for non-simple projects Suggested Resolution: 'Provide clear definition of what is meant by "discipline", along with relevant examples, early in the NPA, rather than leave it to the interpretation/judgement of the applicant or Agency PCM responsible for a particular project Comment 2: Section 21.B.100(b)(3): "be subject of trend analysis" - it would be appropriate for the Agency to share the subject trend analysis with the affected approved design organisation Suggested Resolution: 'Add additional wording to cover the sharing of the trend analysis with the relevant approved design organisation
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.
comment	*174* comment by: *LMI Aerospace* 1. The wording of this section reads very much like a new TC or STC program but also includes repairs in 21.B.100(c). Pertaining to this DOA's comments on sections 21.A.433(a)(2) and 21.A.91 this will be extremely onerous if it is applied to all major repairs, particularly if these are not “Significant” repairs but deviations from approved data. 2. It is suggested that EASA allow for either some flexibility in determining which major repairs require a certification plan or that the Agency can accept DOA procedures to determine the requirements for a certification plan in relation to a major repair.
response	*Noted*. 1. We are aware that the LoI concept needs to be applied considering proportionality. However, the proportionality can be better achieved by wise choosing a different size and complexity of individual documents and actions in the certification process rather than by just skipping some steps of the process. Minor changes and minor repairs are excluded from

	the certification programme but to determine which major should have it and which not is precarious. 2. All major repair design require a certification programme. Complex ones more complex and simple ones just simple.
comment	*200* comment by: *AeroSpace and Defences Industries Association of Europe (ASD)* 21.B.100 (a) The GM should allow flexible determination of CDI by applicants.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.
comment	*201* comment by: *AeroSpace and Defences Industries Association of Europe (ASD)* 21.B.100(b) b2: Criticality of the design is not defined in GM. Critical CDI are addressed with an example link to CS 25.1309 / The following definition is recommended for criticality (not part of the Safety Management Terminology material addressed in the NPA): The degree of impact of an undesired event in terms of EVENT SEVERITY and EVENT LIKEHOOD b3 The set of indicators that captures the maturity of the DOA holder's organisation and their performance must be clear and standardized./ Provide a list of performance KPI's and information how they are calculated. Otherwise a comparison between projects or Organisations – even on a trend level is misleading and not comparable. The results of the measuring (KPI's) shall be shared with the applicant once a year (annual review) or in case of request (trend changes negative), in order to allow the DOA to take actions for improvement.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.
comment	*202* comment by: *AeroSpace and Defences Industries Association of Europe (ASD)*

	21.B.100(d) The pilot projects have evidenced the need to agree on the LOI in a timely manner and also to implement a decision process not vulnerable to conflicts of interests. Proper AMC and Agency work instructions shoud be developped for ensuring that: 1) The Level of involvement should be decided by the PCM with the support from EASA Chief or Senior Experts if needed. Whenever possible, LOI assessment and compliance demonstration assessment should not be performed by the same experts for avoiding potential conflict of interest. 2) The Level of involvement should be notified to the applicant according the agreed milestones of the project schedule developped as per AMC 21.A.20.b Certification programme. 3) Prior to the LOI notification, deviations from the applicant's proposed LOI should be subject to a dialog with the applicant.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	*203* comment by: *AeroSpace and Defences Industries Association of Europe (ASD)* GM1.21.B.100 Compliance Demonstration Item (CDI) The need for limiting a CDI to a discipline on 'simple projects' is not understood. Firstly, 'Simple' is related to the fees and charges regulation. Secondly the breakdown into discipline may be relevant also for 'large' projects. The sentence should read: (removed: On simple projects), a CDI may be as global as a discipline […] The proposed wording could lead to a further breakdown of a CDI into disciplines. Pilot projects have shown that applicants will breakdown the project into separate CDI for differentiating those with novel or critical features from the others, taking into account disciplines when pertinent. The GM should not recommend a further breakdown of CDI. The sentence should read: […] applicants are invited to break down their certification programme into CDIs and to identify (removed: within a discipline):[…] - For the identification of critical CDI, the pilot projects have shown that in-service experience may provide valuable inputs. The sentence should read: [...] critical CDIs, as defined e.g. by the classification in CS 25.1309. In-service experience may be used to support the classification of a CDI as not critical [...]
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	*204* comment by: *AeroSpace and Defences Industries Association of Europe (ASD)* AMC 21.B.100 DOA performance and experience measurement system DOA performance evaluation should be based on objective evidence: • Feedback from previous not novel projects. The set of indicators that rate the success of the DOA holder's organization should include quantitative data: o Comments from EASA on certification program (missing applicable requirements, rejection of proposed means of compliance). o Comments from EASA Panels on compliance demonstrations should be classified (Editorial comment / Clarity to be improved / Compliant but not evidenced / Compliance failed / Unsafe). o Communication o Ability to meet the planning • Monitoring: open Level 1&2 DOA findings relating to a project or to subcontractor management. DOA performance should be evaluated transparently and shared with the concerned DOA holders on a regular basis by the DOA team leader
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	*206* comment by: *SIRIUM AEROTECH* In the "Overview" section of this NPA are listed the criteria to decide LOI. One of those is: "qualifications and experience of the technical staff involved", we understand "involved [in the certification project concerned]". However, in paragraph 21.B.100 only experience of the DOA as a company is considered. A company could allocate its less experienced personnel for a particular project, requiring more involvement from EASA's side, despite the DOA may have large experience. We suggest to include an explicit reference to the experience and performance of the involved staff.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	*230* comment by: *Dassault Aviation* 21.B.100 d : In addition to ASD comments, DASSAULT-AVIATION proposes that the EASA shall justify its retained LOI when it is greater than the one proposed.
response	Not accepted. See our response to comment 147 (sub-comment 1)

comment	*276* comment by: *AeroSpace and Defences Industries Association of Europe (ASD)* 21.B.100(c) ASD concur with the proposal that reflects the current practice for ETSO. Nevertheless ASD would like that EASA review with industry its current assessment method that often provides a high "Level of Involvement" for avionics products. Indeed, the current assessment method called "risk register" is a global assessment over one year combining several criteria and may be not the most appropriate to define the LoI for individual applications.
response	*Noted*. The current practice for ETSO(A) might be slightly reviewed in respect of the LoI concept implementation.

comment	*297* comment by: *Sell GmbH* 21.B.100: The level of involvement shall be extended to all AP-DOAs and not limited to AP-DOAs for ETSO authorisation only, to assure application of equal safety levels and requirements throughout all certification areas.
response	*Noted.* The 21.B.100 LoI rule is applicable to all Part-21 certification processes and all eligible applicants.

comment	*334* comment by: *DGAC France* 21.B.100 (b): as concerns the safety and environment risk assessment, AMC/GM must be developed to clarify this issue.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed

	to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	*335* comment by: *DGAC France* 21.B.100 (c): it seems to define by derogation of 21.B.100 (b) a simplified assessment for major repairs and ETSO. But the redaction is not obvious enough to understand in which way. AMC and GM should explain this derogation.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	*348* comment by: *LHT DO* (b) EASA shall disclose the reasons for classification of its level of involvement to the applicant in order to make this process as transparent as possible.
response	See our response to comment 147 (sub-comment 1)

3. Proposed amendments — Draft Opinion — 21.B.103 Issue of a TC or RTC p. 54-55

comment	*49* comment by: *CAA-NL* **21.B.103** In point (b) first part of the sentence there is a wrong reference, we think it should be: 'By derogation from points (a)(1) and (2) ~~and (b)~~, and...'.
response	*Accepted.* Corrected. See amended 21.B.103. Thanks.

comment	*105* comment by: *Airbus* **1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:** Page 54/67, paragraph 21.B.103(b). **2. PROPOSED TEXT / COMMENT:** The point 21.B.103(b) states: "(b) By derogation from points (a) **and (b),** […]" Can the Agency clarify to which paragraph the underlined text refers? **3. RATIONALE / REASON / JUSTIFICATION:** For sake of clarity.
response	*Noted.* Corrected. See amended 21.B.103. Thanks.

comment	*117* comment by: *KLM Engineering & Maintenance* 21.B.103(b): Typographical error. In par. 21.B.103(b) is indicated: "By derogation from points (a) and (b), and at the request ……." The referenced par. (b) seems to refer to itself. It should probably read: "By derogation from point (a), and at the request …….".
response	*Accepted.* Corrected. See amended 21.B.103. Thanks.

comment	*144* comment by: *FAA* Page 54 and 55: 21.B.103 (a) and 21.B.107(a) and 21.B.110(a) Recommend the regulation be revised to add that the Agency has not found any unsafe feature and that the applicant has submitted the certifying statement under 21.A.20.
response	*Accepted.* The subject requirement is applied in all Part-21 certification process and applies both to the industry stakeholders and the Agency. See also our responses too comments 32, 303 and 123

comment	*231* comment by: *Dassault Aviation* 21.B.103 b: Typo: should refer to (a) only, not to (b).
response	*Noted.* Thanks.

comment	*258* comment by: *Airbus Helicopters* 21.B.103 (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)*" 1. "By derogation from points (a) and (b)" is incorrect. 2. Although the declaration of the applicant is defined in point 21.A.20(d), the sentence is hardly understandable, because the applicant's request to issue the TC before compliance for OSD is established is defined in 21.A.21(e). **Suggestion** "*By derogation from point (a) and according to point 21.A.21(e)*"
response	*Partially accepted*. 1. The typo in 21.B,103(b) is corrected. 2. *Not accepted.* 21.A.21(b) clearly states that the applicant makes the request (to issue the TC before compliance has been demonstrated for OSD *'in the declaration referred to in point 21.A.20(d).'*

3. Proposed amendments — Draft Opinion — 21.B.105 TC basis, EP reqs and OSD cert basis for a major change to a TC p. 55

comment	*50* comment by: *CAA-NL* **21.B.105** Related to our comments to 21.A.101, when those are accepted, for the same arguments the last part of this point can be deleted: '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)~~.'.

response	*Not accepted.* Your comments on 21.A.101 were not accepted.

comment	*62* comment by: *DOA EASA.21J.041 Aero-Dienst GmbH & Co. KG.* It is not clear at which point in time the agency shall make this notification. Please clarify. I suggest: when accepting the Cert. Program. Please include this here or in the GM.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	*261* comment by: *Airbus Helicopters* "*operational suitability data certification basis designated in accordance with point 21.A.101(g)*" The OSD certification basis is defined in 21.A.101(f) (21.A.101(g) does not exist). Also notice that the last part of the sentence is not really useful, because the OSD certification basis is part of the certification basis defined in accordance with 21.A.101. **Suggestion** • Either reference 21.A.101(f) instead of 21.A.101(g), • Or reduce 21.B.105 to the following sentence: "*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*"
response	*Accepted.* The typo is corrected. Note that your other proposal omits the obligation for the Agency to establish and notify the OSD certification basis ONLY in the case of a change affecting the OSD.

3. Proposed amendments — Draft Opinion — 21.B.107 Issue of an approval of a change to a TC p. 55

comment	*106* comment by: *Airbus* **1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:** Page 55/67, paragraph 21.B.107(a). **2. PROPOSED TEXT / COMMENT:** It is proposed to amend the point 21.B.107(a) to read: "(a) The Agency shall issue an approval of a change to a type-certificate provided that: 1. the applicant for a minor change **approval** has complied with point 21.A.95; or 2. the applicant for a major change **approval** 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." **3. RATIONALE / REASON / JUSTIFICATION:** For sake of consistency with previous comments/change proposals raised against point 21.A.263(c)
response	*Partially accepted* Your proposal is carried in a modified way..

comment	*263* comment by: *Airbus Helicopters* 21.B.107 (b) "*at the request of the applicant included in the declaration referred to in point 21.A.20(d)*" Although the declaration of the applicant is defined in point 21.A.20(d), the sentence is hardly understandable, because the request to issue the TC before compliance for OSD is established is defined in 21.A.21(e). **Suggestion** "*according to point 21.A.21(e)*"
response	*Not accepted.* 21.A.21(b) clearly states that the applicant makes the request to issue the TC before

compliance for OSD *'in the declaration referred to in point 21.A.20(d).'*

3. Proposed amendments — Draft Opinion — 21.B.109 TC basis, EP reqs and OSD cert basis for an STC p. 55-56

comment *51* comment by: *CAA-NL*

21.B.109
Related to our comments to 21.A.101, when those are accepted, for the same arguments the last part of this point can be deleted: 'The Agency shall establish and notify the applicant for a suplemental 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)~~.'.

response *Not accepted.*

Your other comments on 21.A.101 were not accepted.

comment *63* comment by: *DOA EASA.21J.041 Aero-Dienst GmbH & Co. KG.*

It is not clear at which point in time the agency shall make this notification. Please clarify. I suggest: when accepting the Cert. Program. Please include this here or in the GM.

response *Noted.*

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment *265* comment by: *Airbus Helicopters*

Head of Subpart E, before 21.B.109

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

This sentence is not appropriate for Subpart E, which is dealing with STCs.

Suggestion
Remove the sentence

response *Not accepted.*

21.B.110(d) refers to the type-certificate.

comment *266* comment by: *Airbus Helicopters*

"*operational suitability data certification basis designated in accordance with point 21.A.101(g)*"

The OSD certification basis is defined in 21.A.101(f) (21.A.101(g) does not exist).

Also notice that the last part of the sentence is not really useful, because the OSD certification basis is part of the certification basis defined in accordance with 21.A.101.

Suggestion

- Either reference 21.A.101(f) instead of 21.A.101(g),
- Or reduce 21.B.109 to the following sentence: "*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*"

response *Partially accepted.*

The typo is corrected your option 2 is carried in a modified form. Note that your other proposal omits the OSD basis.

3. Proposed amendments — Draft Opinion — 21.B.110 Issue of an STC p. 56

comment *25* comment by: *Franz Redak*

21.B.110a2) How will EASA make the OSD basis available to the applicant. Will EASA make this OSD basis publicly available?

response *Noted.*

21.B.109 requests that the Agency shall establish and notify the applicant of the OSD certification basis OSD in the case of a change affecting the operational suitability data. The certification bases are avaialble in TCDSs published by the Agency on EASA website.

comment	*267* comment by: *Airbus Helicopters* 21.B.110 (b) "*and at the request of the applicant included in the declaration referred to in point 21.A.20(d)*" Although the declaration of the applicant is defined in point 21.A.20(d), the sentence is hardly understandable, because the request to issue the TC before compliance for OSD is established is defined in 21.A.21(e). **Suggestion** "*according to point 21.A.21(e)*"
response	*Not accepted.* 21.A.21(b) clearly states that the applicant makes the request to issue the TC before compliance for OSD '*in the declaration referred to in point 21.A.20(d)*.'

comment	*351* comment by: *LHT DO* Please provide information on approving AFM changes
response	*Noted*. Please see our responses to comments 22 and 44 (2)

3. Proposed amendments — Draft Opinion — 21.B.113 TC basis for a major repair design approval p. 56

comment	*156* comment by: *Rolls-Royce* Comment: Is title incomplete? Suggested Resolution: Title should also call up "environmental protection requirements"
response	*Accepted* The title is corrected. Thanks.

3. Proposed amendments — Draft Opinion — 21.B.117 Issue of an ETSO authorisation p. 57

comment	*132* comment by: *THALES AVIONICS* **21.B.117 Issue of an ETSO authorization** *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.* THALES concur with the proposal but think that there is a mistake in the wording. Thales consider that the text should be: “or deviations NOT approved in accordance with point 21.A.610, if any”
response	*Not accepted.* The approved deviation is an approved alternative to a requirement of the applicable ETSO standard and as such becomes part of the compliance demonstration for the ETSO authorization and is potential subject of the Agency’s LoI

comment	*277* comment by: *AeroSpace and Defences Industries Association of Europe (ASD)* ASD think that there is a mistake and consider that the text should be: “or deviations NOT approved in accordance with point 21.A.610, if any”
response	*Not accepted.* The approved deviation is an approved alternative to a requirement of the applicable ETSO standard and as such becomes part of the compliance demonstration for the ETSO authorization and is potential subject of the Agency’s LoI

comment	*352* comment by: *LHT DO* please include common CRIs and CMs into " Definition and Criteria for an Equivalent Change". These documents are very often advised as standards for certification.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed

to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

3. Proposed amendments — Draft Decision — AMC1 21.A.263(c)(8) and (9) Scope and Criteria p. 58

comment	*26* comment by: *Franz Redak* ..the GM and the interpretive material ...are the same: Does that mean that a change in an AMC (later revision) will void the authorisation? We encourage EASA to specify these conditions clearly.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment	*52* comment by: *CAA-NL* **AMC1 21.A.263(c)(8) and (9)** See our comments to 21.A.263.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI..

comment	*64* comment by: *DOA EASA.21J.041 Aero-Dienst GmbH & Co. KG.* Definition and criteria for an "Equivalent Change" (second bullet) I suggest to allow consideration of a group of products with similar attributes. E.G. Aircraft within a certain range of take off mass and comparable equipment technology. Background: DOAs which work on a variety of products with similar technology and attributes will have a disadvantage compared to DOAs working only on one single product. DOAs with a wider range of product may even have a more thorough experience than DOA which work only on one product. However DOAs working only on one product will more easily have a higher number of product wise equivalent changes than DOAs working on a fleet of comparable products.

response

Noted.

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment

107 comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 58/67, paragraph AMC1 21.A263(c)8 and (c)9.

2. PROPOSED TEXT / COMMENT:

The AMC indicates:
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.

It is proposed to split the sentence into 2 separate sentences as these are 2 different aspects.

Proposed change:
"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 should have demonstrated to the satisfaction of the Agency its capability to approve 'equivalent' changes ~~in the future~~ without any involvement of the Agency.

3. RATIONALE / REASON / JUSTIFICATION:
The current text is not clear to the intent of the 2 separate aspects previous approved change and DOA holder capability. Does the second part of the sentence mean that the applicant has to demonstrate on a mod by mod basis their capability to approve equivalent mods in the future? For example, take SFCC standard updates, does the applicant demonstrate once when certifying the first SFCC mod that he is capable to do so for the future SFCC mods? This is what could be interpreted by reading the word "while" in the sentence. But this is not Airbus understanding of the principal that has been discussed. Like for minor mods, it was understood that a DOA holder qualifies for the privilege to approve equivalent major changes, but that this is not a continuous update of the terms of privileges mod type by mod type.

response

Noted.

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI. Draft results will be consulted upon by means of another NPA and a related comment-response document (CRD) leading to an ED decision.

comment	*108* comment by: *Airbus* The AMC indicates: - *The product to which the change is applied….* It is proposed to delete this sentence Propose 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~~.* **3. RATIONALE / REASON / JUSTIFICATION:** The word "product" is heavily prone to interpretation in the context of equivalent changes. Is it referring to same program (Same TC), same model, the same aircraft category (e.g. large aeroplane)? Airbus believes it cannot mean that certain equipment certified for one program, cannot be considered as equivalent for another program, when all the criteria for equivalent changes are met.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment	*109* comment by: *Airbus* **1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:** Page 58/67, paragraph AMC1 21.A263(c)8 and (c)9. **2. PROPOSED TEXT / COMMENT:** The AMC indicates in last bullet: *the Guidance Material (GM) and the interpretative material that will be used for the new change are the same.* Propose change: *the Guidance Material (GM) and the interpretative material that will be used for the new change are the same or equivalent.*

3. RATIONALE / REASON / JUSTIFICATION:
It is proposed to add at the end of the statement “or equivalent” in order to be consistent with the wording about the certification requirement (5th bullet in this AMC) and to allow an equivalency when similar IM are used but are not formally the same.

response

Noted.

Noted.

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment

157 comment by: *Rolls-Royce*

Comment 1:
"while the DOA holder demonstrated to the satisfaction of the Agency its capability to approve equivalent changes in the future" - it would be appropriate to provide Guidance Material as to clarify how, and using what criteria, the Agency will determine DOA demonstrated capability will be assessed/determined. Is it intended the LOI will be continually updated to reflect the current DOA demonstrated capability?
Suggested Resolution:
Add appropriate Guidance Material to ensure consistent approach across all the Agency PCMs

Comment 2:
"the product to which the change is applied" - should this state "product, part or appliance"?
Suggested Resolution:
Consider adding proposed clarification

Comment 3:
"the change does not affect the noise and/or emissions characteristics of the changed product" Not clear why this limitation is applied
Suggested Resolution:
Could the Agency clarify the rationale for introducing this limitation with regard to LOI. Should it be "does not adversely affect"?

Comment 4:
"In particular, with respect to the previous changes already approved by the agency" - the applicability of the listed criteria should be clarified with regard to an "equivalent change" that results in a corresponding change being required to the product TCDS
Suggested Resolution:
Consider adding proposed clarification

response

Noted.

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment	*185* comment by: *CAA CZ* The NPA uses the term "Equivalent Change", used as a criterion for granting applicants privileges for approval subsequent repetitive major changes to TCs and STCs. Although the concept of "Equivalent Change" is described in AMC1 21.A.263(c)(8) and (9), it enables a range of possible interpretations of what is and what is already not the equivalent change. Besides the ambiguity of the definition of "Equivalent Change" itself, from the proposal it is not clear how the Agency will practically proceed in determining the equivalent change.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment	*228* comment by: *Dassault Aviation* Dassault Aviation will not comment AMCs more than preliminarily. Full AMC comments will be issued when NPA2 is released.
response	*Noted.*

comment	*268* comment by: *Airbus Helicopters* The reason for including a condition that "*the change does not affect the noise and/or emissions characteristics of the changed product*" is not understood. Such a condition related to noise and emission impacts has no link to the confidence on the DOA holder and also no link to safety. **Suggestion** Remove this condition.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment	*322* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland*

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

Swiss FOCA: This guidance is not sufficient for the PCM and especially for the DOATL to determine which scope to be delegated to the DOAH.

response

Noted.

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

3. Proposed amendments — Draft Decision — AMC 21.A.605 Cert plan p. 58-59

comment *126* comment by: *THALES AVIONICS*

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) to (8)

THALES consider that the proposed content of the certification plan needs to be clarified (some bullets are unclear) and better justified in the next NPA.
THALES is ready to participe in discussion with EASA to improve and clarify this AMC before the next NPA.

Nevertheless, THALES initial comments are provided hereafter.

response

Noted.

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment *127* comment by: *THALES AVIONICS*

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.

Those 3 actions are not considered to be necessary as their objective is already covered by 21.A.605 (except the update consideration).
Therefore, THALES recommend the deletion of all this part.

response

Noted.

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment

128 comment by: *THALES AVIONICS*

(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);
"Safety means" is not understood. Non-ETSO functions should be associated more with the intended use than with the configurations.

(5) the proposed means of compliance including the list of documents and deliverables to the Agency;
Documents should be understood as "compliance" documents?

(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;
Thales do not understand what it is expected here and do not agree to transform a certification into a safety analysis. Thales recommend the deletion of such alinea.
Thales request that this point can be discussed with the industry before the publication of the next NPA.

(7) how the applicant will record its justifications of compliance;
Thales do not understand the expectations of this bullet. Is it really necessary?

Consequently, Thales propose the following revised text :

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 **and non-ETSO functions** 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 **compliance** 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;*~~
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment	*129* comment by: *THALES AVIONICS* Thales suggest to add the following topic to the information to be contained in a Certification plan : *(x) a proposal for the Agency's level of involvement with its rationale to support its decision to be made in accordance with point 21.B.100 (c).* As in 21.A.15 (b)7 forTC and STC applicants, ETSO applicants should be able to propose a LoI level to the Agency.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

3. Proposed amendments — Draft Decision — GM121.B.100(a) CDI p. 60

comment	*4* comment by: *Prof. Filippo Tomasello* GM1 21.B.100(a) should encompass that the certification programme break down may include as well: 'CDIs for which the demonstration will be based on a statement or assessment produced by an independent QE'
response	*Not accepted.* See our response to your comment 1

comment	*27* comment by: *Franz Redak* ..applicants are invited to break down their CP into CDIs and to identify within a discipline: I understand this is a may but not a must. However, if the appliant elects to do, what standard/detail will be necessary to do so.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment	*65* comment by: *DOA EASA.21J.041 Aero-Dienst GmbH & Co. KG.* The term "critical" is not clearly defined in 25.1309. Clarification is requested to define what "critical CDIs" means.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment	*110* comment by: *Airbus* **1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:** Page 60/67, paragraph GM1 21.B.100(a). **2. PROPOSED TEXT / COMMENT:** Overall the definition of CDI deserves further detailed definition in order to be understood by both the EASA and applicants stakeholders involved in the certification projects and then applied in a harmonised and consistent manner. Furthermore, "Critical CDI" deserves further clarification. As currently worded, it would be difficult for the applicant to identify a critical CDI. CS 25.1309 does not define directly what is critical. Wording from risk management assessment should be used **3. RATIONALE / REASON / JUSTIFICATION:** To allow a harmonised and consistent implementation of the CDI concept without turning it into a complex process.
response	*Noted.*

	These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.
comment	*111* comment by: *Airbus* **1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:** Page 60/67, paragraph GM1 21.B.100(a). **2. PROPOSED TEXT / COMMENT:** The AMC indicates: *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:* *(…)* Overall the wording "discipline" deserves further detailed definition in order: - to get the right breakdown – example: is the software a discipline or is it treated within a greater discipline? Same remark for development assurance? - to be understood by both the EASA and applicants stakeholders involved in the certification projects and then applied in a harmonised and consistent manner. **3. RATIONALE / REASON / JUSTIFICATION:** To allow a harmonised and consistent implementation of the Discipline concept without turning it into a complex process.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.
comment	*255* comment by: *Airbus Helicopters* In the explanatory note, the meaning of "discipline" interpretation may be the ATA decomposition (chapters). In the GM1 21.B.100(a) wording, the meaning of "discipline" is indicated as EASA Panels, conflicting the "domain" used in the explanatory note for is EASA Panel responsibility. Identification of CDI per discipline, as proposed in the NPA, should enable "domain" oriented LOI negotiations with EASA Panel expert. **Suggestion** The inconsistent usage of the wording "discipline" and "domain" should be corrected.

In section GM1 21.B.100(a) discipline is addressing Avionics, flight, structure, hydro-mechanical systems.
The same Panel identifiers are addressed in section 2.4.1 of the NPA on page 17 as "domains".
A consolidated EASA opinion on the "discipline" and "domain" topics should avoid misinterpretation.
Alternative proposal: Certification Program breakdown into CDIs should address simultaneously discipline(s) and domain(s). AHD is currently coding "discipline" using ATA breakdown structure and "domain" using EASA Panel identifiers.
Furthermore, AHD is already using "compliance plan" to isolate specific compliance demonstration activities. Such compliance plans are collecting CDI information in a submit-able format for EASA agreement.
Assuming that EASA wording remains unchanged, AHD recommends the introduction of "compliance plan", where applicable, to decompose planning information with CDI relevance.

response

Noted.

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment *323* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland*

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

"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."

Swiss FOCA: Definition is too generic and must be refined.

response

Noted.

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

3. Proposed amendments — Draft Decision — GM221.B.100(a) Depth of the investigation p. 60

comment *53* comment by: *CAA-NL*

GM2 21.B.100

The last dot of GM2 21.B.100(a) stating "performing the Agency's own inspection/tests, including flight tests." is not correct. The compliance demonstration of the applicant must be complete. Based on this the Agency determine their level of involvement including which tests they want to witness/perform. So the text "own" should be deleted.

response

Noted.

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment *112* comment by: *Airbus*

1. PAGE / PARAGRAPH / SECTION THE COMMENT IS RELATED TO:
Page 60/67, paragraph GM 21.B.100(a) Depth of the investigation.

2. PROPOSED TEXT / COMMENT:

Second bullet indicates: *"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.);"*

The difference between "a review of design and compliance document" and "an engineering evaluation of applicant's compliance documents" is not understood. One of the two wordings should be deleted.

The word "Test" is only related to compliance demonstration test. This should be specified

Proposed change:
"~~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, compliance demonstration (or certification) test plans (laboratory/ground/flight) and test reports, inspection reports/records etc.);"

In third bullet:
- the wording "conformity" deserves clarification. What is the scope of these conformity documents beyond the test articles/specimens conformity records?
- The difference between "a review" and "engineering evaluation" is not understood. One of the two wordings should be deleted.

Proposed change:
~~a review and~~ An engineering evaluation of the applicant's conformity documents, including an evaluation of non-conformances of test articles/specimens;

3. RATIONALE / REASON / JUSTIFICATION:

	For sake of clarity.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment	*324* comment by: *Federal Office of Civil Aviation (FOCA), Switzerland* **GM2 21.B.100(a) Depth of the investigation** "a review and engineering evaluation of the applicant's conformity documents, including an evaluation of non-conformances of test articles/specimens;" *Swiss FOCA: Can only be related to conformity of test articles respectively prototypes, as conformity statements are normally issued by certifying staff under minimum Subpart F, G or Part-145.*
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

3. Proposed amendments — Draft Decision — AMC21.B.100(b)(3) DOA performance and experience measurement system p. 60

comment	*5* comment by: *Prof. Filippo Tomasello* A new AMC 21.B.100(b)(4) should be added as follows: 'The Agency will establish a QE experience measurement system to capture the maturity of the QE organisation and experience. Related indicators may include the level of activity of the QE, its scope and management system and feedback from previous assessments'.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment	*28* comment by: *Franz Redak* We would like to suggest that the DOA performance and measurement system should be (by regulation) transparent and available to the applicant DOA. We would also like to see a way that the DOA can question and challenge such decisions. Unfortunately such decisions are not always done based on objective findings, therefore this decision must be transparent to the DOA.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment	*59* comment by: *DOA EASA.21J.041 Aero-Dienst GmbH & Co. KG* To which extent is the Agency obliged to notify the DOAs regarding their performance and experience ranking and how will this be communicated. Please clarify.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment	*66* comment by: *DOA EASA.21J.041 Aero-Dienst GmbH & Co. KG.* Please clarify if the term "previous" includes projects before entry into force of the LOI regulation or only later projects
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment	*281* comment by: *Airbus Helicopters* The description of the DOA performance and experience measurement system is, for the moment, very imprecise, both considering: • The set of indicators that captures the maturity of the DOA holder's organisation and their performance, • The feedback to the applicant on how the performance is measured and on the

results.

Recommendation
It is expected that a more precise description of the DOA performance and experience measurement system will be provided in the future in the Part 21 AMC/GM, as well as information on how will be organised the communication between the DOA holder and the Agency.

Our understanding is that this will be part of the second step.

response

Noted.

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment

305 comment by: *Sell GmbH*

AMC 21.B.100(b)(3): DOA performance and experience measuring system shall be clearly specified and shown herein to allow all stakeholders to review and to implement appropriate measures, e.g. within DOAs to measure and improve related performance indicators.
In addition the system has to take into consideration all root causes appropriately balancing the performances, i.e. to prevent impairing DOA performances through e.g. insufficient or late actions/answers on EASA side during DOA surveillance or unequal level of requirements and acceptance of DOA procedures. Thus EASA shall provide more standards, e.g. good practices, procedures and templates, to assure a uniform set of guidance for all DOAs resulting in equal performance measurement.

response

Noted.

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment

325 comment by: *Federal Office of Civil Aviation (FOCA), Switzerland*

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."

Swiss FOCA: Transparency is required to be included for all the stakeholders.

response | *Noted.*

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment | *336* comment by: *DGAC France*

AMC 21.B.100(b)(3) the indicators must be developed. It does not seem obvious to define the maturity of the DOA holder's organisation and their performance.

response | *Noted.*

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

comment | *350* comment by: *LHT DO*

DOA performance evaluation should be based on objective parameters and combine the assessment of the DOA Teamleader (DOA Audits) and the performance in previous projects. The process of classification of the DOA performance shall be transparent and in a approachable manner for the applicant.

Ammending the ASD comments:
The risk of the technical field or DAS on which EASA staff is commenting shall be included into the performance evaluation.

response | *Noted.*

These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

4.5. How could the issue/problem evolve? p. 62-63

comment | *29* comment by: *Franz Redak*

Again, we believe it is valid and worth mentioning that the industry is also interested in an effective agency. We currently see response times which do NOT support the efficient

	operation of aircrafts. This is a economic threat to the industry.
response	*Noted*. See also our response to comment 103.

4.7. Analysis of impacts — 4.7.1. Safety p. 64

comment	*207* comment by: *SIRIUM AEROTECH* We agree with the NPA regarding impact on safety of the general provisions of LOI. Nevertheless, we believe impact on safety of the new privilege to approve STCs has not been correctly assessed. There are certain risks which have been ignored: - The definition of "equivalent STC" is ambiguous and subjective. It exists a real risk of misunderstundings or abuses wich would lead to STCs wich are not equivalent indeed to be approved without control. The surveillance of EASA may detect these cases or not, but in any case, the STC would be already installed and creating a safety risk. - The fact that a DOA approved in the past an STC doesn't ensure its future performance, even in the case that the STCs are indeed equivalent. The staff could have been renovated and the new personnel may have not experience at this field. Also, new requirements of Part 21 as EWIS ICA, OSD or flight testing policy may not be correctly implemented. This analysis should take into account that mistakes at exercising the privilege would be a serious risk for safety because STCs, by definition, have an appreciable effect on safety.
response	*Noted.* These implementation issues will be addressed during Phase II of this rulemaking task aimed to provide comprehensive AMC/GM material to support the legislative proposal of the corresponding Opinion for LoI.

4.7.4. Economic impact p. 65

comment	*208* comment by: *SIRIUM AEROTECH* We disagree with the sentence: "design organisations that demonstrate mature and reliable performance may enjoy new privileges, enabling them to gain time, thus enhancing their competitiveness" LOI general provisions for certification projects will indeed create this effect, but privilege to approve STCs has many other aspects not considered by the NPA. Please note that the new privilege is based on equivalent STCs previously approved. Therefore, the DOAs more benefitted are not the best performers, but those big and old with

a large portfolio of STCs already approved. This will create an unfair gap between old/big companies and new/small companies wich will have nothing to do with skills or performance, but mainly with size and age.
The competitivity advantage to approve directly STCs is so big, that this alone fact is enough to prevent new/small DOAs from participating in the STC market regardless its performance and commitment to safety, leaving it in few hands. The economic impact analysis does not take into account the distortion of the market, the closure of DOAs for this reason and the lost of fees, not only for fees not payed by DOAs with privilege, but also fees not payed by DOAs which now will be banned in fact from STCs market or will be forced to stop business.
As an example to illustrate our reasoning, the following situation may happen: The most experienced staff of a DOA decides to leave (or is fired) and create a new company. This personnel is replaced in the original DOA by young trainees. The new DOA formed by skilled and experienced engineers could never make a competitive offer to a customer because they don't have a large collection of STCs, but the old DOA is however able to approve STCs and can offer better prices and delivery times. This would create not only an unfair handicap for certain companies, even when its performance might be good, but also a safety risk.

response | See our response on your comment 209 and the enhanced RIA in the Explanatory Note in the Opinion.

4.7.5. General aviation, SMEs and proportionality issues p. 65-66

comment | *30* comment by: *MAP Aircraft*

We do not share EASA's optimism regarding that the economic impact on small and medium enterprises not will become disproportionate, we believe it rather will be the opposite.

By just considering the numbers and type of modifications that a larger company perform, it will be easier for large companies to show that they have the experience and knowledge for the new privileges and coming future "major approval" privileges than for a small company. EASA says that the introduction will use a risk based approach when dividing the companies into different groups. We believe it would be extremely difficult for EASA to say that a larger company (lets say 200+ employees) has a risky behaviour and poor competence, hence small companies would end up with lesser privileges.

As a direct result larger companies will be able to offer operators major modifications without EASA's involvement or application cost, this will give them a huge competition advantage in comparison to small companies as it will be more predictable and time efficient. In the long run we are afraid that this will create specific niche companies that will deal with certain kinds of majors that in real life will take the entire market share of "available" modifications. This will reduce the economic foundation for smaller companies, which exist, since they now can do things cheaper and quicker than a large company.

As a mitigation action we suggest that the application fee for the new "major

	modifications/repairs privileges" for those organisations that not have been granted these privileges, are removed in order to create a more level playing field. We also believe a more transparent process for the company risk assessment is required where competitors can review why some have been granted rights and some not.
response	See our response on your comment 209 and the enhanced RIA in the Explanatory Note in the Opinion.

