European Union Aviation Safety Agency

Notice of Proposed Amendment 2019-05 (A)

Embodiment of safety management system (SMS) requirements into Part-145 and Part 21

RMT.0251 PHASE II

EXECUTIVE SUMMARY

With reference to Rulemaking Task (RMT).0251 Phase II in EPAS 2019-2023, this Notice of Proposed Amendment (NPA) proposes amendments to Annex I (Part 21) to Regulation (EU) No 748/2012 and Annex II (Part-145) to Regulation (EU) No 1321/2014, in order to:

— introduce safety management principles that implement ICAO Annex 19; and

— foster an organisational culture for effective safety management and effective occurrence reporting in accordance with Commission Regulation (EU) No 376/2014.

Note 1: Phase I of RMT.0251 was limited to the introduction of safety management requirements into Part-CAMO (see Opinion No 06/2016).

Note 2: The review of the occurrence reporting system was governed by RMT.0681, but certain additional changes are proposed through this RMT, in light of the principles of ICAO Annex 19, Chapter 5.

This NPA proposes to consider the applicability of safety management systems (SMSs) to Part-145 approved maintenance organisations, as well as to production and design organisations that are approved in accordance with Subparts G and J of Part 21.

By doing so, safety will be enhanced through:

— the establishment of safety policies and objectives that are associated with sufficient resources;

— the systematic identification of hazards, and a risk management system;

— the safety assurance system, including giving consideration to safety performance; and

— safety promotion.

This RMT also aims to streamline the procedures for oversight, and introduce a set of new, common management system requirements for competent authorities to increase their efficiency.

NPA 2019-05 is divided into three parts. The present NPA 2019-05 (A) includes:

— the procedural information pertaining to the regulatory proposal;

— the explanatory note to the proposed amendments;

— the regulatory impact assessment; and

— a detailed summary of the proposed amendments (see Chapter 7 ‘Appendices’).

The draft implementing rules (IRs) as well as the draft Acceptable Means of Compliance (AMC) and Guidance Material (GM) for Part 21 are proposed in NPA 2019-05 (B), whereas those for Part-145 are proposed in NPA 2019-05 (C).

Action area:	Systemic enablers to safety — safety management		
Affected rules:	Part-145 and Part 21		
Affected stakeholders:	AMOs (Part-145); POA holders; DOA holders; ETSOA holders; competent authorities		
Driver:	Safety	**Rulemaking group:**	No (but Focused Consultation Group)
Impact assessment:	Full	**Rulemaking Procedure:**	Standard

12.7.2017	**17.4.2019**	**2020/Q1**	**2020/Q3**	**2020/Q3**

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1. About this NPA

1.1. How this NPA was developed

The European Union Aviation Safety Agency (EASA) developed this NPA in line with Regulation (EU) 2018/1139[1] (Basic Regulation) and the Rulemaking Procedure[2]. This rulemaking activity is included in the European Plan for Aviation Safety (EPAS)[3] under RMT.0251. The text of this NPA has been developed by EASA based on the input from a focused consultation group (FCG). It is hereby submitted to all interested parties[4] for consultation.

RMT.0251 (old task number: MDM.055) was initiated in October 2010 as an 'Agency task'; it was originally intended to cover all airworthiness domains. Part-M (Annex I to Regulation (EU) No 1321/2014[5]) and Part-145 were covered by the issuing of NPA 2013-01(B) and NPA 2013-01(C) respectively. For efficiency reasons, and due to the parallel RMT for a light Part-M (RMT.0547 in the context of the GA roadmap), it was then decided to split the work into two phases:

— Phase I focused on the introduction of SMSs into Part-M, and its outcome was Opinion No 06/2016 (Part-CAMO), in conjunction with the outcome of RMT.0547 — Opinion No 05/2016 (Part-ML and Part-CAO);

— Phase II focuses on the introduction of SMSs into Part 21 ((Annex I to Regulation (EU) No 748/2012[6]) and Part-145 (Annex I to Regulation (EU) No 1321/2014), with a new consultation based on the results of Phase I. Although no CRD was issued for the first NPA 2013-01(C) on Part-145, the text proposed in this NPA takes into account the comments received on that first NPA.

A new Terms of Reference (ToR) for Phase II document was published on 12 July 2017[7], which established a FCG with competent authority and industry representatives, some of whom had already taken part in Phase I.

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1 Regulation (EU) 2018/1139 of the European Parliament and of the Council of 4 July 2018 on common rules in the field of civil aviation and establishing a European Union Aviation Safety Agency, and amending Regulations (EC) No 2111/2005, (EC) No 1008/2008, (EU) No 996/2010, (EU) No 376/2014 and Directives 2014/30/EU and 2014/53/EU of the European Parliament and of the Council, and repealing Regulations (EC) No 552/2004 and (EC) No 216/2008 of the European Parliament and of the Council and Council Regulation (EEC) No 3922/91 (OJ L 212, 22.8.2018, p. 1) (https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1535612134845&uri= CELEX:32018R1139).

2 EASA is bound to follow a structured rulemaking process as required by Article 115(1) of Regulation (EU) 2018/1139. Such a process has been adopted by the EASA Management Board (MB) and is referred to as the 'Rulemaking Procedure'. See MB Decision No 18-2015 of 15 December 2015 replacing Decision 01/2012 concerning the procedure to be applied by EASA for the issuing of opinions, certification specifications and guidance material (http://www.easa.europa.eu/the-agency/management-board/decisions/easa-mb-decision-18-2015-rulemaking-procedure).

3 https://www.easa.europa.eu/document-library/general-publications?publication_type%5B%5D=2467

4 In accordance with Article 115 of Regulation (EU) 2018/1139 and Articles 6(3) and 7 of the Rulemaking Procedure.

5 Commission Regulation (EU) No 1321/2014 of 26 November 2014 on the continuing airworthiness of aircraft and aeronautical products, parts and appliances, and on the approval of organisations and personnel involved in these tasks (OJ L 362, 17.12.2014, p. 1) (https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549461562202&uri=CELEX:32014R1321).

6 Commission Regulation (EU) No 748/2012 of 3 August 2012 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations (OJ L 224, 21.8.2012, p. 1) (https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549462558558&uri=CELEX:32012R0748).

7 https://www.easa.europa.eu/document-library/terms-of-reference-and-group-compositions/tor-rmt0251b-mdm055-mdm060

Since the publication of Issue 1 of the ToR, ICAO has published the fourth edition of the Safety Management Manual (ICAO Doc 9859), which is aligned with the second issue of ICAO Annex 19. The proposed changes to the rules in this NPA benefit, to a certain extent, from the material in that newly edited ICAO document.

On 20 August 2018, new Basic Regulation (Regulation (EU) 2018/1139), which repealed Regulation (EC) No 216/2008, was published. In Part-145, all references were updated since this NPA proposes changes to all points of the Regulation. For Part 21, only the points affected by SMS have been modified to reference the new Basic Regulation. The remaining points that are not proposed in this NPA to be amended still refer to Regulation (EC) No 216/2008. The update of the references to Regulation (EU) 2018/1139 should not be considered as an assessment of the impact of that Regulation to Part 21. This will be conducted through a dedicated rulemaking task (RMT.0727).

1.2. How to comment on this NPA

Please submit your comments using the automated **Comment-Response Tool (CRT)** available at **http://hub.easa.europa.eu/crt/**[8].

The deadline for submission of comments is **17 July 2019**.

1.3. The next steps

Following the closing of the public commenting period, EASA will review all the comments with the support of the FCG.

Based on the comments received, EASA will issue opinions containing the proposed amendments to Regulations (EU) No 748/2012 and (EU) 1321/2014. Summaries of the comments received will be provided in the opinions. The opinions will be submitted to the European Commission, which will use them as a technical basis in order to take a decision on whether or not to amend the Regulations.

If the Commission decides that the Regulations should be amended, EASA will issue decisions that amend the AMC & GM to comply with the amendments introduced into the Regulation.

The comments received on this NPA and the EASA responses to them will be reflected in comment-response documents (CRDs). This CRD will be available on the EASA website and will be the basis for the development of the Opinions and Decisions, which will be respectively proposed for adoption by the European Commission and approved by EASA.

The opinions will include a proposal for transition measures for organisations and authorities to adapt to the new requirements. The European Commission, along with the EU Member States, will validate it. At this stage of the project, a transitional period of two years after the Regulations enter into force is suggested.

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

2. In summary — why and what

2.1. Why we need to change the rules — issue/rationale

Pursuing the objectives of the Basic Regulation regarding the development of EU rules, EASA shall issue opinions addressed to the European Commission (proposing amendments to regulations) and Decisions (issuing AMC & GM). When doing so, it shall consider International Civil Aviation Organization (ICAO) Standards and Recommended Practices (SARPs) (see EASA Management Board Decision No 18-2015, Article 6).

At the end of 2013, ICAO published the first Edition of the Safety Management Annex (here referred to as 'ICAO Annex 19'). Later in 2016, ICAO published the second edition of that document. According to that document, the use of an SMS is foreseen in maintenance, design and production.

For design and production organisations, the existing legal EU framework already includes organisational requirements that cover certain safety management aspects, but the safety management SARPs[9], which stem from ICAO Annex 19, are not consistently implemented. In particular, Part 21 already imposes, in some cases, the necessity for an organisation to seek an organisational approval (i.e. design organisation approval (DOA) and production organisation approval (POA)) after demonstrating that they are able to ensure the safety of their product through the compliance of the design with the technical specifications or the conformity of the production with the design data. Some provisions required for such organisational approvals are similar to those required for an SMS by ICAO Annex 19, as better explained later in this document.

For maintenance, a decision has already been taken on how to introduce SMS into Part-145 (see **Section 4.3** for further details).

No exemptions have been issued in accordance with Article 71 of the Basic Regulation that are pertinent to the scope of Phase II of this RMT.

2.2. What we want to achieve — objectives

The overall objectives of the EASA system are defined in Article 1 of the Basic Regulation. This proposal will contribute to the achievement of these objectives by addressing the issues outlined in Section 2.1.

The specific objectives of this proposal are to:

— further improve the level of safety with respect to Part-145 and Part 21 organisations;

— overcome obstacles related to the mutual acceptance of approvals;

— foster the principles of safety management as indicated in the ICAO Annex 19 SARPs, second edition, taking due account of the critical elements of a State's safety oversight system as defined in ICAO Annex 19, Appendix 1;

— streamline the procedures for oversight and enforcement, and increase the efficiency of the management system requirements for competent authorities; and

[9] Design, production and maintenance are the last aviation domains into which safety management requirements have not yet been introduced.

— support the implementation of the 2019-2023 EPAS, notably Section 5.2 (e.g. systemic safety enablers, safety management), as a strategic priority.

2.3. How we want to achieve it — overview of the proposals

To develop this regulatory proposal, the FCG was consulted during three meetings between December 2017 and June 2018. An additional written consultation of the draft proposal for Part 21 only, for the sake of maturity, was organised after these three meetings.

2.3.1. Summary of changes to Part-145

For Part-145, the majority of the changes are based on Opinion No 06/2016 (Part-CAMO) and the associated proposed AMC & GM, which are themselves based on Subparts GEN of the authority and organisation requirements (AR/OR) in the Regulations for civil aviation air crew[10] and air operations[11], and the related AMC & GM respectively.

It thus fosters alignment with the content of Regulation (EU) No 965/2012, notably in the case of multiple approvals if an aircraft operator also holds Part-CAMO and/or Part-145 approvals. The newly introduced SMS elements in Part-145 follow the integrated approach used in the other domains, through the introduction of an integrated management system. As example, the new 'management system' of point 145.A.200 for Part-145 is introduced; it incorporates the existing quality system of point 145.A.65 with the ICAO SMS SARPs in an integrated management system. The resulting text resembles ORO.GEN.200 in Regulation (EU) No 965/2012.

This process is called the 'integrated management system'.

However, some differences may exist with imported Part-CAMO text due to regulatory constraints, such as differences in the regulatory numbering system; or the specific needs of each of the EU regulations. For clarity or consistency, the text could not be identical to that in Part-CAMO. In other cases, no equivalent text existed in Part-145, in particular when the introduced changes went beyond the straightforward introduction of a management system, dealing with other general aspects such as applications, alternative means of compliance (AltMoC), changes, access, findings, etc. However, these differences does not impact the intent of the regulator for that NPA.

Some minor improvements to the imported Part-CAMO text have also been proposed through this NPA, mainly for reasons of clarity or language improvement. The text may also benefit from some improvements proposed during the adoption of Part-CAMO being currently under review. Again these changes should not change the meaning, notably for Section B (i.e. the authority requirements).

Several Part-145 points have also been amended to highlight certain risks related to maintenance activities (e.g. fatigue and external working teams in 145.A.47).

[10] Commission Regulation (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 311, 25.11.2011, p. 1) (https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549467168079&uri=CELEX:32011R1178).

[11] Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1) (https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1549466927988&uri=CELEX:32012R0965).

In accordance with ICAO Annex 19, all Part-145 organisations should implement an SMS without exception: the new safety management requirements introduced into the EU regulatory framework apply to all types of Part-145 approved organisations.

A more detailed list of the proposed changes to Part-145 is provided in Appendix II to this NPA.

2.3.2. Summary of changes to Part 21

Rather than 'organisation-centric', the Part 21 Section A requirements are more 'product-centric'. Moving to an integrated management system in Part 21 would have too much diluted the importance of the quality (management) system and the design assurance system, which are specific, integral parts of the production and design system (see points 21.A.139 and 21.A.239). In addition, Part 21 already includes detailed organisational requirements for approved production and design organisations that match some of the ICAO Annex 19 related SARPs.

Fully aligning Part 21 with the SMS requirements in the other domains would thus:

— entail extensive changes to Part 21, making the alignment complex; and

— potentially affect Part 21 organisations, requiring a review of their processes or procedures, without leading to a clear safety benefit.

Consequently, the changes to Part 21 Section A (organisation requirements) have been limited to the introduction of the ICAO SMS framework (ICAO Annex 19, Second Edition, Appendix II), based on a gap analysis performed between the ICAO SMS framework and the existing Part 21 requirements. It is therefore proposed in this NPA that the 12 elements of an SMS applicable to an organisation, as defined in Appendix II to ICAO Annex 19, should be added to the Part 21 organisational requirements, respectively in points 21.A.139 (i.e. 'Quality system' for 'production') and 21.A.239 (i.e. 'Design assurance system'). By doing so, the existing rule structure for Section A remains unchanged, and the volume of changes is limited.

The new safety management requirements apply to all Part 21 approved organisations (POA holders and DOA holders, excluding the alternative procedures to DOAs). See Chapter 4 for further details.

The concepts of hazard identification, risk management and mitigation, as well as occurrence reporting, are already well embedded in the culture and rules associated with the design and production of the products, parts and appliances as described in the various Certification Specifications (CSs) and in points 21.A.3A, 21.A.139 and 21.A.239. This means that the alignment of the occurrence reporting system required by Regulation (EU) No 376/2014[12] has been considered in this NPA to be notably consistent with ICAO Annex 19, Chapter 5 and its Appendix III and the development of RMT.0681.

For Section B, the authority requirements have been aligned with the other aviation domains, in an approach that is similar to the one for Part-145. However, some peculiarities of the Part 21 rules had to be kept. The main following elements have been introduced:

[12] Regulation (EU) No 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007 (https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1532624380599&uri=CELEX:32014R0376).

— risk-based oversight and the recognition of organisations that have good performance through the use of flexible oversight planning cycles and extensions to 36 and 48 months;

— the concept of AltMoC for production organisations; and

— instead of 36 months currently applied, the text proposed a DOA basic oversight cycle of 24 months with the option to extend it to 36 or 48 months when conditions are met, as already regulated in the other domains [see ARO.GEN.305]. Once the proposed regulation becomes applicable, EASA will immediately apply a 36 months cycle to all existing DOAs already meeting the conditions to be eligible for a 36 month oversight cycle.

Finally, a set of AMC & GM has been developed, consistent with those provided in other domains, to demonstrate compliance with the SMS requirement. In this way, an organisation that already holds several approval certificates may reuse the evidence already produced for the other domains or in the case of an integrated management system.

A more detailed list of the proposed changes to Part 21 is provided in Appendix I to this NPA.

2.3.3. Specific commonalities and differences between Part-145 and Part 21

As mentioned earlier, the volume of changes to Part 21 has been kept as low as possible, by building on the existing Part 21 structure. On the contrary, it was easier to reshape and align Part-145 with the Air OPS rules: by doing so, the common regulatory framework is fostered when a CAMO-approved aircraft operator also holds a Part-145 approval.

Although the two Regulations are considered to be aligned with the SMS principles that stem from ICAO Annex 19, they might be different in their wording and regulatory structures. As a result, some SMS principles in Part-145 may have a different regulatory status from that in Part 21. This is inherent in the fact that the two pieces of legislation have evolved in different manners over time. Notably, for Section A, Part 21 focuses more on the 'product', whereas Part-145 focuses more on the organisational requirements. The future roadmap for OR/AR should resolve that difference.

Unlike the proposed changes for Part-145, the Part 21 approach does not foster an 'integrated management system'. However, the Part 21 organisation may go for an integrated management system especially when several approvals are held.

All in all, although the approach taken for Part 21 and for Part-145 differ, the proposed changes do not bring any incompatibility as they basically follow the SMS framework and the spirit of ICAO Annex 19 or ICAO Doc 9859.

Lastly, AMC have been introduced for points 21.A.139 (see AMC1 21.A.139(c)) and 21.A.239 (see AMC1 21.A.239(c)) for the acceptability of the SMS Industry Standard 'Implementing a Safety Management System in Design, Manufacturing and Maintenance Organizations' SM001 Issue A - September 17th, 2018[13] to demonstrate compliance with the EU SMS requirements in Part 21.These AMC identify some gaps between this SMS industry standard and the SMS elements of the management system defined in Part 21.

— SMS Industry Standard SM-0001 has been developed by the Aerospace and Defence Industries Association of Europe (ASD), the Aerospace Industries Association of America (AIA), the

[13] https://www.asd-europe.org/sites/default/files/atoms/files/SMS%20Standard_final%20issue%20A_20180917.pdf

Aerospace Industries Association of Brazil (AIAB), the Aerospace Industries Association of Canada (AIAC) and the General Aviation Manufacturers Association (GAMA).

— Intended to improve safety performance and enhance safety culture, this document provides explanations and some guidance material for compliance with the provisions of ICAO Annex 19, Appendix II 'Framework for a Safety Management System'. It essentially contains:

- some Part 21 best practices to identify hazards and to conduct safety risk management (SRM);
- sources of data for safety assurance as well as safety performance indicators (SPIs);
- interfaces between organisations, notably within consortiums (i.e. corporate SMS) or with suppliers or organisations that have not implemented an SMS;
- considerations regarding other management systems (e.g. quality management system, security management system); and
- an SMS implementation plan and an SMS assessment tool based on the one developed by SM ICG[14].

— However, SMS Industry Standard SM-0001 at Issue A is not found suitable for introduction into the AMC to Part-145.

2.4. What are the expected benefits and drawbacks of the proposals

The proposed changes:

— implement ICAO Annex 19, notably through the introduction of SMS principles, safety risk management and continuous improvement;

— foster an organisational safety culture for effective safety management and effective occurrence reporting, whether it is mandatory or voluntary, to be coherent with Regulation (EU) No 376/2014; and

— streamline as much as possible the Section B oversight requirements for Part-145 and Part 21 organisations, due to an approach that is common with other domains.

The intended effects would be the:

— enhancement of safety by contributing to effective hazard identification, risk management capabilities and error reduction, and by improving transparency;

— promotion of a positive safety culture; and

— improvement in terms of flexibility and proportionality, in particular regarding management system requirements.

Despite the difference in approach between Section A for Part 21 (i.e. gap analysis with ICAO Annex 19) and that of Part-145 (i.e. integrated management system), the alignment of the SMS principles will facilitate the reuse of activities and documentation that has been already developed for

[14] The Safety Management International Collaboration Group (SM ICG) is a group of 18 aviation regulatory bodies, established in 2009 to promote a common understanding of safety management principles and requirements, facilitating their application across the international aviation community. A repository of SMICG products can be accessed free of charge at https://www.skybrary.aero/index.php/Safety_Management_International_Collaboration_Group_(SM_ICG).

compliance demonstration in other domains. This is further supported at the AMC & GM level, where the same material has been used in the two domains, insofar as this was possible. This drawback is therefore mitigated for Part-145-organisations that hold a DOA or a POA, and vice versa.

3. Proposed amendments and rationale

A detailed summary of the regulatory changes can be found:

— for Part 21 in Appendix 7.1; and

— for Part-145 in Appendix 7.2.

3.1. Draft regulation (Draft EASA opinion) for Part 21

Refer to NPA 2019-05 (B)

3.2. Draft AMC & GM (Draft EASA decision) for Part 21

Refer to NPA 2019-05 (B)

3.3. Draft regulation (Draft EASA opinion) for Part-145

Refer to NPA 2019-05 (C)

3.4. Draft AMC and GM (Draft EASA decision) for Part-145

Refer to NPA 2019-05 (C)

4. Impact assessment (IA)

4.1. What is the issue

4.1.1. Introduction

The first edition of ICAO Annex 19 became applicable on 14 November 2013 for design, production and maintenance activities. Without waiting for the EU rules to embed ICAO Annex 19, some organisations that hold multiple approvals, for which an SMS is already mandatory, or that have branches or conduct business in non-EU States where an SMS is already mandatory, have already extended the safety management principles to their design, production and maintenance activities, for the sake of coherence or business needs. Some major organisations, such as large production or maintenance organisations, have also felt the benefit of having a risk management system and a robust occurrence reporting system embedded in their corporate safety culture. Finally, a number of EASA Member States such as France, Switzerland, and the United Kingdom have already mandated the implementation of SMSs for maintenance organisations. Some other EASA Member States have encouraged the implementation of SMSs on a voluntary basis. For all these reasons, an SMS is not a novelty, and the overall impact is limited, notably for the maintenance organisations.

Pursuing the objectives of the Basic Regulation regarding the development of the EU rules, EASA proposes to implement the ICAO safety management SARPs for the design, production and maintenance organisation and authority requirements. Additionally, the Basic Regulation calls for a management system, for continuous improvement of this system, and an occurrence reporting system that supports that management system (see its Annex I, Section 3.1).

Design, production and maintenance are the last aviation domains into which safety management requirements have not yet been introduced.

Failure to implement an SMS as an ICAO international standard will:

(a) pose obstacles for the mutual acceptance of approvals under bilateral agreements;

(b) be detrimental to the objective of continuous improvement of the overall level of safety, as a significant segment of the air transportation system would not implement the safety management principles;

(c) minimise the safety role of a reinforced occurrence reporting system as described in Chapter 5 of ICAO Annex 19 and in Regulation (EU) No 376/2014;

(d) not streamline the management system requirements for the competent authorities of the EASA Member States, which are already required to upgrade their systems and procedures in accordance with the new authority requirements introduced in Regulations (EU) Nos 1178/2011, 290/2012 and 965/2012; and

(e) deny the need to consider the critical elements of a state safety oversight system as defined in ICAO Annex 19, Appendix I.

The way forward is thus the proper consideration of the safety management principles in coherence with what has been already done for the other aviation domains. Later in this document, the reader will see that no options have been proposed for Part-145 (for reasons explained further in the text), whereas for Part 21 some options are proposed to achieve that objective.

The working method adopted for this IA is a qualitative assessment of the possible impacts, supported by a questionnaire, as explained in the next section. It is recognised that this is not easy to precisely quantify the impacts, notably with regard to the real costs. However, the EASA questionnaire helped to identify the most significant contributors to safety and costs (see Section 4.1.2 and Appendix III).

4.1.2. Evidence gathering — EASA questionnaire

EASA sent out a survey in order to gather evidence for this IA from stakeholders. The input supported the analysis of the problem definition and the analysis of the options. The survey was sent on 15 February 2018, and it collected specific SMS data related to the design, production and maintenance domains.

The survey was responded to by 293 organisations (285 organisations with a single or multiple approval(s); 8 associations or individuals) and 11 competent authorities. The organisations that hold multiple approvals were invited to provide a consolidated response, representing all the parts of the organisation that hold approvals.

The details of the survey can be found in Appendix III to this document. Wherever needed, the outcome of the survey is used throughout this IA by referring to the appropriate figures in Appendix III. The most relevant ones are repeated in Section 4.4.2.

4.1.3. Safety risk assessment

Several safety recommendations (SRs) that were addressed to EASA by safety investigation authorities are of interest for this RMT, as they are related to the subject of ICAO Annex 19:

— SR UNKG-2015-001, following the accident to British Airways A319 G-EUOE, which occurred on 24 May 2013, recommends that 'EASA publishes amended AMCs/GM in Part 145.A.47(b) of European Commission Regulation (EC) No 2042/2003, containing requirements for the implementation of an effective fatigue risk management system within approved maintenance organisations';

— SR UNKG-2011-018 following the serious incident to Bombardier DHC-8, SX-BIO, which occurred on 24 April 2010, recommends 'that the European Aviation Safety Agency expand the advisory or guidance material in Annex II (Part 145) of European Commission Regulation (EC) No 2042/2003 on how approved maintenance organisations should manage and monitor the risk of maintenance engineer fatigue as part of their requirement to take human performance limitations into account.';

— According to SR UNKG 2010-072, pertaining to the serious incident to Boeing 737-73V, G-EZJK, which occurred on 12 January 2009 West of Norwich, Norfolk, 'It is recommended that the European Aviation Safety Agency review the regulations and guidance in OPS 1, Part M and Part-145 to ensure they adequately address complex, multi-tier, sub-contract maintenance and operational arrangements. The need for assessment of the overall organisational structure, interfaces, procedures, roles, responsibilities and qualifications/competency of key personnel across all subcontract levels within such arrangements should be highlighted.'.

These SRs, together with their identified risks, have been properly considered in the proposed changes to the Part-145 rules.

4.1.4. Who is affected?

Part-145 maintenance organisations, Part 21 production and design organisations, competent authorities and EASA are affected by the proposal in this NPA.

4.2. What we want to achieve — objectives

Please refer to Section 2.2.

4.3. How it could be achieved — background and options

Part-145

ICAO Annex 19 states that all approved maintenance organisations that provide services to operators or aeroplanes or helicopters engaged in international commercial air transport, in accordance with Annex 6, Parts I or III, should implement an SMS. In the current EASA system, the term 'approved maintenance organisations' refers to either Part-M Subpart F organisations or Part-145 organisations.

With Opinions No 05/2016 'Task force for the review of Part-M for General Aviation (PHASE II)' and No 06/2016 'Embodiment of safety management system (SMS) requirements into Commission Regulation (EU) No 1321/2014 — SMS in Part-M', a new structure for Regulation (EU) No 1321/2014 was proposed, in which technical requirements and organisational requirements (e.g. Part-CAMO, Part-CAO, Part-145) would be addressed in separate Annexes (so Part-M Subparts F and G would eventually disappear). The technical requirements for General Aviation would be provided in a separate Annex (Part-ML/Part-M). The organisations with a General Aviation scope (Part-CAO) would not be required to implement an SMS, whereas other organisations would (i.e. Part-CAMO, and Part-145), but Part-147 organisations were excluded.

This means that a decision has been already taken to limit the introduction of SMSs into Part-145 organisations. No SMS principles will be requested for future Part-CAO approved maintenance organisations, which will address General Aviation activities. Only a Part-145 approved organisation can maintain aircraft operated by licensed air carriers and complex motor-powered aircraft (CMPA), in line with the spirit of ICAO Annex 19 (SMSs required for organisations that maintain aircraft engaged in commercial air transport).

Additionally, ICAO Annex 19 does not make any differentiation in the type of maintenance organisation (e.g. engaged in the maintenance of aeroplanes, helicopters or components, including engines or propellers). The safety management principles have applied without exception to all Part-145 maintenance organisations since 14 November 2013.

The implementation of ICAO Annex 19 is thus expected to be straightforward. **For Part-145, it has been decided to proceed without proposing options (i.e. full compliance with Annex 19).** This has also been well received by the FCG. Furthermore, the results of the questionnaire shown below demonstrate that the majority of the replies are in favour of the implementation of ICAO Annex 19 for all Part-145 activities (see Figure 16 in Appendix III).

However, the proposed changes introduce flexibility provisions regarding an SMS that should be commensurate with the size of the organisation and complexity of the operations, so it will limit the impact on small Part-145 organisations, or organisations with a limited scope of work.

For further details, the reader can also review the regulatory impact assessment (RIA) in NPA 2013-01(A), which resulted in Opinion No 06/2016.

Part 21

ICAO Annex 19 defines the applicability of SMSs to all organisations that are responsible for the design and production of:

— aircraft in accordance with ICAO Annex 8, applicable from 14 November 2013; and

— engines and propellers in accordance with ICAO Annex 8, applicable from 7 November 2019.

Unlike the requirements on maintenance organisations, ICAO Annex 19 does not distinguish between approved and non-approved organisations. This is because, in some regions of the world, the concept of 'approved' organisations for design and production is not systematically used, even for products. In addition, ICAO Annex 19 does not make SMSs applicable for the design and production of 'parts & appliances'.

Note: Regulation (EU) No 376/2014 already imposes a mandatory and voluntary occurrence reporting system on all aviation organisations, independently of their approval status and of what they design or produce. This can be considered a first element that stems from ICAO Annex 19, encouraging organisations to develop a just culture. Therefore, this element will not be subject to options or to analysis.

Starting from the scope defined by ICAO Annex 19, explained in Section 4.1.2, three options have been developed to define the applicability of SMSs to Part 21.

Option 0 — mirroring the scope of ICAO Annex 19

The scope of this option strictly follows that of ICAO Annex 19 (all organisations that design and produce aircraft, engines and propellers). Therefore Option 0 is considered to implement ICAO Annex 19 without any adaptation, and to mandate SMSs for all organisations, whether they are approved or not, that design and produce aircraft, engines and propellers.

Option 1 — approved organisations that produce or design only aircraft, engines and propellers

This option would require the implementation of ICAO Annex 19 by all approved organisations that design and produce only aircraft, engines and propellers (under Subparts J and G). All organisations that design and produce 'parts and appliances' are excluded even when Part 21 requires an approval [i.e. in the case of a European Technical Standard Order (ETSO) or an auxiliary power unit (APU)].

Under this option, this would exclude SMS for:

— Part 21 Subpart F production organisations[15];

— design organisations that are entitled to demonstrate their design capabilities with the acceptance of procedures that are alternative to DOA;

[15] On the basis that the manufacturer of a product, part, or appliance without a POA has convinced the competent authority that a POA was not needed due to a low volume of production; simple technology; the very small size of the organisation; or production for a limited period of time; or starting production activities before achieving full compliance with Subpart G [see point 21.A.124 (b)].

— design organisations that are required to submit only a certification programme, as per points 21.A.14 (b) or (c)[16]; and

— natural/legal persons that hold an ETSO authorisation (or ETSO authorisations), even if they are required to hold a POA.

Since this option would imply that, in some cases, an organisation may be required to be approved even without having an SMS in place (i.e. in the case of an ETSO), two types of DOA and POA would be needed: those who are required to implement an SMS and those who are exempted. This leads to Option 2.

Option **2**— all **approved** organisations

The implementation of ICAO Annex 19 would be limited to all approved organisations that design and produce aircraft, engines and propellers (under Subparts J and G), and to organisations that design and produce parts and appliances when a DOA or POA is required (i.e. a POA is required for an ETSO or a POA/DOA is required for an APU).

Table 1: Part 21 — selected options

Option No	**Title**	Description
0	Full implementation of ICAO Annex 19 by all organisations that are responsible for the design and production of products	**Full compliance with and implementation of ICAO Annex 19** (i.e. for approved and non-approved organisations that design and produce products)
1	Implementation of ICAO Annex 19 is limited to approved organisations that are responsible for the design and production of products	Implementation of ICAO Annex 19 is limited to approved organisations that only design and produce products (parts and appliances are excluded) **It falls short of the requirements of ICAO Annex 19,** as it excludes organisations for General Aviation (i.e. ELA1 & 2, engines, etc.), small organisations for which a POA is not needed, and organisations that are seeking a DOA but to which it has not yet been granted. This approach is coherent with the General Aviation approach adopted for continuing airworthiness organisations. (see Opinions No 05/2016 and No 06/2016)
2	Implementation of ICAO Annex 19 is limited to approved organisations that are responsible for the design and production of products and for 'parts and appliances' when an organisational approval is	The implementation of ICAO Annex 19 is limited to approved organisations that design and produce products as well as parts and appliances under ETSO authorisation. Built on Option 1**, it falls short of the requirements of ICAO Annex 19, except for organisations that are responsible for the design of APUs and the production of ETSO articles, for which an SMS is an additional requirement.**

[16] For ELA 1 or ELA2; or for engine or propeller installed on ELA 1 or 2; or for a piston engine; or a fixed or adjustable pitch propeller; a robust quality system and assurance design system is supposed to be sufficient.

	required under ETSO authorisation.	

Note: the term 'product' means aircraft, engines, or propellers

Compared with Option 0, Option 1 in Europe:

— excludes around 250 organisations that design ELA1/ELA2 (the number of Subpart F organisations is negligible);

— accounts for around 320 EU DOA holders, 30 DOA holders outside EU, and 500 POA holders.

Compared with Option 1, Option 2 would require some additional organisations in Europe to implement SMSs, as follows:

— 3 approved design organisations for the design of APUs;

— around 300 POA holders for the production of parts and appliances that are covered by ETSOs.

Discarded option: 'No action'

Failing to introduce the safety management principles from ICAO Annex 19 into the design, production and maintenance rules would be neither acceptable nor coherent with what has been achieved in the other aviation domains. The implications of this option have been clarified in Section 4.1. Therefore, this option has been discarded.

4.4. What are the impacts

Note: no option has been identified for Part-145. The section below compares the three options for Part 21 that are identified in Section 4.3.

4.4.1. Introduction to the impact analysis

A detailed analysis of the costs and benefits of implementing an SMS is quite challenging due to the very nature of 'safety'. Intangible benefits, such as those from having an improved safety culture, effective regulatory compliance, a management commitment to safety, shareholder value, and public confidence, are difficult to quantify. Also, an effective management system that includes safety risk management results from the interactions of many different organisational elements, actions, and

processes that are ideally embedded within the organisation's existing system. Therefore, the effects of individual elements of the management system framework are not always easy to isolate for the purpose of the analysis of costs and benefits. It is also acknowledged that an SMS creates immediate and direct costs, while its benefits are likely to take time to materialise. This view negates the potential of an SMS, not only to address the risks of major occurrences, but also to identify and tackle production inefficiencies, improve communication, foster a better company culture, and more effectively control contractors and suppliers. Building up risk management capabilities that are not only limited to aviation safety risks will contribute to the adoption of better management strategies. In addition, through an improved relationship with the competent authorities, the implementation of a management system that includes safety risk management could result in a reduced oversight burden. Thus, by considering an SMS as something that is implemented not solely to prevent incidents and accidents, but also to ensure the success of as many elements of an organisation's business as possible, any investment in safety should be seen as an investment in productivity and organisational success.

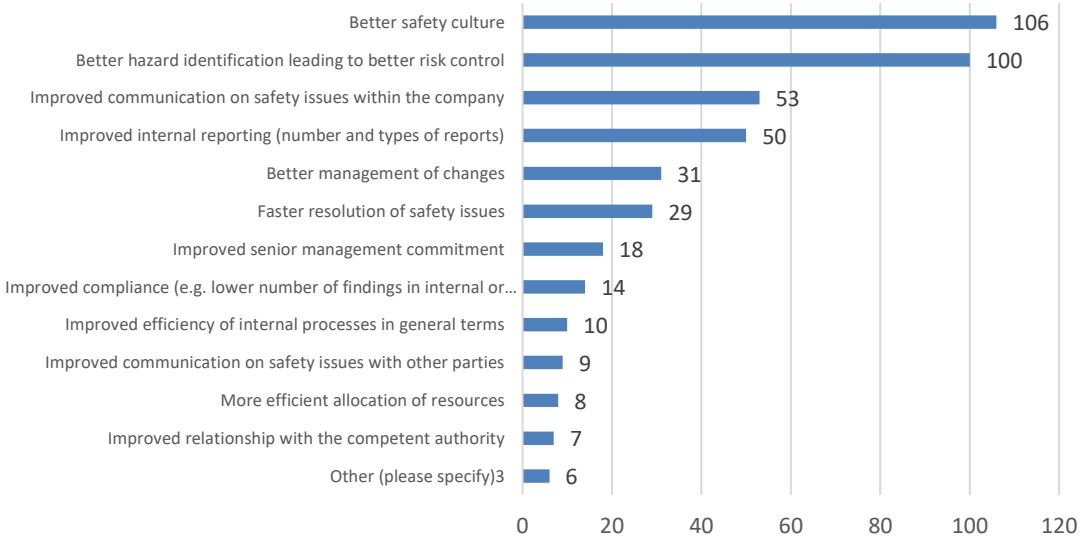
4.4.2. Relevant elements from the EASA questionnaire

The results of the EASA questionnaire (see Appendix III) with regard to the main safety benefits obtained from the implementation of an SMS are shown below. By far the two clearest benefits are:

— a better safety culture; and

— a better hazard identification, which leads to better control of risks.

Figure A - The most significant benefits in SMS implementation (by those who implemented SMS)



The EASA questionnaire highlighted the following elements regarding the main cost drivers in the implementation of an SMS:

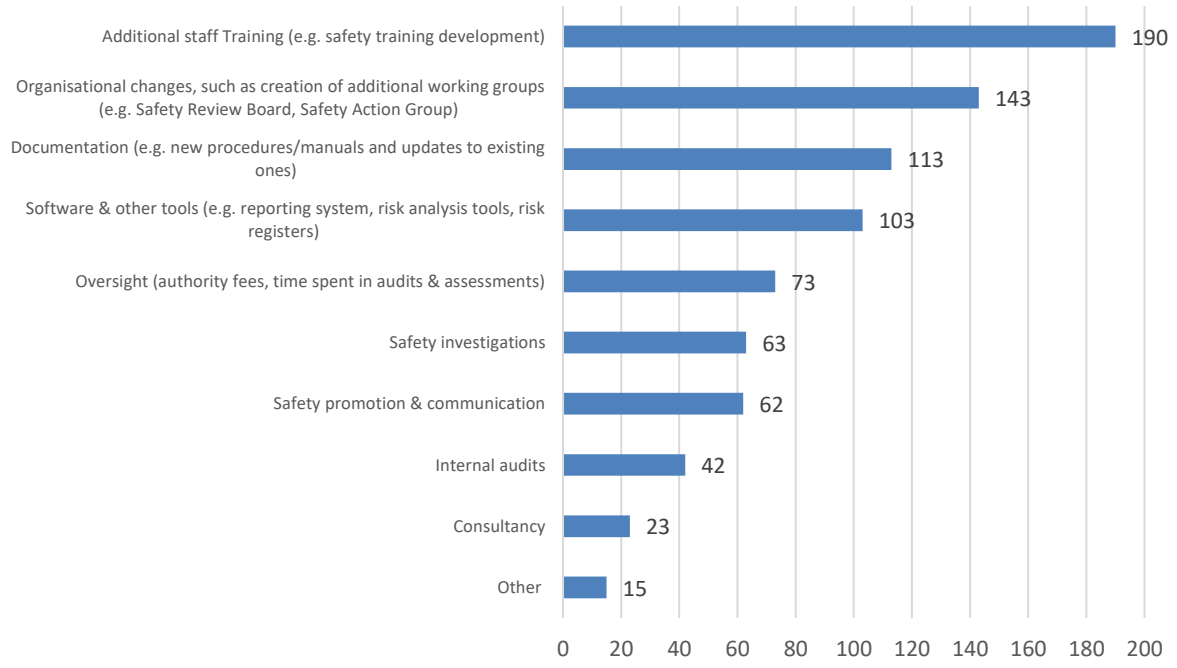
— additional staff training;

— organisational changes, such as the creation of new working groups (e.g. a safety review board);

— documentation (e.g. new procedures/manuals); and

— software and other tools (e.g. a reporting system).

Figure B - The main cost drivers in SMS implementation (by all organisations)



The cost drivers highlighted involved both organisations and authority.

4.4.3. Safety impact

Part 21 | Option 0 — ICAO Annex 19 (all product organisations)

Fully implementing Annex 19 would bring significant positive safety impacts, since all organisations, irrespective of the type of aircraft they produce, would be required to have an SMS in place, whether or not the organisation holds an approval. Figure A in Section 4.4.2 clearly highlights the safety benefits.

However, with this option, organisations that design and produce parts and appliances would not be required to implement an SMS. Some parts, such as APUs, are considered to have a major impact on safety.

Part 21 | Option 1 — all approved organisations (products)

Regulation (EU) No 376/2014 is applicable to all organisations (including the non-approved ones) that are located in Europe, and it mandates some basic elements of an SMS, such as mandatory and voluntary reporting and the development of a safety culture. It should be noticed that these elements are the most important safety benefits that were identified by organisations in their responses to the questionnaire as shown in Figure A in Section 4.4.2. This is why limiting the implementation of SMSs

to approved organisations that produce products would not significantly decrease the resulting safety benefits.

Therefore, even if this option provides less safety benefit than Option 0, the difference can be considered to be negligible. Overall, a positive safety impact is expected.

Part 21 | Option 2 — all approved organisations (products and parts and appliances)

In addition to the organisations defined in Option 1, this option mandates the implementation of an SMS by those organisations that design and produce parts and appliances under ETSO authorisation, but only when an approval is already required by Part 21.

Therefore, organisations that design critical elements such as APUs, and which produce parts and appliances that are covered by ETSO authorisations (i.e. when the organisations are not allowed to produce under Part 21 Subpart F), will be required to implement an SMS. The risks related to the design and production of these ETSO articles would be captured and assessed by those organisations. The aircraft manufacturer would rely on the ETSO authorisation, and would only be responsible for the proper installation of the article. This would be the additional positive safety effect of adopting Option 2.

Concerning the design of an APU (which is a major component of an aircraft), having an SMS in place is considered necessary and appropriate, not only in terms of the 'complexity' or 'criticality' of APUs, but also when considering the privileges associated with the design approval for the modifications and repair designs of those articles. Several accidents, such as uncontained explosions, or the one on 20 January 2015 at Nürnberg airport[17] (i.e. that involve the intake and combustion of de-icing fluid), remind us of how the operation of APUs can pose risks and may endanger human beings if there is a failure, should it be at product safety level or organisational level.

Safety awareness and safety culture will be also enhanced by more safety training, communication and safety promotion for the organisations that design and produce parts and appliances.

Finally, most of the organisations that produce parts and appliances under ETSO authorisations or design/produce APUs, also hold Part-145 approvals for which an SMS will be also required. An integrated (safety) management system will benefit from a safety perspective.

Compared with Option 1, a higher positive safety impact is thus expected, as more organisations would be covered.

4.4.4. Environmental impact

No environmental impact is identified, therefore this aspect is not analysed.

4.4.5. Social impact

The following elements are considered in the social impacts for this proposal: better communication, higher management commitment, fatigue, working conditions, lack of resources, and the level of subcontracting activities. Two of the essential elements of an SMS as defined by ICAO Annex 19 are the development of a safety culture and the provision of better safety training for all staff. The social impact is commensurate with the number of organisations for which an SMS is mandatory.

[17] https://aviation-safety.net/database/record.php?id=20150120-2

Part 21 | Option 0 — ICAO Annex 19 (all product organisations)

Since this option is applicable to all organisations that design and produce aircraft engines and propellers, the largest number of companies will be affected by this option, so it has a positive social impact.

Part 21 | Option 1 — approved organisations (products)

This option excludes non-approved organisations that design and produce aircraft engines and propellers; therefore, its social impact is slightly lower than that of Option 0, but it is still positive. Overall, the difference in comparison with Option 0 can be considered to be negligible.

Part 21 | Option 2 — all approved organisations (products as well as parts and appliances)

This option includes those organisations that design and produce parts and appliances under ETSO authorisation, but only when an approval is already required by Part 21. Therefore, the level of social impact is lower than with Option 0, but higher than with Option 1. Overall, the difference in comparison with Option 0 can be considered to be negligible.

4.4.6. Economic impact

For the organisations who have not yet implemented safety management principles, there would be an economic impact.

The organisations and authorities who have already engaged in this proactive strategy to systematically address safety risks have usefully pinpointed several areas in response to the EASA survey, as shown in Figure B in Section 4.4.2. These elements need to be kept in mind for this analysis.

The following general features can be highlighted:

Positive impact

Some elements of an SMS, such as a positive safety culture or an internal reporting system, have the potential to contribute significantly to the overall safety at little or no cost. For certain elements of an SMS, the implementation will be gradual, which should spread the overall costs over time. The same applies to the authorities, which should progressively deploy SMS management systems over time.

The effective implementation of SMSs will also improve productivity and efficiency, through the adoption of better management strategies and the build-up of risk management capabilities that are not limited to only aviation safety risks. Moreover, the causes of incidents and the contributing factors to them often also cause or contribute to production losses or inefficiencies. The management system framework of an SMS provides an organisational structure that supports managers in taking informed decisions. Without such a framework to manage operational risks, trade-offs between commercial pressures and safety objectives may not be managed effectively, and decisions may not be justified objectively. The effective implementation of a management system could, therefore, contribute to a decrease in insurance costs, to an improved reputation, and to commercial success.

For large, well established production and design organisations, it can be expected that a certain percentage have already implemented SMSs according to the ICAO framework, on a voluntary basis, sometimes under contractual obligations imposed on them by their customers.

The level of involvement (LOI) of an authority might be reduced due to an improvement in the performance of an organisation, as the level of safety might be higher.

Negative impact

The main elements of an SMS that may initially be missing from an organisation, and for which a negative economic impact is expected when they are incorporated, stem from:

(a) developing a safety policy and its related objectives;

(b) appointing key safety personnel to execute the safety policy;

(c) establishing, implementing and maintaining a safety risk management process;

(d) establishing, implementing and maintaining a safety assurance process; and

(e) promoting safety in the organisation.

To mitigate this negative impact, the reader is invited to review the proportionality provisions laid down in the next paragraph, as they contribute to a significant reduction of the costs, notably for small organisations or when the risks associated with the business are limited.

Part 21 |Option 0 — ICAO Annex 19 (all product organisations)

— Negative impact

Organisations for which Part 21 currently mandates an approval (DOA holders and POA holders) will have to adapt their structures, and update their policies, plans, procedures and expositions or handbooks. For them, the economic impact may be considered to be limited because they can build on their existing structures. Nevertheless, training costs and some organisational changes remain as major contributors, as identified in the replies to the EASA questionnaire.

Since all organisations that design and produce aircraft, engines and propellers will be mandated to apply SMSs, each organisation that is currently not required to have an approval will be required to define an organisational structure and to document their procedures in order to be compliant with ICAO Annex 19. For all other organisations that are not required to hold a Part 21 approval (i.e. those that design ELA 1 or ELA and produce according to Subpart F), and which are ‘small’ by definition, the implementation of SMSs will have a greater economic impact. They might be required to hire new personnel, to create some new management positions, or to extend the scope of their existing management positions, and to develop policies, plans, procedures and expositions or handbooks.

— Positive impact

In terms of economic benefits, the implementation of Annex 19 would ensure that there is a level playing field with consistent airworthiness requirements for aircraft that participate in international air transport, and for products for which foreign states accept certificates issued by EASA. In addition, further efficiency/effectiveness would be fostered thanks to:

- more efficient allocation of resources;
- more efficient internal processes;
- greater senior management commitment; and
- faster resolution of safety issues.

For competent authorities, the impact is significant, since the implementation of SMSs by a large number of organisations would be required to be assessed, and some of the competent authorities might not initially have the necessary resources to do this.

Overall, considering that there are both significant positive and negative economic impacts, as highlighted above, an overall neutral effect is expected.

Part 21 | Option 1 — approved organisations (products)

This option excludes non-approved organisations, so the general costs may therefore be much lower than with Option 0; however, fewer safety benefits are expected, as fewer organisations would be affected.

For competent authorities, there will be less impact than with Option 0.

Considering both the negative and positive impacts, which should be of smaller absolute values than with Option 0, an overall neutral impact is expected over time.

Part 21 |Option 2 — all approved organisations (products as well as parts and appliances)

As mentioned earlier, the changes to these additional approved organisations will be limited because the organisations will build on their existing procedures and structures. The flexibility provisions would also apply to make the design/production management system proportionate to the size of the organisation and complexity of the services. The additional costs incurred are considered rather limited, keeping in mind the expected safety benefits.

It is also expected that most of the organisations that produce 'parts and appliances' under ETSO authorisation, and those that design and produce APUs, will also already hold a Part-145 approval for which an SMS will be required; so this will limit the overall economic impact for them.

Overall, neutral impacts are expected, although both the positive and negative impacts may be of greater magnitude than with Option 1.

4.4.7. Proportionality impact

In all these Part 21 options, the following elements have been introduced in order to reduce the implementation costs, which are more significant for smaller organisations:

(a) The acceptance that the design/production management system shall correspond to the size of the organisation, as well as to the nature and complexity of its activities, taking into account the hazards and associated risks that are inherent to these activities (see the proposed changes to 21.A.139(b) and 21.A.239(b));

(b) Flexibility provisions contained in the AMC & GM, which allow different scenarios that are proportionate to the size and complexity of the operations (e.g. a full-time equivalent safety manager is not required as long as the function of a 'safety manager' is properly discharged by another person, or by a group. The same applies for a formal safety review board. Both cases must be subject to a risk assessment and must be agreed by the competent authority);

(c) The planned recognition of SMS Industry Standard SM-0001 as an AMC, which will allow a level playing field with the Federal Aviation Administration (FAA) SMS approach because the recognition of that SMS Industry Standard by the FAA is also planned. The implementation costs could be further reduced by encouraging the implementation of common tools and data-sharing agreements for safety management at the level of industry associations; and

(d) The changes for Part 21 Section A (requirements on organisations) are limited to the introduction of the ICAO SMS framework based on an analysis of the gap between the ICAO SMS framework and the existing Part 21 requirements (see further details in Section 2.3.2). By reducing the complexity of the changes, an organisation can decide to build its SMS on its existing exposition manual, or to produce a separate SMS manual, which limits the impact on their documentation.

Part 21 |Option 0 — ICAO Annex 19 (all product organisations)

Significant negative disproportionate impacts are expected, since small organisations would face implementation costs that would include, but would not be limited to, additional staff, organisational changes, and new manuals. These changes might have significant negative repercussions for their businesses.

Part 21 | Option 1 — approved organisations (products)

Unlike Option 0, SMSs would not be applicable to small organisations that produce or design small aircraft (notably for General Aviation, as ELA1, and ELA2 aircraft, and their engines would be excluded). This is very similar to the approach taken in Opinions Nos 05/2016 and 06/2016 in order to sustain the GA Roadmap.

Therefore, significant positive proportionality impacts are expected.

Part 21 | Option 2 — all approved organisations (products as well as parts and appliances)

This option would maintain the same consistency that is identified in Option 1. Since SMSs would be applicable to organisations that design APUs and that produce parts and appliances covered by ETSO authorisations, some additional small organisations would be impacted. For them, the proportionality provisions mentioned above would significantly reduce the burden. In the same vein, as most of them would also hold a Part-145 approval, the same proportionality provisions are proposed in Part-145 for the sake of coherence.

As for Option 1, significant positive proportionality impacts are expected.

4.5. Conclusion

The table below provides a summary of the qualitative assessments made for the various criteria, which should be read from left to right, comparing Option 0 with Options 1 and 2. The table includes '0' values for Option 0 in order to allow an easy comparison with the other options. However, Option 0 might have both positive and negative impacts, as described in the text. Therefore, the reader should

check the values of Option 1 and 2 in terms of the differences when they are compared with Option 0.

Table 2: Conclusions for the options

Criteria	**Option 0 (basis)** Full implementation of ICAO Annex 19 affects all organisations that are responsible for the design and production of products.	**Option 1** Implementation of ICAO Annex 19 is limited to approved organisations that are responsible for the design and production of products.	**Option 2** Implementation of ICAO Annex 19 is limited to approved organisations that are responsible for the design and production of products and also for parts and appliances when an organisational approval is required under ETSO authorisation.
Safety	0 Better safety culture. Introduction of a systematic hazard identification process, risk controls and measurement of safety performance.	- The impact remains positive, but it is less than with Option 0 because SMSs are not applicable for non-approved organisations.	-/+ The impact remains positive, but is less than with Option 0 but higher than with Option 1, as SMSs are also applicable to parts and appliances under ETSO authorisations, as well as for APUs.
Economic	0 The implementation of an SMS will add costs. The cost-safety-analysis shows that the burden is on smaller organisations.	-/+ Lower costs but also fewer safety benefits than with Option 0. Non-approved organisations are not impacted.	-/+ Lower costs but also fewer benefits than with Option 0. Non-approved organisations are not impacted. However, for ETSO articles, there are higher costs than with Option 1, but these are mitigated by the fact that these organisations hold a maintenance approval for which an SMS is required.
Social	0+	0+	0+
Proportionality	0	+	+

	Significant implementation costs for small organisations	Small production (i.e. non-approved) organisations are not impacted.	Some small production organisations are impacted in a proportionate manner.
Total	0	-/+	+

Option 0 would promote the highest level of safety and the most positive social impact. The economic impact is confirmed for small organisations for which a formal approval is not needed.

Option 1, which falls short of the scope of ICAO Annex 19, has a less negative economic impact.

— It is considered to be an approach that is proportionate for the General Aviation segment (i.e. consistent with the applicability chosen for continuing airworthiness organisations — continuing airworthiness management organisations (CAMOs) and approved maintenance organisations (AMOs)).

— It limits the impact for smaller organisations if an approval is not needed. In addition, this impact is reduced by the fact that approved organisations can build on their existing structures, processes, procedures and exposition manuals or handbooks.

— The costs will be further reduced by including proportionality in the requirements, based on the size of the organisation and on the risks of the activities.

Option 2, which builds on Option 1, would also require approved organisations that design APUs to implement SMSs, (for which Part 21 currently mandates a DOA), as well as organisations that produce parts and appliances covered by an ETSO authorisation when a POA is required.

— It goes slightly beyond the scope of Annex 19.

— The implementation of SMSs for these additional organisations would certainly induce costs, but would also increase the level of safety and the social impact.

— To reduce the costs, the proportionality provisions should be used when the production activities for these parts and appliances bear fewer risks.

— In addition, for most of these organisations, synergies will be achieved through the use of an integrated SMS for their Part 21 and Part-145 activities.

In comparison with Option 2, Option 1 has the drawback that it defines two levels of DOAs and POAs: those that are required to implement the elements of an SMS that were missing (for products) and those that are not required to do so (for parts and appliances). Option 2 would avoid that differentiation in Part 21 (i.e. by avoiding the confusion introduced by compliance with two sets of procedures within the EU regulatory framework or within an organisation). It would also ensure that there is a level playing field and consistent airworthiness requirements for aircraft that participate in international air transport, including the assurance that EU certificates will still be accepted by third countries (therefore there would be a positive economic impact, as shown in the table).

Finally, the EASA questionnaire shows that among the organisations that have an ETSO authorisation, two out of three respondents considered that SMSs should also be applicable to parts and appliances. The rationale certainly stems from the fact that most of these organisations also hold Part-145 approvals, for which an SMS will be required, irrespective of the scope of the approval.

For all these reasons, **Option 2 is the preferred option**, as the applicability of SMSs would be extended to all design and production organisations for which Part 21 currently requires an approval (i.e. DOA holders or POA holders) that design or produce aircraft, engines or propellers, as well as parts and appliances under ETSO authorisation. This is fully in line with the outcome of the last ICAO Air Navigation Conference held in October 2018, urging organisations and authorities to develop robust risk management capabilities. The same conclusion can be drawn from the recent issuance of the Basic Regulation.

Note: the FAA also recommends SMSs for organisations in charge of TSO articles.

Question to stakeholders

Stakeholders are invited to comment on the IA and to provide any qualitative or quantitative information that they may find necessary to bring to the attention of EASA.

As a result, EASA might adjust the selection of the best option, as well as the relevant parts of the impact assessment on a case-by-case basis.

4.6. Monitoring and evaluation

Monitoring is a continuous and systematic process of data collection and analysis about the implementation/application of a rule/activity. It generates factual information for future possible evaluations and impact assessments; it also helps to identify actual implementation problems. With respect to this proposal, EASA would suggest to monitor various elements looking at short and medium term. Indeed, there are elements that should be monitored as soon as the rules are implemented and others for which some years would need to pass before the outcome could be measured. A proposal on indicators to check is presented below:

What to monitor	How to monitor	Who should monitor	How often to monitor
Number of occurrences reported by organisations affected by this initiative, split by severity/risk	ECCAIRS — the split in severity/risk should allow to distinguish the improvement of reporting versus the improvement of safety performance	EASA/competent authority - with the support of the Network of Analyst (NoA)	On a recurrent basis e.g. once a year
Number of occurrences reported by organisations affected by this initiative on topics directly related to SMS or safety performance split by severity/risk	ECCAIRS — the split in severity/risk should allow distinguish the improvement of reporting vs the improvement of safety performance	EASA/competent authority - with the support of the Network of Analyst (NoA)	On a recurrent basis e.g. once a year

Number of DOA/POA holders applying SMS as defined in Part 21 Number and level of findings related to SMS requirements per audit on Part 21 organisations at state level; effectiveness of SMS implementation (SMS maturity indicator)	Surveys, interviews, audits	competent authorities/EASA	On a recurrent basis e.g. once a year
Number of AMOs applying SMS as defined in Part-145 Number and level of findings related to SMS requirements per audit on Part-145 organisations at state level; effectiveness of SMS implementation (SMS maturity indicator)	Surveys, interviews, audits	competent authorities/EASA	On a recurrent basis e.g. once a year

This monitoring will have to be fine-tuned in accordance with the outcome of MST.026 from EPAS 2019-2023, for which the Safety Management Member States Technical bodies (SM.TeB) currently try to establish markers to assess the effective implementation of SMS throughout the European Union.

5. Proposed actions to support implementation

A number of actions took place during the preparation of this NPA, which helped to foster the understanding and implementation of the proposed new rules. It is also understood that more actions will come, notably for Design, Production and Maintenance insofar as the SMS-associated Opinions will reach the final stage (i.e. adoption and entry into force):

— Workshops

A series of thematic SMS workshops were organised, as follows:

— ACAM implementation for the competent authorities on 27 September 2018, as part of Part-M, point M.B.303, where a risk-based approach was discussed with the Member States;

— A 'Product certification & DOA workshop' on 29-31 October 2018, where this NPA was presented; a video is available here;

— An SM ICG Industry day on 13 November 2018 where the topic was 'SMSs made simple'; and

— An SMS workshop on 12-13 February 2019, to which competent authority Air Ops inspectors were invited - SMS implementation was extensively discussed and there are lessons learned to use in the Design, Production and Maintenance domains. The presentations and takeaways are available here.

EASA is also regularly in contact with the Certification Committee (C.COM); the Design and Manufacturing Technical Committee (DM.TeC); Production and Continuing Airworthiness Committee (P & CA) TeB; or Engineering and Maintenance Committee (EM.TeC).

Speakers who would like to propose SMS presentations in the fields of Production, Design and Maintenance can contact EASA at safety.management@easa.europa.eu. This may serve the preparation of an EASA SMS workshop in the fields of Production, Design and Maintenance, once the final text is known, after this consultation.

— SMS industry standards

SMS Industry Standard SM-0001[18] 'Implementing a SMS for Design, Manufacturing and Maintenance Providers' as earlier described in Section 2.3.3 is intended to improve safety and to enhance safety culture.

— Safety promotion and SMS

There is a significant volume of material that promotes SMSs on the EASA website here. An EASA 'safety promotion' policy is currently being developed to better support that activity in the future.

EASA also intends to develop, as appropriate, safety promotion material to better explain SMSs in the fields of design, production and maintenance; several targeted actions are already envisaged.

As part of the introduction of the 'safety risk management' in this NPA, 'fatigue' is a risk to be carefully mitigated, notably for Part-145 maintenance organisations (see Section 4.1.3). Guidelines on how to

[18] https://www.asd-europe.org/sites/default/files/atoms/files/SMS%20Standard_final%20issue%20A_20180917.pdf

introduce an effective fatigue risk management system (FRMS) within approved maintenance organisations will be developed.

Two safety promotion bulletins are being developed about:

— the risks associated with deviation from the use of maintenance data; and

— the risks associated with recurrent defects in aircraft or components.

— When it is ready, this material will be posted and promoted on the EASA website.

— Baines Simmons published a paper on 'Hazard Identification and Risk Management challenges throughout the Supply Chain'.

— Anyone can also propose SMS examples, tools and supporting educational material on the ICAO safety management implementation website (ICAO SMI), which is a repository of SMS documents to support the implementation of SMS and to complement the 4th edition of the ICAO Safety Management Manual (ICAO Doc 9859).

— Finally, SMS experts, who would like to propose safety promotion material or presentations, or SMS implementation cases in the fields of production, design and maintenance, can contact EASA at safety.management@easa.europa.eu.

6. References

6.1. Affected regulations

— Commission Regulation (EU) No 1321/2014 of 26 November 2014 on the continuing airworthiness of aircraft and aeronautical products, parts and appliances, and on the approval of organisations and personnel involved in these tasks (OJ L 362, 17.12.2014, p. 1)

— Commission Regulation (EU) No 748/2012 of 3 August 2012 laying down implementing rules for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations (OJ L 224, 21.8.2012, p. 1)

6.2. Affected decisions

— ED Decision 2012/020/R of the Executive Director of the Agency of 30th October 2012 on Acceptable Means of Compliance and Guidance Material for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations ('AMC and GM to Part 21') repealing Decision No 2003/01/RM of the Executive Director of the Agency of 17 October 2003

— ED Decision 2015/029/R of 17 December 2015 issuing acceptable means of compliance and guidance material to Part-M, Part-145, Part-66, and Part-147 of Regulation (EU) No 1321/2014 and repealing Decision 2003/19/RM of the Executive Director of the Agency of 28 November 2003 'AMC and GM to the Annexes to Regulation (EU) No 1321/2014 — Issue 2'

— ED Decision 2016/011/R of 11 July 2016 amending the Acceptable Means of Compliance and Guidance Material to Annex I (Part-M), Annex II (Part-145) and Annex III (Part-66) to Commission Regulation (EU) No 1321/2014 in order to support the implementation of Commission Regulation (EU) 2015/1536, and issuing the Acceptable Means of Compliance and Guidance Material to Annex Va (Part-T) 'Amendments to the AMC & GM to Annex I to Commission Regulation (EU) No 1321/2014 "Issue 2 — Amendment 1", amendments to the AMC & GM to Annex II to Commission Regulation (EU) No 1321/2014 "Issue 2 — Amendment 1", amendments to the AMC & GM to Annex III to Commission Regulation (EU) No 1321/2014 "Issue 2 — Amendment 1", and issue of the AMC & GM to Annex Va to Commission Regulation (EU) No 1321/2014 "Issue 1"'

6.3. Other reference documents

— Regulation (EU) No 376/2014 of the European Parliament and of the Council of 3 April 2014 on the reporting, analysis and follow-up of occurrences in civil aviation, amending Regulation (EU) No 996/2010 of the European Parliament and of the Council and repealing Directive 2003/42/EC of the European Parliament and of the Council and Commission Regulations (EC) No 1321/2007 and (EC) No 1330/2007

— ICAO Annex 19 'Safety Management', Edition 2, July 2016.

— ICAO Documentation 9859 'Safety Management Manual' (SMM), Edition 4; June 2018.

— Opinions Nos 05/2016 'Task force for the review of Part-M for General Aviation (PHASE II)' and 06/2016 'Embodiment of safety management system (SMS) requirements into Commission Regulation (EU) No 1321/2014 - SMS in Part-M'

— Common, general authority and organisation requirements already published in the areas of air operations (see Regulation (EU) No 965/2012), aircrew (see Regulation (EU) No 1178/2011), aerodromes (see Regulation (EU) No 139/2014), air traffic controller training (see Regulation (EU) 2015/340), and ATM/ANS (see. Regulation (EU) 2017/373).

— Opinion No 07/2016 'Embodiment of level of involvement (LOI) requirements into Part 21'

7. Appendices

7.1. Appendix I — Detailed summary of changes to Part 21

NPA 2019-05 (B) includes the draft implementing rules (IRs) as well the draft Acceptable Means of Compliance (AMC) and Guidance Material (GM) for Part 21. The following text is just a summary of the SMS-related changes to Part-21.

As mentioned in Section 2.1, Part 21 already includes organisational requirements for design and production organisations ensuring the safety of their products. Some of these requirements may be easily traced to the ICAO Annex 19 SARPs, such as:

— the identification of an accountable manager or, in the case of a DOA holder, of a head of the design organisation, ultimate responsible for the activities of the organisation;

— a system to ensure safety (i.e. the design assurance system for the DOA and the quality system for the POA are elements to ensure the safety of the product, part or appliance);

— independent monitoring of compliance with, and the adequacy of, the documented procedures;

— a system to record the activities;

— an exposition or handbook to document the procedures; and

— the management of changes.

A gap analysis was therefore performed first. Where gaps were identified, EASA developed draft text that inserted the missing elements and focused on the final goal of improving safety, without imposing requirements on how organisations should structure themselves in order to reach the final goal. Moreover, it was decided to keep the structure of Section A unchanged, and to reduce the changes as much as possible, keeping the current text if it achieves the goals of ICAO Annex 19.

The majority of changes were made to points 21.A.139 and 21.A.239, which were renamed respectively ‘production management organisation’ and ‘design management organisation’. The management system will include two elements:

(a) a safety management system; and

(b) a quality system for production organisations, or a design assurance system for design organisations.

The requirements related to the second element were not changed. In this way, organisations may keep their current structure and procedures. To build a safety management system, organisations will be required to do the following (ICAO Annex 19 SARPs missing in the current Part 21):

— develop a safety policy and the related objectives;

— appoint key safety personnel to execute the safety policy;

— establish, implement and maintain a safety risk management process;

— establish, implement and maintain a safety assurance process; and

— promote safety in the organisation.

If an organisation holds more than one organisational certificate that was issued on the basis of EU legislation, it is possible to integrate the different management systems into one single system.

A set of AMC & GM is proposed in this NPA that is consistent with the AMC & GM provided in other domains to demonstrate compliance with the SMS requirements. In this way, an organisation that already holds an organisational certificate (e.g. CAMO, Part-145, etc.) may reuse most of the evidence that it has already produced to demonstrate compliance with that regulation.

In this NPA, EASA proposes alternative AMC with which an organisation may also demonstrate compliance with 'SMS Industry Standard SM-0001'[19] which was developed by AIA-USA, AIA-B, AIA-C, ASD and GAMA (see the tables included in AMC1 21.A.139(c) and AMC1 21.A.239(c)). An organisation that intends to demonstrate compliance through the use of the SMS Industry Standard should thus additionally demonstrate compliance through the elements listed in those AMC in order to demonstrate compliance with the EU SMS requirements in Part 21.

The AMC contain proportionality elements that allow an organisation to adapt its management system according to its size and to the nature and complexity of its activities.

Whenever a point in Part 21 was amended to address an SMS requirement, the opportunity was taken to:

— enhance, when possible, the consistency between the requirements in the various subparts (e.g. point 21.A.245 has been amended to harmonise its content with the requirements defined for POA holders in point 21.A.145);

— keep in Section A only organisational requirements, thus separating them from the authority requirements that have been transferred into Section B:

  - the classification of findings in points 21.A.125B, 21.A.158 and 21.A.has been moved to Section B; and
  - some EASA forms pertaining to applicants, such as EASA Form 50, have been moved to Section A;

— move to Subpart A all the general requirements that are valid for all applicants:

  - in point 21.A.3A, requirements related to occurrence reports for production organisations were moved from points 21.A.129 and 21.A.165;
  - two new points 21.A.5 for 'record-keeping' and 21.A.9 for 'investigations' have been added, which replace all the similar requirements that were in different subparts;

— expand point 21.1 to generally define the competent authority; and

— incorporate some improvements, as proposed by the ASD task force 3 (TF3), to add clarity to the text of some points.

Moreover, a new process was included in Subparts F and G (production) for an applicant or for a competent authority to use an AltMoC. This new process is similar to what is already included in other aviation domains. The new point added defines the procedure to be applied by organisations to propose such AltMoC, and by competent authorities to inform EASA and other Member States about

[19] https://www.asd-europe.org/sites/default/files/atoms/files/SMS%20Standard_final%20issue%20A_20180917.pdf

it. It was considered that for design organisations, such a process is not required, since there is only one competent authority (EASA), and the process for an organisation to propose AltMoC is already available as part of EASA procedures. It has been used for a long time with positive results.

Changes in Section B were, in contrast, more extensive. In this case, it was considered beneficial to align the authority requirements with those defined in other aviation domains, and to also include the requirements that are applicable when EASA is the competent authority (which today are contained in EASA procedures). Therefore, several new points have been added to Subpart A of Section B ('General', applicable to all competent authorities) to include requirements for the authority's management system, the management of changes, record-keeping, and the use of qualified entities. Subparts F and G have been amended to harmonise the requirements for the oversight of organisations, while in Subpart J, requirements similar to Subpart G, applicable to EASA when issuing a DOA, and to oversight of organisations, have been included.

Point 21.B.40(b), resolution of disputes, has been deleted since EASA does not have any mandate for mediation of internal disputes in national organisations.

Finally, all the existing AMC and GM that were affected by changes introduced through this RMT were reviewed and aligned as much as possible with those that are anticipated to cover Part-CAMO and Part-145. In several cases, it was noticed that GM did not provide explanations or examples, but rather means of compliance. It was then decided to redefine them as AMC, or to split them into two parts, keeping explanations as GM and means of compliance as AMC.

List of changes to Part 21 IR

Only new, deleted or modified points are listed. Unmodified points are not reported.

Part 21 reference		Action
21.1	~~General~~ Competent authority	Change of the title in harmonisation with the content of the rule; all requirements currently spread in Part 21 and defining the competent authority, have been moved to this point
SECTION A — TECHNICAL REQUIREMENTS		
SUBPART A — GENERAL PROVISIONS		
21.A.1	Scope	Improvement of the text
21.A.3A	~~Failures, malfunctions and defects~~ Occurrence reporting	Requirements for production organisations have been moved from points 21.A.129 and 21.A.165
21.A.5	Record-keeping	Replacement of all the record-keeping requirements spread in Section A
21.A.9	Investigations	Replacement of all the investigation requirements spread in Section A
SUBPART B — TYPE CERTIFICATES AND RESTRICTED TYPE CERTIFICATES		
21.A.44	Obligations of the holder	References have been updated
~~21.A.55~~	~~Record-keeping~~	The requirement has been moved to 21.A.5
SUBPART D — CHANGES TO TYPE CERTIFICATES AND RESTRICTED TYPE CERTIFICATES		
~~21.A.105~~	~~Record-keeping~~	The requirement has been moved to 21.A.5
21.A.109	Obligations and EPA marking	References have been updated
SUBPART E — SUPPLEMENTAL TYPE CERTIFICATES		
21.A.118A	Obligations and EPA marking	References have been updated
SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL		
21.A.124A	Alternative means of compliance	New point to introduce AltMoC
21.A.125B	Findings	Update to move classification and requirements for competent authority to Section B
21.A.125C	Duration and continued validity	Text improvement and harmonisation with similar requirements in other Subparts
21.A.126	Production inspection system	The record-keeping requirements have been moved to 21.A.5
21.A.129	Obligations of the manufacturer	The reporting requirements have been moved to 21.A.3A
SUBPART G — PRODUCTION ORGANISATION APPROVAL		
21.A.134A	Alternative means of compliance	New point to introduce AltMoC
21.A.139	~~Quality~~ Production management system	Introduction of the 12 elements of the safety management system as defined by ICAO Annex 19
21.A.143	Exposition	Improvement of text
21.A.145	~~Approval requirements~~ Resources	Improvement of text
21.A.147	Changes to the ~~approved~~ production management system ~~organisation~~	Improvement of text
~~21.A.157~~	~~Investigations~~	The requirement has been moved to 21.A.9
21.A.158	Findings	Update to move classification and requirements for competent authority to Section B
21.A.159	Duration and continued validity	References have been updated

21.A.165	Obligations of the holder	Reporting requirements have been moved to 21.A.3A
SUBPART H — CERTIFICATES OF AIRWORTHINESS AND RESTRICTED CERTIFICATES OF AIRWORTHINESS		
~~21.A.180~~	~~Inspections~~	The requirement has been moved to 21.A.9
21.A.181	Duration and continued validity	References have been updated
SUBPART I — NOISE CERTIFICATES		
~~21.A.210~~	~~Inspections~~	The requirement has been moved to 21.A.9
21.A.211	Duration and continued validity	References have been updated
SUBPART J — DESIGN ORGANISATION APPROVAL		
21.A.239	Design ~~assurance~~ management system	Introduction of the 12 elements of the safety management system as defined by ICAO Annex 19
21.A.243	~~Data~~ Handbook	Improvement of text
21.A.245	~~Approval requirements~~ Resources	The requirement has been made consistent with requirement 21.A.145
21.A.247	Changes ~~in~~ to the design management ~~assurance~~ system	Improvement of text
~~21.A.257~~	~~Investigations~~	The requirement has been moved to 21.A.9
21.A.258	Findings	Update to move classification and requirements for competent authority to Section B
21.A.259	Duration and continued validity	References have been updated
21.A.263	Privileges	Minor changes proposed by this NPA, based on the text proposed with Opinion No 07/2016 (LOI), replacing 'design assurance system' with 'design management system'
21.A.265	Obligations of the holder	Minor changes proposed by this NPA, based on the text proposed with Opinion No 07/2016 (LOI)
SUBPART M — REPAIRS		
~~21.A.447~~	~~Record-keeping~~	The requirement has been moved to 21.A.5
21.A.451	Obligations and EPA marking	References have been updated
SUBPART O — EUROPEAN TECHNICAL STANDARD ORDER AUTHORISATIONS		
21.A.604	ETSO Authorisation for an Auxiliary Power Unit (APU)	References have been updated
21.A.609	Obligations of holders of ETSO authorisations	References have been updated
~~21.A.613~~	~~Record-keeping~~	The requirement has been moved to 21.A.5
~~21.A.615~~	~~Inspection by the Agency~~	The requirement has been moved to 21.A.9
21.A.619	Duration and continued validity	Improvement of text
SUBPART P — PERMIT TO FLY		
~~21.A.705~~	~~Competent authority~~	The requirement has been moved to 21.1
~~21.A.721~~	~~Inspections~~	The requirement has been moved to 21.A.9
21.A.723	Duration and continued validity	Improvement of text
~~21.A.729~~	~~Record-keeping~~	The requirement has been moved to 21.A.5

SECTION B — PROCEDURES FOR COMPETENT AUTHORITIES		
SUBPART A — GENERAL PROVISIONS		
21.B.5	Scope	The text has been improved to better specify scope of Section B and aligned with Part-CAMO Section B
21.B.10	Oversight documentation	New point aligned with Part-CAMO Section B
21.B.15	Information to EASA	New point aligned with Part-CAMO Section B
~~21.B.20~~	~~Obligations of the competent authority~~	Deleted to align with Part-CAMO Section B
21.B.20	Immediate reaction to a safety problem	New point aligned with Part-CAMO Section B
~~21.B.25~~	~~Requirements for the organisation of the competent authority~~	Deleted to align with Part-CAMO Section B
21.B.25	Management system	New point aligned with Part-CAMO Section B
21.B.30	Allocation of tasks to qualified entities	New point aligned with Part-CAMO Section B
~~21.B.30~~	~~Documented procedures~~	Deleted to align with Part-CAMO Section B
~~21.B.35~~	~~Changes in organisation and procedures~~	Deleted to align with Part-CAMO Section B
21.B.35	Changes in the management system	New point aligned with Part-CAMO Section B
21.B.40	Resolution of disputes	Paragraph b was deleted
~~21.B.45~~	~~Reporting/coordination~~	Deleted to align with Part-CAMO Section B
21.B.55	Record-keeping	The text has been aligned with Part-CAMO Section B
21.B.65	Suspension, limitation and revocation	New point aligned with Part-CAMO Section B
SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL		
21.B.115	Alternative means of compliance	New point aligned with Part-CAMO Section B
~~21.B.120~~	~~Investigation~~	Deleted to align with Part-CAMO Section B
21.B.120	Initial certification procedure	New point aligned with Part-CAMO Section B
21.B.125	Findings and corrective actions	Updated to include classification and requirements for competent authority, previously in Section A
~~21.B.130~~	~~Issue of letter of agreement~~	The content has been moved to 21.B.120, to be consistent with Part-CAMO Section B
~~21.B.145~~	~~Limitation, suspension and revocation of a letter of agreement~~	The requirement has been moved to 21.B.65
~~21.B.150~~	~~Record-keeping~~	The requirement has been moved to 21.B.55
SUBPART G — PRODUCTION ORGANISATION APPROVAL		
21.B.215	Alternative means of compliance	New point aligned with Part-CAMO Section B
~~21.B.220~~	~~Investigation~~	Deleted to align with Part-CAMO Section B
21.B.220	Initial certification procedure	New point aligned with Part-CAMO Section B
21.B.221	Oversight principles	New point aligned with Part-CAMO Section B
21.B.222	Oversight programme	New point aligned with Part-CAMO Section B
21.B.225	Findings and corrective actions	Updated to include classification and requirements for competent authority, previously in Section A
~~21.B.230~~	~~Issue of letter of agreement~~	The content has been moved to 21.B.220, to be consistent with Part-CAMO Section B
~~21.B.235~~	~~Continued surveillance~~	The content has been moved to 21.B.221 and 21.B.222 to align with Part-CAMO Section B

~~21.B.240~~	~~Amendment of a production organisation approval~~	Deleted to align with Part-CAMO Section B
21.B.240	Changes to a production organisation approval	New point aligned with Part-CAMO Section B
~~21.B.245~~	~~Suspension and revocation of a production organisation approval~~	The requirement has been moved to 21.B.65
~~21.B.260~~	~~Record-keeping~~	The requirement has been moved to 21.B.55
SUBPART H — AIRWORTHINESS CERTIFICATES AND RESTRICTED CERTIFICATES OF AIRWORTHINESS		
~~21.B.330~~	~~Suspension and revocation of a noise certificate~~	The requirement has been moved to 21.B.65
~~21.B.345~~	~~Record-keeping~~	The requirement has been moved to 21.B.55
SUBPART I — NOISE CERTIFICATES		
~~21.B.430~~	~~Suspension and revocation of a noise certificate~~	The requirement has been moved to 21.B.65
~~21.B.445~~	~~Record-keeping~~	The requirement has been moved to 21.B.55
SUBPART J — DESIGN ORGANISATION APPROVAL		
21.B.430	Initial certification procedure	New point aligned with Part-CAMO Section B
21.B.431	Oversight principles	New point aligned with Part-CAMO Section B
21.B.432	Oversight programme	New point aligned with Part-CAMO Section B
21.B.433	Findings and corrective actions	New point aligned with Part-CAMO Section B
21.B.435	Changes to a design organisation approval	New point aligned with Part-CAMO Section B
SUBPART P — PERMIT TO FLY		
~~21.B.530~~	~~Revocation of permits to fly~~	The requirement has been moved to 21.B.65
~~21.B.545~~	~~Record-keeping~~	The requirement has been moved to 21.B.55

APPENDICES		
Appendix VIII	EASA Form 52 — Aircraft statement of conformity	References updated
Appendix X	EASA Form 55 — Production organisation approval certificate	References updated
Appendix XI	EASA Form 65 — Letter of agreement for production without production organisation approval	References updated

List of changes to Part 21 AMC & GM

GENERAL	
GM1 Annex 1 Definitions	New
GM1 21.1 Competent authority — Responsibility for implementation	former GM 21.B.20
GM1 21.1(c) Competent authority — Permit to fly	former GM 21.A.705
SECTION A — TECHNICAL REQUIREMENTS	
Subpart A — General provisions	
AMC1 21.A.3A(a)(1) Occurrence reporting — Collection, investigation and analysis of data related to flammability reduction means (FRM) reliability	Amended **to make it also applicable to applicants for a certificate**

AMC2 21.A.3A(a)(1) Occurrence reporting — Collection, investigation and analysis of data related to ETOPS significant occurrences	Amended **to make it also applicable to applicants for a certificate**
GM1 21.A.3A(a) and 21.A.3A(b) Occurrence reporting — Collecting system ~~The system for collection, investigation and analysis of data~~	The title has been amended
GM2 21.A.3A(~~b)(~~a) and (b) Occurrence reporting	The reference in the title has been amended
GM1 21.A.3A(a)(1) and (b)(1) Occurrence reporting — Mandatory and voluntary occurrence reporting	New to provide an overview of Regulation (EU) No 376/2014
GM1 21.A.3A(a)(1)(ii) and (b)(1)(i) Occurrence reporting — Internal safety reporting scheme	New, based on GM1 ORO.GEN.200(a)(3)
AMC1 21.A.3A~~(b)(2)(~~d) Occurrence reporting — Reporting to EASA	The reference has been amended and the text improved
AMC1 21.A.5 Record-keeping	New, based on AMC1 ORO.GEN.220(b)
GM1 21.A.5 Record-keeping	New proposed by ASD TF3
AMC1 21.A.5(a) and 21.A.433(a) Record-keeping — Repair design	former AMC 21.A.433(a) and 21.A.447
GM1 21.A.5(a) and (b) Record-keeping — Recording and archiving system	Former GM 21.A.165(d) and (h), adapted to cover also design organisations
AMC1 21.A.5(e) Record-keeping — Record of personnel involved in design or production	Former AMC 21.A.145(d)(2), adapted to cover also design organisations
GM1 21.A.9 Investigations — Arrangements	Former GM 21.A.157, improvement of text
SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL	
AMC1 21.A.122 Eligibility — Link between design and production	References have been amended
AMC1 21.A.124 Application	Text moved form from AMC 21.B.120(c)(1)
~~GM 21.A.124(a) Application – Application form~~	Deleted, its content has been moved to AMC3 21.B.120(a)
AMC1 21.A.124A Alternative means of compliance	New based on AMC1 ORO.GEN.120(a)
~~GM No 1 to 21.A.125(b) Uncontrolled non-compliance with applicable design data~~	Deleted, its content has been moved to GM1 21.B.125(b)(1), 21.B.225(b)(1) and 21.B430(b)(1)
~~GM No 2 to 21.A.125(b) Examples of level one findings~~	Deleted, its content has been moved to GM1 21.B.125(b)
GM1 21.A.125B(a), 21.A.158(a) and 21.A.258(a) Findings — Causal analysis	New, as proposed in NPA 2013-01(C)
~~GM 21.A.126(b)(6) Production inspection system – Recording and record keeping~~	Deleted, its content has been moved to GM1 21.A.5 (a) and (b)

SUBPART G — PRODUCTION ORGANISATION APPROVAL FOR PRODUCTS, PARTS AND APPLIANCES	
~~GM 21.A.134 Application – Application form and manner~~	Deleted, its content has been moved to AMC1 21.A.134
AMC1 21.A.134 Application	Former AMC21.B.220(c) and GM 21.A.134
AMC1 21.A.134A Alternative means of compliance	New, based on AMC1 ORO.GEN.120(a)
GM1 21.A.139(c) Production management system — Safety management element	New, based on GM2 ORO.GEN.200(a)(1)
AMC1 21.A.139(c) Production management system — Safety management element	New to define the acceptability of the SMS industry standard
AMC1 21.A.139(c)(1) Production management system — Safety policy & objectives	New, based on AMC1 ORO.GEN.200(a)(2)
GM1 21.A.139(c)(1) Production management system — Safety policy	New, based on GM1 ORO.GEN.200(a)(2)
AMC1 21.A.139(c)(2) Production management system — Safety management element — Organisation and accountabilities	New, based on AMC1 ORO.GEN.200(a)(1)
GM1 21.A.139(c)(2) Production management system — Safety management element — Organisation and accountabilities	New, based on AMC1 ORO.GEN.200(a)(1)
AMC1 21.A.139(c)(3) Production management system — Safety risk management — Interfaces between organisations	New, based on GM1 ORO.GEN.200(a)(3)
AMC1 21.A.139(c)(3) and (4) Production management system — Safety management key processes	New, based on AMC1 ORO.GEN.200(a)(3)
GM1 21.A.139(c)(4)(ii) Production management system — Management of change	New, as proposed in NPA 2013-01(C)
AMC1 21.A.139(c)(4)(ii) Production management system — Management of change	New, as proposed in NPA 2013-01(C)
AMC1 21.A.139(c)(5) Production management system — Safety communication	New, based on AMC1 ORO.GEN.200(a)(4)
GM1 21.A.139(c)(5) Production management system — Safety promotion	New GM on safety promotion
AMC1 21.A.139(c)(5)(i) Production management system — Safety training	New, dedicated to safety training
GM1 21.A.139(c)(5)(i) Production management system — Safety training	New, dedicated to safety training
AMC1 ~~GM no1 to~~ 21.A.139~~(a)~~(d) Production management system — Quality system element	Amended to be extended to the production management system
AMC1 ~~GM~~ 21.A.139(d)(2)~~(b)(1)~~ Production management system ~~Quality System~~ — Elements of the quality system	References have been amended
GM1 ~~No2~~ 21.A.139(d)(1)~~(a)~~ Production management system — Conformity of supplied parts or appliances	References have been amended
AMC1 21.A.139(d)(2)(ii)~~(b)(1)(ii)~~ Production management system — Vendor and subcontractor assessment, audit and control — Production Organisation	References have been amended

Approval (POA) holder using documented arrangements with other parties for assessment and surveillance of a supplier	
AMC2 21.A.139(d)(2)(ii) ~~(b)(1)(ii)~~ Production management system — Vendor and sub-contractor assessment, audit and control — Production Organisation Approval (POA) holder using other party supplier certification	References have been amended; the text in the note and the point on competent authority approval have been moved to GM1 21.A.139(d)(2)(ii)
GM1 21.A.139(d)(2)(ii) Production management system — Vendor and sub-contractor assessment, audit and control	The text has been derived from the note and the point on competent authority approval in AMC No2 to 21.A.139(b)(1)(ii)
AMC1 21.A.139(e) Production management system — Documentation	New, based on GM1 ORO.GEN.200(a)(5)
AMC1 21.A.139(f) Production management system — Independent monitoring of compliance and adequacy	New, based on AMC1 ORO.GEN.200(a)(6))
~~GM No 1 to 21.A.139(b)(2) Quality System – Independent quality assurance function~~	Deleted
GM1 ~~No2~~ 21.A.139(f)~~(b)(2)~~ Production management system — Adequacy of procedures and monitoring function	References have been amended
GM1 21.A.143 Exposition - ~~Production Organisation Exposition (POE)~~	Amended to improve the text
AMC1 21.A.143(a)(1) Exposition	New, to include the commitment statement
AMC1 21.A.145(a) Resources	Text derived from GM 21.A.145(a)
GM1 21.A.145(a) Resources ~~Approval Requirements~~	Amended to move text containing means of compliance in AMC1 21.A.145(a)
GM1 21.A.145(b)(2) ~~Approval requirements~~ Resources — Airworthiness, noise, fuel venting and exhaust emissions /production data procedures	Amended to improve the text
AMC1 21.A.145(c)(1) Resources — Accountable manager	New, based on CAMO.A.305 and on GM 21.A.145(c)(1)
GM1 21.A.145(c)(1) ~~Approval requirements~~ Resources — Accountable manager	Amended, some of the text has been moved to AMC1 21.A.145(c)(1)
AMC1 ~~GM~~21.A.145(c)(2) ~~Approval requirements~~ Resources — Responsible managers	Amended to improve the text and include text based on AMC1 ORO.GEN.200(a)(6)
AMC2 21.A.145(c)(2) Resources — Competency of personnel	New, to define competency of personnel
AMC1 21.A.145(d)(1) ~~Approval requirements~~ Resources — Certifying staff	Amended to improve the text
~~AMC 21.A.145(d)(2) Approval requirements – Record of certifying staff~~	Deleted, its content has been moved to AMC1 21.A.5(e)
AMC1 21.A.145(d)(2)~~(3) Approval requirements~~ Resources – Evidence of authorisation	Amended to improve the text

AMC1 21.A.147 Changes to the production management system — Application for variation of scope and terms of the POA	New to include the text deleted from point 21.A.147 and the text from AMC No1 to 21.B.240
GM1 21.A.147~~(a)~~ Changes to the ~~approved~~ production management system ~~organisation~~ — Significant changes	Amended to improve the text
GM1 21.A.149 Transferability	References have been amended
AMC1 21.A.153 Changes to the terms of approval — Application for a change to the terms of approval	References have been amended
~~GM 21.A.157 Investigations – Arrangements~~	deleted
~~GM No 1 to 21.A.158(a) Uncontrolled non-compliance with applicable design data~~	Deleted, its content has been moved to GM1 21.B.125(b)(1), 21.B.225(b)(1) and 21.B430(b)(1)
~~GM No 2 to 21.A.158(a) Examples of level one findings~~	Deleted, its content has been moved to GM1 21.B.125(b)
~~GM 21.A.165(d) and (h) Obligations of the holder – Recording and archiving system~~	Deleted, its content has been moved to GM1 21.A.5(a) and (b))
GM1 21.A.125B(a), 21.A.158(a) and 21.A.258(a) Findings — Causal analysis	New, as proposed in NPA 2013-01(C)
SUBPART J — DESIGN ORGANISATION APPROVAL	
GM1 21.A.239(c) Design management system — Safety management element	New, based on GM2 ORO.GEN.200(a)(1)
AMC1 21.A.239(c) Design management system — Safety management element	New to define acceptability of SMS industry standard
AMC1 21.A.239(c)(1) Design management system — Safety policy & objectives	New, based on AMC1 ORO.GEN.200(a)(2)
GM1 21.A.239(c)(1) Design management system — Safety policy	New, based on GM1 ORO.GEN.200(a)(2)
AMC1 21.A.239(c)(2) Design management system — Safety management element — Organisation and accountabilities	New, based on AMC1 ORO.GEN.200(a)(1)
GM1 21.A.239(c)(2) Design management system — Safety management element — Organisation and accountabilities	New, based on AMC1 ORO.GEN.200(a)(1)
AMC1 21.A.239(c)(3) and (4) Design management system — Safety management key processes	New, based on AMC1 ORO.GEN.200(a)(3)
AMC1 21.A.239(c)(3) Design management system — Safety risk management — Interfaces between organisations	New, based on GM1 ORO.GEN.200(a)(3)
AMC1 21.A.239(c)(4)(ii) Design management system — Management of change	New, as proposed in NPA 2013-01(C)
GM1 21.A.239(c)(4)(ii) Design management system — Management of change	New, as proposed in NPA 2013-01(C)
AMC1 21.A.239(c)(5) Design management system — Safety communication	New, based on AMC1 ORO.GEN.200(a)(4)

GM1 21.A.239(c)(5) Design management system — Safety Promotion	New GM on safety promotion
AMC1 21.A.239(c)(5)(i) Design management system — Safety training	New, dedicated to safety training
GM1 21.A.239(c)(5)(i) Design management system — Safety training	New, dedicated to safety training
GM1 21.A.239(d)~~(a)~~ Design management system — Design assurance ~~system~~ element	Part of the text has been moved to AMC1 21.A.239(d)
AMC1 21.A.239(d) Design management system — Design assurance element	Former GM1 21.A.239(d)
AMC2 ~~GM~~21.A.239(d)~~(a)~~ Design management system — Design assurance element ~~system~~ for minor changes to type design or minor repairs to products	Change of title to reflect the content
~~AMC1 21.A.239(a)(3) Design assurance system – Independent system monitoring~~	Deleted
AMC1 21.A.239(d)(2)~~(b)~~ Design management ~~assurance~~ system — Independent verification ~~checking~~ function of the demonstration of compliance	References have been amended
GM1 21.A.239(d)(3)~~(c)~~ Design management system — Design assurance element ~~system~~	References have been amended
AMC1 21.A.239(e) Design management system — Documentation	New, based on GM1 ORO.GEN.200(a)(5)
AMC1 21.A.239(f) Design management system — Independent monitoring of compliance and adequacy	New, based on AMC1 ORO.GEN.200(a)(6))
AMC1 21.A.243(a) ~~Data~~ Handbook	Amended to improve the text, change references and include the commitment statement
AMC2 21.A.243(a) ~~Data~~ Handbook — Model content of handbook for organisations designing minor changes to type design or minor repairs to products	References have been amended
AMC1 21.A.243(d) Handbook — Statement of qualifications and experience	Text from GM No 1 to 21.A.243(d)
GM1 21.A.243(d) Handbook — Statement of qualifications and experience	Amended to update references, to include safety functions, and to delete means of compliance and move them to AMC1 21.A.243(d)
AMC2 21.A.243(d) Handbook ~~Data requirements~~ — Statement of the qualification and experience – Organisations designing minor changes to type design or minor repairs to products	Amended to improve the text
AMC ~~GM No~~1 21.A.245 Resources ~~Requirements for approval~~	Amended to improve the text and update references
AMC ~~GM No~~ 2 21.A.245 Resources ~~Requirements for approval~~ — Organisations designing minor changes to type design or minor repairs to products	Amended to improve the text

AMC1 21.A.245(a) Resources — Head of the design organisation	New, based on CAMO.A.305 and on GM 21.A.145(c)(1)
AMC1 21.A.245(b) Resources — Responsible managers	New text based on AMC1 ORO.GEN.200(a)(6) and AMC1 21.A.145(c)(2)
AMC2 21.A.245(b) Resources — Competency of personnel	New, to define competency of personnel
AMC1 21.A.247 Changes to the design management system — Application for a significant change or a variation of scope and terms of the DOA	New, text derived from the deleted point 21.A.247
GM1 21.A.247 Changes to ~~in~~ the design management ~~assurance~~ system	Amended to improve the text
~~GM 21.A.257(a) Investigations~~	Deleted, its content has been moved to GM1 21.A.9
GM1 21.A.125B(a), 21.A.158(a) and 21.A.258(a) Findings — Causal analysis	New, as proposed in NPA 2013-01(C)
SUBPART M — REPAIRS	
~~AMC1 AMC 21.A.433(a) and 21.A.447 Repair design and record keeping~~	Deleted, its content has been moved to AMC1 21.A.5(a) and 21.A.433(a)
SUBPART P — PERMIT TO FLY	
~~GM 21.A.705 Competent authority~~	Deleted, its content has been moved to GM1 21.1(c)
SECTION B PROCEDURES FOR COMPETENT AUTHORITIES	
SUBPART A — GENERAL	
~~GM 21.B.20 Responsibility for implementation~~	Deleted, its content has been moved to 21.1(a)(2) and (3)
AMC1 21.B.25 Management system — General	New, based on AMC1 ARO.GEN.120(e)
AMC2 ~~GM~~21.B.25 ~~Organisation~~ Management System — General	Amended to improve the text
~~GM 21.B.25(b) - Resources~~	deleted
~~GM 21.B.25(c) Qualification and training~~	deleted
AMC1 21.B.25(a)(1) Management system — Documented procedures	former AMC 21.B.30(a)
GM1 21.B.25(a)(2) Management system — Personnel	New, based on GM1 ARO.GEN.200(a)(2)
AMC1 21.B.25(a)(3) Management system — Qualification and training — General	New, based on AMC1 ARO.GEN.200(a)(2)
AMC2 21.B.25(a)(3) Management system — Qualification and training — Technical personnel including inspectors	New, based on the current AMC 145.B.10(3)
AMC3 21.B.25(a)(3) Management system — Initial and recurrent training — Inspectors	New, based on AMC2 ARO.GEN.200(a)(2)
AMC1 21.B.25(a)(5) Management system — Safety risk management process	New AMC on safety risk management as part of the management system framework for competent authorities

GM1 21.B.25(a)(5) Management system — Safety risk management process	New GM on the same subject
AMC1 21.B.25(d) Management system — Procedures available to EASA	New AMC based on AMC1 ARO.GEN.200(d)
~~AMC 21.B.30(a) Documented procedures~~	Deleted, its content has been moved to AMC1 21.B.25(a)(1)
GM1 21.B.30 Allocation of tasks to qualified entities — Certification tasks	New, based on GM1 ARO.GEN.205
~~AMC 21.B.35(a) Changes~~	deleted
~~GM No 1 to 21.B.45 Co-ordination with other related activities~~	deleted
~~GM No 2 to 21.B.45 Co-ordination~~	deleted
~~GM No 3 to 21.B.45 Reporting – Information relevant to registers established by the Agency~~	deleted
AMC1 21.B.55(a) Record-keeping — General	New, based on AMC1 ARO.GEN.220(a)
AMC1 21.B.55(a)(1) Record-keeping — Competent authority management system	New, based on AMC1 ARO.GEN.220(a)(1);(2);(3)
GM1 21.B.55 Record-keeping — Design approvals transferred to the Agency	References have been amended
GM1 21.B.55(e) Record-keeping — Traceability of release certificates	former GM 21.B.150(d)
AMC1 21.B.65 Suspension, limitation and revocation — Corrective action plan	former AMC 21.B.245
AMC1 21.B.65(c) Suspension, limitation and revocation — Information on security situation	New AMC, as proposed in NPA 2013-01(C)
GM1 21.B.65 Suspension, limitation and revocation	former GM 21.B.245
SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL	
GM1 21.B.115 and 21.B.215 Alternative means of compliance	New, based on GM1 ARO.GEN.120
AMC1 21.B.115(d) and 21.B.215(d) Alternative means of compliance — Demonstration of compliance	New, based on AMC1 ARO.GEN.120(e)
AMC1 21.B.120(a) Initial certification procedure — Investigation team	New, based on the curent 21.B.120
AMC2 21.B.120(a) Initial certification procedure — ~~Investigation team~~ Qualification criteria for the investigation team members	Amended to improve the text
AMC3 21.B.120(a)~~(c)(1)~~ Initial certification procedure — Evaluation of applications	Amended to improve the text and remove Form 60 that has been moved to AMC1 21.A.124
AMC4 ~~GM~~ 21.B.120(a)~~(c)(3)~~ Initial certification procedure — Investigation preparation and planning	Amended to improve the text and update references
GM1 21.B.120(c) Initial certification procedure — Auditing and investigation findings	The title has been updated
AMC1 21.B.120(d) Initial certification procedure — Issue of the letter of agreement	Former AMC 21.B.130 and GM 21.B.130(b)
GM1 ~~21.B.125(a)~~ 21.B.125(b), 21.B.225(b) and 21.B430(b) Findings and corrective actions — Objective evidence	former GM 21.B.125(a)

GM1 21.B.125(b) Findings and corrective actions — Examples of level 1 findings	Former GM No 2 to 21.A.125B(a)
GM1 21.B.125(b)(1) and 21.B.225(b)(1) Findings and corrective actions — Uncontrolled non-compliance with applicable design data	Former GM No1 to 21.A.125B(a)
AMC1 21.B.125(d) Findings and corrective actions — Notification of findings	New, based on AMC 21.B.225(a)
~~AMC 21.B.130 Issue of the letter of agreement~~	Deleted, its content has been oved to AMC1 21.B.120(d)
~~GM 21.B.130(b) Issue of the letter of agreement~~	Deleted, its content has been oved to AMC1 21.B.120(d)
AMC1 21.B.140 Amendment of a letter of agreement	The text has been improved and references have been amended
~~GM 21.B.150(d) Record keeping – Traceability of release certificates~~	Deleted, its content has been oved to GM1 21.B.55(e)
SUBPART G — PRODUCTION ORGANISATION APPROVAL	
GM1 21.B.115 and 21.B.215 Alternative means of compliance	New, based on GM1 ARO.GEN.120
AMC1 21.B.115(d) and 21.B.215(d) Alternative means of compliance — Demonstration of compliance	New, based on AMC1 ARO.GEN.120(e)
AMC1 21.B.220 and 21.B.430 Initial certification procedure — Verification of compliance	New, based on AMC1 ARO.GEN.310(a)
AMC1 ~~GM No 1 to~~ 21.B.220~~(c) Procedures for investigation~~ Initial certification procedure — Investigation preparation and planning	Amended to improve the text
AMC1 21.B.220 and 21.B.221 Initial certification procedure — Investigation team	New text, based on 21.B.220
AMC1~~GM~~ 21.B.220(a) Initial certification procedure — Investigation team	Amended to improve the text
~~AMC 21.B.220(c) Procedures for investigation – Evaluation of applications~~	Deleted, its content has been oved to AMC1 21.A.134
GM1 ~~No 2 to~~ 21.B.220~~(c)~~ Initial certification procedure — Organisation approval ~~Procedures for investigation~~ — General	Amended to improve the text and update references
GM2 ~~No 3 to~~ 21.B.220~~(c)~~ Initial certification procedure — ~~Procedures for investigation – POA applications~~ Application received from organisations with facilities/partners/suppliers/subcontractors located in a third country	Amended to update references
GM3 ~~No 4 to~~ 21.B.220~~(c)~~ Initial certification procedure ~~Procedures for investigation~~ — Competent authority surveillance of suppliers of a POA holder located in other Member States	Amended to update references
AMC1 21.B.220(d)(1) Initial certification procedure — Issuance of the certificate	former AMC No1 to 21.B.230
AMC1 21.B.221(a), (b) and (c) Oversight principles — Management system assessment	New, based on GM1 ARO.GEN.300(a);(b);(c)
AMC1 21.B.222 and 21.B.432 Oversight programme — Annual review	New, as proposed in NPA 2013-01(C)
GM1 21.B.222(a) Oversight programme — Maintenance of the POA — Work allocation within the competent authority	former GM 21.B.235(b)

AMC1 21.B.222(b) and 21.B.432(b) Oversight programme — Specific nature and complexity of the organisation — results of past oversight	New, based on AMC1 ARO.GEN.305(b);(d);(d1)
AMC2 21.B.222(b) and 21.B.432(b) Oversight programme — Subcontracted activities	New AMC added for determine the need for oversight for subcontracted organisations
GM1 21.B.222(b) Oversight programme	former GM 21.B.235(b) and (c)
AMC1 21.B.222(b)(1) Oversight programme — Audit	New, based on AMC1 ARO.GEN.305(b)(1)
GM1 21.B.222(b)(1)(ii) Oversight programme — Guide to the conduct of monitoring production standards	Former GM 21.B.235(a)(4)
AMC1 21.B.222(c) Oversight programme — Oversight planning cycle audit and inspection	New, based on AMC1 ARO.GEN.305(c)
AMC1 21.B.222(c) and 21.B.432(c) Oversight programme — Oversight planning cycle — Audit	New, based on AMC1 ARO.GEN.305(c)
AMC1 21.B.222(d) Oversight programme — Extension of the oversight planning cycle beyond 24 months	New, as proposed in NPA 2013-01(C)
GM1 ~~21.B.125(a)~~ 21.B.125(b), 21.B.225(b) and 21.B430(b) Findings and corrective actions — Objective evidence	former GM 21.B.125(a)
AMC1 21.B.225(d)~~(a)~~ Findings and corrective actions — Notification of findings	Amended to improve the text
GM1 21.B.125(b)(1) and 21.B.225(b)(1) Findings and corrective actions — Uncontrolled non-compliance with applicable design data	Former GM No1 to 21.A.125B(a)
~~AMC No 1 to 21.B.230 Issue of the certificate~~	Deleted, its content has been moved to AMC1 21.B.220(d)(1)
~~GM 21.B.235(a)(4) Guide to the conduct of monitoring production standards.~~	Deleted, its content has been moved to GM1 21.B.222(b)(1)(ii)
~~GM 21.B.235(b) Maintenance of the POA - Work allocation within the competent authority~~	Deleted, its content has been moved to GM1 21.B.222(a)
~~GM 21.B.235(b) and (c) Continued surveillance~~	Deleted, its content has been moved to GM1 21.B.222(b)
~~AMC 21.B.235(c) Continuation of POA~~	Deleted, its content has been moved to AMC1 21.B.222(b)(1) and 21.B.432(b)(1)
AMC1 ~~No 1 to~~ 21.B.240 Changes to a production organisation approval — Application for significant changes or a variation of scope and terms of the POA	Amended, based on AMC1 ARO.GEN.33 and removal of Form 51 that has been moved to AMC1 21.A.147
~~GM 21.B.245 Continued validity~~	Deleted, its content has been moved to GM1 21.B.65
~~AMC 21.B.245 Corrective action plan~~	Deleted, its content has been moved to AMC1 21.B.65
SUBPART J — DESIGN ORGANISATION APPROVAL	

AMC1 21.B.220 and 21.B.430 Initial certification procedure — Verification of compliance	New, based on AMC1 ARO.GEN.310(a)
AMC1 21.B.430 and 21.B.431 Initial certification procedure — Investigation team	New, based on AMC1 21.B.220 and 21.B.221
AMC1 21.B.430(a) Initial certification procedure — Organisation approval team	New, based on AMC1 21.B.220(a)
AMC1 21.B.430(d)(1) Initial certification procedure — Issuance of the certificate	New based on AMC1 21.B.220(d)(1)
AMC1 21.B.431(a), (b) and (c) Oversight principles — Management system assessment	New, based on GM1 ARO.GEN.300(a);(b);(c)
AMC1 21.B.222 and 21.B.432 Oversight programme — Annual review	New, as proposed in NPA 2013-01(C)
AMC1 21.B.222(b) and 21.B.432(b) Oversight programme — Specific nature and complexity of the organisation — results of past oversight	New, based on AMC1 ARO.GEN.305(b);(d);(d1)
AMC2 21.B.222(b) and 21.B.432(b) Oversight programme — Subcontracted activities	New AMC, added for determine the need for oversight for subcontracted organisations
AMC1 21.B.432(b)(1) Oversight programme — Audit	New, based on AMC1 ARO.GEN.305(b)(1)
AMC1 21.B.432(c) Oversight programme — Oversight planning cycle audit and inspection	New, based on AMC1 ARO.GEN.305(c)
AMC1 21.B.222(c) and 21.B.432(c) Oversight programme — Oversight planning cycle — Audit	New, based on AMC1 ARO.GEN.305(c)
AMC1 21.B.432(d) Oversight programme — Extension of the oversight planning cycle beyond 24 months	New, as proposed in NPA 2013-01(C)
GM1 21.B.125(b), 21.B.225(b) and 21.B4.30(b) Findings and corrective actions — Objective evidence	former GM 21.B.125(a)
AMC1 21.B.433(d) Findings and corrective actions — Notification of findings	New, based on AMC1 21.B.225(d) Findings and corrective actions - Notification of findings
AMC1 21.B.435 Changes to a design organisation approval — Application for significant changes or A variation of scope and terms of the DOA	New, based on on AMC1 ARO.GEN.33

7.2. Appendix II — Detailed summary of changes for Part-145

NPA 2019-05 (C) includes the draft implementing rules (IRs) as well the draft Acceptable Means of Compliance (AMC) and Guidance Material (GM) for Part-145. The following text is just a summary of the SMS-related changes to Part-145.

General changes to Part-145 text (IR/AMC/GM Section A and Section B):

— All references to a 'quality system' are replaced by a 'management system' or 'compliance monitoring' (depending on the context).

— All references to 'continuation training' are replaced by 'recurrent training'.

— All references to a 'surveyor' are replaced by 'inspector'.

— All references to personnel 'competence' are replaced by 'competency'.

— All references to personnel 'human factors training' are replaced by 'safety training'.

— General linguistic improvement.

— All references to 'approval schedule' are replaced by 'terms of approval'. Several changes were made to clarify the use of the terms 'approval' (in the sense of approval process) and 'certificate' (in the sense of the output of an approval process).

— References to Regulation (EC) No 216/2008 have been changed to Regulation (EU) 2018/1139.

— References to 'indirect approval' are adapted, where applicable, to the concept of 'change not requiring prior approval' (see 145.A.85).

— References to Flight Engineer (FE) licences are deleted, as these are no longer foreseen in Part-FCL (Commission Regulation (EU) No 1178/2011). The existing authorisation is to be 'grandfathered' through the amendment of Article 4.

— References to EASA Form 4 are deleted, as also discussed for Part-CAMO, and this is for all cases (nominated post holders, safety manager, compliance monitoring manager). The relevant points are amended to define the acceptance process through oversight and formal acceptance through approving the exposition.

— When the content of existing AMC or GM is amended or for new AMC or GM, the title of the AMC or GM takes a sequential number (e.g. AMC1, GM2, etc.).

— Remark: at the AMC & GM level, similarly to the approach taken for Part-CAMO and explained in Opinion No 06/2016, no distinction will be made between complex and non-complex organisations, and a single set of AMC & GM will be applicable to all Part-145 organisations.

List of changes to the Cover Regulation

COVER REGULATION	
Article 4	New paragraph 9 to ensure that any existing certification authorisation issued on the basis of a flight engineer licence continues to remain valid. New paragraph 10 for the adaptation of the organisation with the management system

List of changes to Part-145 IR*

* For Section B, because it is replaced by a new content aligned with Part-CAMO, the deleted rule points are not listed. For Section A, to give a complete picture, also the unchanged points are indicated.

Numbering convention:

Section A: any existing/amended point keeps the current numbering; any 'new' point takes the CAMO numbering.

Section B: full alignment with the Part-CAMO numbering

Part-145 reference	Action
145.1 ~~General~~ Competent authority	Change of the title in harmonisation with CAMO.A.105; consideration of new Basic Regulation Article 65 on reallocation of competent authority responsibility to EASA upon request of organisations operating in more than one Member State; consideration of new Basic Regulation Article 64 on reallocation of responsibility upon request of Member States
SECTION A — TECHNICAL AND ORGANISATION REQUIREMENTS	
145.A.10 Scope	Alignment with CAMO.A.005 (Scope)
145.A.15 Application for an organisation certificate	Alignment with CAMO.A.115 (Application for an organisation certificate)
145.A.20 Terms of approval	Alignment with part of CAMO.A.125 (Terms of approval and privileges of the organisation)
145.A.25 Facility requirements	No change
145.A.30 Personnel requirements	Alignment of with CAMO.A.305 (Personnel requirements) for the accountable manager and nominated persons The reference to flight engineer has been deleted in (j); the reference to 145.A.37 has been introduced in (k)
145.A.35 Certifying staff and support staff	See 'General changes'; point (j) is moved to 145.A.55 (Record-keeping)
~~145.A.36 Records of airworthiness review staff~~	Deleted, its content has been moved to 145.A.55 (Record-keeping)
145.A.37 Airworthiness review staff	New, based on CAO.A.045 (Airworthiness review staff) (Opinion No 05/2016)
145.A.40 Equipment and tools	No change
145.A.42 Components	No change
145.A.45 Maintenance data	see 'General changes'; the reference to 145.A.202 has been introduced in (c); the reference to HF has been introduced in (e)
145.A.47 Production planning	Points (b) and (d) have been amended to introduce the risks related to (respectively) personnel fatigue and external working teams
145.A.48 Performance of maintenance	Alignment with M.A.201(c) and 145.A.80; adaptation to management system
145.A.50 Certification of maintenance	Alignment with M.A.801 as amended by Opinion No 05/2016
145.A.55 ~~Maintenance and airworthiness review records~~ Record-keeping	Alignment with CAMO.A.220 (Record-keeping), former 145.A.35(j) and 145.A.36; alignment with ML.A.904(d) (Opinion No 05/2016) for airworthiness review records;
145.A.60 Occurrence reporting	Alignment with CAMO.A.160; elements of internal reporting to be covered by 145.A.202
145.A.65 ~~Safety and quality policy,~~ Maintenance procedures ~~and quality system~~	Delete 'safety/quality' elements (see 145.A.200); keep 145.A.65(b) with minor alignment to CAMO.A.315(e) (Continuing airworthiness management)

145.A.70 Maintenance organisation exposition (MOE)	Clarification on the MOE objective; certain alignment with CAMO.A.300 (CAME); deletion of 'where applicable' when not referring to a given implementing rule requirement
145.A.75 Privileges of the organisation	Simplification of (b) to prevent the interpretation that subcontracting maintenance to approved organisation is prohibited; the limitation of airworthiness review privilege inside the Member States has been added (see CAMO.A.125(e))
~~145.A.80 Limitations on the organisation~~	Deleted, its content has been moved to 145.A.48
145.A.85 Changes to the organisation	Alignment with CAMO.A.130 (Changes to the organisation)
145.A.90 Continued validity	Alignment with CAMO.A.135 (Continued validity)
145.A.95 Findings	Alignment with CAMO.A.150 (Findings)
145.A.120 Means of compliance	Alignment with CAMO.A.120 (Means of compliance)
145.A.140 Access	Alignment with CAMO.A.140 (Access)
145.A.155 Immediate reaction to a safety problem	Alignment with CAMO.A.155 (Immediate reaction to a safety problem)
145.A.200 Management system	Alignment with CAMO.A.200 (Management system)
145.A.202 Internal safety reporting scheme	Alignment with CAMO.A.202 (Internal safety reporting scheme)
145.A.205 Contracting and subcontracting	Based on CAMO.A.205 (Contracting and subcontracting) and ORO.GEN.205 (contracted activities) for purchased equipment or services

SECTION B — AUTHORITY REQUIREMENTS ~~PROCEDURES FOR COMPETENT AUTHORITIES~~	
145.B.005 Scope	New/aligned with Part-CAMO Section B
145.B.115 Oversight documentation	New/aligned with Part-CAMO Section B
145.B.120 Means of compliance	New/aligned with Part-CAMO Section B with a minor clarification in point (a)
145.B.125 Information to EASA	New/aligned with Part-CAMO Section B
145.B.135 Immediate reaction to a safety problem	New/aligned with Part-CAMO Section B
145.B.200 Management system	New/aligned with Part-CAMO Section B with a minor difference in point (d)
145.B.205 Allocation of tasks to qualified entities	New/aligned with Part-CAMO Section B with a minor change in point (a) to remove the reference to the Member State, because the regulated entity is the Competent Authority.
145.B.210 Changes in the management system	New/aligned with Part-CAMO Section B
145.B.220 Record-keeping	New/aligned with Part-CAMO Section B
145.B.300 Oversight principles	New/aligned with Part-CAMO Section B with a minor improvement in points (d) and (e)
145.B.305 Oversight programme	New/aligned with Part-CAMO Section B

145.B.310 Initial certification procedure	New/aligned with Part-CAMO Section B with a minor clarification in point (b)
145.B.330 Changes — organisations	New/aligned with Part-CAMO Section B with a clarification in point (e)
145.B.350 Findings and corrective actions	New/aligned with Part-CAMO Section B
145.B.355 Suspension, limitation, and revocation	New/aligned with Part-CAMO Section B

APPENDICES TO PART-145	
Appendix I — Authorised Release Certificate — EASA Form 1	No change
Appendix II — Class and ~~R~~ratings ~~S~~system used for the ~~A~~approval of ~~M~~maintenance ~~O~~organisations ~~referred to in Annex I (Part-M) Subpart F and Annex II (Part-145)~~	Incorporate the content from Appendix IV to Part-M; adapt indirect approval of capability list with the approach of change not requiring prior approval
Appendix III — Maintenance ~~O~~organisation certificate ~~Approval referred to in Annex II (Part-145)~~ — EASA Form 3-145	Alignment with Appendix I to Part-CAMO (Certificate); Change related to the airworthiness review privilege (modified by Opinion No 06/2016)
Appendix IV — Conditions for the use of staff not qualified in accordance with Annex III (Part-66) referred to in points 145.A.30(j)1 and 2	No change

List of changes to Part-145 AMC & GM*

*For Section A, only AMC & GM affected by this RMT are listed. For Section B, because it is replaced by a new content aligned with Part-CAMO, the deleted AMC & GM are not listed.

GENERAL	
GM1 to Annex II (Part-145) Definitions	New
SECTION A — TECHNICAL AND ORGANISATION REQUIREMENTS	
AMC1 145.A.10 Scope	Minor adaptation to management system
GM1 145.A.10 Scope	Adaptation to management system; clarification that the external organisation performing the independent audit is subcontracted.
AMC1 145.A.15 Application for an organisation certificate	Alignment with AMC M.A.702 (to become AMC1 CAMO.A.115)
AMC2 145.A.15 Application for an organisation certificate	New; information on 'pre-audit'
GM1 145.A.15(b) Application for an organisation certificate	New; the purpose is to explain that the 'shall' in 145.A.15(b) does not mean that 'changes not requiring prior approval' (145.A.85(c)) is a privilege and can be used from the start of operation
AMC1 145.A.25(a) Facility requirements	New point (5), introduced to clarify that, considering a risk assessment, flexibility is allowed for certain base maintenance tasks to be carried in facility other than a hangar enclosing the whole aircraft (EM.TEC input).
AMC1 145.A.30(a) Personnel requirements	Alignment with AMC M.A.706(a) (to become AMC1 CAMO.A.305(a))
AMC1 145.A.30(b) Personnel requirements	Partial alignment with AMC M.A.706 (to become AMC1 CAMO.A.305(a)(3)) and adaptation to management system; quality and safety manager are not subject of this AMC
GM1 145.A.30(b) Personnel requirements	New; explanation of the purpose of 'ensuring compliance' (as opposed to 'monitoring compliance')
AMC1 145.A.30(c) Personnel requirements	Adaptation to management system
AMC1 145.A.30(c);(ca) Personnel requirements	New AMC for the safety management and compliance monitoring function (based on AMC1 ORO.GEN.200(a)(1) and AMC1 ORO.GEN.200(a)(6))
GM1 145.A.30(ca) Personnel requirements	New GM for the safety manager, based on GM1 ORO.GEN.200(a)(1)
AMC1 145.A.30(cc) Personnel requirements	New AMC for nominated persons, based on AMC M.A.706 (to become AMC1 CAMO.A.305(c))
AMC1 145.A.30(d) Personnel requirements	Adaptation to management system
AMC1 145.A.30(e) Personnel requirements	Adaptation to management system
AMC2 145.A.30(e) Personnel requirements	Adaptation to management system and change from HF training to safety training
AMC3 145.A.30(e) Personnel requirements	Simplification and update of reference

AMC4 145.A.30(e) Personnel requirements	Simplification and 'general change'
AMC5 145.A.30(e) Personnel requirements	New AMC, based on the current GM2 145.A.30(e), AMC M.A.706(k) (to become AMC3 CAMO.A.305(g)) and AMC M.A.607
GM1 145.A.30(e) Personnel requirements	Adaptation to management system as safety training
GM2 145.A.30(e) Personnel requirements	Elements moved to new AMC5 145.A.30(e); Adaptation to management system and safety training
GM3 145.A.30(e) Personnel requirements	Adaptation to management system
GM4 145.A.30(e) Personnel requirements	New GM, based on EHFAG (former HF CAG) inputs
GM5 145.A.30(e) Personnel requirements	New GM, based on HF CAG inputs
GM6 145.A.30(e) Personnel requirements	New GM, added to clarify the scope of safety training depending on the complexity of the organisation.
AMC1 145.A.30(f) Personnel requirements	See 'general changes'
AMC1 145.A.30(h) Personnel requirements	See 'general changes'
AMC1 145.A.30(j)(4) Personnel requirements	Deletion of the point relevant to flight engineer which no longer exists under Part-FCL.
~~GM 145.A.30(j)(4) Personnel requirements (Flight crew)~~	Deleted because it is relevant to flight engineer which no longer exist under Part-FCL.
AMC1 145.A.30(j)(5) Personnel requirements	Adaptation to management system
AMC1 145.A.30(j)(5)(i) Personnel requirements	Adaptation to management system
AMC1 145.A.30(j)(5)(ii) Personnel requirements	Adaptation to management system
AMC1 145.A.35(a) Certifying staff and support staff	See 'general changes' and update of reference
AMC1 145.A.35(d) Certifying staff and support staff	See 'general changes' and adaptation to management system
AMC1 145.A.35(e) Certifying staff and support staff	See 'general changes' and update of reference
AMC1 145.A.35(f) Certifying staff and support staff	See 'general changes' and update of reference
AMC1 145.A.45(c) Maintenance data	Use of internal safety reporting scheme (145.A.202)
AMC1 145.A.45(d) Maintenance data	Adaptation to management system
AMC1 145.A.45(e) Maintenance data	New point linked to the risk when using a work card system provided by the operator/CAMO
AMC1 145.A.47(b) Production planning	New AMC related to fatigue risk management
~~AMC~~ GM1 145.A.47(b) Production planning	AMC changed to GM and expanded with fatigue information
GM1 145.A.47(d) Production planning	New GM to explain the meaning of 'external working teams'
AMC1 145.A.48(a) ~~AMC 145.A.80 Limitations on the organisation~~ Performance of maintenance	Provision extended to component maintenance organisation; see also 'general changes'
AMC1 145.A.48(c)(2) ~~AMC1 145.A.48(b)~~ Performance of maintenance	Reference of the AMC amended to reflect the revised implementing rule
AMC2 145.A.48(c)(2) ~~AMC2 145.A.48(b)~~ Performance of maintenance	Reference of the AMC amended; clarification provided on the source used for critical task identification

AMC3 145.A.48(c)(2) ~~AMC3 145.A.48(b)~~ Performance of maintenance	Reference of the AMC amended
AMC4 145.A.48(c)(2) ~~AMC4 145.A.48(b)~~ Performance of maintenance	Reference of the AMC amended
AMC1 145.A.48(c)(3) Performance of maintenance	Amended references
GM1 145.A.48(c)(3) Performance of maintenance	Amended references; correct the term 'duplicate' by 'independent'
GM1 145.A.48(c)(4) ~~GM 145.A.48(d)~~ Performance of maintenance — critical design configuration control limitations (CDCCL)	Amended references
GM1 ~~AMC~~ 145.A.50(a) Certification of maintenance	AMC changed into GM; clarification of the responsibilities linked to the issue of a CRS
AMC1 145.A.50(b) Certification of maintenance	Alignment with ICAO Annex 6, Part I, Paragraph 8.8.
AMC1 145.A.50(e) Certification of maintenance	Change relevant to the convention for referencing the rule
AMC1 145.A.55 Record-keeping	New AMC; alignment with AMC1 ORO.GEN.220(b)
GM1 145.A.55 Record-keeping	New GM; alignment with GM1 ORO.GEN.220(b)
GM1 145.A.55(a)(1) Record-keeping ~~Maintenance and airworthiness review records~~	Amended to limit to 'maintenance records'; general points 4., 5. and 6. covered by AMC1 145.A.55
AMC1 145.A.55(a)(3) ~~AMC 145.A.55(c)~~ Record-keeping ~~Maintenance and airworthiness review records~~	Amended reference and title
AMC1 145.A.55(d) ~~AMC 145.A.35(j) Certifying staff and support staff~~ Record-keeping	Amended to limit to certifying staff and support staff records; See 'general changes'
AMC2 145.A.55(d) ~~AMC 145.A.36~~ Record-keeping ~~Records of airworthiness review staff~~	AMC 145.A.36 relocated under 145.A.55(d)
~~AMC 145.A.60(b) Occurrence reporting~~	Deleted; intent covered by the new AMC1 145.A.202
~~AMC 145.A.65(a) Safety and quality policy, maintenance procedures and quality system~~	Deleted; covered by AMC1 145.A.200(a)(2)
AMC1 145.A.65~~(b) Safety and quality policy, m~~Maintenance procedures ~~and quality system~~	Amended reference and use of internal safety reporting scheme (145.A.202)
GM1 145.A.65 Maintenance procedures	New GM added to provide guidance on the design and presentation of technical procedures in line with human factors principles.
GM2 145.A.65~~(b)~~(1) ~~Safety and quality policy, m~~Maintenance procedures ~~and quality system~~	Amended references
AMC1 145.A.65~~(b)~~(2) ~~Safety and quality policy, m~~Maintenance procedures ~~and quality system~~	Amended references
AMC1 145.A.70(a) Maintenance organisation exposition (MOE)	Amended to reflect the change to the implementing rule and adaptation to management system
GM1 145.A.70(a) Maintenance organisation exposition (MOE)	Same as above ; point 9 transferred to new AMC1 145.A.70(a)(1)

AMC1 145.A.70(a)(1) Maintenance organisation exposition (MOE)	New AMC, based on point 9 of GM 145.A.70(a); the text of the accountable manager statement is simplified.
AMC1 145.A.75(b) Privileges of the organisation	See 'general changes' and adaptation to management system and change to 145.A.75; note in paragraph 1 on the FAR Part 145 deleted, because relevant to foreign regulation.
GM1 145.A.75(b) Privileges of the organisation	New GM to clarify that it is not prohibited to subcontract certain activities to an approved organisation. The rule does neither foresee an AMO to work solely as subcontractor (they should exercise their privilege).
AMC1 145.A.85 Changes to the organisation	New AMC; alignment with AMC1 ORO.GEN.130
AMC2 145.A.85 Changes to the organisation	New AMC, based on AMC1 ORO.GEN.130(b)
GM1 145.A.85 Changes to the organisation	New GM to clarify that 145.A.85 is also applicable to MOE changes
GM1 145.A.85(a)(1) Changes to the organisation	New GM to provide example for changes that may affect the scope of the certificate or the terms of approval
GM2 145.A.85(a)(1) Changes to the organisation	New GM; alignment with GM2 ORO.GEN.130(a)
GM1 145.A.85(b) Changes to the organisation	New GM in the spirit of GM1 ORO.GEN.130(b)
GM1 145.A.85(c) Changes to the organisation	New GM clarifying the intent of 'changes not requiring prior approval'
AMC1 145.A.95 Findings	New AMC, based on AMC1 ORO.GEN.150(b)
GM1 145.A.95 Findings	New GM, as proposed in NPA 2013-01(C), also to be used for compliance monitoring (145.A.200(a)(6))
AMC1 145.A.120 Means of compliance	New GM, based on AMC1 ORO.GEN.120(a)
GM1 145.A.200 Management system	New GM explaining the management system concept
AMC1 145.A.200(a)(1) Management system	New AMC, based on AMC1 ORO.GEN.200(a)(1)
GM1 145.A.200(a)(1) Management system	New GM, based on GM2 ORO.GEN.200(a)(1)
GM2 145.A.200(a)(1) Management system	New GM, aligned with GM3 ORO.GEN.200(a)(1)
AMC1 145.A.200(a)(2) Management system	New AMC, based on AMC1 ORO.GEN.200(a)(2)
GM1 145.A.200(a)(2) Management system	New GM, based on GM1 ORO.GEN.200(a)(2) and extended to safety culture and just culture
AMC1 145.A.200(a)(3) Management system	New AMC, based on AMC1 ORO.GEN.200(a)(3)
GM1 145.A.200(a)(3) Management system	New GM, based on GM4 ORO.GEN.200(a)(3)
GM2 145.A.200(a)(3) Management system	New GM, as proposed in NPA 2013-01(C)
AMC1 145.A.200(a)(4) Management system	New AMC, based on AMC1 ORO.GEN.200(a)(4)
GM1 145.A.200(a)(4) Management system	New GM on safety promotion
GM1 145.A.200(a)(5) Management system	New GM, based on GM1 ORO.GEN.200(a)(5)
AMC1 145.A.200(a)(6) Management system	New AMC, based on AMC 145.A.65(c)(1) point 1
AMC2 145.A.200(a)(6) ~~AMC 145.A.65(c)(1) Safety and quality policy, maintenance procedures and quality system~~ Management system	AMC based on AMC 145.A.65(c)(1) points 2. to 11.
AMC3 145.A.200(a)(6) Management system	New AMC, based on GM1 ORO.GEN.200(a)(6)

AMC4 145.A.200(a)(6) ~~AMC 145.A.65(c)(2) Safety and quality policy, maintenance procedures and quality system~~ Management system	AMC based on AMC 145.A.65(c)(2)
GM1 145.A.200(a)(6) Management system	New GM to clarify that the compliance monitoring function itself needs to be monitored for compliance.
GM2 145.A.200(a)(6) ~~GM 145.A.65(c)(1) Safety and quality policy, maintenance procedures and quality system~~ Management system	GM based on GM 145.A.65(c)(1), but extensively revised to provide better guidance and an example on compliance monitoring audit plan.
AMC1 145.A.202 Internal safety reporting scheme	New AMC, based on NPA 2013-01(C)
GM1 145.A.202 Internal safety reporting scheme	New GM, based on GM1 ORO.GEN.200(a)(3)
GM1 145.A.205 Contracting and subcontracting	New GM, based on GM2 ORO.GEN.205 and extended to address particular maintenance aspects
GM2 145.A.205 Contracting and subcontracting	New GM to explain the difference between contracting and subcontracting maintenance
SECTION B — AUTHORITY REQUIREMENTS ~~PROCEDURE FOR COMPETENT AUTHORITIES~~	
GM1 145.B.120 Means of compliance	New GM, based on GM1 ARO.GEN.120
AMC1 145.B.120(e) Means of compliance	New AMC, based on AMC1 ARO.GEN.120(e)
AMC1 145.B.200 Management system	New AMC, based on current AMC 145.B.10(1)
AMC2 145.B.200 Management system	New AMC, based on GM1 ARO.GEN.200(a)
AMC1 145.B.200(a)(1) Management system	New AMC, aligned with AMC1 ARO.GEN.200(a)(1)
GM1 145.B.200(a)(2) Management system	New GM, based on GM1 ARO.GEN.200(a)(2)
AMC1 145.B.200(a)(3) Management system	New AMC, based on AMC1 ARO.GEN.200(a)(2)
AMC2 145.B.200(a)(3) Management system	New AMC, based on the current AMC 145.B.10(3)
AMC3 145.B.200(a)(3) Management system	New AMC, based on AMC2 ARO.GEN.200(a)(2)
AMC1 145.B.200(a)(5) Management system	New AMC on safety risk management as part of the management system framework for competent authorities
GM1 145.B.200(a)(5) Management system	New GM on the same subject
AMC1 145.B.200(d) Management system	New AMC, based on AMC1 ARO.GEN.200(d)
GM1 145.B.205 Allocation of tasks to qualified entities	New GM, based on GM1 ARO.GEN.205
AMC1 145.B.220(a) Record-keeping	AMC based on AMC1 ARO.GEN.220(a) and the current AMC 145.B.55
AMC1 145.B.220(a)(1) Record-keeping	New AMC, based on AMC1 ARO.GEN.220(a)(1);(2);(3)
AMC1 145.B.300(a);(b);(c) Oversight principles	New AMC, based on GM1 ARO.GEN.300(a);(b);(c) and AMC2 ARO.GEN.300(a);(b);(c)
AMC1 145.B.300(f) Oversight principles	New AMC on information deemed useful for oversight
AMC1 145.B.305(a);(b) Oversight programme	New AMC, as proposed in NPA 2013-01(C)
AMC1 145.B.305(b) Oversight programme	New AMC, based on AMC1 ARO.GEN.305(b);(d);(d1)
AMC2 145.B.305(b) Oversight programme	New AMC added for determine the need of oversight for subcontracted organisations
AMC1 145.B.305(b)(1) Oversight programme	New AMC, based on AMC1 ARO.GEN.305(b)(1)
AMC1 145.B.305(c) Oversight programme	New AMC, based on AMC1 ARO.GEN.305(c)

AMC2 145.B.305(c) Oversight programme	New AMC, based on AMC2 ARO.GEN.305(c)
AMC1 145.B.305(d) Oversight programme	New AMC, as proposed in NPA 2013-01(C)
AMC1 145.B.310 Initial certification procedure	New AMC, based on AMC1 ARO.GEN.310(a)
AMC1 145.B.310(a) Initial certification procedure	AMC based on the current AMC 145.B.20(3)
AMC1 145.B.310(c) Initial certification procedure	AMC based on the current AMC 145.B.20(6)
AMC2 145.B.310(c) Initial certification procedure	AMC based on the current AMC 145.B.20(5)
AMC1 145.B.310(d) Initial certification procedure	AMC based on the current AMC 145.B.20(6)
AMC1 145.B.310(e)(2) Initial certification procedure	AMC based on the current AMC 145.B.20(1) and AMC 145.B.25(1)
AMC1 145.B.330 Changes — organisations	AMC based on AMC1 ARO.GEN.330 and the current AMC 145.B.35
GM1 145.B.330 Changes — organisations	New GM, based on GM1 ARO.GEN.330
GM1 145.B.350(b);(c) Findings and corrective actions	GM, based on the current AMC 145.B.50(a)
AMC1 145.B.355(c) Suspension, limitation and revocation	New AMC, as proposed in NPA 2013-01(C)
APPENDICES TO AMC TO ANNEX II (PART-145)	
~~Appendix I to AMC 145.B.20(1) EASA Form 4~~	Deleted because EASA Form 4 is not used any more
Appendix II to AMC2 145.B.310(c) ~~AMC 145.B.20(5)~~ EASA Form 6	Update of reference
Appendix III to AMC 145.A.15 EASA Form 2	Update of reference (Part-M Subpart G is deleted with Opinion No 06/216)
Appendix IV to AMC3 145.A.30(e) and AMC2 145.B.200(a)(3) ~~145.B.10(3)~~ Fuel ~~T~~tank ~~S~~safety ~~T~~training	See 'general changes'

7.3. Appendix III — EASA questionnaire

In the context of the preparation of the RIA for RMT.0251 Phase II, EASA launched a survey to the competent authorities and industry.

The aim of the survey was to gather evidence to support the applicability of SMSs, and to identify where proportionality is needed, as well as to collect data on potential impacts, difficulties and opportunities in the implementation of SMSs.

The input supported the analysis of the problem definition and the analysis of the options. The survey was run from 21 December 2017 until 15 February 2018, and it collected specific SMS data related to the design, production and maintenance domains. Some key results of the survey, including a description of the respondents, are as follows:

The survey was responded to by 293 organisations [285 organisations with a single or multiple approval(s) and 8 associations/individual representatives] and 11 competent authorities. The organisations that hold multiple approvals were invited to provide a consolidated response, representing all parts of the organisation that hold approvals.

The organisations were classified into 12 groups according to their business areas or the approvals they hold.

The following provides a more detailed overview of the organisations that replied to the questionnaire, grouped according to Part 21 and Part-145 and the number of employees:

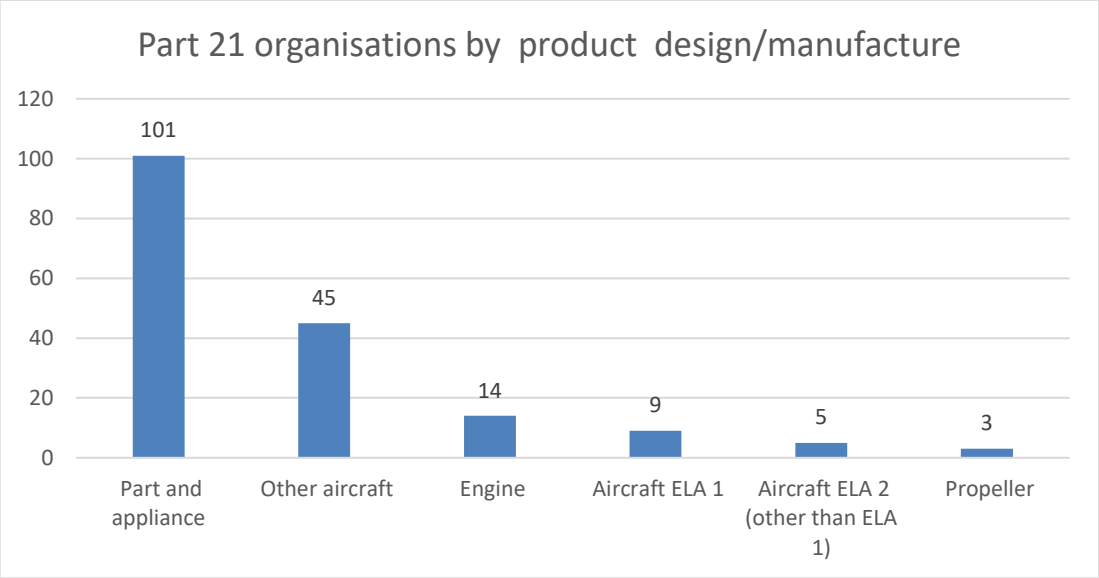


Figure 1: Part 21 organisations by product design/manufacture

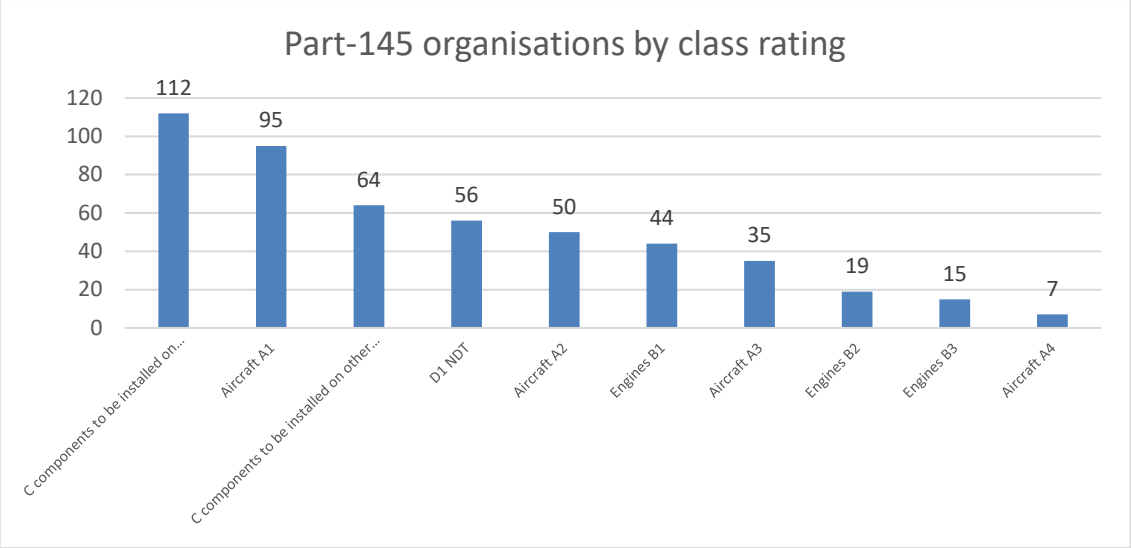


Figure 2: Part-145 organisations by class rating

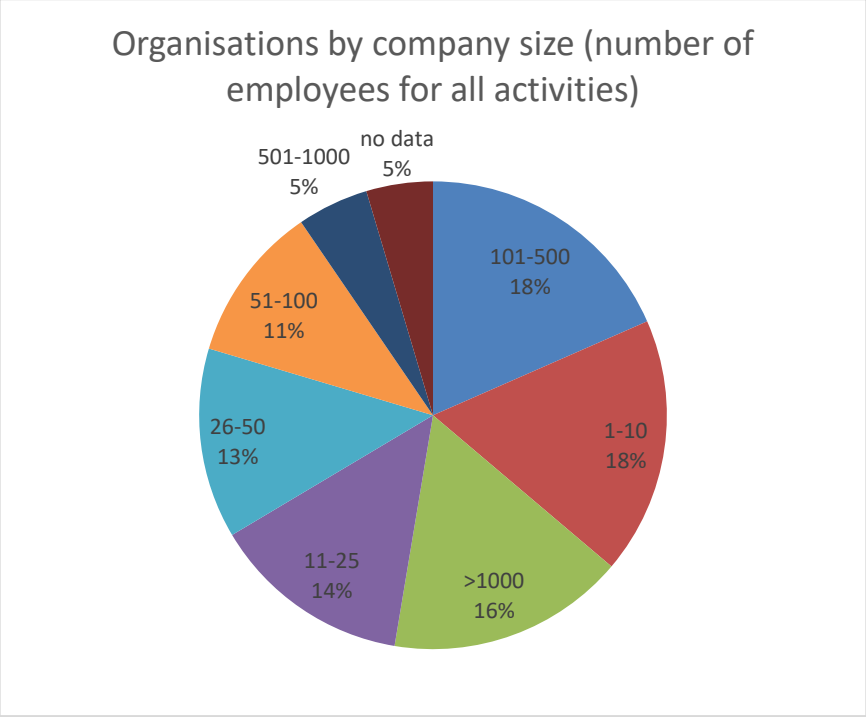


Figure 3: Organisations by company size (number of employees for all activities)

The following are some of the responses to the survey questions on the implementation of SMSs.

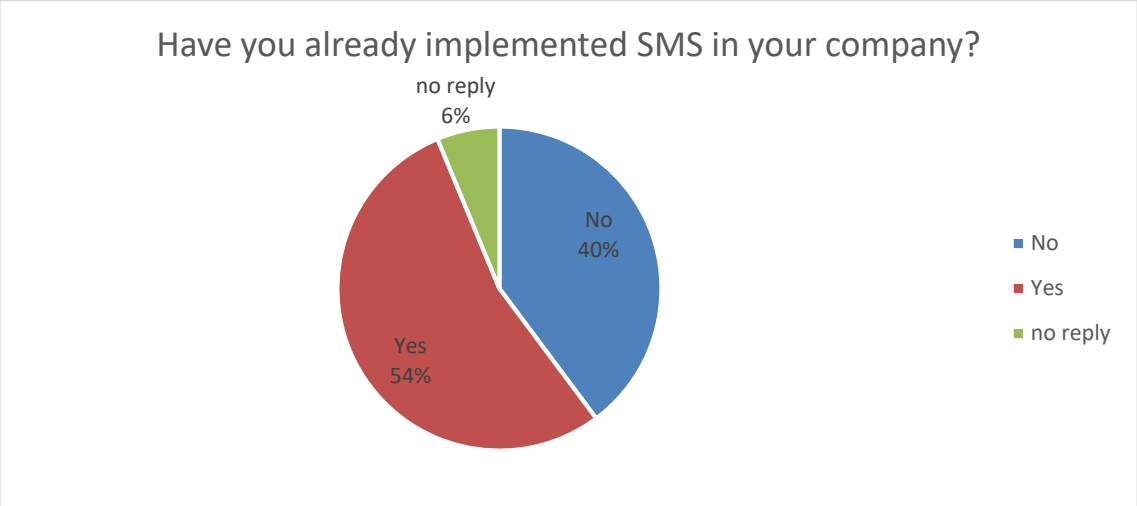


Figure 4: Reply to the question 'Have you already implemented an SMS in your company?'

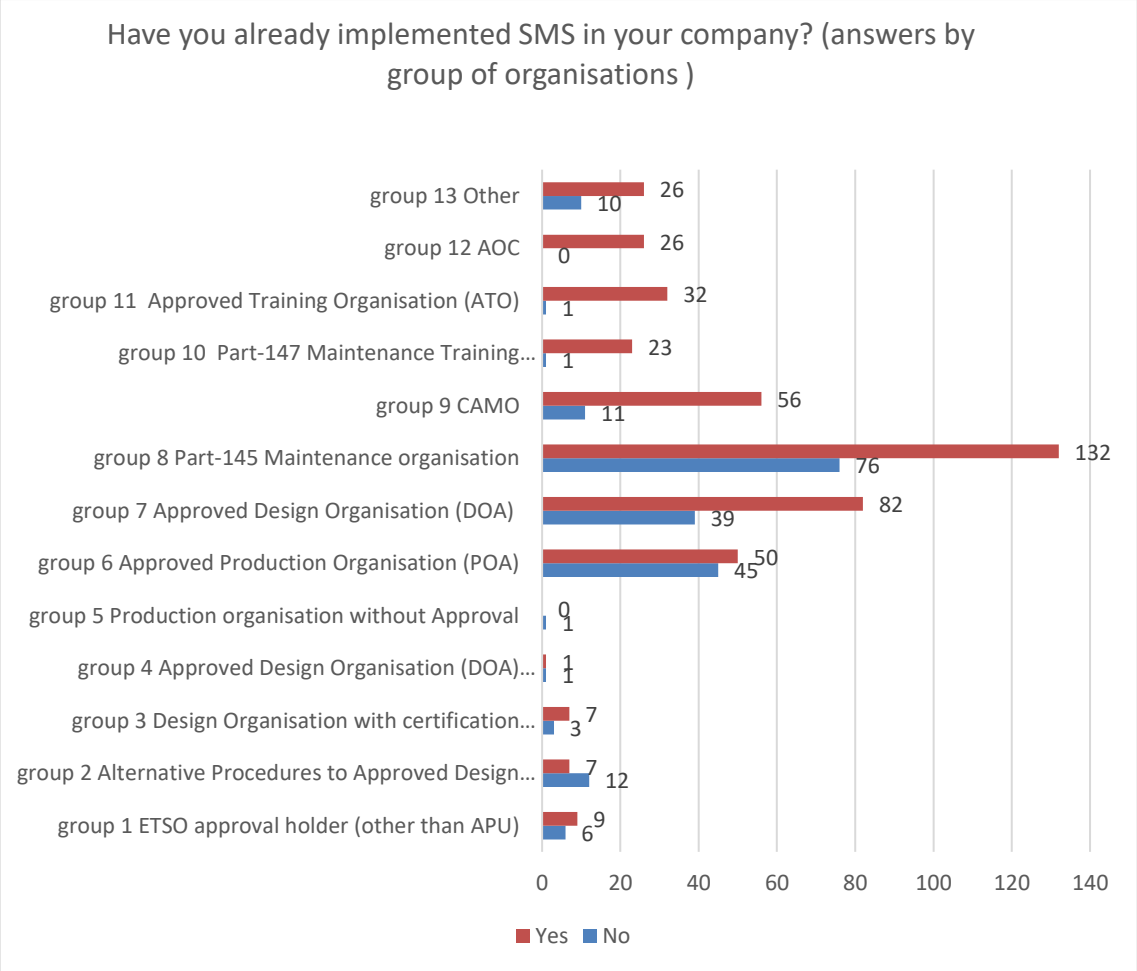


Figure 5: Replies to the question 'Have you already implemented SMS in your company?' (Answers by group of organisations)

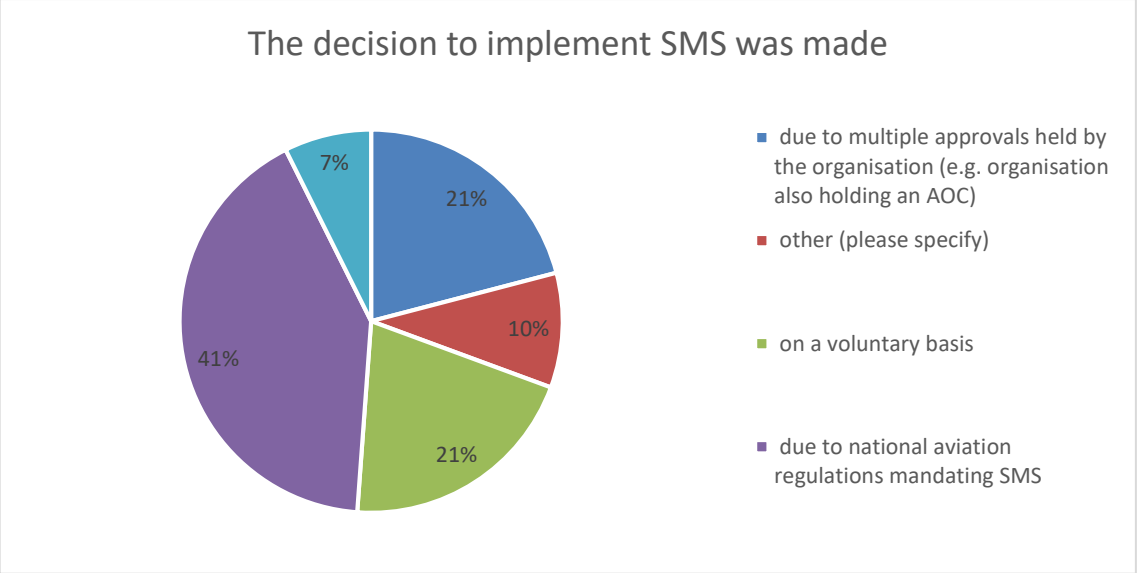


Figure 6: Reasons for implementing an SMS

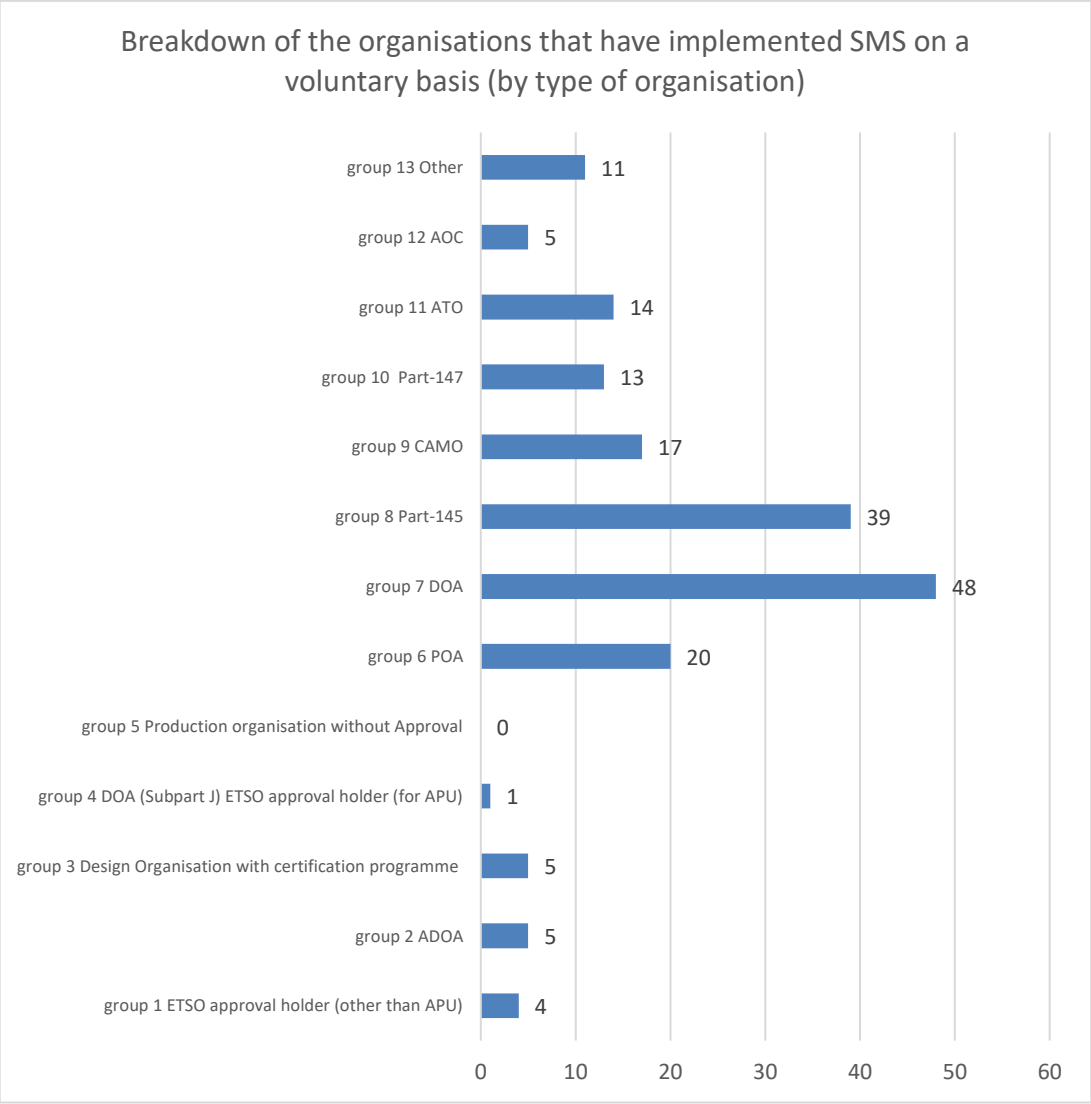


Figure 7: Implementation of an SMS on a voluntary basis

SMS applicability for Part 21

Regarding Part 21, the first question addressed the applicability of SMSs. The following charts show the answers aggregated by organisations, by groups and by the types of product. In all cases, the majority of respondents believed that some SMS requirements should be imposed on all organisations. The questions also allowed respondents to provide comments in support of their answers. In many cases, respondents that were not in favour of the application of SMSs to all organisations, also included comments that proposed the exclusion of small organisations, especially those that only deal with minor changes or that produce products, parts and appliances under Subpart F. In general, several respondents proposed the application of proportional requirements, and even the definition of a minimum set of common requirements, to encourage organisations to develop safety cultures. The following are some of the comments that were received:

— 'In small companies, informal communication can lead to an equivalent level of safety. However, I would still encourage voluntary adoption. E.g. provide suitable templates that they can use and explanations of benefits.'

— 'Some applicable SMS elements (e.g. visible management commitment to safety, safety risk assessment or safety promotion to increase safety awareness among staff) should apply to all aviation parties, as we all work together in one aviation network.'

— 'Safety culture must be in all part of the process.'

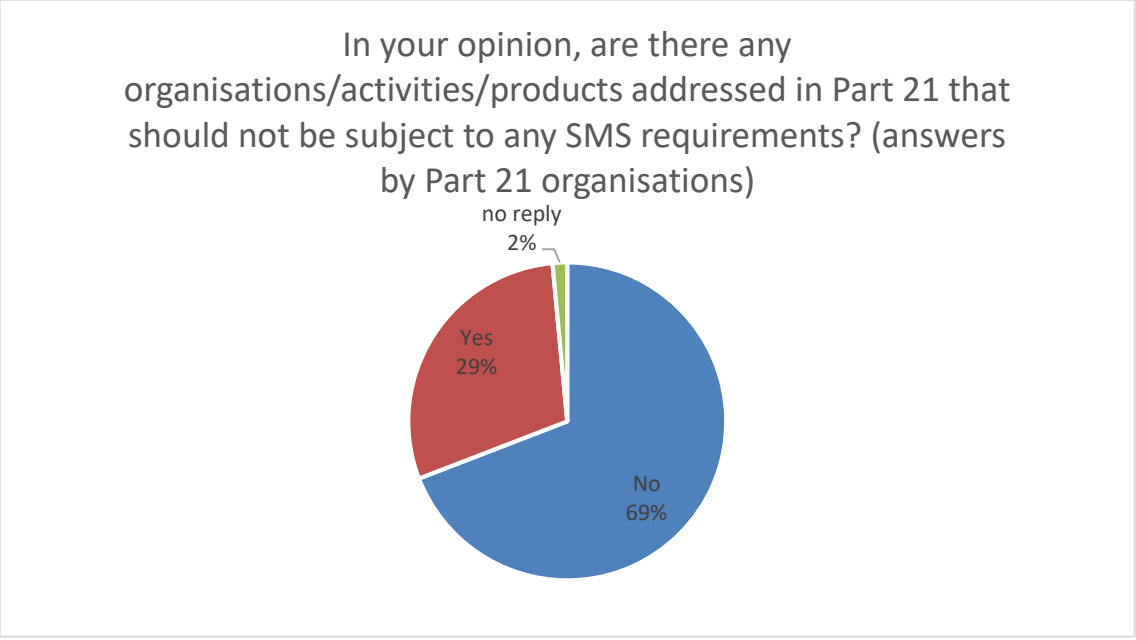


Figure 8: Replies to the question 'In your opinion, are there any organisations/activities/products addressed in Part 21 that should not be subject to any SMS requirements?' (Answers by Part 21 organisations)

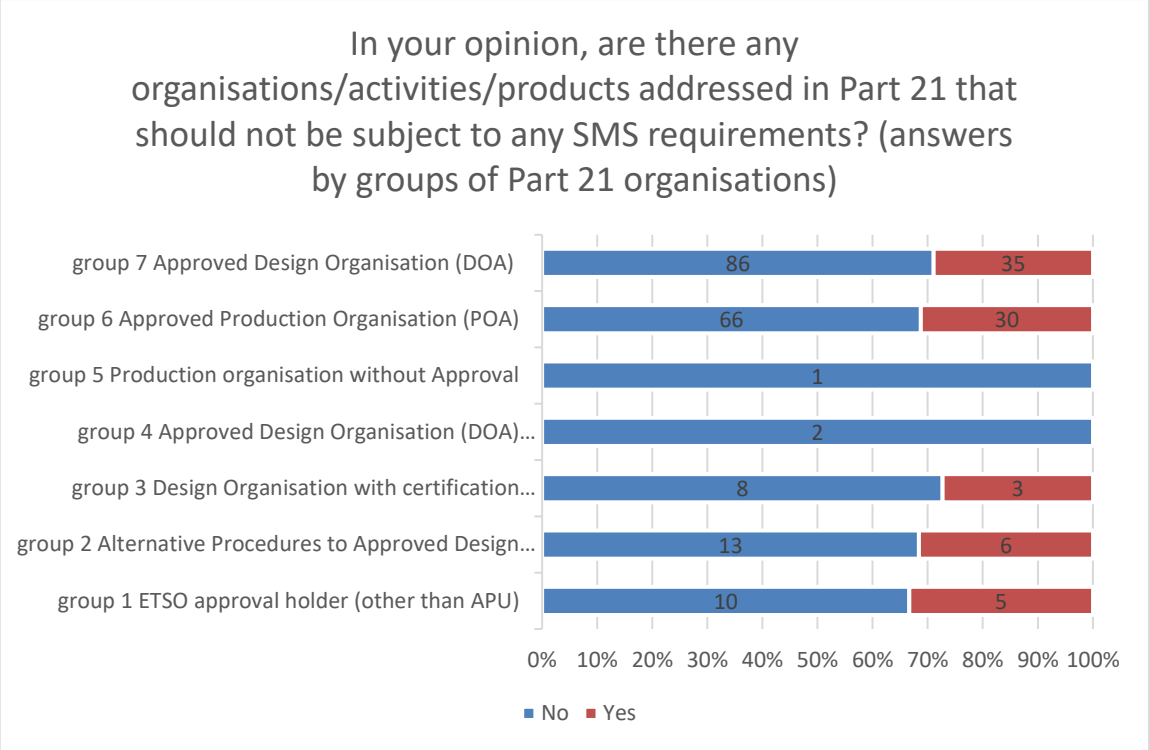


Figure 09: Replies to the question 'In your opinion, are there any organisations/activities/products addressed in Part 21 that should not be subject to any SMS requirements?' (answers by groups of Part 21 organisations)

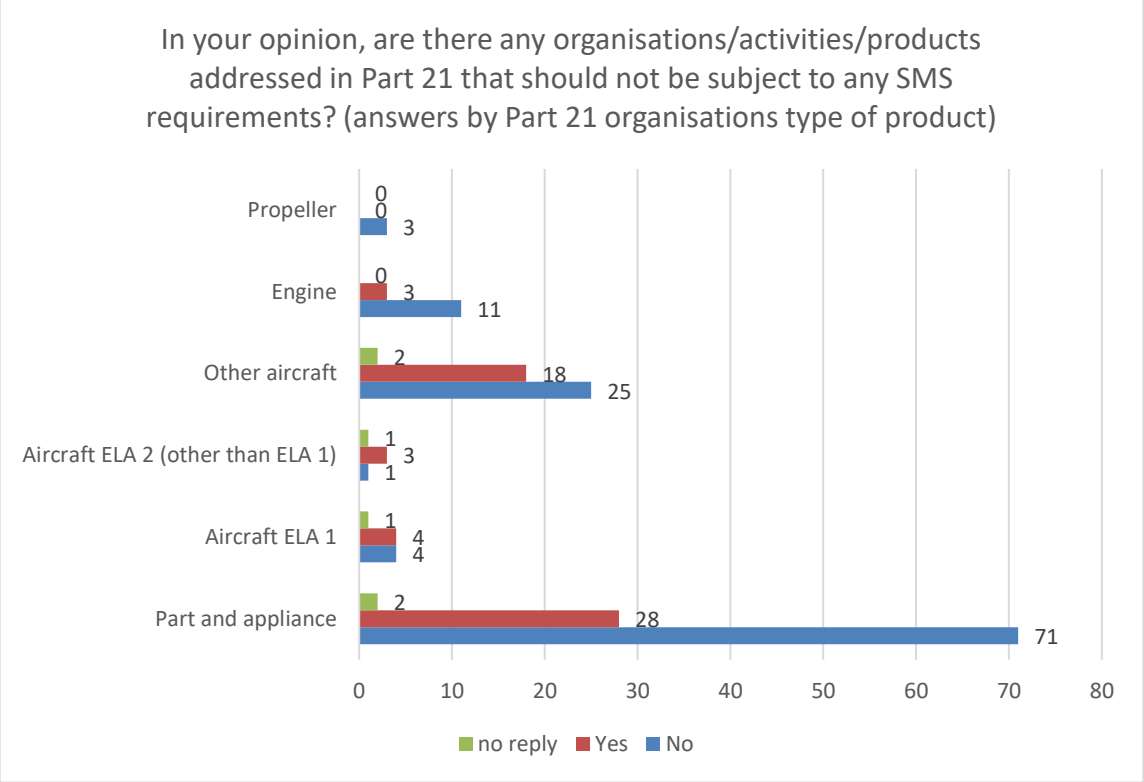


Figure 10: Replies to the question 'In your opinion, are there any organisations/activities/products addressed in Part 21 that should not be subject to any SMS requirements?' (Answers divided by the type of product produced by Part 21 organisations)

SMS applicability for Part-145

Given the decision to apply SMSs to Part-145 (see Section 4.1), the questionnaire was developed to collect feedback on the extent of SMSs within Part-145.

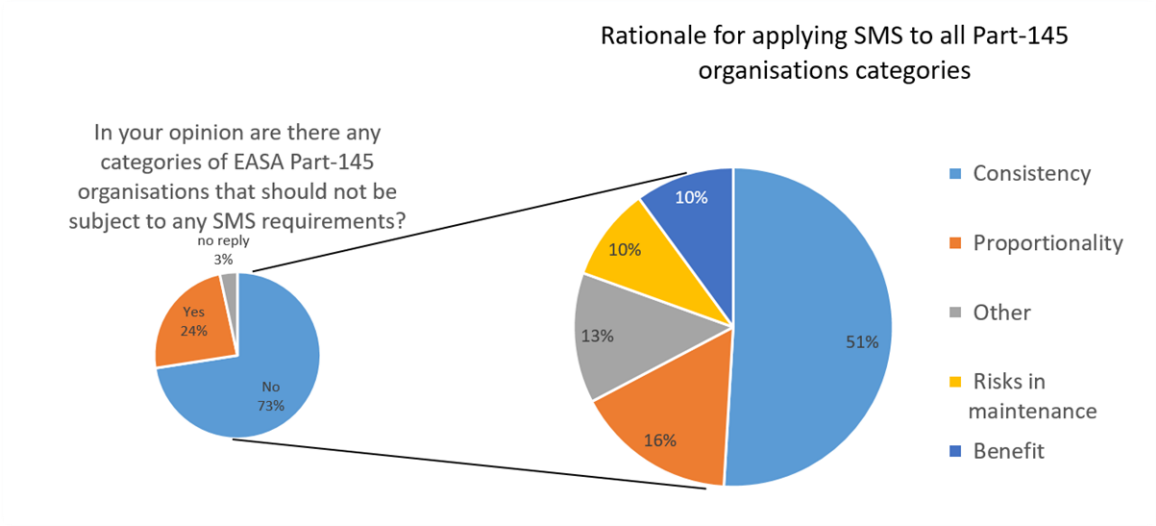


Figure 11: Replies to question 'In your opinion, are there any categories of Part-145 organisations that should not be subject to any SMS requirements?' and the corresponding rationale for the 'no' answers.

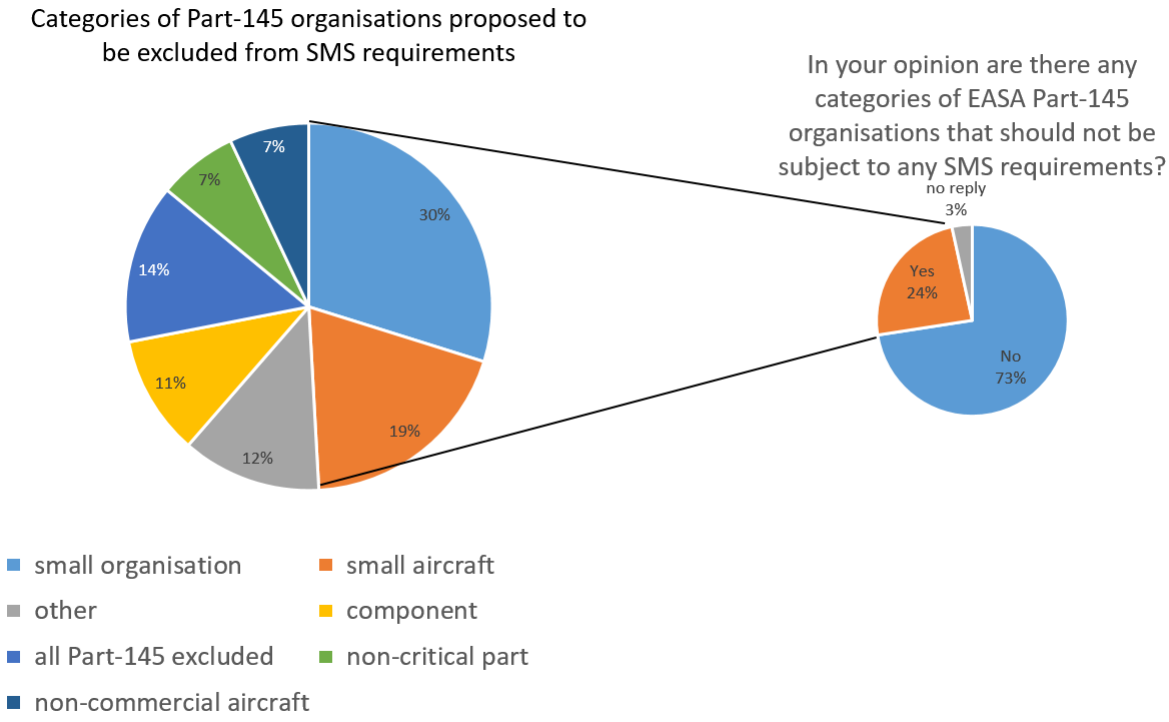


Figure 12: Categories of Part-145 organisations proposed to be excluded from SMS requirements

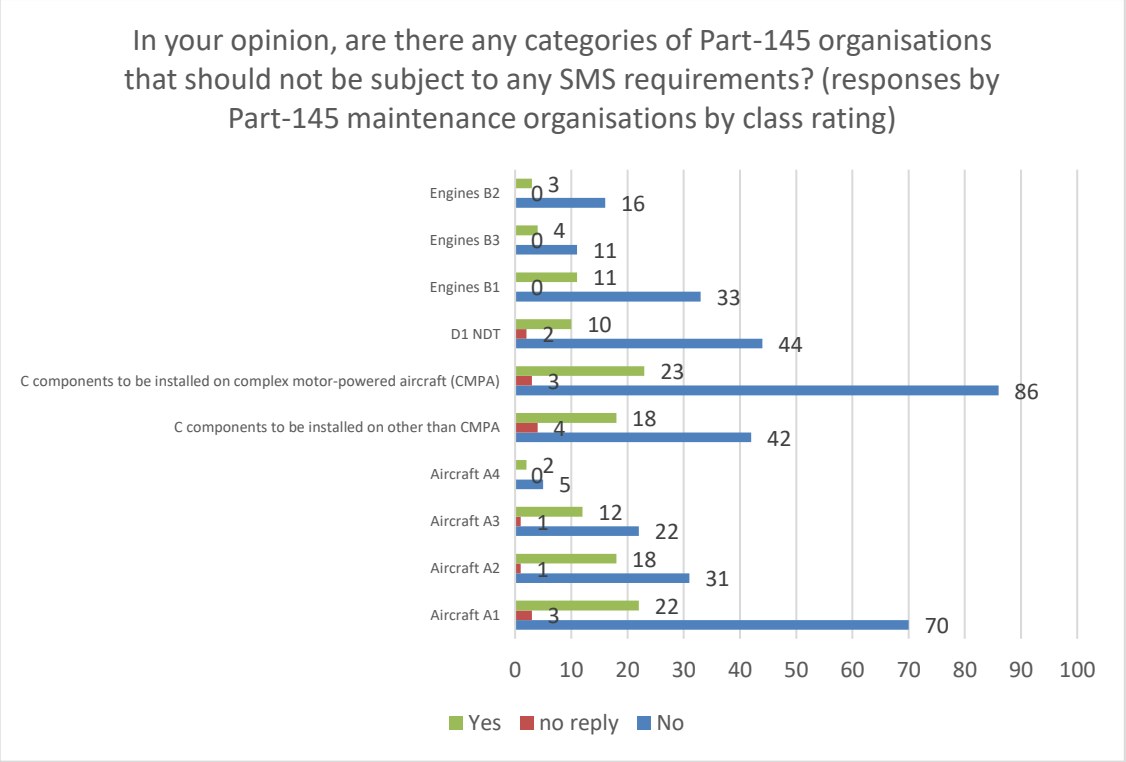


Figure 13: Replies to the question 'In your opinion are there any categories of EASA Part-145 organisations that should not be subject to any SMS requirements?' (Replies by Part-145 Maintenance organisation by class rating.)

Opinions of competent authorities

The same question regarding the applicability of SMSs was addressed to competent authorities. For Part 21, the distribution of answers and justifications is similar to what was provided by organisations and explained above.

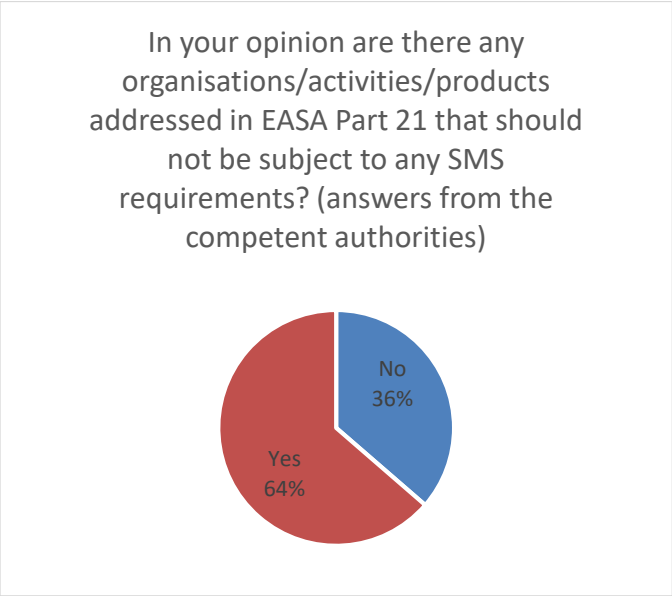


Figure 14: Replies to the question 'In your opinion, are there any organisations/activities/products addressed in Part 21 that should not be subject to any SMS requirements?' (Answers from the competent authorities.)

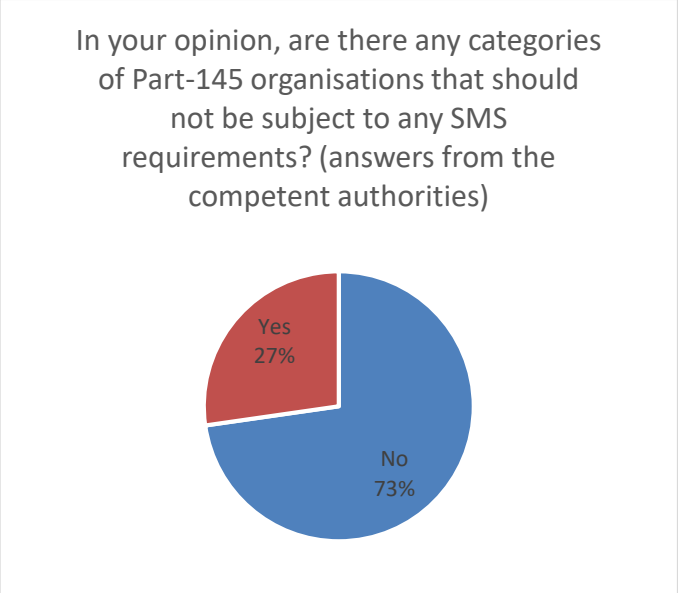


Figure 15: Replies to the question 'In your opinion, are there any categories of Part-145 organisations that should not be subject to any SMS requirements?' (Answers by the competent authorities)