



Opinion No 04/2020

Embodiment of the safety management system requirements into Annex II (Part-145) to Regulation (EU) No 1321/2014 and into Annex I (Part 21) to Regulation (EU) No 748/2012 *‘SMS in Part-145 and Part 21’*

RELATED NPA/CRD: 2019-05(A)(B)(C) — RMT.0251 (MDM.055) PHASE II

EXECUTIVE SUMMARY

The objective of this Opinion, with reference to ICAO Annex 19 ‘Safety Management’ as regards civil aviation and in particular the initial and continuing airworthiness domains, is to establish a safety management system (SMS) framework for design and production (Part 21) as well as maintenance organisations (Part-145), which are the remaining two domains for which ICAO Annex 19 has not been fully transposed yet into the European Union regulatory framework. In addition, Annex II ‘Essential requirements for airworthiness’ to Regulation (EU) 2018/1139 explicitly calls for design, production and maintenance organisations to implement and maintain a management system (MS), including the management of safety risks, and aim for its continuous improvement, supported by the establishment of an occurrence-reporting system.

By establishing such an MS framework, aviation safety will be enhanced through:

- the establishment of safety policies and objectives associated with sufficient resources;
- the systematic identification of hazards and a risk management system;
- safety assurance systems, giving consideration to the safety performance of organisations; and
- safety promotion and communication.

The proposal of this Opinion is in line with the regulatory concept of MS established for other domains, such as Air Operations or Aerodromes, or for continuing airworthiness management organisations (Part-CAMO). By aligning the MS provisions across all aviation domains, it will be ensured that the organisations which have to comply with several MS requirements in different domains can implement a single MS, and that competent authorities that oversee different organisations in different domains can plan and organise their oversight activities on the basis of the same regulatory principles.

It may happen that some differences in the numbering or the contents or even in the terminology used may still exist but, all in all, the same principles are intended to apply in all domains consistently. The main rationales behind these differences are that the Part 21 requirements for design and production are more product-centric whereas the requirements in other domains, such as Part-145, are more organisation-centric, and that the amount of regulatory amendments has been kept as low as possible.

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|-------------------------------|--|------------------------------|---|
| Action area: | Safety | | |
| Affected rules: | Commission Regulation (EU) No 1321/2014 (Annex II (Part-145)); Commission Regulation (EU) No 748/2012 (Annex I (Part 21)) | | |
| Affected stakeholders: | Approved maintenance organisations (AMOs) (Part-145); production organisation approval (POA) holders; design organisation approval (DOA) holders; European Technical Standard Order Authorisation (ETSOA) holders; competent authorities (CAs) | | |
| Driver: | Safety | Rulemaking group: | No (but Focused Consultation Group (FCG)) |
| Impact assessment: | Yes | Rulemaking Procedure: | Standard |

• EASA rulemaking process milestones



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1. About this Opinion

1.1. How this Opinion was developed

The European Union Aviation Safety Agency (EASA) developed this Opinion in line with Regulation (EU) 2018/1139¹ ('Basic Regulation') and the Rulemaking Procedure².

This rulemaking activity is included in the European Plan for Aviation Safety (EPAS) for 2020–2024³ under rulemaking task (RMT).0251 Phase II. The scope and timescales of the task were defined in the related Term of Reference⁴.

For the preparation of the related regulatory impact assessment (RIA) for RMT.0251 Phase II, EASA conducted a survey which was addressed to competent authorities and industry. The aim of the survey was to gather evidence to support the impact assessment and applicability of the safety management system (SMS), and to identify the cases where proportionality is needed, as well as to collect data on potential impacts, difficulties/challenges and opportunities as regards the implementation of SMS. The input provided by the respondents supported the analysis of the problem definition and the analysis of the options. The survey was launched from 21 December 2017 until 15 February 2018, and specific SMS data was collected related to the domains of design, production and maintenance. 293 organisations (285 organisations with a single or multiple approval(s) and 8 associations/individual representatives) as well as 11 competent authorities responded to the survey. The organisations that held multiple approvals at the time were invited to provide a consolidated response, representing all parts of the organisation that hold multiple approvals. Further details on the outcome of the survey are presented in [Section 2.5](#).

Following the survey, a Focus Consultation Group (FCG) was established that comprised subject-matter experts from industry and national aviation authorities (NAAs) who were asked to provide advice to EASA on the preparation of the related notice of proposed amendment (NPA 2015-09 (A)(B)(C) 'Embodiment of safety management system (SMS) requirements into Part-145 and Part 21'⁵) as well as on the preparation of the proposed amendments that are presented in this Opinion.

All interested parties were consulted through NPA 2019-05(A)(B)(C)⁶ from 17 April to 6 September 2019.

2 651 comments were received from interested parties, including industry, NAAs, and social partners. Some additional comments were received after the deadline but were taken into consideration.

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/european-plan-aviation-safety-2020-2024>

⁴ ToR RMT.0251(b) (MDM.055-MDM.060) Issue 1 (<https://www.easa.europa.eu/document-library/terms-of-reference-and-group-compositions/tor-rmt0251b-mdm055-mdm060>).

⁵ <https://www.easa.europa.eu/document-library/notices-of-proposed-amendment/npa-2019-05>

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



A great number of comments were duplicated either for Part 21 or Part-145, or sometimes for both domains.

EASA has addressed and responded to the comments received on the NPA. It reviewed the comments received with the support of the FCG through meetings and further consultation conducted per email. The comments received and EASA's responses to them are presented in Comment-Response Document (CRD) 2019-05⁷. They are limited to the comments received on the proposed amendments to the implementing rules (IRs). EASA, with the support and expert advice from the FCG, will continue the work on the comments on the proposal for the related acceptable means of compliance (AMC) and guidance material (GM) — this means that in the course of 2021, a second CRD will be issued, focusing on the AMC and GM for the preparation of the Decision that will issue the AMC and GM to the IRs.

1.2. The next steps

This Opinion contains the proposed amendments to Commission Regulations (EU) No 1321/2014 (Annex II (Part-145) as well as Annex I (Part-M) for alignment purposes and correction of errors) and No 748/2012 (Annex I (Part 21)) as well as their potential impacts. It is submitted to the European Commission, which will use it as a technical basis in order to prepare EU regulations.

The Decision that contains the related acceptable means of compliance (AMC) and guidance material (GM) will be published by EASA when the related regulations are adopted by the European Commission.

⁷ <http://easa.europa.eu/document-library/comment-response-documents>



2. In summary — why and what

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

In July 2013, ICAO published the first edition of Annex 19 ‘Safety Management’ (referred to as ‘ICAO Annex 19’). Later, in July 2016, ICAO published the second edition. According to ICAO Annex 19, the use of a safety management system (SMS) is foreseen for maintenance, design and production organisations.

For design and production organisations, the existing legal Part 21 framework in the European Union (EU) already includes organisational requirements that cover some safety management aspects, but the safety management Standards and Recommended Practices (SARPs), which stem from ICAO Annex 19, are not fully transposed into the EU regulatory framework for these organisations.

For maintenance organisations, the decision had already been taken to limit the introduction of SMS to Part-145 organisations. According to Commission Regulation (EU) No 1321/2014, as last amended by Commission Implementing Regulation (EU) 2019/1383⁸, no SMS is required in Part-CAO, which addresses general aviation (GA) continuing airworthiness activities. Only a Part-145-approved organisation can maintain aircraft operated by licensed air carriers and complex motor-powered aircraft (CMPA), in line with ICAO Annex 19 (SMS required for organisations that maintain aircraft engaged in international commercial air transport).

Design, production and maintenance are the only domains within the scope of the EASA Basic Regulation for which ICAO Annex 19 has not been fully transposed yet. Annex II to Regulation (EU) 2018/1139 explicitly calls for design, production and maintenance organisations to implement and maintain a management system, including the management of safety risks, and aiming at a continuous safety improvement supported by the establishment of an occurrence-reporting system.

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 the overall objectives by addressing the issues outlined in [Section 2.1](#).

The specific objectives of this proposal are to:

- further improve the level of safety of civil aviation by introducing requirements for the establishment and maintenance of a management system;
- support the mutual acceptance of approvals issued under Part-145 and Part 21;
- foster the principles of safety management;
- streamline the procedures for oversight and enforcement, and increase the efficiency of the management system requirements for competent authorities;
- aim for the continuous safety improvement supported by the establishment of an occurrence-reporting system; and

⁸ Commission Implementing Regulation (EU) 2019/1383 of 8 July 2019 amending and correcting Regulation (EU) No 1321/2014 as regards safety management systems in continuing airworthiness management organisations and alleviations for general aviation aircraft concerning maintenance and continuing airworthiness management (OJ L 228, 4.9.2019, p. 1) (<https://www.easa.europa.eu/document-library/regulations/commission-implementing-regulation-eu-20191383>).

- support the implementation of the European Plan for Aviation Safety (EPAS) for 2020–2024, notably its Chapter 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

Part-145

The majority of the amendments proposed in this Opinion are based on the introduction of SMS into the continuing airworthiness management organisation requirements (Part-CAMO), as adopted by Commission Implementing Regulation (EU) 2019/1383, which are themselves based on the management system requirements of Subparts ‘GEN’ of the Authority and Organisation Requirements (AR/OR) that have been adopted with the Aircrew⁹ and the Air Operations¹⁰ Regulations respectively.

The proposed amendments of this Opinion thus support the alignment with the SMS requirements of Commission Regulation (EU) No 965/2014, notably in the case of multiple approvals if the air operator also holds a Part-CAMO and a Part-145 approval. To be more precise, the SMS elements proposed to be introduced in Part-145 follow the approach used in the other domains, through the introduction of a management system, as required by the Basic Regulation. For example, point 145.A.200 ‘Management system’ is introduced in Part-145 incorporating the existing quality system of point 145.A.65 with the ICAO SMS into a comprehensive management system. The draft resulting text is similar to that of point ORO.GEN.200 ‘Management system’ of Annex III (Part-ORO) to Commission Regulation (EU) No 965/2014.

This overall approach applies for both the organisation requirements and the competent authority requirements.

Furthermore, the occurrence-reporting requirements have been aligned with Regulation (EU) No 376/2014¹¹ following the output of rulemaking task RMT.0681 ‘Alignment with Regulation (EU) No 376/2014’, and the occurrence-reporting system forms part of the management system introduced by this Opinion.

Differences with Part-CAMO can be found in this Opinion due to the domain-specific requirements and the fact that the existing numbering scheme has been kept. Some minor improvements to the Part-CAMO text have also been proposed, mainly for clarity reasons or thanks to valuable comments received during the consultation phase. These amendments though do not change the common SMS principles. Several Part-145 points have been also amended to highlight certain risks related to maintenance activities (e.g. external working teams in point 145.A.47). An explicit reference to take into account the threat of fatigue has been added to the existing consideration of human performance

⁹ Commission Regulation (EU) No 290/2012 of 30 March 2012 amending Regulation (EU) No 1178/2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 100, 5.4.2012, p. 1) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1598623517297&uri=CELEX:32012R0290>).

¹⁰ Commission Regulation (EU) No 965/2012 of 5 October 2012 laying down technical requirements and administrative procedures related to air operations pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council (OJ L 296, 25.10.2012, p. 1) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1598623612580&uri=CELEX:32012R0965>).

¹¹ 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 (OJ L 122, 24.4.2014, p. 18) (<https://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1598627832107&uri=CELEX:32014R0376>).

limitations when developing the production planning, following the publication of a number of safety recommendations stemming from investigation reports of serious incidents or accidents¹².

Further details about the proposed amendments to Part-145 can be found in [Appendix I](#) of this Opinion.

Part 21

As for Part-145, the requirements proposed in this Opinion for Part 21 are based on the safety system requirements adopted for Air Operations, Aircrew and CAMOs, thus promoting common safety management principles throughout all the domains that are within the scope of the Basic Regulation.

In comparison to Part-145 and other domains, the approach for Part 21 was though slightly different although the regulatory intent is to fully match the principles of the management system requirements. This difference is due to the fact that the requirements of Part 21 Section A are product-centric rather than organisation-centric. Organisation approvals required by Part 21 are an integrated element of the product approval. For example, a design organisation has to demonstrate its design capability as a condition to submit an application for the type certification of a new product. This design capability may be demonstrated through the existence of a design organisation approval. The organisation requirements in Subpart J (DOA), therefore, aim to ensure that processes are in place that allow the organisation to design a safe product. The proposed safety management system requirements, therefore, complement 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 contains detailed organisation requirements for approved production and design organisations that are considered to fully transpose some of the Standards and Recommended Practices (SARPs) of ICAO Annex 19 — namely, the concepts of hazard identification, risk management and mitigation, as well as occurrence reporting, are already contained in the requirements associated with the design and production of products and parts.

When relevant, the 12 ICAO elements of an SMS applicable to an organisation have been, therefore, added in point 21.A.139 (today, the ‘quality system’ for production organisations) and in point 21.A.239 (today, the ‘design assurance system’ for design organisations). By doing so, the existing IR structure for Section A remains unchanged. However, the combination of the SMS requirements with the ‘quality system’ for production organisations and the ‘design assurance system’ for design organisations respectively is renamed ‘management system’ in line with the principles of the Basic Regulation (refer to its Annex II, Section 3).

This approach of introducing the SMS requirements into Section A of Part 21 is thus a bit different from the proposed Part-145 requirements and the requirements that exist in the other domains for the organisation requirements. However, for Section B of Part 21, the competent authority requirements are fully aligned with those proposed for Part-145 Section B and the authority requirements in the other domains, promoting an integrated authority management system common to all domains and fostering streamlined procedures.

¹² Refer to [NPA 2019-05 \(A\)](#), Section 4.1.3 ‘Safety risk assessment’, where reference is made to Safety Recommendations SR UNKG-2015-001 and SR UNKG-2011-018.

The alignment of the occurrence-reporting system with Regulation (EU) No 376/2014 has been also considered to be notably consistent with ICAO Annex 19, Chapter 5 and its Appendix III, and with the Basic Regulation.

Following the provisions of the Basic Regulation, the proposed amendments to Part 21 were split into two acts amending Regulation (EU) No 748/2012:

- an implementing act that includes the requirements for the authority when the competence is assigned to the Member State, according to Article 62 of the Basic Regulation; and
- a delegated act that includes the requirements for the applicant and for the authority when the competence is exclusively within the EU, according to Articles 19 and 62 of the Basic Regulation.

Finally, as mentioned above for Part-145, some differences may exist due to regulatory constraints, the numbering scheme applied to the draft regulations, and the specific requirements of Commission Regulation (EU) No 748/2012, notably the terminology that is specific to ‘design and production’. Some minor improvements to the Part-CAMO text have also been proposed, mainly for clarity reasons and also thanks to the comments received during the public consultation phase of this project. These amendments should do not change the overall SMS principles and the regulatory intent of the requirements.

Further details about the proposed amendments to Part 21 can be found in [Appendix II](#) to this Opinion.

2.4. What are the stakeholders’ views — outcome of the consultation

This Opinion addresses approved maintenance organisations (AMOs — Part-145), approved production organisations (POA holders — Part 21 Subpart G), approved design organisations (DOA holders — Part 21 Subpart J), European Technical Standard Order Authorisations holders (ETSOA holders — Part 21 Subpart O), and competent authorities.

In total, around 2 800 comments were received during the consultation phase. A great number of comments were duplicated (refer to the related CRD 2019-05(A)(B)(C) for more details); not counting the duplicates, approximately 1 500 comments were received on the proposed amendments and on the proposed AMC and GM.

Very few comments were received on the SMS applicability to Part 21 and Part-145. Some respondents, mainly from the United States of America (where SMS is currently applicable only on a voluntary basis), would have liked to see SMS not mandatory at all and are concerned about its impact on bilateral agreements. Since the development of these SMS rules by EASA, the FAA now plans to also make SMS mandatory for Part 21 and Part-145 organisations.

A few respondents would have liked to see the SMS requirements also mandatory to subcontractors, even if they are not approved. This approach was found impractical as no enforcement and oversight provisions are legally available. Besides, subcontracted organisations work under the management system of subcontracting organisations.

The concept of proportionality was fully supported. As regards maintenance, SMS is only applicable for Part-145 organisations and not for Part-CAO maintenance organisations. As regards Part 21, the proposed non-applicability of SMS to non-approved organisations that are responsible for the design and production of products was well received although ICAO Annex 19 does not differentiate between ‘approved’ and ‘non-approved’ organisations. The extension of the SMS applicability to all



organisations that design or produce aircraft, engines or propellers, as well as parts under an ETSOA, for which Part 21 currently requires an approval (i.e. DOAs or POAs), was well accepted although it goes beyond Annex 19 for parts.

One competent authority recommended the new IR to apply the same applicability and transition principles with Part-CAMO, i.e. applicability 6 months after the date of entry into force and a transition period (for the closure of findings on IR novelties) of 18 months. This issue will be reviewed by the European Commission with the EU Member States during the adoption procedure of the proposed IRs, but as regards this Opinion, taking into account the experience gained with Part-CAMO and the consequences of the COVID-19 pandemic, EASA proposes the following:

- applicability of the amending regulation: 1 year after the date of entry into force;
- a period of 2 years after the applicability date, during which the time given to close findings on the novelties introduced by the amending regulation, is extended until the end of the 2-year period.

As it was anticipated, the NPA triggered a significant number of comments due to the principle of harmonisation between Part 21 and Part-145, which was an unprecedented approach in terms of rulemaking.

The impact of the proposed amendments was certainly higher for Part 21 due to its product-centric nature and the fully rewritten requirements for competent authorities (i.e. Section B). A number of respondents would have liked to see Part 21 'untouched'. Conversely, some other respondents, mainly those that have a background in Part-145, would have preferred a higher level of consistency between the Part 21 and the Part-145 requirements, notably a more harmonised approach for the Part 21 organisation's management system fully integrating the SMS with compliance monitoring like in Part-145 (see explanations in [Section 2.3](#)). However, rewording and fully renumbering Part 21 to match Part-CAMO and the Air Operations management system requirements would have generated a high volume of amendments to the documentation to be produced by the applicants, with a very limited safety benefit and the risk to confuse an unprepared Part 21 community. Therefore, EASA did not consider it appropriate in terms of timing.

As a general approach, these principles of harmonisation were applied during the review of the comments for the sake of alignment of the IRs across all domains, with the objective to limit the volume of amendments as much as possible. Another justification lies in the fact that some organisations hold Part 21, Part-145 and Part-CAMO approvals at the same time. Notably, such harmonisation has slightly amended the requirements for the oversight provisions, not the principles, whereas it simplifies the procedures for competent authorities across all aviation domains. Consequently, a significant number of comments did not address the (safety) management principles although this was the very essence of this rulemaking project.

The following two paragraphs build on what has been proposed to be aligned and where differences had to be kept.



Alignment of Part 21 with Part-145

- The concept of ‘level 3 findings’ in Part 21 has been removed as it does not exist in almost all the other domains; instead, the concept of ‘observations’ has been introduced in both Part 21 and Part 145, as several competent authorities and industry representatives recommended the use of a mechanism for the assessment of the management system, which is also recommended in the EASA ‘Management System Assessment Tool’¹³ to complement the traditional definitions of ‘level 1 and level 2 findings’ in a performance-based environment.
- ‘Past performance’ as a criterion for extending the period to close a level 2 finding has not been considered, although Part-CAMO contains such provision.
- The ‘issue of a level 1 finding’ was agreed in the case of lack of an accountable manager and is explicitly reflected in the IR.
- A process for establishing transparency as regards the means of compliance used, other than those issued by EASA as an acceptable means of compliance (AMC), called ‘AltMoC process’, has been introduced for production and maintenance, but not for design where there is only one competent authority throughout the European Union (i.e. EASA). This new process was questioned by some stakeholders, but EASA concluded that the concerns expressed were not about the principle as such, but rather about how the process is being or will be applied; indeed, many commentators considered that the introduction of such process would:
 - (a) limit their possibility to use means of compliance other than those contained in the AMC, which it does not; and
 - (b) introduce a new requirement for the acceptance of the use of such other means, which it does not, as other means can already be used today and must be accepted by the competent authority.

EASA thus organised an ad hoc webinar with the FCG experts, who supported in the development of this project, in order to remind that:

- the use of AltMoC is a powerful tool that allows transparency as regards good means of compliance that are accepted by one authority and which could be used by other organisations as well, and eventually giving EASA the visibility and possibility to transpose those means into EASA AMC;
- compliance has to be ensured with the IR, not the EASA AMC: the organisation or the Member State may either demonstrate compliance by using the EASA AMC or any other means of compliance, which further enhances flexibility.

The proposed text for the AltMoC process is thus aligned with the provisions adopted for Part-CAMO (see Commission Implementing Regulation (EU) 2019/1383¹⁴), which are already aligned with the Air Operations IRs (Commission Regulation (EU) No 965/2012¹⁵). By doing so, the AltMoC provisions are consistent among the domains; wording in the IRs which is different

¹³ <https://www.easa.europa.eu/document-library/general-publications/management-system-assessment-tool>

¹⁴ <https://www.easa.europa.eu/regulations#regulations-continuing-airworthiness>

¹⁵ <https://www.easa.europa.eu/regulations#regulations-air-operations>



from that in other domains could create confusion and legal uncertainty, forcing competent authorities to apply different processes.

- Reference to ‘unannounced inspections’ was agreed to be made as a possible tool for the competent authority, in line with the ICAO principles.
- The necessity to meet the accountable manager during the initial certification was agreed, so that the competent authority ensures that the accountable manager understands his or her role and responsibilities.
- In the case of changes requiring prior approval by the competent authority, the wording of the requirement relevant to enforcement action in case of implementation without prior approval has been aligned with the wording of the requirements of the Aerodromes IRs.
- Different types of comments related to the suspension, limitation and revocation of a certificate led to the revision of the wording and the terminology of the related provisions.
- The proposed text now refers to an oversight planning cycle that can vary from 24 (or less, if needed) to 48 months in a performance-based environment, as this is already the case for the other domains. Initially, a period of 24 months was proposed for maintenance and 36 months for design.
- The responsibilities of the person or group of persons that is/are nominated by the accountable manager have been clarified.

Differences between Part 21 and Part-145

- The numbering of the requirements in Part 21 does not reflect the numbering of Part-145 and of the other domains due to its peculiar structure.
- The existing definition of ‘level 1 findings’ for design organisations has been revised, but is not fully aligned due to its peculiarity (i.e. reducing the established or standard safety margins does not mean that the product becomes unsafe; for additional information, please refer to Section 3.1 of CRD 2019-05).
- The requirements for the management system for production and design organisations, embedding the elements of the safety management system, and while being aligned in principle with the requirements for maintenance organisations, do not have the same structure for the reasons explained already in [Section 2.3](#).

Also, a significant number of comments specific to the existing Part 21 or Part-145 requirements have resulted in amending and improving them. As they cannot be exhaustively explained here, please refer to CRD 2019-05 for further details.

Note: The comments (and EASA’s responses to them) on the Acceptable Means of Compliance (AMC) and Guidance Material (GM) to Part 21 and Part-145 will be published in another future CRD 2019-05, together with the EASA Decision that shall issue these AMC and GM.



2.5. What are the expected benefits and drawbacks of the proposal

The proposed amendments are expected to:

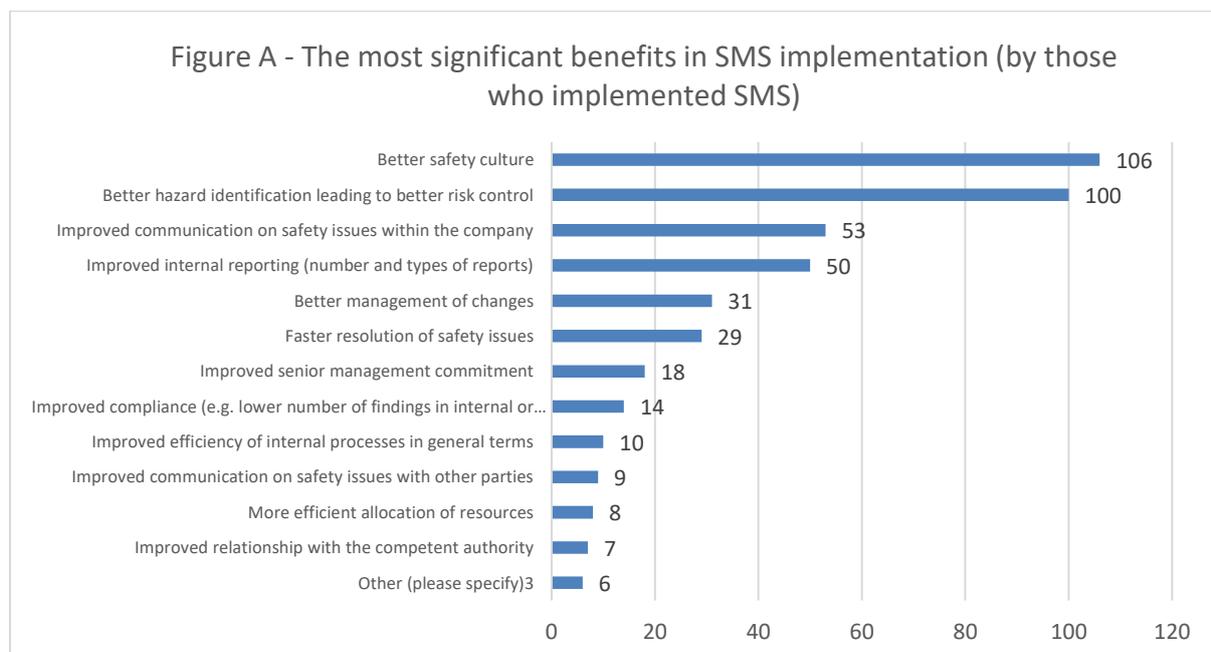
- improve aviation safety by introducing the SMS principles, notably safety risk management, safety performance and continuous improvement;
- foster an organisational safety culture for effective safety management and effective occurrence reporting, be it mandatory or voluntary, to be aligned with Commission Regulation (EU) No 376/2014;
- streamline the competent authority's oversight requirements (i.e. Section B of Part-145 and Part 21) thanks to an approach that is common with that followed for the other domains.

The expected benefits would be to:

- enhance aviation safety by contributing to effective hazard identification and risk assessment; increasing risk management capabilities with the development of mitigation strategies to identified safety issues; and reducing errors;
- improve the measurement and monitoring of the organisation's safety performance;
- foster a positive safety culture; and
- improve flexibility and proportionality, in particular with regard to the management system requirements.

Note: With the COVID-19 pandemic, the ability of the organisations to effectively identify and manage emerging risks has proven to be an efficient tool for the return to normal and safe operations. This applies to all domains, including Part 21 and Part-145.

These safety benefits, being the most significant, were further supported through the EASA survey (as mentioned in [Section 1.1](#) of the Opinion) as follows:



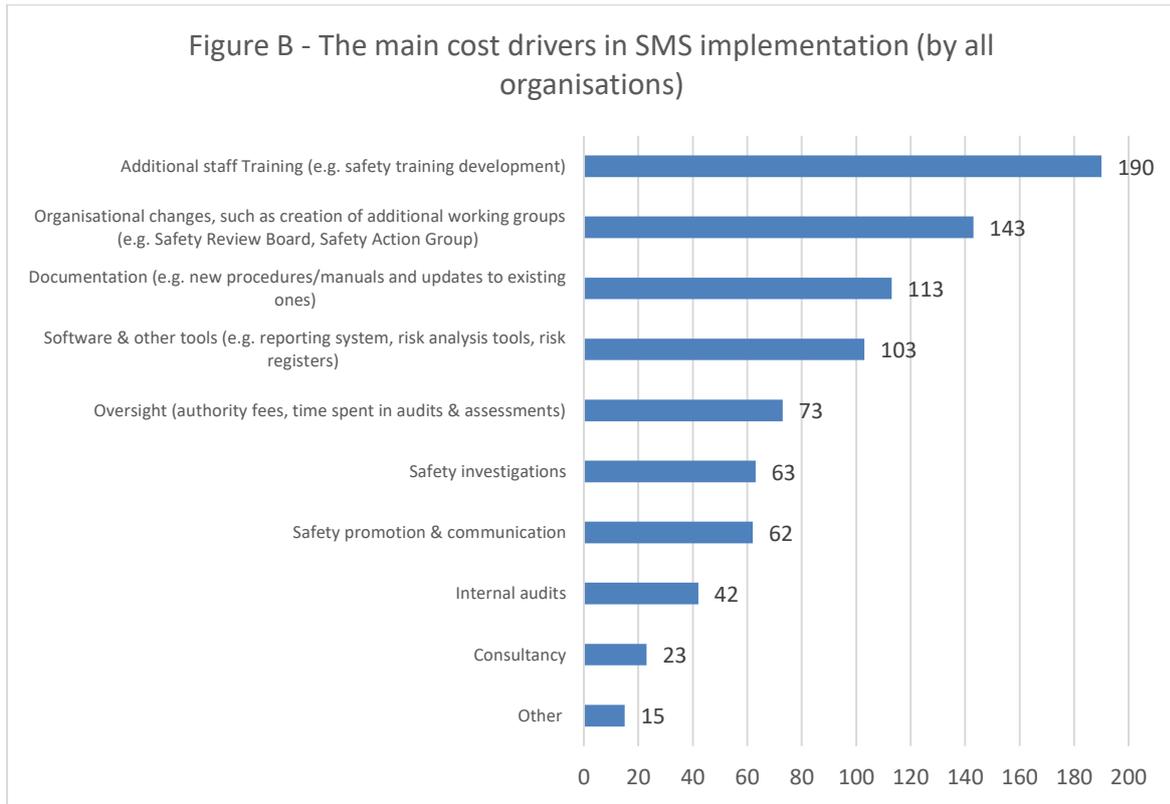
Despite some differences in the approach between Section A of Part 21 and Section A of Part-145, the alignment of the SMS principles will facilitate the reuse of activities and documentation that have already been developed in the other domains for compliance-demonstration purposes. That approach will be further supported at AMC and GM level, where similar means of compliance and guidance material will be provided for the two domains, insofar as this is possible. Consequently, implementing an SMS in a maintenance organisation that also holds a DOA or a POA will allow the same processes to be followed for the implementation of an SMS within the design or production activities, and vice versa.

The proportionality approach limits the economic impact as implementation costs are reduced by the following:

- The acceptance that the 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 them;
- AMC and GM related to SMS shall be developed, proportionate to the size and complexity of the organisation's activities (e.g. a full-time equivalent (FTE) safety manager is not necessary as long as the 'safety manager' function is properly discharged; the same applies for a formal safety review board);
- It is planned to recognise an industry association 'international SMS industry standard' via an AMC to the SMS requirements for design and production organisations, which will allow for a level playing field with the SMS approach followed by other major authorities such as the FAA, the TCCA or ANAC because that international SMS industry standard will be also recognised by these major authorities. 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
- By reducing the complexity and the volume of changes, an organisation may decide to build its SMS on its existing exposition manual, or to produce a separate SMS manual, which limits the impact on the organisation's documentation.



As mentioned in [Section 1.1](#), the main cost drivers were identified through the EASA survey as follows:



2.6. How we monitor and evaluate the rules

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 monitoring various elements looking at the short and medium term. Indeed, there are elements that should be monitored as soon as the IRs are adopted and implemented and elements for which some years would need to pass before the outcome can be measured. The proposal on the indicators to be checked is as follows:

| What to monitor | How to monitor | Who should monitor | How often to monitor |
|--|--|---------------------|--|
| Questions/issues about the understanding and implementation of the IRs | Number of questions/issues received/raised | EASA/NAAs SM TeB | On a recurrent basis, e.g. once a year |
| Effective implementation of SMS in the Part 21 / Part-145 domains | See paragraph 3 of Section 4.2 of EPAS for 2020–2024, where a number of data is proposed for collection and analysis | EASA/NAAs SM TeB | On a recurrent basis, e.g. once a year |

Cologne, 18 December 2020

Patrick KY
Executive Director



3. References

3.1. 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)

3.2. Related decisions

- Decision N° 2012/020/R of the Executive Director of the Agency of 30th October 2012 on acceptable means of compliance and guidance material for the airworthiness and environmental certification of aircraft and related products, parts and appliances, as well as for the certification of design and production organisations ('AMC and GM to Part 21'), repealing Decision No 2003/01/RM of the Executive Director of the Agency of 17 October 2003
- Executive Director Decision 2015/029/R of 17 October 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')

3.3. 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 (OJ L 122, 24.4.2014, p. 18)
- ICAO Annex 19 'Safety Management', Second Edition, July 2016
- ICAO Doc 9859 'Safety Management Manual', 4th Edition, 2018
- Common, general authority and organisation requirements already published in the following domains:
 - Air Operations (ref.: Regulation (EU) No 965/2012),
 - Aircrew (ref.: Regulation (EU) No 1178/2011),
 - Aerodromes (ref.: Regulation (EU) No 139/2014),
 - Air Traffic Controller Training (ref.: Regulation (EU) 2015/340), and
 - ATM/ANS (ref.: Regulation (EU) 2017/373)



4. Related documents

- **CRD to NPA 2019-05(A)(B)(C)¹⁶**
'Embodiment of safety management system (SMS) requirements into Part-145 and Part 21'
RMT.0251 (MDM.055) — Phase II

¹⁶ Available at <https://www.easa.europa.eu/document-library/comment-response-documents>.



5. Appendices

5.1. Appendix II — Summary of the proposed amendments to Regulation (EU) No 1321/2014

The following is a summary of the proposed amendments to Regulation (EU) No 1321/2014.

Amendments to the cover Regulation:

| COVER REGULATION | Description |
|------------------|---|
| Article 4 | New paragraph 7 added to allow for a longer period to close the findings raised by the competent authority on the main novelties introduced in Part-145 by this Opinion (such as management system, AltMoC procedures). |
| Article 5 | New paragraph 7 added to ensure that any existing certification authorisation issued on the basis of a flight engineer (FE) licence continues to remain valid. |

Amendments to Annex I (Part-M):

Amendments:

- Appendix IV is amended to remove the references to Part-145 and keep only those to Part-M Subpart F. This is because the class and rating system information for Part-145 organisations is introduced in Appendix II to Annex II (Part-145).

Corrections:

- In point M.A.403, the references to the points of M.A.801 had to be corrected due to the changes to M.A.801 in Commission Implementing Regulation (EU) 2019/1383.
- In point M.A.502, the reference to ‘B-rated organisation’ had to be corrected and replaced by ‘engine maintenance organisation’. This is because there is no ‘B rating’ in Annex Vd (Part-CAO).

General amendments to Annex II (Part-145), Sections A and B:

- All references to ‘quality system’ have been replaced by ‘management system’ or ‘compliance monitoring’ (depending on the context).
- All references to ‘continuation training’ have been replaced by ‘recurrent training’.
- All references to ‘surveyor’ have been replaced by ‘inspector’.
- All references to personnel ‘competence’ have been replaced by ‘competency’.
- General editorial/linguistic improvements.
- All references to ‘approval schedule’ have been replaced by ‘terms of approval’. Several changes have been 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’ have been adapted, where applicable, to the concept of ‘changes not requiring prior approval’ (see point 145.A.85).
- References to ‘flight engineer (FE) licences’ have been deleted, as these licences 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 5.

List of amendments to Annex II (Part-145):

Section A is amended as follows:

The following general principle has been applied: the current numbering has been kept for existing/amended points, and the Part-CAMO (Annex Vc) numbering has been applied to new points.

| Part-145 reference | Description |
|--|--|
| 145.1 General Competent authority | Change of the title to harmonise it with CAMO.A.105; Consideration of Article 77(2)(b) of the Basic Regulation. Consideration of Article 65 on the reallocation of competent authority responsibilities to EASA upon request of the organisations that operate in more than one Member State; Consideration of the new Basic Regulation Article 64 on the reallocation of responsibility upon request of the 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 | Partial alignment with CAMO.A.115 (Application for an organisation certificate). The last sentence of CAMO.A.115 was found to be redundant with 145.A.85 and 145.A.70 and is, therefore, not retained. |
| 145.A.20 Terms of approval and scope of work | Alignment with ORO.GEN.125 and partial alignment with CAMO.A.125 (Terms of approval and privileges of the organisation). |
| 145.A.25 Facility requirements | No changes |



| | |
|--|--|
| 145.A.30 Personnel requirements | <p>General alignment with CAMO.A.305 and introduction of person(s) nominated for the safety management and compliance monitoring.</p> <p>Clarity introduced in point (b) for the maintenance manager provisions and in point (cb) for the responsibility of the nominated person(s) to the accountable manager.</p> <p>The reference to flight engineer (FE) has been deleted in (j); the reference to point 145.A.37 has been introduced in (k) for the airworthiness review staff.</p> <p>Points (j)(1) and (j)(2) have been reworded for clarity.</p> <p>References to 'commander' have been replaced by 'pilot' in points (j)(3) and (j)(4).</p> |
| 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 contents have been moved to 145.A.55 (Record-keeping). |
| 145.A.37 Airworthiness review staff | New point, based on point CAO.A.045 (Airworthiness review staff) of Annex Vd (Part-CAO), but adapted for organisations purely involved in maintenance. |
| 145.A.40 Equipment and tools | No changes |
| 145.A.42 Components | No changes |
| 145.A.45 Maintenance data | See 'General changes'; the reference to 145.A.202 has been introduced in point (c). |
| 145.A.47 Production planning | <p>Point (b) has been amended to consider the aspect of fatigue in the production planning.</p> <p>Point (d) aims to consider the hazard that results from the presence of external working teams.</p> |
| 145.A.48 Performance of maintenance | Alignment with M.A.201(c), M(L).A.403(b) and 145.A.80; adaptation to the management system. |
| 145.A.50 Certification of maintenance | <p>Alignment with M.A.801 in point (a) and (d).</p> <p>'Aircraft operator' replaced by 'person or organisation that is responsible for the aircraft continuing airworthiness' in points (c) and (f).</p> |
| 145.A.55 Maintenance and airworthiness review records Record-keeping | <p>Alignment with CAMO.A.220 (Record-keeping) and with former 145.A.35(j) and 145.A.36;</p> <p>Alignment with ML.A.904(d) of Annex Vb (Part-ML) for airworthiness review records.</p> |
| 145.A.60 Occurrence reporting | Alignment with the results of RMT.0681 (Alignment with Regulation (EU) No 376/2014); elements of internal reporting to be addressed by 145.A.202. |

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|--|--|
| 145.A.65 Safety and quality policy, maintenance procedures and quality system | <p>‘safety/quality’ elements deleted (see 145.A.200);</p> <p>Point (b) kept with certain alignment to CAMO.A.315(e) (Continuing airworthiness management);</p> <p>The term ‘human performance’ is considered to be covered by ‘human factors’ and is, therefore, deleted here for the purpose of simplification.</p> |
| 145.A.70 Maintenance organisation exposition (MOE) | <p>Clarification and adaptation on the basis of CAMO.A.300;</p> <p>Deletion of ‘where applicable’ when not referring to a given IR requirement.</p> |
| 145.A.75 Privileges of the organisation | <p>Simplification of (b) to prevent the interpretation that subcontracting maintenance to approved organisation is prohibited;</p> <p>Airworthiness review privilege limited to organisations within the Member States (ref.: CAMO.A.125(e)).</p> |
| 145.A.80 Limitations on the organisation | Deleted; its contents have been moved to 145.A.48. |
| 145.A.85 Changes to the organisation | <p>Harmonisation (including adaptation for clarification) with CAMO.A.130 (Changes to the organisation), introducing the changes (not) requiring prior approval.</p> <p>Simplification of point (a)(1) and inclusion of ‘accountable manager’ in point (a)(2).</p> |
| 145.A.90 Continued validity | Alignment with CAMO.A.135 (Continued validity); addition of the possibility of certificate suspension in point (a)(3). |
| 145.A.95 Findings | Alignment with CAMO.A.150 (Findings); introduction of ‘observations’ (issued by the competent authority) to be considered by the organisation. |
| 145.A.120 Means of compliance | Alignment with CAMO.A.120 (Means of compliance). |
| 145.A.140 Access | Alignment with CAMO.A.140 (Access) with minor adaptation. |
| 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) and RMT.0681 (Alignment with Regulation (EU) No 376/2014). |
| 145.A.202 Internal safety reporting scheme | Alignment with CAMO.A.202 (Internal safety reporting scheme) with the exception of point (e). |
| 145.A.205 Contracting and subcontracting | Adapted from CAMO.A.205. |

Section B is replaced by the following:

| SECTION B — AUTHORITY REQUIREMENTS PROCEDURES FOR COMPETENT AUTHORITIES | |
|--|---|
| 145.B.005 Scope | Adapted from Part-CAMO Section B. |
| 145.B.115 Oversight documentation | Alignment with Part-CAMO Section B. |
| 145.B.120 Means of compliance | Alignment with Part-CAMO Section B. |
| 145.B.125 Information to EASA | Alignment with Part-CAMO Section B and RMT.0681 (Alignment with Regulation (EU) No 376/2014). |
| 145.B.135 Immediate reaction to a safety problem | Alignment with Part-CAMO Section B and RMT.0681 (Alignment with Regulation (EU) No 376/2014). |
| 145.B.200 Management system | Alignment with Part-CAMO Section B and RMT.0681 (Alignment with Regulation (EU) No 376/2014); The availability of the competent authorities' procedure to the organisations is considered to be covered by national law. |
| 145.B.205 Allocation of tasks to qualified entities | Alignment 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 | Alignment with Part-CAMO Section B. |
| 145.B.220 Record-keeping | Alignment with Part-CAMO Section B, with clarification in point (a)(4)(vi) and introduction of 'observations'. Relevant Basic Regulation articles specified in point (a)(7). |
| 145.B.300 Oversight principles | Alignment with Part-CAMO Section B; 'safety oversight' term changed to 'oversight' to allow for the verification of compliance with requirements other than safety (e.g. environment), as applicable. Point (b)(3) reworded to clarify that unannounced inspections are possible, but not an obligation; Improvement of points (e); 'unannounced inspections' removed from point (f) because they are not considered relevant in this point. |
| 145.B.305 Oversight programme | Alignment with Part-CAMO Section B; Point (b)(1) reworded to clarify that unannounced inspections are possible, but not an obligation. |
| 145.B.310 Initial certification procedure | Alignment with Part-CAMO Section B; Improvement of point (b) in relation to the meeting with the accountable manager; Rearrangement of the elements listed in point (c); Reference to Appendix II introduced in point (e)(1). |
| 145.B.330 Changes — organisations | Alignment with Part-CAMO Section B; |

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| | <p>Reference to the principles of 145.B.300 provided in point (e) for the management of changes not requiring prior approval;</p> <p>Point (d) reworded in accordance with ADR.AR.C.040(e) in order to prevent an obligation to suspend/limit/revoke.</p> |
| 145.B.350 Findings and corrective actions | <p>Alignment with Part-CAMO Section B;</p> <p>The obligation to inform other Member States about findings is limited to level 1 and to EU Member States;</p> <p>Definition of 'level 2 findings' reworded to capture non-compliance with a requirement other than safety related (e.g. environment).</p> <p>Past safety performance removed from the element to consider when extending the 3-month period;</p> <p>Introduction of 'observations'.</p> |
| 145.B.355 Suspension, limitation, and revocation | <p>Alignment with Part-CAMO Section B;</p> <p>Point (a) reworded for clarity;</p> <p>Point (c) amended to include the possibility to 'limit' the organisation, and to refer to the oversight cycle, rather than to 24 months. Reference to 'on-site audit' removed; reference to 'security' situation removed and replaced by 'circumstances outside the control of the competent authority'.</p> |

APPENDICES TO PART-145

| | |
|---|---|
| Appendix I — Authorised Release Certificate — EASA Form 1 | No changes |
| Appendix II — Class and ratings system used for the terms of approval of Part-145 maintenance organisations referred to in Annex I (Part-M) Subpart F and Annex II (Part-145) | <p>Incorporation of the contents from Appendix IV to Part-M;</p> <p>Deletion of Subpart F references;</p> <p>Adaptation of the indirect approval of the capability list with the approach of changes not requiring prior approval;</p> <p>The possibility to issue Authorised Release Certificates (ARCs) (for Part-ML aircraft) is added to the LIMITATION of A3 (helicopters) class rating.</p> |
| Appendix III — Maintenance Organisation Certificate — EASA Form 3-145 | No changes |
| 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 changes |



5.2. Appendix II — Detailed summary of the proposed amendments to Part-21

| Part 21 reference | Action |
|--|--|
| 21.1 General Competent authority | Change of title to harmonise it with the contents; Competent authority for each subpart of Section A and B has been defined in this point. |
| 21.2 Scope | New point that defines the scope of Section A and B. |
| SECTION A — TECHNICAL REQUIREMENTS | |
| 21.A.1 Scope | Minor improvement of text and reference updated. |
| SUBPART A — GENERAL PROVISIONS | |
| 21.A.3A Failures, malfunctions and defects Reporting system | Introduction of voluntary reporting; Requirements for production organisations transferred from points 21.A.129 and 21.A.165. |
| 21.A.5 Record-keeping | Replacing all record-keeping requirements spread over in Section A. |
| 21.A.9 Access and investigations | Replacing all investigation requirements spread over in Section A. |
| SUBPART B — TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES | |
| 21.A.44 Obligations of the holder | References updated. |
| 21.A.47 Transferability | Applicability to ETSO authorisation for APU added. |
| 21.A.55 Record-keeping | Requirement moved to point 21.A.5. |
| SUBPART D — CHANGES TO TYPE-CERTIFICATES AND RESTRICTED TYPE-CERTIFICATES | |
| 21.A.105 Record-keeping | Requirement moved to point 21.A.5. |
| 21.A.109 Obligations and EPA marking | References updated. |
| SUBPART E — SUPPLEMENTAL TYPE-CERTIFICATES | |
| 21.A.118A Obligations and EPA marking | References updated. |
| SUBPART F — PRODUCTION WITHOUT PRODUCTION ORGANISATION APPROVAL | |
| 21.A.124A Alternative means of compliance | New point to introduce the AltMoC process. |
| 21.A.125B Findings | Classification and requirements for competent authorities moved to Section B. |
| 21.A.125C Duration and continued validity | References updated, text improved and harmonised with similar requirements in other subparts. |
| 21.A.126 Production inspection system | Record-keeping requirements moved to point 21.A.5. |
| 21.A.129 Obligations of the manufacturer | Reporting requirements moved to point 21.A.3A. |
| SUBPART G — PRODUCTION ORGANISATION APPROVAL | |
| 21.A.134A Alternative means of compliance | New point to introduce the AltMoC process. |
| 21.A.139 Quality Production management system | Introduction of the safety management according to the 12 elements defined in ICAO Annex 19. |
| 21.A.143 Production organisation exposition | Minor improvement of text and reference updated. |
| 21.A.145 Approval requirements Resources | Minor improvement of text and reference updated. |
| 21.A.147 Changes to the approved production management system organisation | Minor improvement of text and reference updated. |
| 21.A.157 Investigations | Requirement moved to point 21.A.9. |

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| 21.A.158 | Findings | Classification and requirements for competent authorities moved to Section B. |
| 21.A.159 | Duration and continued validity | References updated, text improved and harmonised with similar requirements in other subparts. |
| 21.A.165 | Obligations of the holder | Reporting requirements moved to point 21.A.3A. |
| SUBPART H — CERTIFICATES OF AIRWORTHINESS AND RESTRICTED CERTIFICATES OF AIRWORTHINESS | | |
| 21.A.180 | Inspection | Requirement moved to point 21.A.9. |
| 21.A.181 | Duration and continued validity | References updated, text improved and harmonised with similar requirements in other subparts. |
| SUBPART I — NOISE CERTIFICATES | | |
| 21.A.210 | Inspection | Requirement moved to point 21.A.9. |
| 21.A.211 | Duration and continued validity | References updated, text improved and harmonised with similar requirements in other subparts. |
| SUBPART J — DESIGN ORGANISATION APPROVAL | | |
| 21.A.239 | Design assurance management system | Introduction of the safety management according to the 12 elements defined in ICAO Annex 19. |
| 21.A.243 | Data Handbook | References updated and text improved. |
| 21.A.245 | Approval requirements Resources | Structure of the point made consistent with the requirement in point 21.A.145. Introduction of the requirements for a chief of the office of the airworthiness function; a chief of the independent monitoring of compliance and adequacy function; and depending on the size of the organisation and on the nature and complexity of its activities, any other person or group of persons that are needed to ensure that the organisation is in compliance with the requirements of Part 21. |
| 21.A.247 | Changes in to the design management assurance system | References updated and text improved. |
| 21.A.257 | Investigations | Requirement moved to point 21.A.9. |
| 21.A.258 | Findings | Classification and requirements for competent authorities moved to Section B. |
| 21.A.259 | Duration and continued validity | References updated and text improved. |
| 21.A.263 | Privileges | References updated and text improved. |
| 21.A.265 | Obligations of the holder | References updated and text improved. Points of Subpart A added. |
| SUBPART M — REPAIRS | | |
| 21.A.447 | Record-keeping | Requirement moved to point 21.A.5. |
| 21.A.451 | Obligations and European Part Approval (EPA) marking | References updated and text improved. |
| SUBPART O — EUROPEAN TECHNICAL STANDARD ORDER AUTHORISATIONS | | |
| 21.A.604 | ETSO Authorisation for an Auxiliary Power Unit (APU) | References updated and text improved. |
| 21.A.609 | Obligations of holders of ETSO authorisations | References updated and text improved. |
| 21.A.613 | Record-keeping | Requirement moved to point 21.A.5. |

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|----------------------------------|-------------------------------------|---------------------------------------|
| 21.A.619 | Inspection by the Agency | Requirement moved to point 21.A.9. |
| 21.A.619 | Duration and continued validity | References updated and text improved. |
| SUBPART P – PERMIT TO FLY | | |
| 21.A.705 | Competent authority | Requirement moved to point 21.1. |
| 21.A.721 | Inspections | Requirement moved to point 21.A.9. |
| 21.A.723 | Duration and continued validity | References updated and text improved. |
| 21.A.729 | Record keeping | Requirement moved to point 21.A.5. |



| SECTION B — PROCEDURES FOR COMPETENT AUTHORITIES | | |
|--|---|---|
| SUBPART A — GENERAL PROVISIONS | | |
| 21.B.5 | Scope | Content moved to 21.2. |
| 21.B.10 | Oversight documentation | New point aligned with Part-CAMO Section B. |
| 21.B.15 | Information to the Agency | 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 | Deleted |
| 21.B.45 | Reporting/coordination | Deleted to align with Part-CAMO Section B. |
| 21.B.55 | Record-keeping | Text 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 authorities previously contained in Section A. |
| 21.B.130 | Issue of letter of agreement | Included in 21.B.120, to be consistent with Part-CAMO Section B. |
| 21.B.145 | Limitation, suspension and revocation of a letter of agreement | Requirement moved to 21.B.65. |
| 21.B.150 | Record-keeping | Requirement 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 authorities previously contained in Section A. |
| 21.B.230 | Issue of letter of agreement | Included in 21.B.220, to be consistent with Part-CAMO Section B. |
| 21.B.235 | Continued surveillance | Deleted 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 | Requirement moved to 21.B.65. |
| 21.B.260 | Record-keeping | Requirement moved to 21.B.55. |
| SUBPART H — AIRWORTHINESS CERTIFICATES AND RESTRICTED CERTIFICATES OF AIRWORTHINESS | | |

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|---|--|---|
| 21.B.330 | Suspension and revocation of a noise certificate | Requirement moved to 21.B.65. |
| 21.B.345 | Record-keeping | Requirement moved to 21.B.55. |
| SUBPART I – NOISE CERTIFICATES | | |
| 21.B.430 | Suspension and revocation of a noise certificate | Requirement moved to 21.B.65. |
| 21.B.445 | Record-keeping | Requirement 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 | Requirement moved to 21.B.65. |
| 21.B.545 | Record-keeping | Requirement moved to 21.B.55. |

