



Terms of Reference

for rulemaking task RMT.0251(b) (MDM.055-MDM.060)

Embodiment of safety management system requirements into Commission Regulations (EU) Nos 1321/2014 and 748/2012 ‘Phase II — SMS for EASA Part-21 design organisations, EASA Part-21 production organisations and EASA Part-145 maintenance organisations’

ISSUE 1

Issue/rationale

With reference to ICAO Annex 19, the objective of this Rulemaking Task is to set up a framework for safety management in the remaining initial and continuing airworthiness domains.

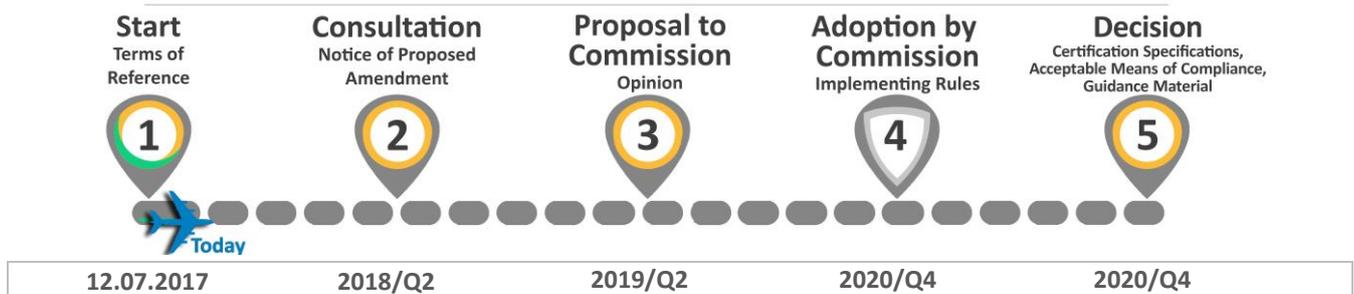
Phase I of this Rulemaking Task delivered Opinion 06/2016 for SMS in continuing airworthiness management organisations; proposing a new Annex to Regulation (EU) No 1321/2014 ‘Part-CAMO’. Part-CAMO includes SMS requirements and related authority oversight and management system requirements and is intended for continuing airworthiness management organisations (CAMO’s) managing aircraft used by licensed air carriers or of complex motor-powered aircraft.

Phase II of this Rulemaking Task will introduce SMS requirements and related authority oversight and management system requirements for EASA Part-21 approved design organisations, approved production organisations and EASA Part-145 approved maintenance organisations. It shall consider the work done in Phase I. This task will also assess the need to amend Part-21 for production without production organisation approval and for design under alternative procedures to DOA.

These Terms of Reference only cover Phase II of the Rulemaking Task.

Action area:	Safety Management		
Affected rules:	Commission Regulation (EU) No 748/2012, Part-21 and related AMC & GM Part-21 Commission Regulation (EU) No 1321/2014 Annex I Part-M, Annex II Part-145 and related AMC & GM		
Affected stakeholders:	CAMOs, Part-145 Maintenance Organisations, Part-21 Production and Design Organisations and national aviation authorities (NAAs)		
Driver:	Safety	Rulemaking group:	No
Impact assessment:	Full	Rulemaking Procedure:	Standard

• EASA rulemaking process milestones



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

- ICAO Annex 19 'Safety Management' introduced standards for safety management based on a framework for the implementation and maintenance of a State Safety Programme (SSP) by States and of Safety Management Systems (SMS) by service providers.
- In accordance with ICAO Annex 19, Edition 2, Chapter 3 standards States shall require (among others) that:
 1. Approved maintenance organisations providing services to operators of aeroplanes or helicopters engaged in international commercial air transport in accordance with Part I or Part III to Section II of ICAO Annex 6 ('Operation of Aircraft'), respectively implement a safety management system (SMS). This standard became applicable on 18 November 2010.
 2. Organisations responsible for the type design or manufacture of aircraft, engines, and propellers in accordance with ICAO Annex 8 implement a safety management system (SMS). For design and manufacture of aircraft this standard became applicable in November 2013. For design and manufacture of engines and propellers the standard will become applicable in November 2019.

Related safety issues:

The following safety recommendation(s) (SRs) addressed to EASA from aircraft accident investigation report(s) and published by the designated safety investigation authority¹ will be considered during this RMT;

- **UNKG-2015-001** following the accident to a British Airways A319 that occurred at London Heathrow Airport on 24 May 2013, in which the fan cowl doors from both engines detached from the aircraft during take-off causing serious damage to the airframe and certain systems.
- SR text: 'It is recommended that the European Aviation Safety Agency publishes amended Acceptable Means of Compliance and Guidance Material 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.'

New SRs related to this task may be considered after the publication of this ToR, where appropriate.

There are no exemptions² in accordance with Article 14 'Flexibility provisions' and/or Article 22 'Air operation certification' of Regulation (EC) No 216/2008³ that are pertinent to the scope of Phase II of this RMT.

¹ Regulation (EU) No 996/2010 of the European Parliament and of the Council of 20 October 2010 on the investigation and prevention of accidents and incidents in civil aviation and repealing Directive 94/56/EC (OJ L 295, 12.11.2010, p. 35) (<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1479716039678&uri=CELEX:32010R0996>).

² Exemptions having an impact on the development of this RMT content and referring to:

- Article 14.1: Measures taken as an immediate reaction to a safety problem;
- Article 14.4: Exemptions from substantive requirements laid down in the Basic Regulation and its implementing rules in the event of unforeseen urgent operational circumstances or operational needs of a limited duration;
- Article 14.6: Derogation from the rule(s) implementing the Basic Regulation where an equivalent level of protection to that attained by the application of the said rules can be achieved by other means;
- Article 22.2(b): Individual flight time specifications schemes deviating from the applicable certification specifications which ensure compliance with essential requirements and, as appropriate, the related implementing rules.



There are no alternative means of compliance (AltMoC) relevant to the content of Phase II of this RMT.

ICAO references relevant to the content of this RMT:

- For the changes to the authority requirements (Section B): ICAO Annex 19 ‘Safety Management’, Edition 2, Chapter 3 and Appendix I; and
- For the changes to the organisation requirements (Section A): ICAO Annex 19 ‘Safety Management’, Edition 2, Chapter 4 and Appendix II.

Note: Chapter 5 and Appendix 3 of ICAO Annex 19 are the subject of Regulation (EU) No 374/2014⁴ (see also notice of proposed amendment (NPA) 2016-19 ‘Alignment of implementing rules and acceptable means of compliance/guidance material with Regulation (EU) No 376/2014 — Occurrence reporting’⁵.)

2. What we want to achieve — objective

The overall objectives of the EASA system are defined in Article 2 of Regulation (EC) No 216/2008. This task will contribute to the achievement of the overall objectives by addressing the issues outlined in Chapter 1.

The specific objective of this proposal is to further increase aviation safety by introducing safety management in the scope of Part-21 design and manufacturing and Part-145 maintenance.

This aims at ensuring that design, manufacturing, and maintenance organisations:

- take a systematic approach to identifying aviation safety hazards, including their own organisational hazards, to assess the associated risks, and to effectively mitigate their consequences; and
- foster an organisational culture for effective safety management and effective occurrence reporting in accordance with Regulation (EU) No 376/2014 ‘Occurrence reporting’.

This also aims at promoting a performance-based approach to oversight, including the monitoring of effectiveness of management systems and assessing the performance of an organisation.

This will be achieved by adapting Regulations (EU) No 748/2012 and 1321/2014⁶ and corresponding AMC/GM to ensure compliance with the relevant ICAO Annex 19 safety management and oversight standards and recommended practices (SARPS) in the field of design, manufacture, and maintenance. The task will support the implementation of ICAO SARPS on State Safety Programme (SSP), without explicitly regulating SSP.

Additional objectives are to:

- harmonise organisation management system requirements for Part-21 design and production organisations, as well as for Part-145 approved maintenance organisations;

³ Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79, 19.3.2008, p. 1) (<http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=146719701894&uri=CELEX:32008R0216>).

⁴ 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, 24/04/2014, p. 18-43)

⁵ <http://www.easa.europa.eu/system/files/dfu/NPA%202016-19.pdf>

⁶ 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)



- ensure effective compliance monitoring in organisations as part of the management system;
- promote a proportionate and integrated approach to SMS, as proposed with Opinion 06/2016 'Part-CAMO', facilitating the integration of new SMS elements into existing management systems and ensuring compatibility with other management system standards implemented within an organisation;
- determine the need to enhance human factors provisions in Part-21 and Part-145 in close cooperation with the EASA Human Factors Collaborative and Analysis Group (CAG);
- support the implementation of 'EASA level of involvement in product certification' (Opinion 07/2016);
- improve overall consistency by streamlining certification and oversight processes for Part-21 design and production organisations, as well as for Part-145 maintenance organisations, as far as practicable;
- introduce management system requirements for competent authorities, as proposed with Opinion 06/2016 'Part-CAMO', and as already applicable in the areas of air operations, aircrew, aerodromes, ATM/ANS;
- apply 'better regulation' principles by:
 - focusing on the safety objective to improve resilience of implementing rules;
 - moving detailed implementation aspects to the AMC level to increase overall flexibility, where appropriate; and
- facilitate international harmonisation.

Finally, through this rulemaking task EASA will:

- address a number of issues identified during Phase I of RMT.0251, in particular the need to further improve consistency between Part-145, Part-M and the new Part-CAMO (Opinion 06/2016)⁷; and
- assess whether the 'authority requirements' for areas where only EASA is the competent authority should be included in Part-21 Section B (as for other domains where EASA may be the competent authority) or kept at the level of the EASA working procedures (as is the case today for Part-21).

The intended effects would mainly be to:

- enhance safety by contributing to effective hazard identification, error reduction, and by improving transparency in design, manufacture, and maintenance;
- improve consistency in the management system and oversight requirements;
- improve flexibility and proportionality, in particular as regards management system requirements;
- support the management of safety risks across the total aviation system.

NOTE:

- During the RMT.0251 (MDM.055) Phase I, which resulted in the publication of Opinion 06/2016⁸, it was proposed to assess the benefits of consolidating common elements in the authority- (Section B) and organisation (Section A) requirements across Regulation (EU) No 1321/2014, as part of RMT.0251 Phase II. In the meantime an EASA roadmap for simpler, better, and performance-based general authority and organisations requirements was initiated. The roadmap proposes the

⁷ Refer to Appendix 2 of Opinion 06/2016.

⁸ Refer to Appendix 2 of Opinion 06/2016.



adoption of consolidated, common authority- and organisation requirements for safety management across all aviation domains within a 10-year timeframe. The roadmap objectives will supersede this specific objective. Therefore, consolidating common elements in the authority- (Section B) and organisation (Section A) requirements across Regulation (EU) No 1321/2014 will not be considered as part of RMT.0251 Phase II.

3. How we want to achieve it:

During the development of the draft rules and the regulatory impact assessment (RIA), the following activities will be considered:

- performing a detailed gap analysis of the existing requirements in Regulations (EU) No 748/2012 and 1321/2014 and corresponding AMCs/GM against ICAO Annex 19, Edition 2;
- closely monitoring the development of industry standards for SMS in design, manufacture and continuing airworthiness and considering the inclusion of suitable industry standards as acceptable means of compliance (AMC);
- building on the material developed and stakeholder feedback received on;
 - NPA 2013-01(C) (including related NPA comments and draft comment-response document (CRD), and
 - Opinion 06/2016 'Part-CAMO' and associated AMC and GM material currently being developed.

4. What are the deliverables

- NPA with draft implementing rules, AMC, GM to:
 - Commission Regulation (EU) No 748/2012 (Part-21),
 - Annex I to Commission Regulation (EU) No 1321/2014 (Part-M), and
 - Annex II to Commission Regulation (EU) No 1321/2014 (Part-145).
- Opinion with proposed amendments to the above implementing rules for Commission Regulation (EU) No 748/2012 (Part-21), and Commission Regulation (EU) No 1321/2014; Annex I (Part-M) and Annex II (Part-145)
- Decision with AMC & GM to Commission Regulation (EU) No 748/2012 (Part-21), and to Commission Regulation (EU) No 1321/2014 (Annex I (Part-M) and Annex II (Part-145)); and
- Safety promotion material on safety management and oversight of SMS in design, manufacture and maintenance.

5. How we consult

EASA will make use of a focused consultation group with industry- and authority representatives covering design, manufacture, and maintenance. A calendar of meetings will be defined to support the drafting of the NPA, the analysis of the NPA comments, the preparation of the RIA, and the drafting of the opinion.

Stakeholder consultation may, in addition, be performed through any one or a combination of the following:



- technical workshops or conferences (including teleconferences),
- surveys to collect data for the regulatory impact assessment,
- focused consultation on key issues via surveys or sharing documents per email with a limited group of stakeholders, and/or
- written advisory bodies' consultations.

6. Interface issues

This rulemaking task will be coordinated with any possible future rulemaking activities on safety management related authority- or organisation requirements. It will also be closely coordinated with any forthcoming rulemaking activity on cyber security related to any items relevant for safety management.

7. Reference documents

7.1. Affected regulations

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

7.2. Affected decisions

- 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
- Executive Director 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'

7.3. Reference documents

- ICAO Annex 19 'Safety Management', Edition 2, July 2016;
- NPA 2013-01(C) 'Part-145' Embodiment of Safety Management System (SMS) requirements into Commission Regulation (EC) No 2042/2003 - RMT.0251 (MDM.055)⁹;
- Opinion 06/2016 'Embodiment of safety management system (SMS) requirements into Commission Regulation (EU) No 1321/2014 - SMS in Part-M'¹⁰;

⁹ <http://www.easa.europa.eu/system/files/dfu/NPA%202013-01%20%28C%29%20Part-145.pdf>



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- UK-CAA Position Paper 01 EASA R/AGNA/02/05 dated 19-06-2007 on enhancing Human Factors, Human Performance and Internal Occurrence Reporting Systems into Part 21;
 - Opinion 07/2016 ‘Opinion 07/2016 ‘Embodiment of level of involvement requirements into Part-21’¹¹;
 - Common, general authority- and organisation requirements already published in the areas of air operations (cf. Regulation (EU) No 965/2012), aircrew (cf. Regulation (EU) No 1178/2011), aerodromes (cf. Regulation (EU) No 139/2014); air traffic controller training (cf. Regulation (EU) 2015/340) and ATM/ANS (cf. Regulation (EU) 2017/373);
 - Draft EASA roadmap for simpler, better and performance based general authority and organisation-s requirements (MAB 02-2017 WP06a); and
 - European Commission Better Regulation Guidelines.

¹⁰ <http://www.easa.europa.eu/document-library/opinions/opinion-062016>

¹¹ <http://www.easa.europa.eu/document-library/opinions/opinion-072016>

