European Aviation Safety Agency *21 Jan 2013*

NOTICE OF PROPOSED AMENDMENT (NPA) 2013-01

DRAFT DECISION OF THE EXECUTIVE DIRECTOR OF THE EUROPEAN AVIATION SAFETY AGENCY

amending Decision No 2003/19/RM of the Executive Director of the European Aviation Safety Agency of 28 November 2003 on Acceptable Means of Compliance (AMC) and Guidance Material (GM) to Commission Regulation (EC) No 2042/2003 of 20 November 2003 on the continuing airworthiness of aircraft and aeronautical products, parts and appliances, and on the approval of organisations and personnel involved in these tasks

and

DRAFT OPINION OF THE EUROPEAN AVIATION SAFETY AGENCY

for a Commission Regulation amending Commission Regulation (EC) No 2042/2003 on the continuing airworthiness of aircraft and aeronautical products, parts and appliances, and on the approval of organisations and personnel involved in these tasks

NPA 2013-01 (A)

Embodiment of Safety Management System (SMS) requirements into Commission Regulation (EC) No 2042/2003

RMT.0251 (MDM.055)

EXPLANATORY NOTE and REGULATORY IMPACT ASSESSMENT

DRAFT COVER REGULATION

Executive Summary

This NPA proposes extensive changes to Annexes I 'Part-M' and II 'Part-145' to Commission Regulation (EC) No 2042/2003 to implement the ICAO SMS framework and to support the implementation of SSP/EASP. It relates to the ongoing EASp actions SYS 1.3 and SYS 2.2.

The majority of changes are based on Subparts GEN of the authority and organisation requirements, and related AMC/GM that have been issued with the Regulations for civil aviation air crew[1] and air operations[2] respectively. The existing rule structure remains unchanged.

(a) Changes to Section A (technical requirements) mainly focus on the creation of streamlined, consolidated management system requirements that, while built upon existing quality systems, improve consistency in organisation approvals, and introduce additional requirements related to hazard identification, risk evaluation, and effective risk mitigation. The new requirements ensure compatibility with existing management systems, and facilitate systems integration for organisations holding more than one approval. As part of these changes, all items related to Human Factors have been reviewed and complemented, where necessary. The proposed management system framework, together with the Essential Requirements of the Basic Regulation, address all elements of the ICAO SMS framework (as per draft Annex 19) while ensuring proportionality and flexibility.

(b) Changes to Section B (authority requirements) take due account of the critical elements of a State's safety oversight system as defined by ICAO, and serve the standardisation objective set out in the Basic Regulation. This aims at streamlining procedures for oversight and enforcement, and introduces a set of new management system requirements for competent authorities to increase efficiency, and support the establishment of a comprehensive aviation safety management system at EU level encompassing EU and Member State responsibilities for safety management.

The NPA includes a proposal for transition measures for organisations and authorities to adapt to the new requirements.

An NPA with changes to Annexes III 'Part-66' and IV 'Part-147' will be published at a second stage. It will closely follow the changes proposed with this NPA.

[1] Commission Regulation (EU) No 290/2012 amending Commission Regulation (EU) No 1178/2011.

[2] Commission Regulation (EU) No 965/2012.

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A. Explanatory Note

I. General

1. The purpose of this Notice of Proposed Amendment (NPA) is to envisage amending Commission Regulation (EC) No 2042/2003 of 20 November 2003 on the continuing airworthiness of aircraft and aeronautical products, parts and appliances, and on the approval of organisations and personnel involved in these tasks, and amending related ED Decision No 2003/19/RM of the Executive Director of the European Aviation Safety Agency of 28 November 2003 on Acceptable Means of Compliance (AMC) and Guidance Material (GM) for the implementation of organisation management system and authority requirements providing for compliance with the relevant ICAO standards on Safety management (SMS and SSP) in the field of continuing airworthiness. The scope of this rulemaking activity is outlined in Terms of Reference MDM.055 issue I, v.2 published on 18 July 2011, and is described in more detail below.

2. The European Aviation Safety Agency (hereinafter referred to as the 'Agency') is directly involved in the rule-shaping process. It assists the Commission in its executive tasks by preparing draft regulations, and amendments thereof, for the implementation of the Basic Regulation[3] which are adopted as 'Opinions' (Article 19(1)). It also adopts Certification Specifications, including Acceptable Means of Compliance, and Guidance Material to be used in the certification process (Article 19(2)).

3. When developing rules, the Agency is bound to follow a structured process as required by Article 52(1) of the Basic Regulation. Such process has been adopted by the Agency's Management Board ,and is referred to as 'The Rulemaking Procedure'[4]. This rulemaking activity is included in the Agency's Rulemaking Programme for 2013-2016. It implements the rulemaking task RMT.0251 (MDM.055).

4. The text of this NPA has been developed by the Agency. It is submitted for consultation with all interested parties in accordance with Article 52 of the Basic Regulation and Articles 5(3) and 6 of the Rulemaking Procedure.

5. The proposed rule has taken into account the development of European Union and International law (ICAO), and the harmonisation with the rules of other authorities of the European Union main partners as set out in the objectives of Article 2 of the Basic Regulation. The proposed rule addresses all relevant ICAO Standards and Recommended Practices in the area of SMS.

6. NPA 2012-xx includes the Cover Regulation, changes to Annex I Part-M, and to Annex II Part-145. A separate NPA covering changes to Part-66 and to Part-147 will be published in a second phase.

7. The overall NPA structure is as follows:

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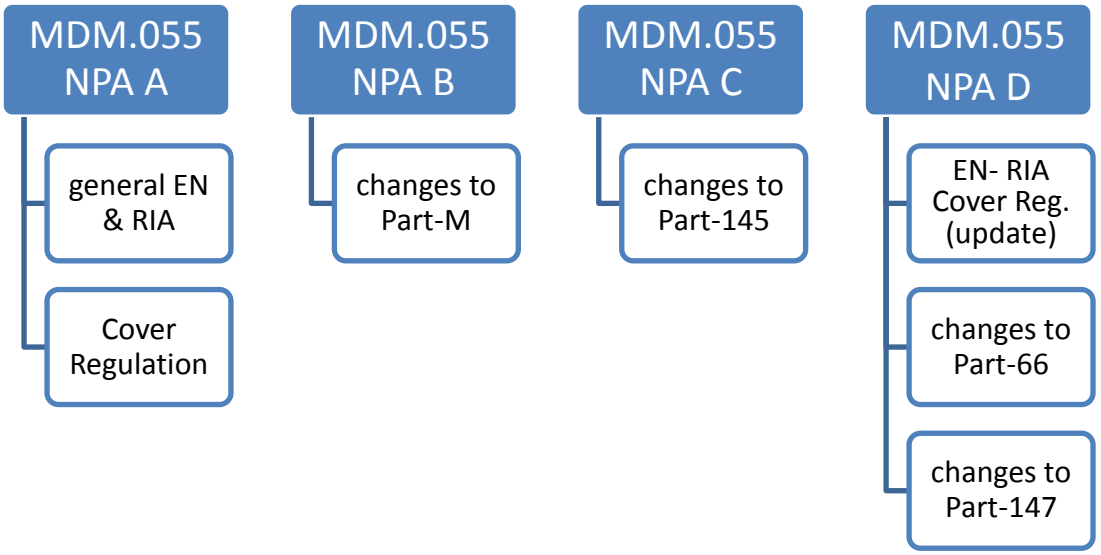
[3] Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79, 19.03.2008, p. 1). Regulation as last amended by Regulation (EC) No 1108/2009 of the European Parliament and of the Council of 21 October 2009 (OJ L 309, 24.11.2009, p. 51).

[4] Management Board decision concerning the procedure to be applied by the Agency for the issuing of opinions, Certification Specifications, and Guidance Material (Rulemaking Procedure), EASA MB 08-2007, 13.6.2007.



The NPAs B and C provide a more detailed description of changes, including a table listing all new and amended IRs, AMC, and GM. In order to facilitate processing and consultation, all new and amended AMC and GM have been included with the corresponding Implementing Rules, and appendices to AMC have been inserted directly after the corresponding AMC.

II. Consultation

8. To achieve optimal consultation, the Agency is publishing the draft Opinion and draft Decision of the Executive Director on its internet site. Comments should be provided within 3 months in accordance with Article 6(4) of the Rulemaking Procedure. This comment period considers that the new rule material, based on that developed through Rulemaking Task OPS.001/FCL.001, has already been subject to the full consultation and legislative process.

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

10. The deadline for the submission of comments is **22 April 2013**.

III. Comment-Response Document

11. All comments received in time will be incorporated in a Comment-Response Document (CRD). The CRD will be available on the Agency's website, and in the Comment-Response Tool (CRT).

IV. Content of the draft Opinion/Decision

Task objective and basis for drafting

12. The principal objective of RMT MDM.055 is to adapt Commission Regulation (EC) No 2042/2003 and corresponding AMC/GM for the implementation of management system requirements providing for compliance with the relevant ICAO standards on Safety Management Systems (SMS) and State Safety Programme (SSP) in the field of continuing airworthiness. This shall ensure compliance with the latest ICAO standards

[5] In case the use of the Comment-Response Tool is prevented by technical problems, please report them to the CRT webmaster (crt@easa.europa.eu).

and recommended practices, thus facilitating international harmonisation, and enhancing safety by introducing new safety management requirements.

13. Subparts GEN of the authority and organisation requirements developed in the context of the extension of the Agency remit to the fields of air crew and air operations form the basis for the current rulemaking task. This 'generic' portion of the authority and organisation requirements had been designed to ensure general applicability throughout all areas within the Agency's remit. In line with this, consultation on the corresponding NPAs was initiated with a view to this general applicability.

More specifically, the amendments proposed with this rulemaking task are based on:

(a) Commission Regulation (EU) No 290/2012[6]:

(1) Subpart GEN of Annex VI Part-ARA and ED Decision 2012/006/R; and

(2) Subpart GEN Annex VII Part-ORA and ED Decision 2012/007/R.

(b) Commission Regulation (EU) No 965/2012[7]:

(1) Subpart GEN Annex II Part-ARO and ED Decision 2012/016/R

(2) Subpart GEN Annex III Part-ORO and ED Decision 2012/017/R.

Some specific AMC and GM in the area of management system are based on CASA draft Advisory Circular AC 145-1(0) dated March 2012 'Safety Management Systems for Approved Maintenance Organisations'[8].

Organisation requirements and management system

14. The Agency supports a holistic approach towards management systems by incorporating safety management principles into the management systems of an organisation and the authority. The evaluation of the ICAO SMS standards and recommended practices (SARPs) showed that many elements of the ICAO SMS are also addressed by the 'Consistency of Organisation Approvals' (COrA) initiative which had been started under the JAA (see also Advance-Notice of Proposed Amendment, A-NPA 15-2006[9]). The ICAO objective of introducing SMS in all aviation fields can be best supported by introducing streamlined requirements for certification and oversight together with a common management system framework, complemented with area-specific requirements where necessary.

15. Common organisation requirements, along with the corresponding authority requirements, contribute to implementing some essential recommendations of the COrA report. JAA had introduced the concept of approved organisations in all its regulated fields as an important tool to promote safety. As the JARs had been developed progressively, and more or less independently for each field, the regulatory material varied in many aspects. Inconsistencies regarding organisation approvals became apparent while implementing the JARs, and while some of them were justified by the specificity of the field that was addressed, many others were not justified. The Agency chose a gradual approach for harmonising organisation approvals: In a first step, these recommendations were taken into account for drafting the implementing rules for air

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[6] Commission Regulation (EU) No 290/2012 of 30/3/2012 amending Regulation (EU) No 1178/2011 of 3/11/2011 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).

[7] Commission Regulation (EU) No 965/2012 of 5/10/2012 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).

[8] http://www.casa.gov.au/wcmswr/_assets/main/newrules/parts/145/download/draftac145-1-0.pdf

[9] http://www.easa.europa.eu/rulemaking/docs/npa/2006/final%20A-NPA%2015-2006%20COrA%20(26.09.06).pdf

crew and air operations. With this rulemaking task, the COrA recommendations are being considered for continuing airworthiness organisations. Improved consistency in organisation approvals further aims to facilitate acceptance of EASA rules by its main counterparts, such as FAA and TCCA. Acceptance of approvals and certificates in the framework of bilateral aviation safety agreements will greatly benefit from harmonised and streamlined requirements for granting such approvals and certificates.

16. An efficient and effective management system requires the organisation to analyse and assess its system, processes, and their interrelations in order to identify strengths, non-conformities, weaknesses, and hazards in view of ensuring continued compliance and achieving continual improvement. This is not only most adequate in the EASA regulatory and institutional system that relies on organisation approvals, but also probably best adapted for the implementation of the ICAO SMS framework. The management system requirements combine safety management and compliance monitoring provisions into a single set of requirements. The proposed management system framework while addressing all elements of the ICAO SMS framework as per future ICAO Annex 19, promotes an integrated approach to the management of an organisation by including the additional safety management components into the existing organisation requirements, rather than adding them as a separate framework. This aims at encouraging organisations to embed safety management into all safety relevant activities, instead of (super)imposing another system onto their existing management systems.

17. Through the adoption of a common management system framework for all approved organisations in the area of airworthiness, air operations, and air crew, the implementation of safety management processes will be facilitated for those organisations holding more than one approval. This approach entails a wider applicability of the EASA management system framework compared to that of the existing ICAO SMS SARPS in Annexes 1 and 6 which basically mandate an SMS only for those activities that are directly related to the operation of aircraft. By contrast, the Agency is of the opinion that all 'components' of the Air Transportation System, contributing with different degrees to the overall level of safety, need to be considered. From a systems safety perspective, this will not only support 'interoperability' of those components, but also encourage the adoption and promotion of common principles and semantics in the area of safety management.

Proportionality and flexibility

18. In determining the right balance between Implementing Rules and AMC composing the management system framework, the Agency considered the need to ensure resilience of the rules at times where progress in digital communications, computer science, and other disciplines open the way to a wide range of technical alternatives, and where the number of available choices tends to proliferate, with ever increasing complexity and density of operations. This increased complexity in operations and related business models, with multiple interactions between the elements of the Air Transportation System, not only requires authorities and organisations to implement effective management systems, it also requires flexibility for organisations to meet or exceed the safety objectives defined by the Implementing Rules by adopting means of compliance and risk mitigation strategies, as they see fit, depending on their particular organisation, business model, infrastructures, and type of operations.

19. Therefore, the proposed management system requirements are structured so as to clearly set the safety objective in the Implementing Rule while the detailed means of achieving this objective are defined as AMC. This provides flexibility, as an organisation may propose means alternative to those established in the Agency AMC in order to meet or exceed the objective set at rule level. This is particularly relevant in the area of safety risk management, an area where a 'one size fits all' approach typically will not work. Therefore, no overly detailed requirements are included at the level of the Implementing Rules. Hence, the management system core requirements (cf. M.A.616, M.A.712, or

145.A.65) focus on what is essential for safety management, by mandating the organisation to:

(a) clearly define responsibilities and accountabilities;

(b) establish a safety policy;

(c) ensure the identification of aviation safety hazards entailed by its activities, ensure their evaluation, and the management of associated risks;

(d) take actions to mitigate the risks and verify their effectiveness;

(e) maintain personnel trained, competent, and informed about significant safety issues;

(f) document all management system key processes; and

(g) monitor compliance, while considering any additional requirements that are applicable to the organisation.

20. These core requirements come with a series of AMC providing means to comply. Where necessary, these are complemented with Guidance Material to assist in the understanding and implementation of specific elements. Proportionality is provided by proposing two sets of AMC for the most relevant management system requirements: one for complex organisations, another one for non-complex organisations. Criteria for determining organisational complexity are proposed in a dedicated AMC. These do not only consider the size of the organisation, but also specific risk criteria related to the type of activity (cf. AMC1 M.A.712(b) and AMC1 145.A.65(b) 'size, nature, and complexity of the activity'). These criteria are provided as AMC to Section A, as it is the responsibility of the organisation to determine what is needed in terms of management system in order to be able to demonstrate compliance with the Implementing Rules. Defining such criteria in an AMC further provides flexibility to adapt to specific cases, as it is not possible to define criteria that would be proportionate for all possible types of organisations.

21. The table below provides an overview of the new AMC/GM complementing the new management system requirements with a reference to the corresponding ORA/ORO (hereafter referred to as 'ORX') AMC/GM where applicable (in the order of Part-M):

Part-M Subpart G	**Part-145**	**Subject**	**Corresponding ORX AMC/GM**
AMC1 M.A.712(a)(1);(2);(3);(5)	AMC1 145.A.65(a)(1)	Management system for non-complex organisations	AMC 1 ORX.GEN.200(a)(1). AMC1 ORX.GEN.200 (a)(1);(2);(3);(5)
AMC1 M.A.712(a)(1)			
GM1 M.A.712 (a)(1)	GM1 145.A.65(a)(1)*	Safety manager	GM1 ORX.GEN.200(a)(1).
GM2 M.A.712(a)(1)	GM2 145.A.65(a)(1)	Possibility to establish one or more safety action groups	GM2 ORX.GEN.200(a)(1)
AMC1 M.A.712(a)(2)*	AMC1 145.A.65(a)(2)	Safety policy	AMC1 ORX.GEN.200(a)(2).
GM1 M.A.712(a)(2)	GM1 145.A.65(a)(2)	Safety policy	GM1 ORX.GEN.200(a)(2)
AMC1 M.A.712(a)(3)	AMC1 145.A.65(a)(3)	Safety management key processes	AMC 1 ORX.GEN.200(a)(3)
n/a	AMC2 145.A.65(a)(3)	Fatigue risk management scheme	n/a
GM1 M.A.712(a)(3)	GM1	Safety risk management	n/a

Part-M Subpart G	Part-145	Subject	Corresponding ORX AMC/GM
	145.A.65(a)(3)		adapted from CASA draft Advisory Circular 145-1(0)
GM2 M.A.712(a)(3)	GM2 145.A.65(a)(3)	Safety risk management (hazard identification)	n/a
n/a	GM3 145.A.65(a)(3)	Safety risk management	n/a initially proposed with Part-OR (see CRD 2008-22c, and 2009-02c ref. GM2 OR.OPS.GEN.200(a)(5)).
GM3 M.A.712(a)(3)	GM4 145.A.65(a)(3)	Management of change	n/a adapted from CASA draft Advisory Circular 145-1(0)
GM4 M.A.712(a)(3)	GM5 145.A.65(a)(3)	Emergency Response Plan (ERP)	n/a
n/a	GM6 145.A.65(a)(3)	Emergency Response Planning	n/a adapted from CASA draft Advisory Circular 145-1(0)
n/a	GM7 145.A.65(a)(3)	Fatigue Risk Management Scheme (FRMS)	n/a
AMC1 M.A.712(a)(4)	AMC1 145.A.65(a)(4)	Training/Communication on safety	AMC1 ORX.GEN.200(a)(4)
GM1 M.A.712(a)(4)	n/a	Training/Communication on safety	GM1 ORX.GEN.(200(a)(4)
AMC1 M.A.712(a)(5)	n/a	Procedures	n/a
GM1 M.A.712(a)(5)	GM1 145.A.65(a)(5)	Management system documentation	GM1 ORX.GEN.200(a)(5)
AMC1 M.A.712(a)(6)	AMC1 145.A.65(a)(6)	Compliance monitoring – general	AMC1 ORX.GEN.200(a)(6)
n/a	AMC2 145.A.65(a)(6)	Compliance monitoring – maintenance procedures	n/a
n/a	AMC3 145.A.65(a)(6)	Compliance monitoring – audit planning cycles	n/a
n/a	AMC4 145.A.65(a)(6)	Compliance monitoring – Independence of the audit	GM1 ORX.GEN.200(a)(6)
n/a	AMC5 145.A.65(a)(6)	Compliance monitoring – Feedback system of findings	n/a
n/a	GM1 145.A.65(a)(6)	Compliance monitoring – maintenance procedures	n/a
GM1 M.A.712(a)(6)	GM2	Terminology	GM3 ORX.GEN.200(a)(6)

Part-M Subpart G	Part-145	Subject	Corresponding ORX AMC/GM
	145.A.65(a)(6		
AMC1 M.A.712(b)	AMC1 145.A.65(b)Management system*	Size, nature and complexity of the organisation	AMC1 ORX.GEN.200(b)
GM1 M.A.712(b)	n/a	Meaning of 'not involved in the management of continuing airworthiness management of CMPA or CAT aircraft'	n/a
AMC1 M.A.712(e) Appendix XIII to AMC M.A.712(e)	n/a	Organisational review	n/a

For Part-M Subpart F organisations the Agency proposes to define these as non-complex organisations by default in relation to the management system.

Moreover, in order to take into account possible outcomes of the actions recommended by the European General Aviation Safety Strategy Group appointed to the EASA Management Board and the Part-M General Aviation Task Force,[10] it is proposed to grant a transition period of three years starting from the entry into force of the amending Regulation to allow organisations to adapt their management system to the new requirements for all:

(a) maintenance organisations approved in accordance with Part-M Subpart F; and

(b) organisations approved in accordance with Part-M Subpart G not involved in continuing airworthiness management of aircraft used in commercial air transport or CMPA.

This should be sufficient to allow any possible actions requested by the European General Aviation Safety Strategy Group or the Part-M General Aviation Task Force in this area to become effective.

Authority requirements

22. Sections B of Annexes I and II have been reviewed in order to transpose those Part-ARX Subpart GEN authority requirements that are currently not addressed. This is not only a major step towards harmonising and streamlining authority requirements throughout the EASA rules, but it also introduces specific provisions to assist Member States in fulfilling their obligations under the Chicago Convention as related to the implementation of State Safety Programmes (SSPs). These address some elements that are essential for establishing a comprehensive management system at EU level, encompassing the European Union's and Member States' responsibilities for safety management. In this respect, the additional authority requirements included at Implementing Rule level (addressed to the competent authority) and the new Article 7 of the Cover Regulation on oversight capabilities (addressed to the Member State) directly support the implementation of the European Aviation Safety Programme (EASP).

23. More specifically, existing ICAO SARPs on implementing an SSP require the State to establish mechanisms to ensure effective monitoring of the Critical Elements (CEs) of a

[10] Cf. NPA 2012-17 'Part-M General Aviation Task Force' http://easa.europa.eu/rulemaking/docs/npa/2012/2012-17/NPA%202012-17.pdf)

State's safety oversight system[11]. The additional Section B requirements and related AMC, therefore, address the following CEs:

— CE-3: State civil aviation system and safety oversight functions;

— CE-4: Technical personnel qualification and training;

— CE-5: Technical guidance, tools, and the provision of safety-critical information;

— CE-6: Licensing, certification, authorisation and/or approval obligations;

— CE-7: Surveillance obligations; and

— CE-8: Resolution of safety concerns.

Under the new management system framework, the competent authority will be required to implement a function to monitor compliance of its management system with the relevant requirements and adequacy of the procedures, including the establishment of an internal audit process and a safety risk management process.

The new authority requirements further aim at enhancing cooperation and exchange of information between authorities and the Agency, as well as between the authorities themselves. In particular, a requirement is added to ensure competent authorities will provide safety-significant information to the Agency (cf. M.B.106 and 145.B.14). The existence of the European Central Repository is acknowledged; however, the Agency needs to receive information directly in order to be able to take timely action.

Two cases could be envisaged:

(a) The Agency is the Competent Authority and has issued the relevant certificates/ approvals/ authorisations: For those cases, occurrences should be received when national authorities through their occurrence reporting systems receive information that would indicate an issue which also affects certificates, approvals or authorisations issued by the Agency. However, there is a need to establish criteria to define which occurrences should be received.

(1) For example, for design, the occurrences that should be sent should correspond to what is classified 'unsafe condition' in Part 21, and there is no evidence that they were sent to the Design Approval Holder (DAH)[1]. For maintenance, the occurrence that should be sent should indicate a significant non-compliance with Part-M requirements which lowers the safety standard and hazards seriously the flight safety. In the case of maintenance, the wording paraphrases a situation that would be classified as level 1 finding during an audit or inspection.

(2) The purpose of the examples is to provide an idea of what types of occurrences are of interest to the Agency. Feedback should be provided to reporters.

(b) The Agency is not the Competent Authority: In such cases safety-significant information may relate to studies that would contribute to launching rulemaking tasks (in any fields of the competence of the Agency) or developing the European Aviation Safety Plan. Examples could be: statistical analyses, root cause analyses, etc.

For the final Decision, an AMC will be developed along those lines and taking into account the feedback received to this NPA.

Alternative means of compliance

[11] See ICAO Annex 1 Attachment C and ICAO Annex 6 Attachment J 'Framework for the State Safety programme' § 3.1.

24. New requirements on the processing of means of compliance alternative to the AMC issued by the Agency are provided (cf. M.B.104 and 145.B.12): To ensure standardisation and harmonisation, an obligation is established for the competent authority to notify the Agency of each alternative means of compliance that it has approved or is using, as well as to make available to all organisations and persons under its oversight the alternative means of compliance the competent authority itself uses to achieve compliance with the applicable rules. It is important to note that the approval by a competent authority of an alternative means of compliance for a person or organisation under its oversight is not transferable: Other persons or organisations wishing to use the same alternative means of compliance have to process them again with their competent authority (cf. M.A.203, M.A.620, M.A.720, or 145.A.82).

As for the role and obligations included for the Agency, they find their legal basis in the powers attributed to the Agency to monitor the implementation of rules by competent authorities, and to standardise their performance (see Articles 10 and 24 of the Basic Regulation).

Management system for competent authorities

25. New requirements are introduced for competent authorities to establish and maintain a management system in order to discharge their responsibilities as embedded in Sections B (see M.B.110 and 145.B.20). These management system requirements are complemented by a specific provision to establish procedures for the effective exchange of information and assistance of other authorities. This further implements the requirements of Article 15(1) of the Basic Regulation. The management system requirements for competent authorities support the implementation of SSPs through creating an effective oversight system. The main elements of such management system emulate typical management system requirements applicable to organisations in terms of:

(a) documented policies and procedures;

(b) sufficient and adequately qualified personnel, including the obligation to plan the availability of personnel;

(c) nomination of management personnel for the different areas of activity;

(d) adequate facilities and accommodation;

(e) a function to monitor compliance of the management system, including an internal audit process and safety risk management process;

(f) the nomination of a person, or group of persons responsible for the compliance monitoring function;

(g) the need to ensure that certification and oversight tasks performed on behalf of the competent authority conform to the applicable requirements;

(h) a system to identify changes that affect the management system, and to take action to ensure it remains effective; and

(i) a system of record keeping to ensure traceability of activities performed.

With a view to supporting the standardisation process, and facilitating the move of that process towards continuous monitoring[12], competent authorities will also be required to provide the Agency with relevant documentation on their management system, and on changes thereto.

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12 The Continuous Monitoring Approach (CMA) will involve the establishment of a system to continuously monitor Member States according to a harmonised and consistent approach. Monitoring of Member States' safety oversight capability will be based on the following four key steps: (1) collect and validate safety data, (2) analyse and measure level of safety oversight capability, (3) identify deficiencies and assess the related risks, (4) develop and implement strategies for risk mitigation.

26. A new requirement is added on the use of qualified entities (cf. M.B.11 and 145.B.21) to warrant that any certification or oversight task performed on behalf of the competent authority conforms to the applicable requirements, similar to what is required from organisations when contracting activities within their scope of approval. This new requirement is directly relevant to ensuring a high level of safety in competent authority certification and oversight activities, as well as uniform implementation of the relevant Basic Regulation provisions as it may be expected that competent authorities will increasingly rely on third parties to perform some specific tasks.

27. All Section B requirements related to the initial certification, oversight, changes to a certificate and findings, corrective actions, and enforcement have been aligned with the authority requirements in Subparts GEN of Part-ARA/ARO. As a result of this review, all provisions dealing with 'indirect approval' or 'changes acceptable to the authority' have been amended for improved clarity by distinguishing between changes requiring prior approval and changes not requiring prior approval. The amended provisions fully meet the intent of 'indirect approval' or changes 'acceptable to the authority' while providing more flexibility: The competent authority may agree on a case by case basis on the specific scope of changes not requiring prior approval, and on the management of such changes, including how these should be notified to the competent authority.

Oversight

28. Another important element proposed with the NPA, also stemming from the COrA initiative, is the move towards an oversight system for continuous monitoring of the safety performance of organisations and considering specific risks entailed by their activities. The relevant oversight provisions have been reviewed to align with those applicable in the scope of Commission Regulations (EU) No 290/2012 and 965/2012 (cf. Subparts GEN of ARA/ARO). This now provides flexibility to extend the oversight planning cycle up to a maximum of 48 months. Criteria for extension are included at Implementing Rule level, as follows:

— An extension up to 36 months may only be applied when the organisation has demonstrated an effective identification of aviation safety hazards and management of associated risks, and has continuously demonstrated that it has full control over all changes. Additional conditions are that during the previous oversight planning cycle no level 1 findings had been issued and that all corrective actions had been implemented within the time period accepted by the competent authority .

— A further extension up to 48 months may only be applied if the organisation complies with all of the aforementioned conditions, and in addition has established a system for continuous reporting to the competent authority on its safety performance and regulatory compliance. Such reporting system must be accepted by the competent authority.

Moreover, it is proposed that the oversight planning cycle (timelines) and oversight programme (contents) be reviewed annually to ensure they remain appropriate. Linked to this, it is proposed that whenever the competent authority extends the oversight planning cycle beyond 24 months, it should perform a 'programme validation inspection' at the organisation once within each 12-month segment of the oversight planning cycle.

Competent authorities will need to develop and implement methodologies to assess the safety performance of their industry. Guidance material is included to this effect.

The new oversight provisions are intended to increase the level of safety through:

— promoting a systems approach to managing oversight;

— encouraging competent authorities to further enhance their 'safety information systems' as a basis for continuous monitoring; and

— more efficient use of resources by targeting oversight towards those organisations and activities with the lowest safety performance.

Moreover, evolving towards an oversight system that will encourage safety management thinking and behaviours, 'empowers' organisations to manage risks that are not addressed by regulations, and creates incentives for safety management implementation through a reduction in the oversight 'burden', will support effective implementation of the new management system provisions for organisations.

Origin of changes

29. The table below provides an overview of the new rules in Section B of Part-M (Subpart G only) and Part-145 with reference to the corresponding ARA/ARO ('ARX') rule paragraph (in the order of Part-M):

Part-M Subpart G	***Part-145***	***Subject***	***Corresponding ARX rule ref.***
M.B.103	145.B.11	Oversight documentation	ARX.GEN.115
M.B.104	145.B.12	Means of compliance	ARX.GEN.120
M.B.105	145.B.13	Information to the Agency	ARX.GEN.125
M.B.106	145.B.14	Immediate reaction to a safety problem	ARX.GEN.135
M.B.110	145.B.20	Management system	ARX.GEN.200
M.B.111	145.B.21	Allocation of tasks to qualified entities	ARX.GEN.205
M.B.112	145.B.22	Changes to the management system	ARX.GEN.210
M.B.114	145.B.55	Record keeping	ARX.GEN.220
M.B.130	145.B.30	Oversight principles	ARX.GEN.300
M.B.702	145.B.32	Initial certification procedure	ARX.GEN.310
M.B.704	145.B.33	Oversight programme	ARX.GEN.305
M.B.705	145.B.50	Findings and corrective actions	ARX.GEN.350
M.B.706	145.B.35	Changes	ARX.GEN.330

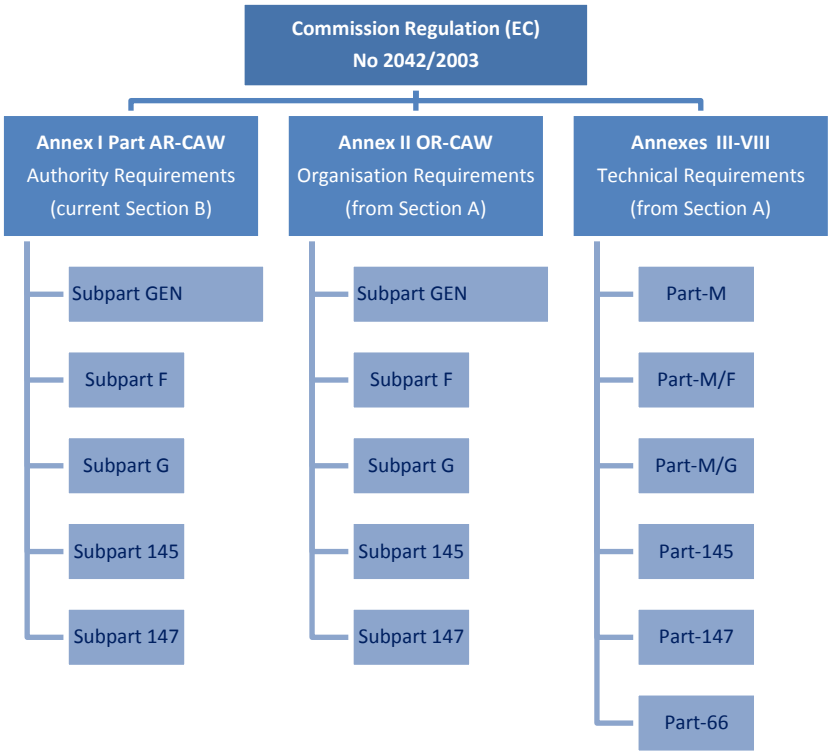
Rule structure

30. Subparts GEN of the authority and organisation requirements developed in the context of air crew and air operations have been transposed without changing the current structure of Commission Regulation (EC) No 2042/2003. This entailed replicating these authority and organisation requirements and related AMC/GM in each of the Annexes/Subparts concerned, i.e.:

- Annex I 'Part-M' Subpart F,
- Annex I 'Part-M' Subpart G,
- Annex II 'Part-145'
- and later on also Annex IV 'Part-147'.

Considering the extent of resulting duplication, the Agency seeks the views of stakeholders on the possible effects and benefits of the following options:

A. Adapting the rule structure of Commission Regulation (EC) No 2042/2003 by separating technical requirements from organisational requirements and 'isolating' all general requirements and related AMC/GM in Sections A and B, meaning those that are identical in all Parts. This would allow including these generally applicable provisions only once in a dedicated Subpart GEN, which would then be complemented with additional requirements specific to each area, such as:



This would not only better align with the rule structure in Regulations (EU) No 290/2012 and 965/2012, but also facilitate future amendments to the regulatory material proposed with this NPA, while ensuring no inconsistencies will be introduced through subsequent rulemaking, as well as prepare for the future adoption of a horizontal rule structure[13] for all EASA Regulations.

or

B. Keeping the current rule structure while reviewing the numbering system throughout Commission Regulation (EC) No 2042/2003 in a way as to enable identification of all rules, AMC and GM that are identical, i.e. those rules, AMC and GM would get the same basic reference number in all Parts/Subparts, complemented by a Part/Subpart identifier, similar to the numbering system adopted for air crew and air operations; such as (example for Section B -Section A could be amended in analogy to that):

Part-M Subpart G	***Part-145***	***Title***
M.B.**115**	145.B.**115**	Oversight documentation
M.B.**120**	145.B.**120**	Means of compliance
M.B.**125**	145.B.**125**	Information to the Agency

[13] Refer to NPA 2008-22a, paragraphs 25 to 30.

Part-M Subpart G	***Part-145***	***Title***
M.B.**135**	145.B.**135**	Immediate reaction to a safety problem
M.B.**200**	145.B.**200**	Management system
M.B.**205**	145.B.**205**	Allocation of tasks to qualified entities
M.B.**210**	145.B.**210**	Changes to the management system
M.B.**220**	145.B.**220**	Record keeping
etc.	…	…

This option would necessitate the application of the new numbering convention to all provisions (rules, AMC, and GM) throughout Regulation (EC) No 2042/2003.

or

C. Keeping the current rule structure and numbering system, while extracting all AMC and GM related to the new 'Management system' requirements in Sections A of Part-M Subpart F, Part-M Subpart G, and Part-145 (and later on Part-147) to include them in a single document, similar to current Agency AMC-20 or CASA draft Advisory Circular AC 145-1(0). This would mainly concern the AMC and GM to M.A.616; M.A.712, and 145.A.65 (and later on 147.A.130).

and/or

D. Keeping the current rule structure and numbering system, while extracting all AMC and GM related to 'Oversight principles' and 'Oversight programme' in Sections B of Part-M Subpart F, Part-M Subpart G, and Part-145 (and later on Part-147) to include them in a single document, as for option **C**.

Whereas options **B**, **C** and **D** could be implemented as part of this rulemaking task, option **A** would require a new rulemaking task.

Transition measures proposed

31. The NPA includes a proposal for specific transition measures both for organisations and authorities to adapt to the new requirements. It should be noted that the final transition measures to be adopted for the amending Regulation will be determined at the level of the European Commission, when submitting the legislative proposal to the EASA Committee.

The transition measures proposed with Article 2 of the amending cover regulation are represented in the table below:

Article	Action	D +1 year	D+2 years	D+3 years
D = date of entry into force (20th day after publication)				
2.1	applicability of the whole amending Regulation (organisations and authorities)			
3(a)	Part-M Subpart G organisations CATor CMPA to adapt their management system, procedures and manuals			
3(b)	Part-145 organisations to adapt their management system, procedures and manuals			
3(c)	Part-M Subpart G org. other than CAT or CMPA to adapt their management system, procedures, manuals			
3(d)	Part-M Subpart F organisations to adapt their management system, procedures and manuals			

Based on this proposal, whereas competent authorities would need to adapt to the new requirements at the latest one year after the entry into force, organisations would have additional time to show full compliance with the new management system requirements

and related amendments. This would mean in practice that the competent authority may raise a non-compliance finding on the basis of the new provisions introduced with the amending regulation starting from the date of applicability; however, the corrective action implementation period granted should consider the applicable transition period. This also implies that during the transition period the competent authority may not suspend, limit or revoke a certificate on the grounds of a level 1 finding relating to any of the new requirements. An implementation plan for gradual implementation of the new provisions should ideally be agreed with the competent authority before the date of applicability of the amending regulation (D + 1 year).

Other changes proposed

32. Considering the extent of changes to Sections A and B expected for task MDM.055, some further issues being directly or indirectly related to SMS or SSP implementation have been addressed through RMT MDM.055. These additional changes are described in NPAs B and C .

V. Regulatory Impact Assessment

1. Process and consultation

The working method adopted for this Regulatory Impact Assessment (RIA) is to perform a qualitative assessment of possible impacts. This choice considers the following facts:

(a) No up-to-date data sets are available to the Agency regarding the typical size, and main activity of approved organisations in the remit of Commission Regulation (EC) No 2042/2003.

(b) SMS is becoming an international standard and failing to implement it:

(1) will create obstacles for mutual acceptance of approvals under bilateral agreements, by not complying with ICAO Annex 6 amendment No. 30, dated 24 March 2006, and, more importantly,

(2) will 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 safety management principles.

(c) The Agency already committed to the implementation of SMS and SSP related requirements in the area of airworthiness as part of the EASp.

(d) A number of EASA States have already mandated the implementation of SMS for maintenance organisations, and some other EASA States have encouraged SMS implementation on a voluntary basis.

(e) Part-M Subpart G approved organisations also holding an AOC as licensed air carriers in accordance with Community law are required to upgrade their management system to the new requirements encompassing safety management under Commission Regulation (EU) No 965/2012, no later than 28 October 2014 (see Article 7 point 1.a) which is before the expected entry into force of the amending Regulation following this NPA.

(f) Competent authorities are already required to upgrade their systems and procedures to the new authority requirements introduced with Commission Regulation (EU) No 290/2012 and Commission Regulation (EU) No 965/2012, and the related 'opt-out' provisions will end in April 2013 and October 2014 respectively which is before the expected entry into force of the amending regulation for this NPA.

2. Issue analysis and risk assessment

2.1. Issue which the NPA is intended to address and sectors concerned

The current rules for airworthiness foresee different types of organisation approvals with different systems for managing safety/quality issues. Despite the fact that these systems have been able to achieve relatively good safety results, the Agency already identified (cf. COrA report as the outcome of rulemaking task MDM.004 'Consistency of Organisation Approvals') that the existence of multiple safety/quality management system frameworks with differing, duplicated or inconsistent requirements can have not just negative economic but possibly adverse safety impacts caused by confusions, in particular if implemented within a single organisation. Such organisations have been identified to have a greater potential for making errors which can affect safety.

It was also concluded that the additional resources necessary to be deployed by both the organisations and the competent authorities performing their oversight to control the various differences, duplications and inconsistencies should rather be used to address safety issues.

The potential for hazards, failures and operational errors is an inherent feature of complex, dynamic socio-technical systems such as aviation. The expected benefit from the uniform implementation of a single management system framework for effective safety management in all types of aviation organisations within the remit of the Basic Regulation requires the development within those organisations of capabilities to identify aviation safety hazards, to assess the associated risks and to effectively mitigate their consequences. If safety management is not implemented, this potential will not be developed at the level of individual organisations and the combined effects of this gap may have a significant safety impact on the entire aviation system.

Considering the proposed applicability of the new management system framework encompassing safety management in the area of continuing airworthiness and the possibility to exempt certain types of organisations from these new requirements, consistency with the applicability of that new framework as set out in Commission Regulation (EU) No 290/2012 has been sought with the current proposal:

Commission Regulation (EU) No 290/2012 requires the following organisations to implement the new management system requirements:

(a) Approved Training Organisations (ATOs) for pilot training, including those only providing training for non-professional licences (Private Pilot Licence, Balloon Pilot Licence, Sailplane Pilot Licence);

(b) Holders of a Flight Simulation Training Device (FSTD) qualification certificate; and

(c) Aero-medical centres.

Therefore, the following organisations, regardless of their size, nature, and complexity, should be required to implement the new management system requirements:

(a) Part-M Subpart G organisations;

(b) Part-145 organisations;

(c) Part-M Subpart F organisations; and

(d) Part-147 organisations.

To ensure proportionality, the AMC provide specific alleviations to certain elements of the management system for organisations that qualify as non-complex. In particular, these are proposed for:

(a) all Subpart F organisations;

(b) all Part-147 organisations;

(c) Part-M Subpart G organisations with up to 10 continuing airworthiness management staff (full-time equivalents) not involved in continuing airworthiness management of complex motor-powered aircraft or aircraft used in commercial air transport; and

(d) Part-145 organisations with up to 20 maintenance staff (full-time equivalents) unless certain complexity criteria apply.

All changes proposed to Part-M Subpart G for organisations not involved in the continuing airworthiness management of complex motor-powered aircraft or aircraft used in commercial air transport as well as to Part-M Subpart F should be considered 'provisional' at this stage, pending the outcome of the actions recommended to the Agency by the European General Aviation Safety Strategy Group appointed to the EASA Management Board. These actions may entail a full review of existing organisation approvals for those organisations not involved in the design, production, operation, maintenance or continuing airworthiness management of complex motor-powered aircraft or aircraft used in commercial air transport.

2.2. What are the risks (probability and severity)?

In the past decades, accidents and occurrences were to a large extent the result of some common causes. Common cause hazards are the ones that are most effectively addressed through prescriptive requirements. Although it cannot be assumed that all common cause hazards have been or even can be ultimately addressed, it is widely accepted that fewer accidents will be related to broadly distributed exposure factors. Accidents and incidents will typically become more 'random' in terms of causation, with causes becoming more specific and unique to given operators, aircraft, events, regions, etc. To address these random causes, a proactive approach is required that will rely on organisations' capability to effectively manage risks, stemming both from common cause hazards or random causes.

If safety management is not implemented within the scope of Commission Regulation (EC) No 2042/2003, the potential for effective safety management will not be developped in the area of continuing airworthiness management, maintenance and maintenance training organisations, which is expected to adversely impact the safety level of the entire aviation system. This assumption is supported by the recurrence of maintenance errors in high risk events, as shown in a number of safety recommendations issued following serious incidents and accidents where maintenance has been identified as direct contributing factor.

Similarly, in a number of accidents and serious incidents, human error, coordination, and performance issues in the Part-M Subpart G organisation have contributed to adverse events and maintenance errors within the contracted maintenance organisation. Continuing Airworthiness Management Organisations (CAMOs) play a key role in the management of safety critical airworthiness factors, and there is evidence that shows they are not immune to the threats posed by human factors. These organisations may suffer errors themselves in their airworthiness management functions or generate pressures on maintenance organisations through a lack of cohesion with the Part-145 HF activities. The following risk areas have been identified:

(a) Performance influencing factors — causing failure in the CAMO airworthiness management functions;

(b) CAMO human/system interface — addressing the specific use of IT systems for the management of airworthiness, as related to planning, scheduling, AD compliance, recording of changes and repairs, etc.;

(c) Organisation interfaces — addressing the need to manage the risks associated with inter-organisation communication and integration of error management systems;

(d) Airworthiness management environment — ensuring that the CAMO creates a working environment that allows proper airworthiness management; and

(e) Organisational factors — CAMO placing inappropriate demands or undue pressure on its own or contracted maintenance provider(s) increasing the likelihood of errors.

Maintenance personnel fatigue crystallises as an area requiring specific attention. Aircraft maintenance personnel play an important role in aviation safety by ensuring that aircraft are maintained and repaired to safely carry passengers and cargo. Fatigue is an intrinsic aspect of all scheduled or unscheduled maintenance operations, essentially because of applicable shift work schemes and because maintenance work is mentally and physically demanding, hence requiring high alertness. Moreover, due to a very fast growing aviation industry and the competitive environment, aircraft maintenance personnel might face time constraints tighter than usual, temporarily reduced staff, or constrained working space. Numerous studies have shown that all of these conditions heighten aircraft maintenance personnel fatigue in their daily tasks.

This is compounded by the fact that aircraft mechanics and engineers usually take great pride in their work and often feel committed to getting the aircraft back up and flying and

prefer to see the job through to the end regardless of how long this might take ('can do' attitude). Although there is a hierarchical control structure within all approved maintenance organisations, maintenance personnel tend to take control themselves of their own working time. Therefore, probability is high that there will always be someone willing to work excessive hours.

ICAO, in its Human Factors manual for maintenance states that aviation maintenance personnel are subjected to physical and mental fatigue mainly due to 'excessive hours of work, poor planning, insufficient staffing, poor shift scheduling and a working environment with no proper control of temperature, humidity or noise'[14]. Fatigued maintenance personnel means a higher likelihood of maintenance errors occuring, resulting in potentially harmful occurrences and a decrease in production efficiency, undermining the workforce, aircraft and workplace safety. Consequently, the NPA stresses the importance of managing safety hazards stemming from maintenance personnel fatigue and proposes the implementation of a formalised fatigue risk management scheme as part of the overall management of safety whenever the maximum work and minimum rest hours laid down in Directive (EC) 2003/88/EC ('European Working Time Directive') are not complied with.

There are reasonable grounds to believe that in some incident reporting aircraft maintenance personnel fatigue is masked by other psychological or physical factors, such as action mistakes, diverted or adversely affected attention, poor workspace environment, and work overload. A detailed analysis of occurrences from the perspective of human factors might have raised the number of aircraft maintenance personnel fatigue events.

Two recent safety recommendations (SRs) considered for this NPA are listed below:

(a) SR following serious incident to Bombardier DHC-8, SX-BIO occurred on 24 April 2010: 'It is recommended 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.'

(b) SR following serious incident to Boeing 737-73V, G-EZJK 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.'

Considering the preceding argumentation for effective safety management in the area of continuing airworthiness management, the potential for maintenance errors and more specifically the impact of maintenance personnel fatigue, the following risk classification is proposed :

[14] ICAO Doc 9824 AN/450 Human factors guidelines for aircraft maintenance manual.

Probability of occurrence		Severity of occurrence				
		Negligible	Minor	Major	Hazardous	Catastrophic
		1	2	3	5	8
Extremely improbable	1					
Improbable	2					
Remote	3				15	
Occasional	4					
Frequent	5					

3. Objectives

The principal objective is to adapt Commission Regulation (EC) No 2042/2003 and corresponding AMC/GM for implementation of organisation management system and authority requirements providing for compliance with the relevant ICAO SARPs on safety management (future Annex 19) in the field of continuing airworthiness, thus facilitating international harmonisation.

Additional objectives are to:

(a) improve overall consistency and harmonise organisation management system requirements applicable to the different types of organisations;
(b) streamline certification and oversight processes, as far as practicable; and
(c) improve resilience of implementing rules by focusing on the safety objective and leaving specific methods and implementation means to the AMC level.

The intended effects would mainly be to:

(a) enhance safety by contributing to hazard identification and risk management, and by improving transparency;
(b) improve efficiency in certification and oversight processes.

4. Options identified

0	Baseline option (no change in rules, risks remain as outlined in Section 2.2)
1	A rulemaking action to achieve the specific objectives specified in Section 3

5. Methodology and data requirements (only for full RIA)

See section 1 of the RIA.

6. Analysis of the impacts

6.1. Safety impacts

The proposed rule changes intend to further improve the overall level of safety by developing safety and risk management capabilities of organisations and authorities within the remit of Commission Regulation (EC) No 2042/2003.

For organisations holding more than one approval within the scope of the Basic Regulation, it will be possible to combine or integrate the different management systems as the same management system framework will apply. This is expected to increase the efficiency and reliability of processes for hazard identification and risk assessment.

Streamlined authority requirements, including the new management system requirements and the new approach to oversight, will enhance the potential of competent authorities to focus their actions on areas presenting a higher risk. Moreover, the additional authority requirements for the exchange of safety information will effectively support the implementation of SSP/EASP.

The safety benefits of the rule changes will only be 'measurable' after some time, as it is widely recognised that the implementation of effective safety management needs a series of changes to occur within an organisation or an authority that require some time to become effective. This is particularly relevant in the area of safety culture, which cannot be 'engineered' through regulations.

6.2. Social impacts

No negative social impacts are expected. The implementation of effective fatigue risk management schemes and a close monitoring of duty times for compliance with maximum work hours and minimum rest periods in accordance with Directive 2003/88/EC are expected to create a positive social impact by improving working conditions of existing staff and/or by increasing the demand for additional maintenance staff.

6.3. Economic impacts

6.3.1 Industry

Organisations approved within the remit of Commission Regulation (EC) No 2042/2003 will be required to adapt their management system to comply with the new requirements, and to follow the corresponding AMC or approved alternative means of compliance. For larger maintenance organisations, it can be expected that a certain percentage have already implemented SMS following the ICAO framework, on a voluntary basis, under contractual obligations imposed on them by their customers, or because they are part of an air operator having implemented an SMS.

Also, Part-M Subpart G organisations approved as part of an AOC are already required to adapt their management system under Commission Regulation (EU) No 965/2012. Moreover, it can be expected that a certain number of maintenance organisations have already implemented on a voluntary basis or as part of industry certification schemes some type of advanced internal maintenance occurrence reporting scheme, threat and error management scheme or similar schemes that would constitute a solid foundation for implementing the new requirements on hazard identification/internal occurrence reporting.

Similarly, as a number of Member States have already strongly encouraged SMS implementation for Part-145 maintenance organisations (such as France, Switzerland, and the United Kingdom, together representing 40 % of all EASA States' Part-145 maintenance organisations, based on 2011 figures), it can be expected that a significant portion of the industry has already started implementing most of the changes that will be required by the new management system framework. In this context it is important to stress that the EASA management system framework has been designed in a way as to leverage the existing quality system and that it provides significantly more flexibility as does the ICAO SMS framework, by including all detailed means to comply at AMC level. On the other hand, organisations that have implemented their SMS based on the ICAO framework should be able to adapt to the new provisions without unnecessary burden, as they should already have in place the main elements of the new management system framework.

At the level of approved organisations, the additional processes and organisational changes to be implemented are summarised below, indicating, where relevant, possible alleviations for smaller/non-complex organisations:

(a) Designation of a safety manager or person fulfilling the role of safety manager;

Note 1. It is possible that the same person acts as safety manager and compliance monitoring manager.

Note 2. In non-complex organisations, the accountable manager, compliance monitoring manager, or one of the nominated post-holders may fulfil the role of safety manager.

(b) Processes for hazard identification, including incident investigation and an internal safety reporting scheme;

(c) A fatigue risk management scheme (FRMS) for all Part-145 maintenance organisations deviating from Directive 2003/88/EC;

(d) Processes for safety risk management;

(e) Safety action planning, including the establishment of a safety review board (SRB);

Note 1. In non-complex organisations, the functions of the SRB may be assumed by the accountable manager.

(f) Safety performance monitoring;

(g) Emergency response planning;

(h) A process for the management of change;

(i) Safety training and promotion; and

(j) Management system record keeping.

Regarding FRMS, it should be mentioned that the European Commission is currently evaluating the effects of the European Working Time Directive[15], and it cannot be excluded that in the specific area of aviation personnel the provisions of the Directive will be replaced by a European regulation at some stage. The management of maintenance engineer fatigue may then be subject to specific prescriptive rules. Implementation of effective FRMS will prepare organisations for the advent of such prescriptive rules. More importantly, effective fatigue risk management will improve the productivity of maintenance personnel, and reduce the number of errors and incidents that together will provide return on investment for the organisation[16].

The above described changes create implementation costs that are proportionally more significant for smaller organisations. These implementation costs can be reduced by providing the possibility for organisations to propose alternative means of compliance for any of the elements contained at AMC level, if they can demonstrate that an equivalent level of safety can be met. This flexibility provided is also intended to encourage the development of novel, more efficient solutions in the area of safety management processes. The implementation costs can further be reduced by encouraging the implementation of common tools and data sharing agreements for the management of safety at the level of industry associations, for example in the context of the European Strategic Safety Initiative (ESSI).

Once organisations have demonstrated effective implementation of the new management system framework, they should see a reduction in the amount of and costs associated with competent authority oversight. Conversely, organisations which have not been able to implement robust safety management processes will be penalised as the oversight burden may increase.

Finally, effective implementation will benefit not only safety, but it is also expected to benefit productivity and efficiency, through the adoption of better management strategies and building up risk management capabilities not only limited to aviation safety risks. Moreover, the causes and contributing factors of incidents and accidents are very often also causing or contributing to production losses or inefficiencies (fatigue being a typical example). The management system framework provides an organisational structure which supports managers to take informed decisions. Without such a framework to manage operational risk, trade-offs between commercial pressures and safety objectives may not be managed effectively and decisions not be justified objectively. Effective management system implementation will, therefore, contribute to a decrease in insurance costs, improved reputation, and commercial success.

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[15] http://ec.europa.eu/social/main.jsp?catId=706&langId=en&intPageId=205

[16] A 'Return on Investment Calculator', including training material and a user guide, is available through the FAA Aircraft Maintenance Human Factors Web Portal: https://hfskyway.faa.gov/hfskyway/fatiguehome.aspx

See also: University of London, Marc Giovannoli 'Fatigue monitoring to improve productivity and safety in aviation maintenance'.

6.3.2 Authorities

The new management system requirements in Section B define a range of new processes and tasks for competent authorities, in particular:

(a) the transmission to the Agency of procedures and amendments thereto, the information to the Agency regarding changes affecting the management system;

(b) the definition and implementation of procedures for participation in a mutual exchange of information and assistance to other competent authorities;

(c) the implementation of a compliance monitoring system, including an internal audit process and safety risk management process;

(d) the implementation of a system to initially and continuously assess qualified entities performing certification or oversight tasks on behalf of the competent authority;

(e) maintaining a list of all organisation certificates issued;

(f) keeping records of the evaluation of alternative means of compliance proposed by persons and organisations and the assessment of alternative means of compliance used by the competent authority itself;

(g) the implementation of a system to plan the availability of personnel;

(h) the development and implementation of methodologies to assess the safety performance of organisations; and

(i) the implementation of a system for continuous monitoring of safety performance, considering compliance and risk management capability of organisations.

Whereas for most of these tasks it may be assumed that authorities can rely on existing resources and communication channels, it is acknowledged that implementing some of them will require a reallocation of resources. The responsibilities of Member States for providing the necessary oversight capabilities and resources to competent authorities to perform their tasks in accordance with applicable requirements have been emphasised through the inclusion of the new Article 7 'Oversight capabilities' in the Cover Regulation. This shall form the 'legal basis' for ensuring that all additional tasks can be financed.

In the medium term, streamlined requirements for oversight, certification and enforcement, as well as the implementation by competent authorities of management systems, including compliance monitoring and safety risk management, are expected to increase efficiency in certification and oversight processes not only related to safety, but also related to costs.

As the new authority requirements and related provisions are fully aligned with those already in place under the new rules in the area of civil aviation air crew and air operations, competent authorities have already initiated the implementation of the required changes and the adaptation of their systems and procedures, which implies that they would simply need to extend the scope of these provisions to the area of Commission Regulation (EC) No 2042/2003[17].

Finally, all of the new processes and tasks arising for competent authorities are intended to support the achievement of the principal objective of the Basic Regulation in terms of safety, standardisation and harmonisation, considering the ICAO SARPs related to the establishment of an SSP. The transition measures proposed with the draft Cover Regulation consider the need for authorities to adapt to the new requirements.

6.4. Environmental impacts

None identified.

[17] The opt-outs defined for Commission Regulations (EU) 290/2012 and 965/2012 will run until 8 April 2013 and 28 October 2014 respectively, which implies the relevant authority requirements should be fully implemented before the amending Regulation produced with rulemaking task MDM.055 is expected to enter into force.

6.5. Proportionality issues

Effective management systems will benefit all types of organisations by supporting managers to take informed decisions, and more effectively allocate their limited resources against risks. In order to limit the impact of the new provisions on smaller, non-complex organisations, all existing alleviations related to the possibility to substitute the quality system (now referred to as 'compliance monitoring function') by an organisational review have been maintained, and further alleviations proposed to acknowledge that the new safety management processes have to be implemented with a limited number of staff. Moreover, for Part-M Subpart G organisations not involved in continuing airworthiness management of aircraft used in commercial air transport or complex motor-powered aircraft, as well as for Subpart F organisations, a three-year transition period is proposed to provide more time to these organisations to implement all additional provisions, in particular those related to hazard identification and safety risk management.

6.6. Impact on regulatory coordination and harmonisation

Considering the current diverse implementation of SMS within different EASA Member States, it is essential to ensure the same SMS rules will apply to all approved organisations within the remit of Commission Regulation (EC) No 2042/2003 to meet the objectives set out in the Basic Regulation and support the establishment of a comprehensive aviation safety management system at EU level encompassing EU and Member State responsibilities for safety management.

Regarding international harmonisation, not implementing a management system framework encompassing SMS in the area of Commission Regulation (EC) No 2042/2003 would create significant obstacles for mutual acceptance of organisation certificates under existing and future bilateral agreements and would be contrary to the objectives of international harmonisation in the area of SMS as fostered by the future ICAO Annex 19 and the Agency's participation in the Safety Management International Collaboration Group.

7. Conclusion and preferred option

Based on the above considerations, the need for an amendment to Commission Regulation (EC) No 2042/2003 is supported on the grounds of safety, increased efficiency, and international harmonisation.

B. Draft Opinion

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

1. Deleted text is shown with a strike through: ~~deleted~~.
2. New text is highlighted with grey shading: new.
3. […] indicates that remaining text is unchanged in front of, or following the reflected amendment.

I. Draft Opinion amending Commission Regulation (EC) No 2042/2003

Article 1

1. Article 1 of Commission Regulation (EC) No 2042/2003 is amended as follows:

Article 1 — Objective and scope

1. This Regulation establishes common technical requirements and administrative procedures for ensuring the continuing airworthiness of aircraft, including any component for installation thereto, which are:
   (a) registered in a Member State; or
   (b) registered in a third country and used by an operator for which a Member State ensures oversight of operations.
2. Paragraph 1 shall not apply to aircraft, the regulatory safety oversight of which has been transferred to a third country and which are not used by a Community operator, or to aircraft referred to in Annex II to ~~the basic~~ Regulation (EC) No 216/2008.
3. The provisions of this Regulation related to commercial air transport are applicable to licensed air carriers as defined by Community law.

2. Article 2 of Commission Regulation (EC) No 2042/2003 is amended as follows:

Article 2 — Definitions

Within the scope of ~~the basic~~ this Regulation, the following definitions shall apply:

(a) 'Acceptable Means of Compliance (AMC)' are non-binding standards adopted by the Agency to illustrate means to establish compliance with the Basic Regulation and its Implementing Rules;

(b) 'Alternative means of compliance' are those that propose an alternative to an existing AMC or those that propose new means to establish compliance with Regulation (EC) No 216/2008 and its Implementing Rules for which no associated AMC have been adopted by the Agency;

~~(a)~~ (c) 'Aircraft' means any machine that can derive support in the atmosphere from the reactions of the air other than reactions of the air against the earth's surface;

~~(b)~~ (d) 'Certifying staff' means personnel responsible for the release of an aircraft or a component after maintenance;

~~(c)~~ (e) 'Component' means any engine, propeller, part, or appliance;

~~(d)~~ (f) 'Continuing airworthiness' means all of the processes ensuring that, at any time in its operating life, the aircraft complies with the airworthiness requirements in force and is in a condition for safe operation;

~~(e)~~ (g) 'JAA' means 'Joint Aviation Authorities';

~~(f)~~ (h) 'JAR' means 'Joint Aviation Requirements';

~~(g)~~ (i) 'Large aircraft' means an aircraft, classified as an aeroplane with a maximum take-off mass of more than 5 700 kg, or a multi-engined helicopter;

~~(h)~~ (j) 'Maintenance' means any one or combination of overhaul, repair, inspection, replacement, modification or defect rectification of an aircraft or component, with the exception of pre-flight inspection;

~~(i)~~ (k) 'Organisation' means a natural person, a legal person or part of a legal person. Such an organisation may be established at more than one location whether or not within the territory of the Member States;

~~(j)~~ (l) 'Pre-flight inspection' means the inspection carried out before flight to ensure that the aircraft is fit for the intended flight.

~~(k)~~ (m) 'ELA1 aircraft' means the following manned European Light Aircraft:

(i) an aeroplane with a maximum take-off mass (MTOM) of 1 200 kg or less that is not classified as complex motor-powered aircraft;

(ii) a sailplane or powered sailplane of 1 200 kg MTOM or less;

(iii) a balloon with a maximum design lifting gas or hot air volume of not more than 3 400 m^3 for hot air balloons, 1 050 m^3 for gas balloons, 300 m^3 for tethered gas balloons; or

(iv) an airship designed for not more than four occupants and a maximum design lifting gas or hot air volume of not more than 3 400 m^3 for hot air airships and 1 000 m^3 for gas airships.

~~(l)~~ (n) 'LSA aircraft' means a light sport aeroplane which has all of the following characteristics:

(i) a Maximum Tale-off Mass (MTOM) of not more than 600 kg;

(ii) a maximum stalling speed in the landing configuration (VS0) of not more than 45 knots Calibrated Airspeed (CAS) at the aircraft's maximum certificated take-off mass and most critical centre of gravity;

(iii) a maximum seating capacity of no more than two persons, including the pilot;

(iv) a single, non-turbine engine fitted with a propeller; and

(v) a non-pressurised cabin;

~~(m)~~ (o) 'Principal place of business' means the head office or the registered office of the undertaking within which the principal financial functions and operational control of the activities referred to in this Regulation are exercised.

3. A new Article 7 is included in Commission Regulation (EC) No 2042/2003, as follows:

Article 7 — Oversight capabilities

1. Member States shall designate one or more entities as the competent authority within that Member State with the necessary powers and allocated responsibilities for the certification and oversight of persons and organisations subject to this Regulation.

2. If a Member State designates more than one entity as competent authority:

(a) the areas of competence of each competent authority shall be clearly defined in terms of responsibilities and geographic limitation; and

(b) coordination shall be established between those entities to ensure effective oversight of all organisations and persons subject to this Regulation within their respective remits.

3. Member States shall ensure that the competent authority(ies) has (have) the necessary capability to ensure the oversight of all persons and organisations covered by their

oversight programme, including sufficient resources to fulfil the requirements of this Regulation.

4. Member States shall ensure that competent authority personnel do not perform oversight activities when there is evidence that this could result directly or indirectly in a conflict of interest, in particular when relating to family or financial interest.

5. Personnel authorised by the competent authority to carry out certification and/or oversight tasks shall be empowered to perform, at least, the following tasks:

   (a) examine the records, data, procedures, and any other material relevant to the execution of the certification and/or oversight task;

   (b) take copies of, or extracts from such records, data, procedures, and other material;

   (c) ask for an oral explanation on site;

   (d) enter relevant premises, operating sites, or means of transport;

   (e) perform audits, investigations, assessments, inspections, including unannounced inspections; and

   (f) take or initiate enforcement measures as appropriate.

6. The tasks under paragraph 5 shall be carried out in compliance with the legal provisions of the relevant Member State.

4. Existing Article 7 of Commission Regulation (EC) No 2042/2003, is renumbered Article 8, as follows:

Article 8 — Entry into force

5. Existing Article 8 of Commission Regulation (EC) No 2042/2003, is renumbered Article 9, as follows:

Article 9 — Agency measures

Article 2 — Entry into force

1. This Regulation shall enter into force on the 20th day following that of its publication in the Official Journal of the European Union. It shall become applicable one year after the entry into force.

2. Limited certifying staff authorisations issued in accordance with 145.A.30(j)(3) or (j)(4) to holders of a flight engineer licence which are valid at the date of entry into force of this Regulation shall remain valid until they expire or they are revoked by the maintenance organisation.

3. By way of derogation from paragraph 1:

   (a) Organisations approved in accordance with Annex I to Commission Regulation (EC) No 2042/2003 'Part-M' Subpart G involved in the continuing airworthiness management of aircraft used in commercial air transport or complex motor-powered aircraft shall adapt their management system, training programmes, procedures, and manuals to be compliant with this Regulation two years after its entry into force at the latest.

   (b) Organisations approved in accordance with Annex II to Commission Regulation (EC) No 2042/2003 'Part-145' shall adapt their management system, training

programmes, procedures and manuals to be compliant with Annex II to this Regulation two years after its entry into force at the latest.

(c) Organisations approved in accordance with Annex I to Commission Regulation (EC) No 2042/2003 'Part-M' Subpart G not involved in the continuing airworthiness management of aircraft used in commercial air transport or complex motor-powered aircraft shall adapt their management system, training programmes, procedures and manuals to be compliant with this Regulation three years after its entry into force at the latest.

(d) Organisations approved in accordance with Annex I to Commission Regulation (EC) No 2042/2003 'Part-M' Subpart F shall adapt their management system, training programmes, procedures and manuals to be compliant with Annex I to this Regulation three years after its entry into force at the latest.

4. Member State shall notify the Commission and the Agency of the programme for implementation of this Regulation containing actions envisaged and related timing.

This Regulation shall be binding in its entirety and directly applicable in all Member States in accordance with the Treaties.