



## Comment-Response Document 2013-01(A)

### Embodiment of safety management system (SMS) requirements into Commission Regulation (EU)

#### No 1321/2014 — SMS in Part-M

### ‘Explanatory Note and Regulatory Impact Assessment Draft Cover Regulation’

CRD TO NPA 2013-01(A) — RMT.0251 (MDM.055) Phase I — 12.5.2016

Related Opinion: 06/2016

#### EXECUTIVE SUMMARY

This Comment-Response Document (CRD) contains the comments received on NPA 2013-01(A), published on 21 January 2013, and the responses provided thereto by EASA.

Based on the analysis of comments and on additional focused stakeholder consultation, Opinion No 06/2016 is developed.

Said Opinion introduces safety management in continuing airworthiness management through the creation of a new Annex Vc (Part-CAMO) to Commission Regulation (EU) No 1321/2014 dedicated to continuing airworthiness management organisations (CAMOs), which are managing aircraft operated by licensed air carriers and/or complex motor-powered aircraft (CMPA), representing an estimated 65 % of all currently approved CAMOs. Only Part-CAMO-approved CAMOs will be required to implement SMS based on a set of proportional management system requirements.

The new Annex Vc (Part-CAMO) will supersede the current Subpart G of Annex I (Part-M) to Commission Regulation (EU) No 1321/2014. The changes introduced to the Part-M Subpart G requirements are globally aligned with the general authority and organisation requirements adopted in the other domains (Aircrew, Air Operations, ADR, ATM/ANS).

Applicability		Process map	
Affected regulations and decisions:	Commission Regulation (EU) No 1321/2014; Commission Regulation (EU) No 748/2012; Decision 2015/029/R	Concept paper:	No
Affected stakeholders:	Air operators; CAMOs; competent authorities	Terms of reference (Issue 2):	25.2.2016
Driver/origin:	Safety	Rulemaking group:	No
Reference:	N/A	RIA type:	Full
		Technical consultation during NPA drafting:	No
		Publication date of the NPA:	21.1.2013
		Duration of NPA consultation:	4 months
		Review group:	No
		Focused consultation:	Yes
		Publication date of the Opinion:	2016/Q2
		Publication date of the Decision:	2017/Q2



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## 1. Summary of comments and responses

130 comments were received on NPA 2013-01(A) 'Explanatory Note and Regulatory Impact Assessment — Draft Cover Regulation' from interested parties, mainly from industry, sports federations, NAAs, and a small number of individuals.

Industry and individuals:

AEA
Aerospace Industries Association
AIR FRANCE
Airbus
Baines Simmons Limited
Boeing
British Gliding Association
Cengiz Turkoglu - City University London
Diamond Aircraft
Europe Air Sports
European Sailplane Manufacturers
FNAM-French Aviation Industry Federation
GAMA
GE Aviation
KLM Engineering & Maintenance
Luftsport Verband Bayern / Germany
NHAF Technical committee
Rega/Swiss Air-Ambulance
SVFB/SAMA
Swiss International Airlines

Competent authorities:

Austro Control Ltd.
CAA The Netherlands
Direction Générale de l'Aviation Civile, France
Federal Office of Civil Aviation, Switzerland
Finnish Transport Safety Agency
Swedish Transport Agency
CAA United Kingdom

Many of the comments made on NPA 2013-01(A) were also repeated on NPA 2013-01(B) 'Embodiment of Safety Management System (SMS) requirements into Commission Regulation (EC) No 2042/2003 — Part-M'. A number of comments was made on the regulatory impact assessment (RIA), which was generally seen as 'too qualitative'. Considering these comments, the Agency conducted two surveys, which were addressed to NAAs and CAMOs respectively, in order to gather data in support of the RIA. An updated RIA is provided with Opinion No 06/2016, which also provides a summary of all NPA 2013-01(A) and NPA 2013-01(B) comments.

Comments made on NPA 2013-01(A) will also be considered in Phase II of RMT.0251 (MDM.055). This concerns in particular the following comments: #50, #57, #63, #64, #65, #90.



## 2. Individual comments and responses

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

- (a) **Accepted** — The Agency agrees with the comment and any proposed amendment is wholly transferred to the revised text.
- (b) **Partially accepted** — The Agency either agrees partially with the comment, or agrees with it but the proposed amendment is only partially transferred to the revised text.
- (c) **Noted** — The Agency acknowledges the comment but no change to the existing text is considered necessary.
- (d) **Not accepted** — The comment or proposed amendment is not shared by the Agency.



## CRD table of comments and responses

(For the resulting implementing rule text, please refer to Opinion No 06/2016)

## (General Comments)

comment

1

comment by: SVFB/SAMA

**ECOGAS, the "European Council of General and Business Aviation Support"**

draft v130511-0058

**ECOGAS is supporting the approach to address Safety Management with a holistic approach, reducing duplication of different functions of the past to manage safety and integrating QM fully into the SM.**

**Our comments are based on our MRO members encompassing organisations with one staff up to organisations with more than a few hundred and up to several thousands.**

**We have no doubt that for major organisations a SM is not only a must but done in the way it is depicted in 2013-01a, it should not only promote safety but could have the cited positive economical effect if done properly.**

**Our critical comments are mainly targeting SM where it concerns SME's.**

The introduction of "complex" organisations is beneficial.

However the past experience with SMS in some NAA's has clearly delivered feedback, that SM for Small and Medium Enterprise (SME) MRO's had no benefit, it only produced a (waste) of paper.

We therefore propose to set the limits where the SM becomes mandatory quite higher for Part M/F and Part 145.

In addition we request more parameters to make the differentiation and to come to tailored solutions.

The approach to have only two categories: small up to 20 and major from 21 up to 20'000 and more is far from proportionate for most SME's.

We propose the following differentiation, also in line with 2012-01 c SMS in 145. Such differentiation would grant safe operation AND promote economical organisations:

Definition: an organisation unit is either a Flight Operation, a ATO, part 145, a component shop, a line station, a CAMO etc.

shift-work (with a 3 shift system) 365x24 counts as 2 additional organisation units, a 2 shift system as 1 orga unit.

1) For organisation with only one organisational unit, no shift work < 200 => **not complex**

a) Organisations with 2 org units > 150 complex (e.g. a two shift system, early and late shift, no night shift)



b) Organisations with 3 org units > 100 complex ( e.g. a full 24 hours shift system, or a one shift system and two additional line stations)

c) Organisations with 4 org units > 50 complex

d) Organisations with 5 or more org units > 20 complex

2) For part M/G there should be a similar differentiation made available

In respect to M/G organisations: the CAMO process can be quite complex overseeing different organisations, locations, operators and so on and a similar set of deciding parameters should be established for CAMO.

An partial alternative approach would be to exempt all activities with aircraft below 5.7 T regardless of their type of Operation, Commercial or non commercial, with the exemption of CAT (Airline and airline like)

Both proposals are taking into account **com(2011) 670 final** from the Commission to the council and the European Parliament<sup>1</sup> and are an expression of a data driven and risk based approach. Currently and for some years to come, the data to change to a data driven approach according this same communication will not be available and it would not be correct to force regulation critical for the economical survival on SME's without proved data.

For organisations with <10 a statement of the owner and a straightforward explanation as to how the owner is assuring safety withing his organisation should satisfy the requirement. .

Such description should be no more than 1 to 3 pages for organisations with up to 10 staff, about 10 pages up to 50. This should remain a user friendly set of pages of organisations up to 100 staff. Thereafter the processes are due to dimension, distances and staff involved justifying more voluminous paperwork, as there will be dedicated staff to prepare, promote and train the material successfully.

We will only comment few details of the NPA 2013-1a,b,c itself and only where we see a priority need, because in general the description is well designed and understandable.

Many of the well intended proposals will remain without the intended economical effect due to wrong limits set in the basic regulation elsewhere.

This problem would be solved by mandating all aircraft up to 5.7 T to cabable part M/F MRO's as long as they stay below the above given limits. This would leave airlines and charter MRO's to the 145 where they belong to. It would also need further transfer of Part M themes into 145, a reduction of Part M for Business Aviation and a much simpler Part M light for leisure aviation.

If this is not done most organisations will remain with the part 145 in order to keep the glider towing, the sightseeing and the ATO training aircraft as their clients und thus imposing on them the regulation well adapted for organisations > 200 staff.

1

This sharing of effort and concentration on identified issues will lead to action being taken cross the Union

in a coordinated fashion,

thus leading to a joined-up approach to safety

management. Such an approach will lead to legislation and guidance material being focused



response

on the issues **that can make a difference, on oversight targeted on areas of greatest safety significance, and on research and recommendations being directed accurately at the high risk areas.** It will also ensure the best use of limited resources by focusing them on those areas **where greatest safety benefits can be achieved.**

Partially accepted.

Regarding the **types of operations** that should be considered as commercial operations and commercial air transport (CAT), CAT for the purpose of Regulation (EU) No 1321/2014 only refers to the operations of licensed air carriers (Regulation (EC) No 1008/2008).

On the issue of **proportionality**, it is important to note that, unlike the ICAO SMS framework, the EASA management system framework proposed with NPA 2013-01(A) provides maximum flexibility to industry as all detailed provisions on safety risk management, compliance monitoring, safety training and communication are included at AMC level. This ensures that the provisions can be applied whatever the size, nature and complexity of the organisation. The proposed degrees of complexity are in fact elements to be considered under the organisation's safety risk management.

Regarding the impact of SMS on small organisations not involved in the maintenance or continuing airworthiness management of large aircraft or aircraft used for CAT, the comment is accepted.

The related opinion will not impose the implementation of an SMS on those organisations. They will be eligible for the new **Part-CAO**, which will mostly consider the existing Part-M Subpart F and G requirements. In addition, the new 'light' Part-M will introduce further alleviations for all ELA2 aircraft and for helicopters certified for up to four occupants and up to 1 200 kg maximum take-off mass (MTOM), regardless of the type of operation. Organisations involved in the continuing airworthiness management of complex motor-powered aircraft (CMPA) or aircraft used for CAT will be required to implement a management system including safety risk management processes, as defined in the new Part-CAMO.

comment

2

comment by: *Diamond Aircraft*

Diamond Aircraft Industries response to the NPA 2013-01, draft decision of the Executive Director of the European Aviation Safety Agency amending Decision No 2003/19/RM and draft opinion of the European Aviation Safety Agency for a Commission Regulation amending Commission Regulation 2042/2003 embodiment of Safety Management System (SMS) – RMT.0251 (MDM.055)

General comment:

As long as not otherwise stated, this comment covers NPA 2013-01 (A),(B) and (C) in a unique manner.

The ICAO driven necessary implementation of a Safety Management System into all areas of aviation is a challenge to the authorities as for the industry. The expectation of all parties involved is focused on effectiveness in increasing safety and lowering costs. The new system



should be implemented easy without big effort for the organisations and generating an increase of safety.

But the NPAs are disappointing. With the presented NPAs neither an increase of safety nor a very limited burden due to the additional administration will be achieved. It is an erroneous belief to generate safety solely with an imposed regulation, with an imposed management system and with additional administration. The real and not only the formal implementation of a SMS will take several years and should start with a very limited scope to become integrated and effective in the day to day business.

It is kind of human natural behaviour, a human factor to accept new methods, new procedures if they have or will expect a personnel benefit. Discussing "Human Factor Principles" in the GM, none of the topics "Change Management", or "Human behaviour" or "Supporting learning abilities" are touched. The intended change to generate a throughout pro active behaviour is of systemic nature, hence those elements are a kind of necessary precondition.

It has to be well noted that EASA tried to scale the required SMS to the size and the scope of the organisation and to assist the organisations with information how to formal implement an SMS. Never the less: to transpose training and information material like chapters from the CAA document UK CAP 716 into the present AMC/GM creates a kind of obligation to comply with the whole content beside all the intended simplifications for some types of organisations. This is a misleading understanding of the use of training material!!

The SMS content of this NPA is focused on additional structures as the backbone for the specific SMS. This represents an old fashioned understanding because the undoubtful methods for the change management are missing. The requirement shall keep the focus on the topic – safety management – itself and the GM on the process of identification the organisations individual threatening of safety.

The legal obligation to implement a SMS shall address specific threats to be avoided based on undoubted facts and data. It can't be questioned that's EASA core business is to collect, evaluate and disseminate such data. The evaluation of data may result in identifying specific circumstances which increase the possibility of a harmful occurrence(s). The organisations responsibilities will be – SSP's existing or not - to sort out these data and to judge if and which measures incl. methods of safety management principles are useful to avoid a real danger to safety.

Throughout the whole NPA not one example is given about an identified safety threat and how this should be managed in several kinds of organisations (acc. the new NPA definitions) in all necessary dimensions. Neither EASA's Report "European Aviation Safety Plan 2013-2016" nor the Annual Safety Reviews of the past years contains any indications for maintenance or continued airworthiness management related occurrences or accidents. So, it becomes very theoretical to develop a useful SMS for 145 or Part M Organisations

EASA's approach to improve safety has been stated in the last European Aviation Safety Plan 2013-2016, chapter 4, page 12:

*"One of the cornerstones to improving safety in Europe is providing organisations and authorities with a framework to manage risks at their level. Safety management systems (SMS) provide such framework. Enabling SMS within the aviation system starts with introducing regulation and follows with actual implementation."*

But EASA itself and the Commission knows - this approach will not be of success!

Reading the same European Aviation Safety Plan 2013-2016, chapter 4, the documents





declares on page 13:

*"Organisation Requirements include consolidated general requirements for management systems, designed to embed the ICAO SMS SARPs in a way as to ensure compatibility with existing management systems and to encourage integrated management. The Agency believes that SMS should not be implemented through an additional requirement superimposed onto the existing rules. ..."*

Commission and EASA published few month ago a common working paper drawing the attention to the risks of overregulation. This paper, named "ROADMAP FOR REGULATION OF GENERAL AVIATION" published at 18 November 2012 is very clear and full of self awareness. Important aspect: Most of the statements are of generic validity and indicate a rethinking about present methods of rulemaking operation:

#### *2. A new approach based on risk...*

*A reoccurring feature in recent discussions has been the need to focus regulation on actual risk and to prioritise rules that target the biggest and most relevant risks. Traditionally much regulation has been blanket regulation, which aimed to cover all possible risks by saying something about everything, although the vast majority of fatalities are caused by a small set of recurring causes.( ...) . The resulting culture of indifference and non-compliance is a major safety risk as those people who choose to ignore rules they consider irrelevant, tend to apply the same attitude to all rules. ...*

#### *4. The limits of effectiveness for prescriptive regulation and what should we learn from it*

*... . It is evident that additional regulation would not change anything, but what we are tackling with is a very human mix of genuine mistakes and attitude problems. Hence, if we wish to improve*

*(GA) safety further, we need to find more intelligent methods of reaching the (pilots)*

*. ...*

*The present NPA demonstrates: EASA has not learned its lesson till now even though EASA started in March 2012 with the ToR to FCL.014 (RMT.0421) due to a missing proportionality between basic ICAO SMS requirements and EU/EASA regulation. This has been stated by EASA as:*

#### *2. Problem/Statement of issue and justification; reason for regulatory evolution*

*During the consultation phases associated with rulemaking task FCL.001, stakeholders expressed concerns about the level of detail required for ATOs representing the non-profit sector and providing training mainly for the LAPL and the other private licences or the associated ratings and certificates. The Agency addressed most of these concerns by simplifying some of the requirements in Section I of Subpart ATO. The Agency committed to improving 'proportionality' of the rules concerning non-complex ATOs and included rulemaking task RMT.0421 in the Rulemaking Programme 2012–2015 in order to review the AMC/GM for non-complex ATOs to provide more detailed information.*

*At the same time while processing to develop new, more applicable rules for training organisations with a lower risk level, EASA created the present NPA repeating the meanwhile identified weak points for a different field of application. With a simple "copy and paste" SMS related text modules have been shifted from the FCL regulation (290/2012) to this NPA, knowing that they are less practicable.*

Definitions on AMC level:



EASA trends to create an increasing number of definitions on AMC level, not only limited to the present NPA but it continued with this NPA. Definitions shall be part of a legal binding requirement, not part of any "soft law". With respect to GM1 M.A.616 (a) (3) this GM shall only be used to list several examples without any formal definition. The nature of definitions should be to be overall valid. But definitions on AMC level are a kind of antagonism because they are also open for the "alternate/alternative means of compliance procedure" with all of the related consequences.

Also the use of the term "complex" in connection with organisations seems to be problematic. "Complex" is used in article 3 of the "Basic Regulation (BR)" to define aircraft (it shall be noticed that the content of the definitions has to be discussed at the next amendment of the BR) but not for organisations. At the time, each kind of organisation pursuant to the BR is defined by the content itself.

The fact, that the BR does not contain any legal definition with respect to the size of organisations, does not empower the Agency acc. article 18 (c) to create AMC material like AMC1 M.A.712 (b) (1); and others, that in practice will be taken as a regulation.

It is understood, that the Agency tried to create material to make M.A.712 (b) more operational, but the look a like legal definition of complex or non complex organisations is beyond the agency's responsibility.

Not withstanding this definition, the regulation contains another one. The term "small organisation" is used throughout the requirement.

M.A.712 (e) contains the definition what has to be understood as a small organisation. It becomes more complicated reading

Appendix VIII to AMC1 M.A.616(d) *Depending on the complexity of the small organisation (number and type of aircraft, number of different fleets, subcontracting of specialised services, etc.),.*

So, in the end the focus is not concentrated

on the core topic what endangers safety and what are the appropriate mitigation measures, the focus is directed to look for arguments to avoid the burdensome structures for the extended SM Systems described in the regulation.

As a matter of fact, it will not be expected to gain EASA to rebuild this NPA from the base but the work should be postponed until RMT.0421 has been finished (probably end 2013) and the results shall be considered before continuing the work on the present NPA.

response Partially accepted.

It is widely acknowledged that SMS creates immediate and direct costs, while its benefits will likely take time to materialise. This view negates the potential of SMS not only to address the risks of major occurrences, but also to identify and tackle production inefficiencies, improve communication, foster a better company culture, and control more effectively contractors and suppliers. In addition, through an improved relationship with the authorities, SMS implementation should result in a reduced oversight burden. Although traditionally aviation safety regulations have not been primarily driven by cost-benefit considerations, SMS should bring about greater regulator sensitivity to the economics of safety. Thus, by viewing SMS as something implemented not solely to prevent incidents and accidents, but to ensure the success of as many elements of an organisation's business as possible, any investment in safety will be seen as an investment in productivity and organisational success.

On the issue of proportionality, it is important to note that, unlike the ICAO SMS framework, the EASA management system framework proposed with NPA 2013-01(A) and the related opinion provides maximum flexibility to industry as all detailed provisions on safety risk management, compliance monitoring, safety training and communication are included at AMC level. This ensures that the provisions can be applied whatever the size, nature and complexity of the organisation.

Regarding the impact of SMS on small organisations not involved in the maintenance or continuing airworthiness management of large aircraft or aircraft used for CAT, the comment is accepted.

The related opinion will not impose the implementation of an SMS on those organisations. They will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements. In addition, the new 'light' Part-M will introduce further alleviations for all ELA2 aircraft and for helicopters certified for up to four occupants and up to 1 200 kg MTOM, regardless of the type of operation. Organisations involved in the continuing airworthiness management of CMPA or aircraft used for CAT will be required to implement a management system including safety risk management processes, as defined in the new Part-CAMO.

Regarding the general comment on the added value of SMS in the continuing airworthiness management and maintenance and the comments on the European Aviation Safety Plan 2013-2016 or annual safety reviews, the comments are noted. While SMS is closely associated with a data-based approach, it is important to stress that effective safety risk management may add value in any organisation and this is the reason why for example the ISO 9001 series and IAQG/EN9110 series standards are evolving to include risk management as an integral part of any management system.

The introduction of SMS in the continuing airworthiness management and maintenance of CAT and CMPA is also intended to create a more effective organisational framework to maximise the efforts undertaken in relation to human factors (HF) management.

comment

28

comment by: *KLM Engineering & Maintenance*

General comment; the NPA should have been written to provide a blanket of management system requirements w.r.t. the existing Continuing Airworthiness regulations to accommodate ICAO SMS requirements. Instead it adds a new level of regulatory requirements to the existing Annex I and II. Combined with a harder definition of AMC material by the introduction of new articles 145.A.82 and M.A.203, existing and new AMC material is now forced on organisations to a level of unacceptable micromanagement.

response

Not accepted.

The additional safety-management-related elements build upon the existing management system requirements and are more proportional than the ICAO Annex 19 framework, which includes all 12 SMS elements at the level of ICAO Standards.

AMC material is not imposed on organisations as they may develop alternative means of compliance.



comment	29	comment by: KLM Engineering & Maintenance
	Standardisation of terminology for line locations. For AMO's: Line Maintenance Location and for Operators: Line Station	
response	<p>Noted.</p> <p>The comment will be considered for Phase II and for the ARO/ORO follow-up task RMT.0516 &amp; RMT.0517.</p>	

comment	57	comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)
	<p><b>Common comments</b></p> <p><b>General</b></p> <p>We welcome the proposal to have different AMC's between complex and non-complex organisations (CAMO).</p> <p>Anyhow, since this is a new concept for many organisation we believe that there is a need for clear guidance material, specially for small complex organisations. It is our experience that small organisations more frequently express their need for clear guidance compared to larger organisations that usually have a better resource situation and therefore better capability to managing new regulations. The benefit of clear guidance in particular for small organisations is to, among other things, help them to determine the need of resources to implement and maintain the new standard.</p> <p><b>Part-145 non-complex organisation</b></p> <p>It is difficult to read understand and find out the alleviations for a non-complex Part-145 organisation. In Part-M for the CAMO is it more clearly to find the difference between a complex and a non-complex organisation.</p> <p>Especially "small" complex and non-complex organisations need clear guidance to understand and to give them a possibility for proper implementation.</p> <p><b>The use of wording "Recurrent training" and "Continuation training" in Part-M and Part-145</b></p> <p>Inconsistent use of the wording "recurrent training" and "continuation training".</p> <p><i>"Recurrent Training" used on the following pages:</i></p> <ul style="list-style-type: none"> <li>· Part-M - Page 66, 89, 126, 131, 132, 133, 184.</li> <li>· Part-145 - Page 53, 58, 145, 147-149.</li> </ul> <p><i>"Continuation Training" used on the following pages:</i></p> <ul style="list-style-type: none"> <li>· Part-M - Page 89-90, 122, 132, 134.</li> <li>· Part-145 - Page 55, 69, 70, 90, 148-149, 181-184.</li> </ul> <p><b>The competence for Compliance Monitoring Manager (CMM)</b></p> <p>GM1 M.A.706(c) point the CMM as one of the appointed persons and that makes the AMC1</p>	



M.A.706(g) applicable. This makes the competence requirement “higher” for the CMM in an MG compared with MF, 145 or AOC.

· Is that the intention?

· We propose adequate competence requirement when a person have the CMM function in several certificates.

In that case it will mean the CMM in organisations with several certificates must have practical experience from maintenance and/or continuing airworthiness to be competent.

*CMM in a 145, ref AMC1 145.A.30(c)*

*3(c) be able to demonstrate relevant knowledge, background and appropriate experience related to the activities of the organisation, including knowledge and experience in compliance monitoring; and*

*CMM, ref AMC1 ORO.GEN.200(a)(6)*

*(c) (3) (iii) be able to demonstrate relevant knowledge, background and appropriate experience related to the activities of the operator, including knowledge and experience in compliance monitoring; and*

#### **Competence for managers, staff and key personnel**

The competences are well described in GM5 145.A.30(e).

Why not have similar charts for MF and MG as well?

- Compliance Monitoring Manager
- Compliance Monitoring Staff
- Safety Manager
- Safety key personnel

#### **Training — Personnel Involved In Compliance Monitoring**

The training is different described in the regulation for the auditor.

For the auditors in the Part-145, it is described in AMC5 145.A.30(e) and GM5 145.A.30(e). No equivalent found in Part-M for MF and MG.

For the auditors in the MG, it is described in the M.A.706(k). That describes it is up to the standard agreed by the competent authority.

We propose common requirements for the auditors (CAMO/MF/145/AOC

response

Partially accepted.

Following a recommendation made by the Focused Consultation Group, the application of complexity criteria for the determination of applicable AMCs (**complex/non-complex organisations**) will not be maintained for the new Part-CAMO. Consequently there will be a single set of management system AMCs to be used by all Part-CAMO approved organisations. Specific needs may be addressed through alternative means of compliance.

The Focused Consultation Group further recommended that this change to management-system-related AMCs and GM be also considered for the other domains.

The need for GM is acknowledged. Specific implementation support in relation to SMS in maintenance and continuing airworthiness management will be provided in the framework of the EASA's safety promotion programme (a safety promotion task will be proposed for the



planning cycle 2017–2021). This may entail templates for manuals, implementation guidelines, etc.

Regarding inconsistent use of the wording ‘recurrent training’ and ‘continuation training’: this comment is accepted. The Part-CAMO rules and related AMCs & GM will be reviewed to only use the term ‘recurrent training’.

Regarding your comment on different qualification standards for managers, key personnel and compliance monitoring staff, this will be discussed when finalising the AMCs and GM to Part-CAMO (Phase I) and taken up also for Phase II, to ensure a consistent approach for Part-CAMO, Part-145, Design and Production Organisations.

For information, the European Human Factors Advisory Group (EHFAG) will be tasked to propose GM on the qualifications and experience of the safety manager, for inclusion with the Part-CAMO AMCs and GM. .

comment 64

comment by: Airbus

Attachment [#1](#)

Comments as per attachment included below:

**Comment No. 1: 1. PARAGRAPH / SECTION YOUR COMMENT IS RELATED TO:** NPA 2013-01(A), page 14/30, section A., paragraph IV., sub-paragraph 30. —Rule structure **2. PROPOSED TEXT / COMMENT:** Amongst the different options proposed by the EASA, Airbus prefers the option A. However, can the EASA tell which subpart will address the pilot-owner maintenance? **3. RATIONALE / REASON / JUSTIFICATION:** Although an additional workload for the Agency and the industry is anticipated by this choice, Airbus is in favour of the separation of technical and organisational requirements: It brings consistency throughout European regulation structure.

**Comment No. 2: 1. PARAGRAPH / SECTION YOUR COMMENT IS RELATED TO:** NPA 2013-01(A), pages 20-21/30, section A., paragraph V., sub-paragraph 2.2. —What are the risks (probability and severity)? **2. PROPOSED TEXT / COMMENT:** It seems that consideration for fatigue is limited to maintenance personnel, although this sub- paragraph acknowledges that —in a number of accidents and serious incidents, human error, co-ordination, and performance issues in the Part-M Subpart G organisation have contributed to ad-verse events and maintenance errors within the contracted maintenance organisation . It is proposed to take into account personnel fatigue also for Part-M Subpart G organisations. **3. RATIONALE / REASON / JUSTIFICATION:** To ensure effective management of human factors/human performance and limitations in the area of continuing airworthiness management and to create a positive social impact by improving working conditions of existing staff and/or by increasing the demand for additional Part-M Subpart G organisation staff (ref. also to NPA 2013-01(A), page 23, section A., paragraph V., sub- paragraph 6.2).

**Comment No. 3: 1. PARAGRAPH / SECTION YOUR COMMENT IS RELATED TO:** NPA 2013-01(A), page 27/30, section B., paragraph I. Article 1 —Objective and scope **2. PROPOSED TEXT / COMMENT:** The point 2. is amended to delete —the basic and to add —(EC) No 216/2008 . It is proposed to check, and to amend as necessary, the Part-M, Part-145, Part-66



and Part-147 for consistency. **3. RATIONALE / REASON / JUSTIFICATION:** For consistency.

**Comment No. 4: 1. PARAGRAPH / SECTION YOUR COMMENT IS RELATED TO:** NPA 2013-01(A), page 27/30, section B., paragraph I. Article 2 —Definitions **2. PROPOSED TEXT / COMMENT:** It is proposed to amend the definition of ‘Alternative means of compliance’ as follows: QUOTE (b) ‘Alternative means of compliance’ are those means that are proposed submitted by the applicant to the competent authority as an alternative to an existing AMC or those that propose as 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; UNQUOTE **3. RATIONALE / REASON / JUSTIFICATION:** For clarity.

**Comment No. 5: 1. PARAGRAPH / SECTION YOUR COMMENT IS RELATED TO:** NPA 2013-01(A), page 27/30, section B., paragraph I. Article 2 —Definitions **2. PROPOSED TEXT / COMMENT:** Definitions are given for the terms ‘Acceptable Means of Compliance’ and ‘alternative means of compliance’. It is proposed that the Agency includes a definition for ‘Guidance Material’ as well. **3. RATIONALE / REASON / JUSTIFICATION:** For clarity and consistency.

**Comment No. 6: 1. PARAGRAPH / SECTION YOUR COMMENT IS RELATED TO:** NPA 2013-01(A), page 29/30, section B., paragraph I. Article 7 —Oversight capabilities **2. PROPOSED TEXT / COMMENT:** The point 5. of the Article 7 lists some (—at least ) empowerment details. It would be appropriate to define also the limits of this empowerment (confidentiality, protection of proprietary data, etc...). **3. RATIONALE / REASON / JUSTIFICATION:** To balance requirements and prevent possible confusion, errors, or extensive judgment.

response

Noted.

**Response to comment 1:**

The possibility to adapt the rule structure of Regulation (EU) No 1321/2014 as per Option A of the Explanatory Note will be assessed in Phase II. This will also consider the outcome of the proposal made by the EASA Rulemaking Advisory Group (RAG) to consider a better rule structure to address the common authority and organisation requirements (horizontal rule structure). Different options are being determined and will be the subject of a dedicated impact assessment.

The elements related to pilot-owner maintenance are proposed to be included as Appendix II ‘Limited pilot-owner maintenance’ to the new Part-ML (Annex Vb to Regulation (EU) No 1321/2014).

**Response to comment 2:**

The introduction of SMS requirements in the new Part-CAMO is intended to address all types of risks in continuing airworthiness management, including fatigue, but without imposing a formal fatigue risk management scheme. Nevertheless, the regulatory impact assessment (RIA) to be provided with the Part-CAMO opinion will be updated to consider the comment made.

**Response to comment 3:**

Accepted: Consistency will be ensured across the different Parts. Most of the required changes will be done in Phase II.

**Response to comment 4:**

Not accepted: It is not possible to change the definition at this stage, as it has already been



adopted in the different domains. See also response to comment 1. A horizontal rule structure would facilitate assessing and adopting such changes across domains.

**Response to comment 5:**

Noted: The proposal will be assessed in RMT.0251 (MDM.055) Phase II as the definition would also need to be added for the other domains.

**Response to comment 6:**

We acknowledge the importance of the items raised in your comment; we propose to address them in the AMCs to the Part-CAMO authority oversight requirements (Phase I).

comment

66

comment by: *British Gliding Association*

General comment

British Gliding Association

The concept of a formalised and regulated safety management system is too onerous for many small organisations and sporting organisations with a dispersed workforce. The requirements should be laid down only for commercial air transport leaving small organisations to self manage and for larger sporting organisations to develop their own appropriate safety management systems appropriate to the activity, perceived risk and type of operation.

response

Accepted.

The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on **General Aviation** CAMOs (CAMOs that are not involved in CAT and are not managing CMPA). Linked to that, those organisations will not have to introduce HF training nor assess HF-related competences of their staff. They will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements.

comment

77

comment by: *Swiss International Airlines / Bruno Pfister*

General Comments

1) SWISS Intl Air Lines has voiced already earlier that

- SMS is intended to go beyond COMPLIANCE => COMPLIANCE is only ONE ELEMENT of QUALITY

- therefore, calling the Quality Manager Compliance Monitoring Manager in effect limits his scope

- the Quality Manager should not become a Postholder as this would limit his freedom to think "outside of the box"

2) No required qualifications for the Compliance Monitoring Manager are considered to be inadequate/not acceptable

Specific Comments

1) AMC1 145.A.30 (c) 3(b) is in conflict with 145.A.30 (c)

the difference between "appoint" and "nominate" is not clear

2) GM 145.A.30 Table: Compliance Monitoring Staff should also have knowledge of





	occurrence reporting systems
response	<p>Noted.</p> <p>The new management system provisions build upon those elements that are already in place today in most organisations approved within the scope of Regulation (EU) No 1321/2014, i.e. the <b>'quality-system-related'</b> provisions that actually only deliver the 'compliance monitoring function' of the new management system requirements. Organisations may refer to the different functions using their own terminology, as long as they can demonstrate the correspondence between these and the functions required by Part-CAMO.</p> <p>Following the recommendations made by the Focused Consultation Group, Part-CAMO will require the nomination of a person or group of persons for the compliance monitoring function. AMC's on the qualification and experience of the compliance monitoring manager will be added.</p>
comment	<p>80 <span style="float: right;">comment by: UK CAA</span></p> <p>Please be advised that the UK CAA do not have any comments on NPA 2013-01 (A).</p>
response	<p>Noted.</p>
comment	<p>87 <span style="float: right;">comment by: AEA</span></p> <p>General comment; the NPA should have been written to provide a blanket of management system requirements w.r.t. the existing Continuing Airworthiness regulations to accommodate ICAO SMS requirements. Instead it adds a new level of regulatory requirements to the existing Annex I and II. Combined with a harder definition of AMC material by the introduction of new articles 145.A.82 and M.A.203, existing and new AMC material is now forced on organisations to a level of unacceptable micromanagement.</p> <p>Standardisation of terminology for line locations. For AMO's: Line Maintenance Location and for Operators: Line Station</p>
response	<p>Please refer to the response to comment #29.</p>
comment	<p>90 <span style="float: right;">comment by: GE Aviation</span></p> <div style="border: 1px solid black; padding: 10px; margin: 10px 0;"> <p style="text-align: center;"><u>GE Aviation</u></p> <p><b><u>Sarah Knife</u></b></p> </div>

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May 22 2013

**Subject: EASA NPA 2013-01 Embodiment of Safety Management System (SMS) requirements into Commission Regulation (EC) No 2042/2003**

GE Aviation appreciates the opportunity to respond to EASA's NPA introducing proposed new Safety Management Systems (SMS) regulations for part 145 organizations, and to provide input to the regulatory process. We fully support the core management system concepts of 145.A.65.

GE Aviation, like many large manufacturing sector companies, provides a variety of aviation products and services, and holds multiple certificates and approvals, including design and production certificates under part 21, as well as part 145 repair station certificates in the US and also in the EU.

We have been working with national authorities for many years to develop our own SMS, and welcome the broader use of structured risk management throughout the industry. Introduction of such an approach, with recognition of the limitations of the risk management process, should avoid negative impacts on existing, highly effective and uniquely suited processes and systems for effectively managing safety. These existing systems and activities have evolved along with the sophistication and efficiency of the products themselves, and already largely satisfy the tenets of the SMS Framework. The detailed comments we have developed in response to this NPA are intended to help avoid unintended adverse impacts on existing safety and quality systems in the maintenance environment.

GE Aviation recognizes that this proposal for Safety Management System implementation is part of a broader restructuring of EASA requirements. However, GAMA is very concerned that the size and scope of the proposed changes are so extensive that there will be significant impact on the vast majority of industry organizations and National Aviation Authorities. Further, due to the sheer size of the proposal and the countless process changes contained in the NPA, the domain experts in the quality and maintenance shop organizations that will be directly affected likely lack the personnel and resources necessary to effectively evaluate this NPA and assess the true impact of the proposal. This NPA is such a significant change to existing processes that at the very least, there must be a more detailed and practical transition management plan that provides an adequate schedule to implement these changes to minimize the impact to both industry and authorities and to ensure no impact on safety.



In addition, we are concerned about the potential complexity, cost, and resource burden associated with regulatory compliance activities for this proposed set of rules and guidance. We include in our detailed comments some discussion of the regulatory impact assessment, which should be updated to more fully address the effects of this package.

We are also concerned about the balance between the material appearing as regulation vs. AMC. In the executive summary of NPA 2013-01(C), EASA describes that “the new management system provisions are introduced to ensure maximum flexibility by defining core requirements of the management system”. However, GE Aviation is concerned that the very prescriptive nature of much of the AMC material and the process for approving alternative means of compliance, such as the proposed risk assessments for deviations from certain AMC, completely contradicts and in fact removes the intended flexibility.

The AMC material proposed as part of this NPA seems to be changing from an explanation/clarification of the regulations and an acceptable method of compliance to a detailed prescriptive requirement which is essentially EASA implementing regulation by AMC. This concern is further supported by the text from NPA 2013-01(A) “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 organizations and persons under its oversight the alternative means of compliance the competent authority itself uses to achieve compliance with the applicable rules.”

GE Aviation is concerned that the prescriptive and detailed nature of the proposed AMC language means that the only flexibility available for industry to implement a proportional company SMS rather than a forced “one size fits all” EASA SMS program is through many alternative means of compliance. Because so many alternative means of compliance would be necessary, the obligation for an NAA to report every alternative means of compliance will influence the competent authority to only accept compliance to the AMC rather than using it as guidance material due to the administrative burden. The overall outcome may be that enforcement of overly-prescriptive policy and guidance could disrupt and diminish the effectiveness of existing safety systems.

In addition to the issue of overly prescriptive guidance, some elements of the guidance advocate processes which are not practicable. For example, in GM1 145.A.95 Findings, the draft language requires a procedure to establish root cause analysis to identify all possible systemic and contributing factors (regulatory, human factors, organizational, managerial, cultural, technical, etc.). There is no practical approach for either industry or authority to determine compliance with such a general requirement to identify all possible factors. Similarly, the guidance requires safety risk management in multiple locations, applied to issues and processes where there is no accepted methodology for performing risk management. For instance, in the case of AMC1 145.a.45d which requires an organization to develop and maintain policy for the management of risk associated with maintenance instruction, Production Planning, Fatigue risk management, there is no accepted methodology for performing a safety risk assessment and the assessment would be based entirely upon opinion. This situation – having to invent an approach and then defend it to an organization being prevented from implementing a desired change – places the safety manager in an untenable situation. Safety risk management should not be required for scenarios where there is no data or standard methodology available.

GE Aviation is further concerned that adding detailed interpretations to the concepts expressed in the ICAO framework may lead to lack of harmony between different national versions of SMS, impeding mutual acceptance among international authorities.

Again, we thank you for the opportunity to review this important proposal and trust that you



response

will consider our detailed comments (attached) prior to finalizing the document.

Sincerely

Sarah Knife, Ph.D.

Airplane & Regulatory Safety,

GE Aviation Commercial Flight Safety

Noted.

**As this comment is mainly relevant to Part-145, it will be addressed in Phase II.**

Regarding the AMC:

The status of the AMC has not been changed with NPA 2013-01(A): AMCs are non-binding, and regulated persons may choose to demonstrate compliance through alternative means. When they chose to do so, the burden of demonstration of compliance is upon them. This has always been the case in the context of the EASA rules, the new elements are to increase transparency by requiring competent authorities to make available the information on alternative means of compliance that have been accepted, and to support rulemaking and standardisation by requiring competent authorities to notify EASA of any alternative means of compliance they have accepted for their industry, have issued or are using themselves. These requirements on the processing of applications for the approval of alternative means of compliance aim to enhance transparency and support standardisation; they are not intended to change the legal status of the EASA AMCs. With the current system, any organisation intending to use an alternative means of compliance needs to demonstrate an equivalent level of safety, and this general principle remains unchanged.

A further review of all existing AMCs to Regulation (EU) No 1321/2014 may be required in Phase II to include at AMC level only those elements that genuinely constitute means to comply, and this is necessary with or without a specific requirement on alternative means of compliance processing.

Regarding the GM:

GM is included to provide additional guidance, clarification, or to illustrate the elements included at implementing rule (IR) or AMC level. The elements contained in the GM are 'for reference only', they cannot impose any obligations on regulated persons and no findings can be raised against GM. Therefore, the specific comments on the prescriptive nature of some of the GM are not accepted.

Specific implementation support in relation to SMS in the maintenance and continuing airworthiness management will be provided in the framework of the EASA's safety promotion programme (a safety promotion task will be proposed for the planning cycle 2017–2021). This may entail templates for manuals, implementation guidelines, etc.

comment 110

comment by: KLM Engineering &amp; Maintenance

General comment:



response

About the CRT: When adding comments, from time to time it became evident that the paragraph which was commented on did not match its page number (in the "View your Comments" mode) in the NPA 2013-01 (A) , (B) and (C) . Is it a bug in the CRT?

Noted.

This technical issue has been notified to the EASA's Rulemaking Process Support team.

comment

111

comment by: *European Sailplane Manufacturers*

The European sailplane manufacturers do not suppose the changes as described in this NPA2013-01 - at least not for their sector or organisations dealing only with ELA2 aircraft.

The main reasons - also explained in more detail in following comments) are:

...No safety benefit for sport and recreational aviation has been proven.

...Introduction will make 2042/2003 much more complicated.

...Introduction of SMS procedures will result into a modification of organisation manuals for all organisations which means a lot of effort and money.

...Within the General Aviation Communities this should be coordinated by regarding bodies (i.e. the General Aviation Part-M Task Force and the General Aviation Group appointed by the management board).

response

Accepted.

The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on **General Aviation CAMOs** (CAMOs that are not involved in CAT and are not managing CMPA). Linked to that, those organisations will not have to introduce HF training nor assess HF-related competences of their staff. They will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements.

comment

112

comment by: *European Sailplane Manufacturers*

The whole NPA2013-01 is a fine example why EASA rulemaking and associated rules are not appreciated by stakeholders of the General Aviation communities:

A) The proposed rule changes are motivated by the needs of commercial air transport. This is a good reason (everyone wants to board an airliner from time to time...), but not for our sector of aviation.

B) Studying, analysing and commenting the proposed change is nearly impossible for a person still required to earn money by doing some productive work.

NPA2013-01A...30 pages

NPA2013-01B...218 pages



	<p>NPA2013-01C...184 pages</p> <p>In total this means that for everybody concerned with a CAMO / M/F / 145 organisation there is a need to read through more than 400 pages of text!!!!!!</p> <p>This by far exceeds the possibilities of small organisations which would be affected. (And we believe it also exceeds the possibilities of other stakeholders, including NAAs...)</p> <p>C) Possibility of General Aviation stakeholders to influence the text of the NPA was not given. It is a shame that the only possibility to influence the outcome of such a fundamental change to 2042/2003 for General Aviation stakeholders is by commenting this NPA.</p> <p>This should be improved by giving at least the General Aviation Part-M Task Force and the still to be appointed General Aviation Group a possibility to participate before such a NPA is being published.</p> <p>Therefore the sailplane manufacturers can only offer their displeasure in the regard of how this NPA was prepared and published.</p> <p>Additionally it has to be understood that this exactly is the way to introduce disproportionate rules which will after some time need just another "improvement" by more rulemaking activities. (At least good time for rulemakers...)</p>
response	<p>Partially accepted.</p> <p>The possibility for General Aviation stakeholders to influence the rulemaking process was provided, in particular through the Part-M General Aviation Task Force. It was stated in NPA 2013-01(A) that 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 <b>were to be considered 'provisional'</b>.</p> <p>The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on <b>General Aviation CAMOs</b> (CAMOs that are not involved in CAT and are not managing CMPA). Linked to that, those organisations will not have to introduce HF training nor assess HF-related competences of their staff. They will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements.</p>
comment	<p>113</p> <p>comment by: <i>Federal Office of Civil Aviation, FOCA, Switzerland</i></p> <p>In general terms, FOCA welcomes the approach regarding the embodiment of Safety Management System (SMS) requirements into Commission Regulation (EC) No 2042/2003 as it is proposed in this NPA. However, in addition to our detailed comments on the various specific provisions, we would like to make three comments regarding the general approach proposed in this NPA.</p> <p>Firstly, there are several states in Europe (including Switzerland) who already have introduced requirements regarding SMS for their respective industries. The approach proposed by EASA has to take into account these efforts and needs to ensure that costs associated to the transition of these systems to the new harmonized requirements can be kept to a minimum.</p> <p>Secondly, we would like to emphasize the importance of the scalability of the proposal. For</p>



response

SMS to be effective, it is of paramount importance that the approach is understood and well accepted by the industry that is addressed by the respective requirements. Therefore, the regulatory burden in particular for less complex organizations must be kept to a minimum and a pragmatic application of the requirements must be ensured. Furthermore, the importance of a scalable system in the sense of “one size does not fit all” is underlined in the European Strategy for General Aviation, which was recently adopted by the EASA Management Board. Hence, scalability is not only called for from a technical point of view, but also enjoys broad support on the political level.

Lastly, the regulatory approach chosen for the embodiment of SMS requirements needs to allow for the transition from a compliance based to a more performance/risk based approach to safety oversight. Therefore, requirements should whenever possible be formulated openly and try to limit oversight by “box ticking”.

Noted.

The related opinion does not introduce SMS as a separate element, but proposes to upgrade the existing management system with specific features aiming for effective hazard identification and safety risk assessment. The new management system ‘framework’ was originally designed to apply to all organisations required to hold an organisational approval within the scope of Regulation (EC) No 216/2008, i.e. all those activities for which the regulator had already determined that the level of risks entailed implied the obligation for an organisation approval and requires continuing oversight. The way this management system framework for safety is being proposed is far less prescriptive than the ICAO SMS framework as per Annex 19 Edition 1: The new set of management system requirements focuses on the safety objectives and leaves the implementation details at AMC level. This should also address the case of Member States having already implemented SMS for continuing airworthiness. As the organisation requirements are ‘objective-based’, it should be possible to upgrade existing systems, without undue burden, if needed by making use of alternative means of compliance.

As regards the impact on authorities, the intent is to align the Part-CAMO Section B requirements as far as practicable with the requirements already applicable in the areas of aircrew and air operations.

Regarding the last point, RAG is currently working on an SMS assessment tool that focuses on effective implementation, rather than on checking against prescriptive requirements. This is intended to assist competent authorities to move towards more performance-based oversight.

comment

119

comment by: AEA

## General Comments

1) AEA has voiced already earlier that

- SMS is intended to go beyond COMPLIANCE => COMPLIANCE is only ONE ELEMENT of QUALITY

- therefore, calling the Quality Manager Compliance Monitoring Manager in effects limits his scope

- the Quality Manager should not become a Postholder as this would limit his freedom to think "outside of the box"



response

2) No required qualifications for the Compliance Monitoring Manager are considered to be inadequate/not acceptable

Specific Comments

1) AMC1 145.A.30 (c) 3(b) is in conflict with 145.A.30 (c)  
the difference between "appoint" and "nominate" is not clear

2) GM 145.A.30 Table: Compliance Monitoring staff should also have knowledge of occurrence reporting systems

Please refer to the response to comment #77.

comment

123

comment by: *FNAM-French Aviation Industry Federation*

FNAM (Fédération Nationale de l'Aviation Marchande) is the French National Professional Union / Trade Association for Air Transport, grouping as full-members:

- CSTA: French Airlines Professional Union (incl. Air France)
- SNEH: French Helicopters Operators Professional Union
- CSAE: French Handling Operators Professional Union
- GIPAG: French General Aviation Operators Professional Union
- GPMA: French Ground Operations Operators Professional Union
- EBAA France: French Business Airlines Professional Union

And as associated members:

- SAMERA: French Airport Material Handling & Catering Professional Union
- UAF: French Airports Professional Union

#### Introduction

The NPA 2013-01 introduces many changes in comparison with

- The Commission Regulation (EC) No 2042/2003;
- The Decision No 2003/19/RM;
- The Acceptable Means of Compliance and Guidance Material related to Commission Regulation (EC) No 2042/2003.

The comments hereafter SHALL BE considered as an identification of some of the major issues the FNAM asks EASA to discuss with third-parties before any publication of the proposed regulation.

In consequence, the comments hereafter SHALL NOT BE considered:

- As a recognition of the third-parties consultation process carried out by the European Parliament and of the Council;
- As an acceptance or an acknowledgement of the proposed regulation, as a whole or of any part of it;
- As exhaustive: the fact that some articles (or any part of them) are not commented does not mean the FNAM has (or may have) no comments about them, neither the FNAM accepts or acknowledges them All the following comments are thus limited to our understanding of the effectively published proposed regulation, notwithstanding their consistency with any other pieces of regulation.

#### FNAM General Comments

The implementation of the Safety Management System (SMS) within the Part-M and Part-145 organisations is a vast programme. All organisations, complex and non-complex ones will be affected by this future regulation. It will have a real economic impact on them and will





increase the workload due to the high number of new requirements which will need to be implemented.

The success of this future regulation implementation depends on the flexibility given to the organisations and how it will be integrated to the organization's work activities.

The FNAM welcomes this NPA considering that this latter will imply a strengthening of the harmonisation and the Level Playing Field within the European States thanks to the enforcing of their same level of safety.

In order to give to the EASA the point of views of the members of the FNAM, you will find below the general comments.

The FNAM is considering the following axes to enhance the project of regulation of the Commission:

1. The transition period to implement the new requirements should be extended to a longer period due to high volume of changes it represents;
2. The perimeter of application of this NPA has to be redefined and a more specific classification of the type of organisations should be achieved;
3. The Human Factor principles should be reconsidered;
4. The coherence with already existing SMS in other fields (Flight Operations, Approved Training Organisation..) should be made.

These axes are detailed below.

1. The transition measured schedule to implement the new requirements should be extended to a longer period due to high volume of changes it represents

The SMS will bring many changes within the organization of the companies. It has to be more progressive in order not to bring an administrative burden to these latter. The number of requirements enhanced by this NPA will generate an increase of work and of resources to satisfy them.

For instance,

☐☐ New responsibilities are assigned to the Safety Manager which involve new technical knowledges from him/her: *"The organisation should identify a person who fulfils the role of safety manager, and who is responsible for coordinating all safety management related processes and tasks. This person may be the accountable manager, or a person with an operational role in the organisation."* (AMC1 M.A.616(a)). Any organization will have to train their proper manager or find a new manager with the appropriated level of knowledges. This action will require time and will lead to additional costs for the organisations. This is not appropriate considering their actual economic situation.

☐☐ A risk assessment has to be carried out before each operational changes, major organisational changes, changes in key personnel, and changes that may affect the maintenance, ect. However, all these analysis will require a colossal work from the organisations and will involve an increase of the resources. It may be even more difficult for the SME to undertake this assessment analysis. Thus, the FNAM is asking to the EASA to give to the organisations a certain level of flexibility on the identification of items on which risk assessment has to be established.

Additional time should be given to the organisations in order to allow them to be able to adapt their structure to the new requirements. It will help the organisation to show full compliance with the new management system. Thus, the FNAM is asking to the EASA to review the transition period and take benefit from this additional time to deepen the RIA.

2. The perimeter of application of this NPA has to be redefined and a more specific classification of the type of organisations should be achieved

EASA has recognized that the approach has to be different for complex and non-complex

organisations. The FNAM welcomes this approach. Therefore, some changes may be required.

The FNAM noticed that the new requirements issued under the Implementing Rules between the non-complex organisations and the complex organisations are not so different. Too many requirements are imposed to the non-complex organisations which will be not economically affordable and where the efficiency of the flight safety in terms of costs it will require is not proven.

First of all, the FNAM is recommending to exclude the organisations belonging to General Aviation maintenance activities from the perimeter of the SMS requirements added through this NPA in the Commission Regulation (EC) No 2042/2003 (Part-M/F and Part-M/G). Indeed, it would be far too complicated for these organisations to implement the SMS requirements as requested by the NPA. It would involve heavy economic consequences without proven safety efficiency. At least, some major alleviation are requested.

Secondly, the boundaries between complex and non complex organisations are far too narrow. Only two classifications (complex and non-complex) of organisations are not enough. There is a too high gap in the organisations described as a complex organisation. It can go from an organisation having 20 FTE for Part-M Subpart F and Part-145 organisations or 10 FTE for Part-M Subpart G to 20,000 FTE or more for the major organisations.

The FNAM emphasises the importance to well proportionate the requirements of the implementation of the new management system according to various factors, such as the number of employees, number of certificates held, number of bases, different types of equipments operated as well as the operational environment, must be considered. It can not just be proportionate to the number of FTE. Thus the FNAM is asking to create three categories of organisations (small, medium and large ones) which will depend on the factors just described above and which will allow a better differentiation on the number and consistence of requirements.

### 3. The Human Factor principles should be reconsidered

New requirements catch the FNAM's attention. In "AMC2 145.A.47(b) Production planning", it is stating that :

*"(b) Reasonable work hour limits should not be exceeded merely for management convenience even when staff is willing to work extended hours. When maximum work hours are exceeded, the organisation and the individual staff member should have a written plan on how the fatigue risk will be mitigated. This may include:*

*(1) additional supervision and independent inspection;*

*(2) limitation of tasks to non-safety critical;*

*(3) use of additional rest breaks; and*

*(4) permission to nap in accordance with guidelines approved by the organisation."*

The FNAM is asking to precisely define what is "Reasonable work hour".

The FNAM reminds that the European Union has already established work and rest time limits and their minimum standard in the "Directive 2003/88/EC" and in the "Directive 2000/79/EC". It is not from the scope of the EASA to establish social requirements but it belongs to the States sovereignty. The FNAM is requesting to remove those principles from the SMS requirements.

### 4. The coherence with already existing SMS in other fields (Flight Operations, Approved Training Organisation...) should be made.

An organisation can hold several types of certificates. As it is stated in the following paragraph: *"(c) Where the organisation holds one or more additional organisation certificates within the scope of Regulation (EC) 216/2008, the management system may be combined or integrated with that required under the additional certificate(s) held"* (M.A.616 Management system). The FNAM is asking to the EASA to define the words "combined" and "integrated" in order to avoid any misinterpretation. The FNAM is suggesting that each organization should

response

have the flexibility to decide which type of organizational structure it wants to establish. In particular for the small organisations, it would be more manageable for them to have only of SMS structure which gathers the monitoring of their different types of certificates. The interfacing of the different SMS by activities within an organisation would make the system more efficient and would involve less administrative load.

The FNAM is asking for a complete interfacing and cohesion between the SMS requirements of the:

- Regulation (EU) N° 1178/2011,
- Regulation (EU) N° 965/2012,
- Regulation (EC) N° 2042/2003.

To conclude, through these different axes of enhancement, the FNAM is suggesting to:

- extend the period of transition for implementing the new requirements;
- give some flexibility for the maintenance organisations on the identification of items on which risk assessment has to be established;
- allow the organisations, which hold different types of certificates, to coordinate their SMS organizational structure as it is more convenient for them;
- remove General Aviation maintenance activities from the scope of this NPA (Part-M/F and Part-M/G);
- remove Human Factor principle from the SMS requirements;
- create three categories of organisations with higher boundaries between each of them.

Noted.

The transition period for the implementation of the new requirements will be defined during the adoption process of the amending regulation, and is expected to be in line with the transition periods for similar amendments applied to other areas. The EASA's related opinion will include a recommendation to define a 2-year transition period in line with the need to provide sufficient time for organisations to adapt their systems.

Organisations involved in the continuing airworthiness management of CMPA or aircraft used for CAT (licensed air carriers) will be required to implement a management system including safety risk management processes, as defined in the new Part-CAMO, which mostly aligns with the management system requirements in the area of aircrew and air operations. All other organisations, which are eligible for the new Part-CAO, will see no major changes to the existing Section A requirements.

Regarding the perimeter of SMS application, as a general principle, all organisations exposed to or possibly contributing to aviation safety risks should ideally be subject to SMS requirements, which entails that such requirements must be proportional and flexible. The management system requirements proposed in Part-CAMO only include core requirements at IR level and all the detailed means to comply are included in the AMCs. However, EASA recognises the need for possible exceptions from this general principle depending on the overall contribution of a particular activity to the safety of the total system and the relative costs and benefits of SMS implementation both for organisations and authorities. This is why at this stage only organisations involved in the continuing airworthiness management of CMPA or aircraft used for CAT will be required to implement a management system including safety risk management.

Regarding a more specific classification of the type of organisations (complex/non-complex), the introduction of three or even more categories poses the risk of a very narrow interpretation of the different criteria by competent authorities. This would also imply that different sets of AMC are provided for each of the types (e.g. small, medium, large). This may result in organisations blindly following the AMCs that apply to them rather than analysing

their systems and procedures to define what is needed to effectively manage risks. Following a recommendation made by the Focused Consultation Group, the application of complexity criteria for the determination of applicable AMCs (**complex/non-complex organisations**) will not be maintained in the new Part-CAMO. Consequently, there will be a single set of management system AMCs to be used by all Part-CAMO approved organisations. Specific needs may be addressed through alternative means of compliance .

Regarding General Aviation, please also refer to the response to comment #537.

Regarding the introduction of Human Factor principles, the comment is not accepted. Human Factors are an integral part of any management system for safety. The changes introduced with Part-CAMO in relation to HF competencies and training have been agreed with the European Human Factors Advisory Group (EHFAG) and validated by the Focused Consultation Group, which was established to assist EASA with the drafting of the opinion for RMT.0251 (MDM.055) Phase I.

Regarding the need to ensure coherence with already existing SMS in other fields (flight operations, approved training organisations, etc.), the opinion to be issued for Part-CAMO will consider alignment, as far as practicable, with the management system already applicable in the areas of air operations and aircrew.

comment 124

comment by: DGAC FRANCE

#### Scope of NPA 2013-01

Annex 19 of the Chicago Convention (adopted by the ICAO Council and subject to ongoing consultation with Contracting States through the state letter 2013/30) requires, in the maintenance field, an SMS acceptable by the authority for " approved maintenance organizations providing services to operators of aeroplanes or helicopters engaged in international commercial air transport, in accordance with Annex 6, Part I or Part III, Section II, respectively". A similar provision was previously included in ICAO Annex 6, Part 1 for aircraft and Part 3, Section II for helicopters.

This NPA however expands the scope of Annex 19 requirements by introducing mandatory SMS for all approved maintenance organisations. Thus, approved organisations under Part M Subpart F and approved organisations under Part M Subpart G involved with aircraft operated in general aviation, although they are presently excluded from the scope of ICAO Annex 19, would be affected by the future European regulation.

In the current context of simplification wished for general aviation, adding such constraints to these organisations would be in contradiction with the conclusions of the European General Aviation Safety Strategy Group.

Furthermore, the implementation of such provisions would encourage the use of independent Part 66 licensed staff. A paradoxical result, probable but not desirable, could be that some organisations would give up their approvals that would become too demanding. In this regard, DGAC experience in implementing SMS for operators involved in commercial air transport or for Part 145 approved maintenance organisations has showed the difficulty for these organisations to fully understand the concept of SMS. This finding would be, with no doubt, confirmed for organisations working in the field of general aviation.

DGAC therefore demands that NPA 2013-01 regulatory proposals related to SMS be limited to organisations working on airplanes or helicopters engaged in commercial air transport (as



response

required by the provisions of ICAO Annex 19) or complex powered aircraft operated in general aviation (as Regulation (EC) 2042/2003 requires these aircraft to be maintained by a Part 145 approved organisation and their airworthiness to be managed by a part M/G approved organisation).

I note, in this regard, that if Regulation (EC) 2042/2003 deals with aircraft based on the "large aircraft" criterion, the NPA 2013-01 defines the requirements according to the "complex powered aircraft" criterion as it anticipates the changes in process for Regulation (EC) 2042/2003 (opinion 2012-06). It seems imperative that the next Regulation (EC) 2042/2003 does not introduce different requirements between heavy and complex motorized aircraft. The regulation, in its integrity, should apply either to heavy or to complex motorized aircraft.

Accepted.

The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on General Aviation CAMOs (CAMOs that are not involved in CAT and are not managing CMPA). Linked to that, those organisations will not have to introduce HF training nor assess HF-related competences of their staff. They will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements.

On the differences in definitions for large aircraft and CMPA:

The opinion to be produced for the new Part-CAMO will consider the definition of CMPA in line with the upcoming changes to Regulation (EU) No 1321/2014 by amending Regulation (EU) 2015/1536 (Opinion No 06/2012 'Alignment of Commission Regulation (EC) No 2042/2003 with Regulation (EC) No 216/2008 and with ICAO Annex 6 requirement for human factor principles to be observed in the design and application of the aircraft maintenance programme'). This will replace the references to large aircraft.

comment

125

comment by: DGAC FRANCE

Regulatory requirements introduced by this NPA and unrelated to SGS

This NPA introduces changes other than those related to the consideration of SMS in Part M and Part 145.

Some of them that are consensual will probably not rise debate; in such cases, it is a shame to wait for the implementation of SMS to apply them even, as they would make a significant improvement. For instance, 145.B.45 § (c) will allow to suspend an approval when the inspectors can not carry out an audit for more than 24 months, in a country when the security is not ensured for example.

Others, however, are considered substantial and their development must be addressed through specific(s) NPA(s) so that detailed discussions can be conducted before considering any implementation. Without being exhaustive, I note the following examples related to organisations: the introduction of human factors concepts for the staff employed by Part M / G organisations, the requirement for all Part-145 organisations to implement a Fatigue Risk Management Scheme and for the authorities, the introduction of a new categorization of organisations (wide / not wide, complex / non-complex, very small ..) that are not necessarily well suited to the types of profile of the managed organisations.

response

Noted.

Regarding the introduction of human factors elements in Part-M, it is important that HF



concepts be understood and applied by CAMO staff as they can contribute to events through their own errors or by causing errors to be made within the contracted maintenance organisation. The management system framework, including safety risk management, safety training and safety promotion, creates the proper framework for managing HF-related issues in continuing airworthiness management.

Regarding the comment related to the requirement for all Part-145 organisations to implement a fatigue risk management scheme, this will be assessed in Phase II of RMT.0251 (MDM.055).

Regarding the comment on the categorisation of organisations, following a recommendation made by the Focused Consultation Group, the application of complexity criteria for the determination of applicable AMCs (complex/non-complex organisations) will not be maintained for the new Part-CAMO.

comment

126

comment by: DGAC FRANCE

**Too detailed organisational requirements for the Authorities:**

This NPA goes way too far in terms of details applicable to the authorities' organisation. The 145.B.20 GM1 (a) (2) indicating how the Authority should compute its human resources needed to perform organisations oversight, for example, is too prescriptive and is not at all justified.

DGAC remind you the contents of letter No. 11-237 of 30 November 2011 relating to air operations, where it indicated that it belonged to Member States to define precisely how to organize themselves in order to comply with the rules contained in the part ARO and that from this point of view, the AMC and GM were written in a way that is too detailed and prescriptive.

response

Not accepted.

Guidance material (GM) is not prescriptive.

The changes proposed with NPA 2013-01(B) and (C) in the area of Section B are fully aligned with the corresponding Subpart GEN of the authority requirements already adopted through Regulations (EU) Nos 290/2012 (aircrew) and 965/2012 (air operations). This is also in line with the Terms of Reference for task RMT.0251 (MDM.055) that were issued on 18 July 2011: they indicated that one element of the task would be to implement in Section B relevant provisions linked with the implementation of an SSP in the framework of the European Aviation Safety Programme (EASP), based on the proposal made with Part-AR (authority requirements) (Opinions Nos 03/2011 and 04/2011 at that time). This is intended to enable competent authorities to streamline their systems and procedures to improve efficiency in certification and oversight in the fields of aircrew, air operations, continuing airworthiness and later on in the area of initial airworthiness.

This does not only support the implementation of SSPs, it also implements some of the long-term recommendations of the 'Consistency of Organisation Approvals' (CORA) report (see Advance-Notice of Proposed Amendment (A-NPA) No 15-20061).

<sup>1</sup> [http://www.easa.europa.eu/rulemaking/docs/npa/2006/final%20A-NPA%2015-2006%20CORA%20\(26.09.06\).pdf](http://www.easa.europa.eu/rulemaking/docs/npa/2006/final%20A-NPA%2015-2006%20CORA%20(26.09.06).pdf)



comment 127

comment by: DGAC FRANCE

**An alternative AMC concept that modifies the existing balance:**

It should be noted that an alternative AMC shall only ensure compliance with the implementing rules (IR) and not dual compliance with the provisions contained in the implementing rules (IR) and the associated (not alternative) AMC.

However, AMC1 MB104 (d) (3) suggests that this dual compliance is required. (similarly paragraphs in Part 145 ! )

Under other regulations, synchronized drafting and review of IR and AMC could possibly justify such a wording but the 2042/2003 Regulation AMCs have not been developed for this purpose.

It is therefore requested to either delete AMC1 MB104 (d) (3) or to amend it so that it only includes a reference to the implementing rule to which it guarantees compliance.

Finally, it is not unreasonable to consider the revision of that similar paragraph in other texts implementing the Basic Regulation.

response Partially accepted.

As a result of the changes to M.B.104 (now CAMO.B.120), AMC1 to point (d)(3) is deleted. The intent is to demonstrate compliance with the safety objectives as defined at IR level.

The new Section B requirements proposed for the processing of applications for the approval of alternative means of compliance aim to enhance transparency and support standardisation; they are not intended to change the legal status of the EASA AMCs. With the current system, any organisation intending to use an alternative means of compliance needs to demonstrate an equivalent level of safety, and this general principle remains unchanged.

It is accepted that a further review of the existing AMCs to Regulation (EU) No 1321/2014 may be required to include at AMC level only those elements that genuinely constitute means to comply. Such review would be necessary with or without Section B requirements on alternative means of compliance processing. Considering the possible impact of such review, this can only be done as part of Phase II.

comment 128

comment by: DGAC FRANCE

**The requirements are to be implemented in short delays ... despite insufficient Regulatory Impact Assessment (RIA):**

The RIA proposed by EASA is purely qualitative and only emphasizes the interest of SMS for safety. The Agency recognizes that the implementation of such regulation is costly, without further details.

DGAC would strongly appreciate a real assessment of the costs incurred for organisations and authorities to be carried out; the evaluation could also reinforce the idea of delaying the implementation of the proposed new rules or even of abandoning certain requirements (general aviation).

response Accepted.

While promoting a proactive approach to the management of safety can be seen as a simple logical necessity not requiring empirical evidence to support its use within safety management processes, EASA acknowledges the need to further enhance the RIA for the



related opinion, in particular to formulate detailed recommendations for specific transition measures and opt-outs. For that purpose, data and input from authorities and industry was sought through an online survey conducted in 2015/Q4.

In this context it should be noted that the EASA's approach, different from the ICAO approach, is to structure the SMS framework in the form of generally applicable management system requirements that build upon existing quality systems and leave detailed means of achieving the safety objective at AMC level. This provides flexibility, as an organisation may propose means alternative to those established in the EASA AMC in order to meet or exceed the objective set at IR level.

Also, whereas determination of the direct cost impact associated with SMS implementation for a particular category of service provider may be straightforward, there is a general difficulty in quantifying the benefits of SMS in high-risk/low-probability transport domains, such as aviation.

Title Page

p. 1

comment 30

comment by: René Meier, Europe Air Sports

Europe Air Sports thanks the Agency for preparing NPA 2013-01. We studied the provisions proposed by the Agency, discussed the texts within our Board, with the Board of European Powered Flying Union (EPFU) and with the group of experts in international affairs of the Aero-Club of Switzerland (AeCS). In other words: This is a "three parties opinion". Thank you for taking note of this fact.

Unfortunately, we think that the proposals of this NPA do to a great extent not fit our needs, these are in our view too much based on assumptions stemming from Commercial Air Transport.

We also read that all provisions related to Commercial Air Transport are solely applicable to licensed air carriers as defined by Community law. Our operations are therefore completely out of the scope of this NPA.

As "do nothing" is no option as regards NPA 2013-01 we discussed Part A and Part B with our members which asked us to submit appropriate comments.

We particularly miss specific issues of the sports and recreational flight operations, particularly when we think of gliding operations: Gliding is a sport, gliding has nothing to do with Commercial Air Transport. Ballooning is not "air transport": There are no timetables, no predetermined destinations. The existence of documents of the Agency bearing titles like "Commercial Air Transport with Sailplanes and Balloons" does not change this fact. It might be "fun" or "recreational activity", but never "air transport" in the real meaning of the term.

In the views of Europe Air Sports, of EPFU, and of AeCS the general direction of the provisions as drafted is not the one we were looking for, it does not correspond to the idea of a lighter Part-M applicable to General Aviation, on the contrary, we feel that your SMS proposals make it even heavier towards Part-145 in diminishing privileges of Subpart-F organisations.

Our members think a transfer of these drafts to the Part-M for General Aviation Task Force is the only feasible way in order to avoid a duplication of efforts as our community does not





	<p>live in the world SMS is intended for.</p> <p>And, frankly, looking at the statistics, we all know that aviation is very safe today. Regularly reading Agency texts, however, people a bit less involved than we are must get the impression that aviation safety is on the brink of collapse, caused by maintenance organisations overworking their staff.</p>
response	<p>Accepted.</p> <p>The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on <b>General Aviation CAMOs</b> (CAMOs that are not involved in CAT aircraft and are not managing any CMPA), nor for Subpart F organisations. These organisations will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements, meaning no requirements on safety risk management.</p> <p>The <b>Part-M General Aviation Task Force</b> was represented by ECOGAS in the Focused Consultation Group, which was established to assist EASA with the drafting of the opinion for RMT.0251 (MDM.055) Phase I.</p> <p>In addition, it was consulted on the applicability of SMS and its recommendations were considered for the related opinion.</p>
comment	<p>45</p> <p>comment by: Rega/Swiss Air-Ambulance</p> <p>no comment</p>
response	<p>Noted.</p>

## Executive Summary

p. 2

comment

75

comment by: Aerospace Industries Association

Attachment [#2](#)

Please see attached response document from the Aerospace Industries Association (AIA) reflecting the view of AIA and our members on this NPA.

response

Noted.

**On the disruptive impact on industry:**

The opinion for the new Part-CAMO does not introduce SMS as a separate element, but proposes to upgrade the existing management system (termed 'quality system') with specific features aiming for effective hazard identification and safety risk assessment. Maximising the potential of service providers and authorities to identify hazards and manage risks across the total aviation system will ensure that we maintain and further improve the enviable safety record of the aviation industry under changing conditions.

The way this management system framework for safety is being proposed for the new Part-CAMO is far less prescriptive than the ICAO SMS framework, as only the core requirements are included at IR level and the details on implementation are defined as AMC, thus providing flexibility.

The changes proposed to the new Part-CAMO will not have any noticeable impact on non-EASA regulatory authorities as Part-M Subpart G is currently not covered under any bilateral aviation safety agreement. The changes to Part-145 'Design and Production Organisations' (Phase II of the rulemaking task) will be assessed for their impact on foreign authorities.

The need for specific implementation support in the area of SMS in continuing airworthiness and maintenance is fully acknowledged. Safety promotion and guidance material will be developed for that purpose in parallel with the relevant rulemaking activities. A safety promotion task will be proposed for the EASA planning cycle 2017–2021.

To promote a common understanding of the SMS concepts globally and encourage harmonised implementation, EASA actively participates in the Safety Management International Collaboration Group (SM ICG).

**Regarding the status of AMC material:**

The status of AMC has not been changed with NPA 2013-01(A)/related opinion: AMCs are non-binding, and regulated persons may choose to demonstrate compliance through alternative means of compliance. When they chose to do so, the burden of demonstration of compliance is upon them. This has always been the case in the context of the EASA rules; the aim of the new elements is to increase transparency by requiring competent authorities to make available information on alternative means of compliance that have been accepted and to support rulemaking and standardisation by requiring competent authorities to notify EASA of any AltMoC they have accepted for their industry, have issued or are using themselves. These requirements on the processing of applications for the approval of alternative means of compliance are not changing the legal status of the EASA AMCs. With the current system, any organisation intending to use an alternative means of compliance



needs to demonstrate an equivalent level of safety, and this general principle remains unchanged.

A further review of all existing AMCs to Regulation (EU) No 1321/2014 may be required in Phase II to include at AMC level only those elements that genuinely constitute means to comply, and this is necessary with or without a requirement on alternative means of compliance processing.

comment 116

comment by: Boeing

#### General comment

Boeing and other companies have been working with national authorities for many years to develop safety management best practices, and welcome the broader use of structured risk management throughout the industry. Introduction of such an approach, coupled with the full recognition of existing successful practices and the practical limitations of the risk management process, should help to minimize the negative impacts on highly effective and uniquely suited processes and systems for effectively managing aviation safety in place today. These existing systems and activities have evolved along with the sophistication and efficiency of the products themselves, and largely satisfy the tenets of the ICAO SMS Framework.

#### General comment

The NPAs acknowledge that EASA is proposing extensive changes to Annexes I 'Part-M' and II 'Part-145' and that these changes are part of a broader restructuring of EASA requirements. It should be recognized that these changes will have a significant disruptive impact to the industry and regulatory authorities and potentially authority to authority working arrangements, unless the transition is well coordinated among all stakeholders. The transition must minimize the disruption to aviation, an industry with an enviable safety record.

response Noted.

The related opinion does not introduce SMS as a separate element, but proposes to upgrade the existing management system with specific features aiming for effective hazard identification and safety risk assessment. The new management system 'framework' is performance-based and was initially designed to apply to all organisations required to hold an organisational approval within the scope of Regulation (EC) No 216/2008, i.e. all those activities for which the regulator had already determined that the level of risks entailed implied the obligation for an organisation approval and requires continuing oversight. The way this management system framework for safety is being proposed is far less prescriptive than the ICAO SMS framework as per Annex 19 Edition 1 Appendix 2.

EASA fully acknowledged the need for gradual implementation with the support of safety promotion material and by adopting specific transition measures. The proposal made with the opinion allows for a 2-year transition period starting from the date of applicability of the amending regulation, which would allow for a minimum of 3 years from now.

Maximising the potential of service providers and authorities to identify hazards and manage risks across the total aviation system will ensure that we maintain and further improve the



enviable safety record of the aviation industry under changing conditions.  
Please refer also to the response to comment #75.

comment 120

comment by: GAMA

The General Aviation Manufacturers Association (GAMA) is an international trade association representing over 80 of the world's leading manufacturers of general aviation airplanes and rotorcraft, engines, avionics, components and related services. GAMA's members also operate repair stations, fixed based operations, pilot and maintenance training facilities and they manage fleets of aircraft.

GAMA appreciates the opportunity to provide feedback regarding EASA NPA 2013-01 *Embodiment of Safety Management System (SMS) requirements into Commission Regulation (EC) No 2042/2003*, and offers the following comments.

#### GENERAL COMMENTS

##### General Aviation Impact

GAMA appreciates EASA's recognition of the efforts of the European General Aviation Safety Strategy Group and the Part-M General Aviation Task Force's recommendations as stated in NPA 2013-01(B)

*"when drafting rules, a clear distinction be made between organisations involved with commercial air transport and other organisations, to ensure General Aviation will be considered 'as a sector in its own right and not as a watered-down Commercial Air Transport by-product.'"*

NPA 2013-01(B) states the Agency decided not to propose a unique maintenance organisation approval system at this stage because of the development and efforts of these groups. However NPA 2013-01(A) states,

*"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."*

GAMA requests clarification what the provisional status implies. If provisional status intends to implement the full effect of the requirements until the European General Aviation Safety Strategy Group's and Part-M Task Force's recommendations are identified, then GAMA would object as it would be an unnecessary burden for a temporary implementation. GAMA does support a proposal to allow the Safety Strategy Group to develop appropriate management systems which are proportional to the General Aviation segment of industry and that the recommendations are given an appropriate transition period to allow organisations to adapt their management systems to the new requirements

*"to allow any possible actions requested by the European General Aviation Safety Strategy*



	<p><i>Group or the Part-M General Aviation Task Force in this area to become effective.”</i></p> <p>GAMA would also not support a proposal if the provisional status implies that the full effects of the requirements are imposed after three years absent any recommendations from the Safety Strategy and Part-M Taskforce. EASA has recognized that the proposed SMS requirements would not be appropriate for General Aviation and has elected to defer to the European General Aviation Safety Strategy Group and Part-M working group recommendations; therefore it would be inappropriate to place a three year time line on the recommendations. Particularly because the working groups are currently establishing proportional management systems that will unlikely be implemented before the three year deadline has expired. At that point, it would be inappropriate to impose acknowledged inappropriate requirements because of a deadline especially when EASA is aware of existing efforts to develop an appropriate system.</p>
response	<p>Accepted.</p> <p>The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS for <b>General Aviation CAMOs</b> (CAMOs that are not involved in CAT aircraft and are not managing any CMPA). Those CAMOs will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements, meaning no requirements on safety risk management.</p> <p>The <b>Part-M General Aviation Task Force</b> was represented by ECOGAS in the Focused Consultation Group, which was established to assist EASA with the drafting of the related opinion for RMT.0251 (MDM.055) Phase I. In addition, it was consulted on the applicability of SMS and its recommendations were considered for the opinion: the implementation of an SMS will not be required for General Aviation CAMOs (CAMOs that are not involved in CAT and are not managing CMPA). They will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements.</p>

## Explanatory Note I. General

p. 4-5

comment	<p>65</p> <p>comment by: <i>Finnish Transport Safety Agency</i></p> <p>Finland has no comments, no objections on this document.</p>
response	<p>Noted.</p>



## Explanatory Note IV. Content of the draft Opinion/Decision -Task objective and basis for drafting

p. 5-6

comment

62

comment by: *Baines Simmons Limited***Basis of proposed requirements**

We broadly support the use of generally applicable authority and organisational requirements that are common to Air Operations and Continuing Airworthiness, as this reduces Competent Authority complexity and workload and encourages the single Management System concept through operations, continuing airworthiness and maintenance (and, potentially, maintenance training) activities within operators holding such approvals.

response

Noted.

## Explanatory Note IV. Content of the draft Opinion/Decision - Organisation requirements and management system

p. 6-7

comment

6

comment by: *SVFB/SAMA***1. ICAO ANNEX 19 applies SMS as follows:**

.....

**CHAPTER 4. SAFETY MANAGEMENT SYSTEM (SMS)****4.1 General**

4.1.1 Except as required in 4.2, the SMS of a service provider shall:

- a) be established in accordance with the framework elements contained in Appendix 2; and  
**be commensurate with the size of the service provider and the complexity of its aviation products or services.**

an and further

4.1.3 The SMS of a certified operator of aeroplanes or helicopters authorized to conduct **international commercial air transport**, in accordance with Annex 6, Part I or Part III, Section II,

respectively, shall be subject to the acceptance of the State of the Operator.

4.1.4 The SMS of an approved maintenance organization providing services to operator of aeroplanes or helicopters engaged in **international commercial air transport**, in accordance with Annex 6, Part I or Part III, Section II, respectively shall be subject to the



acceptance of the State(s)  
responsible for the organization's approval.

#### 4.2 International General Aviation - aeroplanes

4.2.1 The SMS of an **international general aviation operator**,  
conducting operations **of large turbojet aeroplanes** in accordance with Annex 6, Part II, Section 3  
shall be appropriate to the size and complexity of the operation.

#### 2. The EU in COM(2007)869 final "An Agenda for a Sustainable future in General- and Business Aviation in Europe"

The safety objectives to be aimed at by the Regulator may be not as high for general aviation as for

**commercial air transport, as recognized by ICAO** (in its Annex 6, Part II) .

understanding that general aviation itself may cover a wide range of activities (including some commercial and non commercial activities), safety

objectives may also be different along this range, leading to different levels of requirements

#### 3 . The EU in its Council Conclusions on Smart Regulation 31.May 2011 compet 223 stated:

.....

15. INVITES the commission to

...

- elaborate the guidelines on preparing ex-post evaluations to examine the effectiveness and efficiency of EU legislation and to identify new opportunities to simplify, improve legislation, **and to reduce the overall regulatory burdens, in particular for SMEs;**

25. COMMITS ITSELF, AND INVITES THE EUROPEAN PARLIAMENT to better consider the implementation and enforcement-related impacts, **including the compliance costs**, of their substantive amendments;

#### 4 . CASA restricts it to organisations > 50 staff.

EASA imposes stricter regulation within the field of GA and BA without broad statistical evidence.

We urge EASA to reconsider the limits as proposed in our first comment before.

In summary: EASA's holistic approach to introduce SM is supported by ECOGAS.

As introduction of SM is a heavy intrusion into organisations with heavy economical consequences mainly for SME's we request EASA to make the system optional for SME's along reasonable limits proposed in our comment (1) above.



Data are not available, or not accessible or not properly evaluated in statistical relevant numbers for such heavy rulemaking on SME's as even stated in COM(2011) 670 final from the Commission to the Council and the European Parliament on page 4/11:

" No one source provides all the required information, and an EU hazard identification process must make use of a combination of all sources, both reactive, proactive and predictive, and by sharing this information it can provide decision makers with comprehensive air safety "intelligence". Typical hazards in an aviation environment include such things as poor weather conditions,

mountainous terrain surrounding an airport, or failure of an aircraft engine.

However, whilst the EU has access to all these sources of information, it is particularly in the area of occurrence reporting that a significant fault line exists. Despite the adoption of Directive 2003/42/EC<sup>10</sup>, occurrence reporting in the EU and the use of the ECR are still affected by a number of shortcomings which limit the usefulness of the occurrence reporting system for accident prevention purposes. These problems are, notably, low quality of information, incomplete data, insufficient clarity in reporting obligations and in the flow of information, and legal and organisational obstacles to ensuring adequate access to the ECR information to enable information sharing"

it goes on on page 6/11:

The Commission will come forward, subject to the results of the impact assessment being conducted as part of the review of legislation on occurrence reporting, with a proposal to further develop safety analysis at EU level.

It is obvious it will take time until the above action 2 will be completed. It is not acceptable to impose regulation with heavy economical consequences without proper data.

For major MRO's (and organisations) the SM approach is fact and all major organisations have already a SMS System, for them, the new SM regulation makes things better.

response

Partially accepted.

Regarding the **types of operations** that should be considered as commercial operations and CAT, CAT for the purpose of Regulation (EU) No 1321/2014 only refers to the operations of licensed air carriers (Regulation (EC) No 1008/2008).

The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS for **General Aviation CAMOs** (CAMOs that are not involved in CAT and are not managing CMPA), nor for Subpart F organisations. Linked to that, those organisations will not have to introduce HF training nor assess HF-related competences of their staff. They will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements.

On the issue of **proportionality**, it is important to note that, unlike the ICAO SMS framework, the EASA management system framework proposed with NPA 2013-01(B) provides maximum flexibility to industry as all detailed provisions on safety risk management, compliance monitoring, safety training and communication are included at AMC level. This ensures that the provisions can be applied whatever the size, nature and complexity of the organisation. The proposed degrees of complexity are in fact elements to be considered under the organisation's safety risk management.

Regarding the impact of SMS on small organisations not involved in the maintenance or continuing airworthiness management of large aircraft or aircraft used for CAT, the comment





is accepted.

The related opinion will not impose the implementation of an SMS on those organisations. They will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements. In addition, the new 'light' Part-M will introduce further alleviations for all ELA2 aircraft and helicopters certified for up to four occupants and up to 1 200 kg MTOM, regardless of the type of operation. Organisations involved in the continuing airworthiness management of CMPA or aircraft used for CAT will be required to implement a management system including safety risk management processes, as defined in the new Part-CAMO.

comment

7

comment by: SVFB/SAMA

see our comment (1) above in regards to ICAO 19.  
ICAO in its proposal differentiates between International Business Aviation with Turbojets.

response

Please refer to the response to comment #6 above.

comment

92

comment by: GE Aviation

The proposed holistic approach introducing a common management system framework is likely to provide considerable disruption of existing systems which function well to support safety and quality. GE Aviation proposes a more incremental approach, focused on assessing which areas of the SARPs are not being supported by existing systems and requirements, so that change is only introduced where it is needed. This incremental approach will reduce the risk of unintended adverse safety impact and greatly reduce the regulatory burden. In particular, GE Aviation suggests retention of the current system in which Safety and Quality are complementary, but separate, functions.

response

Not accepted.

For SMS to function effectively, a holistic approach is needed with the different elements supporting each other. This does not mean that SMS implementation should not be done gradually or incrementally. The rules should not define the implementation path, but the objectives to be met when the implementation phase is completed.

Unlike the ICAO SMS framework, the EASA management system framework proposed with NPA 2013-01(B) provides maximum flexibility to industry as all detailed provisions on safety risk management, compliance monitoring, safety training and communication are included at AMC level. This ensures that the provisions can be applied whatever the size, nature and complexity of the organisation.

For the new Part-CAMO, responsibilities have been defined both for safety management and compliance monitoring (cf. new point CAMO.A.305 'Personnel requirements'). Organisations may decide on how to allocate these responsibilities.



comment	93	comment by: GE Aviation
	<p>GE Aviation has found that the application of SMS principles requires tailoring for different domains of the aviation system, depending on the time-criticality of risk, balance between judgment and technical analysis, level of structure v.s flexibility in activities, richness of data available and other factors. Establishing “the same” system for different areas of the enterprise can only be done at the most general level (such as the ICAO framework), detailed implementation will necessarily vary dramatically. GE Aviation therefore suggests that the EASA goal of a common framework can best be supported by keeping requirements to high-level concepts, as EASA has done in the rule, and limiting prescriptive AMC material to an absolute minimum.</p>	
response	<p>Noted.</p> <p>Please refer to the response to the comment above. The comment will also be considered for finalising the AMCs and GM to the new Part-CAMO.</p>	
comment	122	comment by: GAMA
	<p><u>A.IV.16.</u> – “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.”</p> <p>GAMA supports this statement and would request that AS9110 be included as acceptable AMC to SMS compliance similar to what EASA has referenced in NPA 2013-01(B) page 17 regarding industry standards.</p>	
response	<p>Noted.</p> <p>AS/EN9110 does not currently address safety risk management, therefore it cannot be considered as an AMC for SMS.</p> <p>As the primary focus of AS/EN9110 is maintenance and not continuing airworthiness management, the comment may be more relevant to Part-145. Also, considering that the AS/EN9100 series standards are currently being reviewed in particular to introduce the concept of risk-based thinking, it is proposed to reassess the proposal, both for Part-CAMO and Part-145 organisations, in Phase II. Other industry standards that may be developed for SMS in continuing airworthiness could also be considered in Phase II.</p>	



## Explanatory Note IV. Content of the draft Opinion/Decision - Proportionality and flexibility

p. 7-10

comment	9	comment by: SVFB/SAMA
	18 & 19: we see the intention to be proportionate and fully support the idea. Implementation in reality often does not follow such recommendations.	
response	Noted.	

comment	11	comment by: SVFB/SAMA
	19. page 8/51: 145.A.65 we support this new setup (a) to (g) IF as we said earlier: for a up to 5 staff this must be a description of one to 3 pages, for up to 20 10 pages must be enough see comment x on page n/m.	
response	Noted.  Organisations will still need to provide a continuing airworthiness management exposition (CAME) complying with the list of elements included in the new point CAMO.A.300. Safety-management-related processes can be described as part of the CAME or be the subject of a separate document. The extent of safety-management-related documentation will indeed depend on the size, nature and complexity of the organisation.	

comment	13	comment by: SVFB/SAMA
	21. to move subjects from M into 145 is a good move. In fact it should go as far as having all necessary regulation for 145 in 145 and only those for 14.	
	However today's narrow limit as to what and on what operation the Part M/F organisation is restricted to are driving 95% of all SME's into a 145 certificate and so imposing on them entails a huge set of organisational structures on the Part M/F which is normally a SME. Part M/F should be allowed to work on all aircraft up to 5.7T irrespective of its operational label: Non-commercial or commercial as long as it is not CAT in the sense of EU regulation, Airlines.	
response	Noted.  Part-M/Subpart F, as currently applicable, do allow to work on all aircraft up to 5 700 kg MTOM except if operated by licensed air carriers. The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on <b>General Aviation CAMOs</b> (CAMOs that are not involved in CAT aircraft and are not managing any CMPA). Those CAMOs will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements, meaning no requirements on safety risk management and the possibility to cover continuing airworthiness management and	



maintenance under the same approval.

comment

15

comment by: SVFB/SAMA

21. after the table on page 10/30

For Part M/F organisations the Agency proposes to define these as non complex organisations by default:

**Good approach**, however, by the restrictions due to commercial and the scope of what is commercial, **the positive impact is erased**.

Therefore it becomes even more important to downgrade as many MRO's.

This in turn depends on a suitable definition of commercial which must be developed as to reach the goal.

Or the privileges of Part M/F shall be expanded to "commercial" up to 18 Pax as long it is not CAT (Airline like operation maintenance)

response

Please refer to the response to comment #13 above.

comment

31

comment by: René Meier, Europe Air Sports

Proportionality and flexibility

18.

page 7/31

Sorry, but we fully disagree.

Rationale:

Our operations did not become more complex during recent years, our operations decreased in numbers because of e.g. Part-M and restrictive application of other regulations by competent authorities. Also, our business model did not change. do not need new implementing. With the statements made here an SMS for Commercial Air Transport may be supported, but not in any way for sports and recreational flight operations.

response

Noted.

The RIA to be included in the related opinion will be amended to better differentiate between different industry segments. Please refer also to the response to comment #13 above.

comment

32

comment by: René Meier, Europe Air Sports

Proportionality and flexibility

19.

page 7 and 8/31

We read in your text that a "one size fits all approach typically will not work." This is a



	<p>positive statements supported by all our members. We think, however, that confusion will be created over how and where all these future changes will become applicable.</p> <p>"No overly detailed requirements are included" the Agency writes. But in the sentence before we read "...This provides flexibility, as an organisation may propose means alternative to those established in the Agency AMC <u>in order to meet or exceed</u> the objective set at rule level." What will happen now? Dozens of proposals will be written, based on this text. Instead of harmonizing the requirements we shall become aware of the opposite, and "a level playing field" one of the most popular terms of recent years, will definitely be out of reach in future.</p> <p>Rationale:</p> <p>SMS will increase costs, undoubtedly. The consequence is crystal-clear: In the field of sports and recreational aviation we will experience a further reduction in flight hours which will decrease safety. It will never be the perfect SMS which produces the well-trained pilot, his/her training to perfection will always depend on his/her perception of the proportionality of legislative or administrative measures and on the financial means available for flying activities.</p>
response	<p>Noted.</p> <p>The standardisation objective enshrined in Regulation (EC) No 216/2008 is not affected by this rulemaking proposal. The introduction of a controlled process for the approval of alternative means of compliance will ensure that the safety objectives defined at IR level will be met, while allowing for different means to comply, which is in the interest of industry.</p> <p>Regarding the impact of SMS on sports and recreational aviation, please refer to the response to comment #13.</p>
comment	<p>51 <span style="float: right;">comment by: René Meier, Europe Air Sports</span></p> <p>Organisation requirements and management system 17. page 7/31</p> <p>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. Therefore all our activities are exempt from SMS, we think.</p> <p>Rationale:</p> <p>Sports and recreational activities are not part of this system. There is no such thing like commercial air transport with sailplanes and balloons. Approved training organisations are not part of the Air Transportation System.</p> <p>If the Agency disagrees: Please define "Air Transport System", then we shall be in a position to re-assess our opinion.</p>
response	<p>Noted.</p> <p>While the EASA's General Aviation Strategy promotes an approach where different levels of risks are accepted for commercial aviation and for recreational aviation respectively, this does not imply that sports and recreational activities should not be considered part of the overall air transportation system. These activities do contribute to the system, be it through providing an entry level for an aviation career, fostering an aviation culture or sharing the same airspace.</p>



comment

78

comment by: *European Sailplane Manufacturers*

The European sailplane manufacturers appreciate that for simple organisations, i.e. Part-M / Subpart F (M/F) and CAMOs not managing CAT aircraft (CAMO-small) less restrictive measures are proposed.

Indeed these are typical organisations involved in continuing airworthiness processes for sport aviation activities, as is the case with sailplanes.

Nevertheless we do not concur with the approach proposed:

A) Automatic transition after period of 3 years:

We consider an automatic transition after 3 years as too fast and even more so it is not proportionate to make this automatic.

Even if the described General Aviation Group (GA Group) will be starting to work in 2013, it may take too long to modify this process within this 3 year period.

The worst possible outcome will be a need for regarding change in the organisations processes due to introduction of SMS shortly followed by another need for change due to alleviations proposed by the GA Group.

The correct approach would be to allocate this decision to the GA Group and/or the Part-M Task Force and not to include SMS automatically.

B) Range of organisations:

M/F and CAMO-small organisations are not the only one types of organisations working with aircraft of the sport aviation sector.

It should be considered, that each Part-145, M/F or CAMO-small organisation dealing only with ELA2 aircraft should be exempted from the introduction of SMS pending the actions of the GA Group (and/or the Part-M task force).

response

Noted.

Any existing Part-145, Part-M/Subpart F or CAMO organisation dealing only with ELA2 aircraft is eligible for the new combined Part-CAO approval.

The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on **General Aviation CAMOs** (CAMOs that are not involved in CAT aircraft and are not managing any CMPA). Those CAMOs will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements, meaning no requirements on safety risk management.

The **Part-M General Aviation Task Force** was represented by ECOGAS in the Focused Consultation Group, which was established to assist EASA with the drafting of the related opinion for RMT.0251 (MDM.055) Phase I. In addition, it was consulted on the applicability of SMS and its recommendations were considered for the final opinion: the implementation of an SMS will not be required for General Aviation CAMOs (CAMOs that are not involved in CAT and are not managing CMPA). They will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements.



comment	95	comment by: GE Aviation
	<p>GE Aviation questions whether organizational complexity is the appropriate metric for determining the rigor of regulatory oversight. Large, complex organizations have developed internal systems to manage that complexity, and frequently deliver the highest safety performance in the business. It is not clear why EASA has developed a dual standard, of compliance, allowing small (non-complex) organizations to meet a lesser safety standard.</p>	
response	<p>Accepted.</p> <p>Following a recommendation made by the Focused Consultation Group, the application of complexity criteria for the determination of applicable AMCs (<b>complex/non-complex organisations</b>) will not be maintained for the new Part-CAMO.</p> <p>Consequently, there will be a single set of management system AMCs to be used by all Part-CAMO approved organisations. Specific needs may be addressed through alternative means of compliance .</p> <p>The Focused Consultation Group further recommended that this change in management-system-related AMCs and GM be also considered for the other domains.</p>	
comment	114	comment by: Federal Office of Civil Aviation, FOCA, Switzerland
	<p>FOCA appreciates the differentiation between a setup of rules at IR level and AMC for complex and non-complex organizations. However, due to the fact that measuring the complexity of an organization is in itself a complex task, which can hardly be reduced to a few quantitative indicators such as number of staff, we believe that the decision to classify organizations as complex or non-complex should be in the competence of the Member States' NAAs.</p> <p>This would ensure that the heterogeneous structure of the continuing airworthiness industry in Europe, whose regulation necessitates a certain level of subsidiarity, is adequately reflected in the proposal.</p>	
response	<p>Noted.</p> <p>Following a recommendation made by the Focused Consultation Group, the application of complexity criteria for the determination of applicable AMCs (<b>complex/non-complex organisations</b>) will not be maintained for the new Part-CAMO. The Focused Consultation Group further recommended that this change to the management-system-related AMCs and GM be also considered for the other domains.</p> <p>Consequently, there will be a single set of management system AMCs to be used by all Part-CAMO approved organisations. Specific needs may be addressed through alternative means of compliance. In this way, 'scalability' and related complexity markers are no longer defined through the AMCs, and organisations will need to demonstrate effective implementation of the management system that takes account of their specific size, nature and complexity. Competent authorities will define criteria in order to assess organisations in line with performance-based oversight principles. In addition, they should be supported by agreed methods and tools to assess the effectiveness of the management system. The RAG group 'cross-domain SMS assessment' is currently developing such tool. It will focus on what</p>	



effective implementation would mean for the different SMS elements.

#### Explanatory Note IV. Content of the draft Opinion/Decision - Authority requirements

p. 10-11

comment	52	comment by: <i>René Meier, Europe Air Sports</i>
	Proportionality and flexibility 21., last sentence page 10/31 typo error: Please separate "in" from "force".	
response	Accepted. This error will be corrected in case the same text is reused.	
comment	53	comment by: <i>René Meier, Europe Air Sports</i>
	Authority requirements 22. page 10/31 Please add spaces on the second line of the paragraph between "Part-ARX" and "Subpart GEN", and between "...and that new Article 7" and the following "of the Cover Regulation...."	
response	Accepted. These errors will be corrected in case the same text is reused.	
comment	54	comment by: <i>René Meier, Europe Air Sports</i>
	Authority requirements 23. page 10 and 11/31 Please add a space between "...SARPs" and " on implementing..." as well as before "therefore" and before "address" and before "the following" on top of the text on page 11	
response	Accepted. These errors will be corrected in case the same text is reused.	





comment

79

comment by: *European Sailplane Manufacturers*

Here again we observe a "copy and paste" approach by EASA to implement ICAO rules into the EASA system.

This might be fully understandable and correct in the context of commercial air transport (CAT), but we disagree that these rules are fitting to operations of private owned aircraft in the context of sport and recreational flying.

Therefore a clear division is needed to avoid introduction of even more complex and onerous rules into the lower end of aviation within the EASA context.

Our proposal:

No introduction of SMS processes into those parts of aviation where ELA2 aircraft are being operated.

response

Accepted.

Any existing Part-145, Part-M/Subpart F or CAMO organisation dealing only with ELA2 aircraft is eligible for the new combined Part-CAO approval.

The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on **General Aviation CAMOs** (CAMOs that are not involved in CAT aircraft and are not managing any CMPA). Those CAMOs will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements, meaning no requirements on safety risk management.

The **Part-M General Aviation Task Force** was represented by ECOGAS in the Focused Consultation Group, which was established to assist EASA with the drafting of the related opinion for RMT.0251 (MDM.055) Phase I. In addition, it was consulted on the applicability of SMS and its recommendations were considered for the final opinion: the implementation of an SMS will not be required for General Aviation CAMOs (CAMOs that are not involved in CAT and are not managing CMPA). They will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements.

**Explanatory Note IV. Content of the draft Opinion/Decision - Alternative means of compliance**

p. 11-12

comment

3

comment by: *Austro Control Ltd.*

Comment:

"Alternative means of Compliance" item 24. of Part A - NPA 01-2013:

The complete repetitive Processing of an alternative means of compliance (Alt.MC) already approved, published and used by an organisation under the oversight on a Competent Authority is considered to be an not necessary administrative burden (for the other organisations and the competent authority). If another organisation intends to use such an Alt.MC the process should be limited to an internal evaluation process which only takes care about possible existing differences between the conditions described in the approved and



	<p>published Alt.MC and the circumstances in the organisation which intends to use the same Alt.MC already approved, published and used. The Alt.MC shall be available for immediate use for all Organisations which meet the conditions of the Alt.MC under the oversight of the approving and publishing Competent Authority.</p> <p>Justification:</p> <p>When an Alt.MC has been approved and published by a competent authority, the equivalent level of safety to reach the intend of the basic regulation and its implementing rules has been established. The conditions under which such an Alt.MC can be used have to be specified in the Alt.MC itself. If there are no differences between the intended users (organisations or persons) of such an Alt.MC they should be allowed to use it directly as described after an internal validation of the conditions described in the Alt.MC by the user without a new application to and approval by the Competent Authority. The proper validation of the organization and/or person will be anyway subject to various audits and/or inspections by the competent authority.</p> <p>Proposal:</p> <p>Consider a revision of M.A. 203(d), 145.A.82(b) in such a way that each organisation And/or person who intends to use an already approved and published Alt.MC under the oversight of the approving and publishing Alt.MC Competent Authority may use such an Alt.MC after internal validation of the conditions of the Alt.MC and provision of such validation to the Competent Authority without an additional application to and approval by the Competent Authority. During the the routine oversight the Competent Authority has to verify the proper validation of the conditions described in the Alt.MC.</p> <p>Also consider a revision of M.A.104 and 145.B.12 that not always the complete process have to be performed if an Alt.MC is already approved, published and used by at least one organisation under the oversight of the Competent Authority approving and publishing the Alt.MC.</p>
response	<p>Not accepted.</p> <p>The text, as proposed with NPA 2013-01(B), is fully aligned with that already applicable under Regulations (EU) Nos 290/2012 and 965/2012; consistency must be ensured with the procedures already being implemented at Member State level.</p> <p>An alternative means of compliance from an organisation is approved for the individual case and considering the specifics of that organisation. To provide a general presumption of compliance, there are two possibilities:</p> <ul style="list-style-type: none"> <li>— EASA, based on the information provided by the competent authority, concludes that the alternative means of compliance is of general interest and subsequently covers it through issuing an EASA AMC.</li> <li>— The competent authority considers the alternative means of compliance of general interest for organisations under its oversight and decides to issue the AMC as national AMC in line with the new point CAMO.B.120(e).</li> </ul>
comment	<p>27</p> <p>comment by: <i>KLM Engineering &amp; Maintenance</i></p> <p>This may impact commercial/ competition confidentiality</p>
response	<p>Noted.</p>



Considering the elements addressed in the Part-CAMO AMCs, it can be expected that documents to be provided in support of alternative means of compliance proposed by applicants do not require a level of detail that could disclose intellectual property or any information that may be sensitive in terms of competition. In any case, national administrative law on protection of intellectual property will apply.

comment

88

comment by: AEA

This may impact commercial/ competition confidentiality

response

Please refer to the response to comment #27 above.

comment

115

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

The process for the applicant is too complicated because proposal foresees that AMOCs are not transferable. Once an AMOC is approved by the competent authority, other applicants with the same requirements and position should be able to apply the concerned AMOC without unnecessarily repeating the process.

response

Not accepted.

The text, as proposed with NPA 2013-01(B), is fully aligned with that already applicable under Regulations (EU) Nos 290/2012 and 965/2012; consistency must be ensured with the procedures already being implemented at Member State level.

An alternative means of compliance from an organisation is approved for the individual case and considering the specifics of that organisation. To provide a general presumption of compliance, there are two possibilities:

- EASA, based on the information provided by the competent authority, concludes that the alternative means of compliance is of general interest and subsequently covers it through issuing an EASA AMC.
- The competent authority considers the alternative means of compliance of general interest for organisations under its oversight and decides to issue the AMC as national AMC in line with the new point CAMO.B.120(e).

#### Explanatory Note IV. Content of the draft Opinion/Decision - Management system for competent authorities

p. 12-13

comment

55

comment by: *René Meier, Europe Air Sports*

response	<p>Management system for competent authorities</p> <p>25.</p> <p>page 12/30</p> <p>Nasty remark, after having read all about "documented policies and procedures, planned availability of personnel, a function to monitor compliance, internal audit process, safety risk management process, system to identify changes that affect the management system, system of record keeping": Will there be enough funds available to pay staff looking after the aircraft?</p>
	<p>Noted.</p> <p>A well-managed competent authority, aware of its own risks and non-compliances, will be more effective in discharging its oversight responsibilities.</p>

**Explanatory Note IV. Content of the draft Opinion/Decision - Oversight**

p. 13-14

comment	<p>33</p> <p>comment by: <i>René Meier, Europe Air Sports</i></p> <p>Oversight</p> <p>28.</p> <p>page 13/31</p> <p>We thank the Agency for these extension possibilities.</p> <p>Rationale:</p> <p>"Efficient use of resources" is a key element for keeping costs down as well as reducing the oversight burden.</p>
	<p>response</p> <p>Noted.</p>

comment	<p>56</p> <p>comment by: <i>NHAF Technical committee</i></p> <p>Norsk Helikopteransattes Forbund, does not support the proposed change in oversight system. We strongly recommend keeping the national and international control system, who physically visits the maintenance organization on an annual basis.</p> <p>The already published safety statistics, are based upon current systems. By changing the oversight system to a performance based system, close control will be lost.</p> <p>Reporting systems are not yet in place, with referral to:</p> <p>REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL</p> <p>on occurrence reporting in civil aviation amending Regulation (EU) No 996/2010 and repealing Directive No 2003/42/EC, Commission Regulation (EC) No 1321/2007 and Commission Regulation (EC) No 1330/2007</p> <p>Without a proper reporting system, (who also protect the reporter), a performance based oversight system could easily fail to operate properly.</p>



response

Noted.

Reporting systems are being consolidated on the basis of Regulation (EU) No 376/2014, which is applicable since November 2015. This Regulation also introduces more specific requirements on ensuring the application of just culture principles.

Regarding the extension of the oversight planning cycle, following a recommendation by the Focused Consultation Group, an AMC will be added to introduce an annual inspection as follows:

**AMC1 CAMO.B.305(d) Oversight programme**

**EXTENSION OF THE OVERSIGHT PLANNING CYCLE BEYOND 24 MONTHS**

- (a) Where the competent authority applies an oversight planning cycle that exceeds 24 months, it should perform at a minimum one inspection of the organisation within each 12-month segment of the applicable oversight planning cycle to validate the oversight programme.
- (b) In case the results of this inspection indicate a decrease in the safety performance of the organisation, the competent authority should revert back to a 24-month oversight planning cycle and review the oversight programme accordingly.

comment

81

comment by: *European Sailplane Manufacturers*

The basic concept of lessening the oversight spent on "good performing" organisations is in principle applauded by the sailplane manufacturers.

Nevertheless this has some issues which will in reality not lead to a real alleviation for small organisations typically involved in activities concerning continuing airworthiness with small aircraft (e.g. ELA2).

1) Too complex regulations:

It already is the case that many small organisations receive findings during audits by the NAAs which are not based on technical discrepancies / maintenance shortcomings but simply on non-compliance with the more and more complicated regulations.

This will lead to the impression on the side of the authorities that these are organisations "not performing good" and in consequence the level of oversight might even increase.

This can be only changed by much less complicated rules and the NPA2013-01 only proposes severe complications instead of simplifications.

2) NAA workload:

For the NAAs it will be important not to lessen the overall workload in their oversight duties. If all organisations in their area of responsibility would be "good performing" then theoretically there would be much less work to be done by the NAA.

As no NAA would accept reduction of personnel strength based upon such a system, in reality the level of oversight will not be reduced.

Our proposal would be to limit the level of oversight functions of the NAA for organisations dealing with ELA2 aircraft in any cases without the additional efforts needed to introduce SMS systems, etc...



response

Noted.

Performance-based oversight does not imply that an authority will be able to reduce resources for oversight; it aims for a more efficient allocation of oversight resources based on an assessment of risk and performance.

ELA2 aircraft will be eligible for the new Part-CAO, for which the existing oversight requirements will be transposed with minimal changes. One of the changes proposed is to facilitate the implementation of changes by the organisation without requiring a formal approval by the competent authority, based on an agreed change control procedure. In addition, the new Part-ML will shift tasks to individuals as opposed to organisations, which should reduce the overall oversight burden for owners and operators of such aircraft.

comment

82

comment by: *European Sailplane Manufacturers*

In the second to last bullet it is proposed to enhance the "safety information systems" of the NAA.

This is an approach which the sailplane manufacturers would really appreciate.

Reducing the work of the NAA to the auditing of organisations has resulted into a situation, where much of the communication between the audited organisations and the NAA has been directed into discussion of findings and modifications of organisation approvals.

If the NAA would be allowed to spend more time into the education and training of how to fulfil the regulations and implement safe procedures, this would be of more benefit to all stakeholders.

response

Noted.

Nothing in the existing EASA requirements would prevent authorities from investing in education and training of regulated entities. Under the ICAO SSP framework each Contracting State should implement a safety management system that is not only composed of safety risk management, safety assurance and oversight processes, but which also promotes training and communication on safety.

Cf. Attachment A to Annex 19:

**SSP component 4:**

State safety promotion

- Internal training, communication and dissemination of safety information
- External training, communication and dissemination of safety information

The SSP components will be more explicitly addressed in the next issue of the EASA Basic Regulation, and this should lead to a review of the authority requirements in the different domains to determine if safety promotion needs to be further regulated.



comment	96	comment by: <i>GE Aviation</i>
	<p>GE Aviation is concerned about the apparent conflict between the proposal for continuous monitoring by the authority, and the ICAO concept of organizations taking responsibility for understanding and controlling the risks specific to their own operations. Continuous reporting of safety performance to the authorities is likely to divert safety resources from the primary task of understanding and controlling risk in a timely, prioritize manner.</p> <p>The “systems approach” advocated by EASA should place greater emphasis on prioritization, so that safety resources can control the greatest risks most effectively, rather than attempting to address all risks.</p>	
response	<p>Noted.</p> <p>Performance-based oversight primarily focuses on a more efficient allocation of oversight resources based on an assessment of risk and performance. The term ‘continuous monitoring’ used in the Explanatory Note was not suggesting that the authorities should narrowly monitor the organisations; it was to express that they should evolve from a system with a single audit performed towards the end of the applicable oversight cycle to a system where the authority would use different sources of information throughout the oversight cycle to be able to make decisions on the allocation of oversight resources, which in the case of mature organisations could also include regular reports on safety performance from the organisations. The possibility to extend the oversight planning cycle for organisations having demonstrated a good compliance record and good safety performance, coupled with the provisions of allowing organisations to implement changes without prior approval under specific conditions all aim to encourage the organisations’ risk management capability.</p>	
comment	97	comment by: <i>GE Aviation</i>
	<p>GE Aviation concurs that organizations should be encouraged to manage their own risks. It is not clear how the proposed NPA reduces oversight burden for organizations that accomplish this, when compared to the current (pre-NPA) level of oversight.</p>	
response	<p>Noted.</p> <p>Please refer to the response to comment #96 above.</p>	

**Explanatory Note IV. Content of the draft Opinion/Decision - Rule structure**

p. 14-16

comment	4	comment by: <i>Austro Control Ltd.</i>
	<p>Comment:</p> <p>Rule structure item 30. of Part A - NPA 2013-01:</p> <p>Option A of the rule structure would be the preferred option from the point of view of Austro Control Ltd.</p>	



	<p>Justification:</p> <p>The structure would allow having common organisational rules for all approvals issued under EC No 2042/2003 and ensure harmonisation between OPS, Air Crew and CAW rules. Also it would allow to include the generally applicable provisions only once in a dedicated Subpart GEN. This would also help avoid duplicated mistakes in the different annexes of the implementing rule as there are some of such mistakes currently in the NPA. [e.g. M.B.114(a)6, M.B.702(e)1, M.B.704(d)2, M.B.704(d)4, AMC1 M.B.704 (a);(b) item (b), AMC 1 M.B.704(b) (a)6, M.B.707 (c), GM1 145.B12]</p> <p>Proposal:</p> <p>EASA should consider to initiate a rulemaking task to adopt EC 2042/2003 regulations structure according to Option A.</p>
response	<p>Noted.</p> <p>EASA decided to assess the possibility to adapt the rule structure of Regulation (EU) No 1321/2014 in Phase II of RMT.0251 (MDM.055). This will also consider any outcome of the proposal made by the EASA RAG to consider a better rule structure to address the common authority and organisation requirements (horizontal rule structure). Different options are being determined for this purpose and will be the subject of a dedicated impact assessment.</p>
comment	<p>34</p> <p>comment by: <i>René Meier, Europe Air Sports</i></p> <p>Rule structure 30. page 14/31 Europe Air Sports, EPFU and AeCS support option "A". Rationale: We shall get in a not so distant future a regulation easy to read and to apply. Option "A" proposes logical structure, simple to follow, easy to adapt, with no duplications. Future amendments may be inserted easily, the risk of inconsistencies will be reduced to a minimum.</p>
response	<p>Noted.</p> <p>Please refer to the response to comment #4 above.</p>
comment	<p>46</p> <p>comment by: <i>CAA-NL</i></p> <p>We would prefer option the implementation of Option A in line with the horizontal rule structure and the total system approach. As it is stated that this is not possible under this rulemaking task, the second best option is option B. We further think that it may be necessary to include Subpart 66 under Part AR-CAW in option A.</p>
response	<p>Noted.</p>



Please refer to the response to comment #4.

comment	<p>58 comment by: <i>Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)</i></p> <p><b>· Item 30 Rule structure</b> The Swedish Transport Agency prefers option <b>C</b> and <b>D</b> for the rule structure of the implementation of SMS.</p>
response	<p>Noted.</p> <p>Please refer to the response to comment #4.</p> <p>Option A results as the preferred option through the comments made to NPA 2013-01 .</p>

comment	<p>63 comment by: <i>Baines Simmons Limited</i></p> <p><b>Rule Structure</b> We strongly advocate the adoption of option 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. We support this option as the <u>only</u> way forward in the light of the prior adoption of the Aircrew and Air Operations Regulations in this “horizontal structure”, for the following reasons:</p> <ul style="list-style-type: none"> <li>• Consistency in presentation of (and differentiation between) authority, organisational, and technical requirements;</li> <li>• Avoidance of significant duplication of the “same” requirements between Part-M, Part-145 (and Part-147/Part-66 in the next phase);</li> <li>• Simplification of the rules structure encourages higher degree of compliance and hence safety of operations.</li> <li>• CAT operators are required to have Management Systems in place by October 2014. Adopting the same requirements within a recognisably similar structure in 2042/2003 will subsequently assist those operators in demonstrating compliance by their own in-house Part-M(G) (and Part-145) activities and ease the Competent Authorities’ burden of assessment and approval.</li> <li>• This would also provide an opportunity to remove <u>existing</u> duplicated material between Part-M and Part-145 (e.g. Subpart E versus 145.A.42, Subpart D, etc.)</li> </ul> <p>We believe the above benefits far outweigh the potential for negative impact of the “new” structure on standalone Part-M(G), Part-145, and Part-147 organisations, who will not have been directly affected by the Air Operations Regulation and the “horizontal structure”. The other options will result in the application of a new numbering system to all existing requirements and will therefore also represent a risk for confusion, without the benefit of aligning with the aircrew/air operations requirement philosophy/structure.</p>
response	<p>Noted.</p>



Please refer to the response to comment #4.

Regarding CAT operators, as per Regulation (EU) No 965/2012 it should be noted that the new Part-CAMO closely follows the structure and contents of ARO.GEN and ORA.GEN.

comment

83

comment by: *European Sailplane Manufacturers*

It is understood that especially within the EASA rulemaking directorate, a reshaping of the structure of the rules (here within the 2042/2003) would be the favored option.

(Last but not least the purpose and the spirit of rulemaking is to make new rules...)

But please consider the perspective of those stakeholders which have to live and work with the rules:

In the case of a small repair shop, which might be holding an approval as M/F maintenance organisation and CAMO the situation today is the following:

This small company is essentially doing the same as in the last 20 years:  
Maintaining small aircraft (e.g. ELA2) and conducting annual inspections.

In comparison to 20 years ago this company has already been forced to now hold two approvals instead of one (at least in some EASA member states).

The change to this complete different set of rules has costed this organisation some hard efforts which resulted into new manuals for the organisations but did not change the actual work to be done on the aircraft.

Unfortunately this effort had to be financed by this small company.

Now EASA rulemaking proposes introduction of even more procedures....

It is therefore nice to know that rulemaking has had a vision of just another rule structure, but please consider that such a large change in the regulatory structure would again force this small company to make such changes and to pay for the associated costs.

But still the only thing this company wants to is:  
Maintaining small aircraft (e.g. ELA2) and conducting annual inspections.

So please realize, that even a more elegant rule structure is of no benefit for the organisations being regulated WITH THE ONLY EXCEPTION THAT REAL SIMPLIFICATIONS ARE BEING INTRODUCED.

Introduction of SMS processes will make things even more complicated therefore a fundamental change of the rule structure is not supported by the sailplane manufacturers.

response

Noted.

Please refer to the response to comment #4.

The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS for **General Aviation CAMOs** (CAMOs that are not involved in CAT and are not managing CMPA). These will be eligible for the new Part-CAO, which will mostly



consider the existing Part-M Subpart F and G requirements.

For Phase II, it will be assessed how a possible change to the rule structure could be implemented without creating undue burden on organisations. This would primarily be a matter of proper transition measures, providing guidance material, manual templates and possibly IT tools to facilitate filtering of the applicable requirements.

comment 117

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

When considering an amended rule structure, it must be taken into consideration that the existing rule structure in the technical parts is already implemented in the industry and NAAs. All written material is related to this rule structure. Only with a huge amount of effort and costs, a change of the existing structure is feasible. This is not commensurate and the gain in advantages is minor. Hence, an alignment with the OPS-structure is not required and the rule structure should be maintained as it is with SMS requirements directly implemented into the various parts.

In case a majority of Member States and Stakeholders is in favor of an amended rule structure, we deem proposal (B) – reviewing the numbering system in a way to enable identification of all rules, GM and AMC with an identical reference number – to be the only feasible as well as justifiable alternative. We do not support proposals (A), (C) and (D).

response Noted.

EASA decided to assess the possibility to adapt the rule structure of Regulation (EU) No 1321/2014 in Phase II of RMT.0251 (MDM.055). This will also consider any outcome of the proposal made by the EASA RAG to consider a better rule structure to address the common authority and organisation requirements (horizontal rule structure). Different options are being determined for this purpose and will be the subject of a dedicated impact assessment.

#### Explanatory Note IV. Content of the draft Opinion/Decision - Transition measures proposed

p. 16-17

comment 16

comment by: *SVFB/SAMA*

31.

article 21 on pg 10v30 / for Part M /F organisation the Agency proposed to define these as none complex organisations by default in relation to the management system.  
Here it is included !

response Noted.

This issue is no longer relevant as the related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on **General Aviation CAMOs** (CAMOs



that are not involved in CAT and are not managing CMPA). These will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements.

comment	35	comment by: <i>René Meier, Europe Air Sports</i>
	<p>Transition measures proposed</p> <p>31. page 16/31</p> <p>We agree to these proposals. We also propose to the Agency not to offer opt-out possibilities.</p> <p>Rationale:</p> <p>In order to achieve the level playing field mentioned before all provisions should enter into force on the same day in all Member States.</p> <p>In the view of our organisations there is no need for national specificities.</p>	
response	<p>Noted.</p> <p>The applicability dates and possible opt-outs to be adopted will ultimately be decided in the EASA Committee, and EASA can only make recommendations in this respect. In addition to the possible deferred applicability or opt-outs, a transition period of 2 years will be proposed to provide sufficient time to CAMOs to upgrade their systems in order to comply with the new Part-CAMO.</p>	
comment	67	comment by: <i>British Gliding Association</i>
	<p>British Gliding Association</p> <p>31 Transition measures proposed</p> <p>The description of Part M subpart G organisations in Part A and Part B does not align regarding applicability of SMS. Part A specifies an entry in to force of +3 years for subpart G not carrying CAM but Part B excludes subpart G not involved in CAM.</p>	
response	<p>Noted.</p> <p>This issue is no longer relevant as the related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on <b>General Aviation CAMOs</b> (CAMOs that are not involved in CAT and are not managing CMPA). These will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements.</p>	
comment	68	comment by: <i>FNAM-French Aviation Industry Federation</i>
	<p>The SMS will bring many changes within the organization of the companies. It has to be more progressive in order not to bring an administrative burden to these latter. The number of requirements enhanced by this NPA will generate an increase of work and of resources to satisfy them.</p>	



response

Additional time should be given to the organisations in order to allow them to be able to adapt their structure to the new requirements. It will help the organisation to show full compliance with the new management system. Thus, the FNAM is asking to the EASA to review the transition period and take benefit from this additional time to deepen the RIA.

Noted.

Based on the proposal made with the opinion, organisations would have 3 years from now to upgrade to the new Part-CAMO (1 year for the publication of the amending regulation and 2 years to close any findings).

The RIA that is provided with the opinion considers more data, based on an online survey with NAAs and CAMOs, to capture the number and types of CAMOs and get some insights on elements determining costs and benefits of SMS.

comment

84

comment by: *European Sailplane Manufacturers*

In the diagramm and the text the different time intervalls for implementation of the SMS procedures are described.

The sailplane manufacturers have to main comments to this timeline:

A) This is too ambitious.

When 2042/2003 with Part-M and other rules was introduced into aviation it was over a longer period, as non-commercial aviation was first exempted.

Still the effort spent on both sides (organisations and NAAs) was extraordinary.

And a lot of frictions was observed until all changes where implemented.

The proposed SMS introduction will affect all organsation approvals and therefore the effort will be in the same level of magnitude.

Therefore the timeline is too ambitous.

B) This is a decision which should be allowed to be made by General Aviation seperately.

With the rather newly introduced General Aviation Part-M Task Force and the proposed General Aviation Group at last it has been recognized by EASA that this sector of aviation needs a seperate approach to the regulations regarding with continuing airworthiness.

It is neither fair nor appropriate that the proposed SMS procedures (which have been tailored for operations within commercial aviation) should be implemented without taking into account the special needs of General Aviation.

As long as these two groups (Task Force and General Aviation Group) are not actively involved, consequently no such fundamental change should be implemented for General Aviation.

Therefore the sailplane manufacturers oppose introduction of SMS procedures according to the proposed timeline.

response

Noted.



The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on **General Aviation CAMOs** (CAMOs that are not involved in CAT aircraft and are not managing any CMPA).

Those CAMOs will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements, meaning no requirements on safety risk management.

comment

118

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

The time allowed to adopt the new requirements is too short. Neither the NAA nor the industry is able to ensure compliance, which in some cases will require reorganization, within this timeline. Therefore the transition should be extended according the proposed periods plus 1 year, i.e. D+2 years, D+3 years, D+4 years.

response

Noted.

Based on the proposal made with the opinion, organisations would have 3 years from now to upgrade to the new Part-CAMO (on average it takes 1 year from the opinion to the publication of the amending regulation, and the proposal is to provide a transition period of 2 years for CAMOs to close any findings that may arise from the new Part-CAMO requirements).

## Explanatory Note V. Regulatory Impact Assessment 1. Process and consultation

p. 18

comment

85

comment by: *European Sailplane Manufacturers*

In bullet (b) of 1. Process and consultation it is correctly explained, that SMS are becoming an international standard

...because of ICAO regulations

...because management principles needed for the Air Transportation System

The sailplane manufacturers point out here, that for exactly these reasons implementation of SMS is not a need for sport and recreational aviation!

This is a system invented and needed for commercial air transport.

Because we see no indication within sport and recreational aviation, that maintenance procedures already in place lead to a safety problem, we strongly oppose introduction of further rules only complicating the existing system.

response

Accepted.

The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on **General Aviation CAMOs** (CAMOs that are not involved in CAT



aircraft and are not managing any CMPA).

Those CAMOs will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements, meaning no requirements on safety risk management.

comment

86

comment by: *European Sailplane Manufacturers*

The essence of "1. Process and consultation" is:

...SMS is needed for commercial air transport.

...EASA has already dedicated to introduce such a system.

...Licensed air carries are required to introduce SMS anyway.

...NAA also have to follow.

These reasons are all applicable to commercial air transport.

But they are not applicable to sport and recreational flying activities.

IF THERE IS NO NEED FOR A CHANGE; THEN THE CHANGE IS NOT NEEDED!!!

We observe that introduction of SMS to sport and recreational flying activities will

...but a large effort onto the regarding organisations

...no safety benefit is visible

...will make rules and procedures even more complicated

Therefore we strongly propose to introduce such measures only for the part of aviation where it is needed, but not for sport and recreational activities.

response

Accepted.

The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on **General Aviation CAMOs** (CAMOs that are not involved in CAT aircraft and are not managing any CMPA).

Those CAMOs will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements, meaning no requirements on safety risk management.

## Explanatory Note V. Regulatory Impact Assessment 2. Issue analysis and risk assessment 2.1.

### Issue which the NPA is intended to address and sectors concerned

p. 18-19

comment

18

comment by: *SVFB/SAMA*

2. Issue analyses and risk assessment

2.1 quote: ... 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.

....

A very true statement giving some reason for cautious optimism.

response Noted.

comment

20

comment by: SVFB/SAMA

2.1 page 19/30

(c) Part M/F are included here and in the introduction they are **explicitly excluded**: inconsistency.

response Noted.

This item highlighted in the comment is no longer relevant as the related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on **General Aviation CAMOs** (CAMOs that are not involved in CAT and are not managing CMPA). These will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements.

comment

21

comment by: SVFB/SAMA

The approach to have only two categories: small up to 20 and major from 21 up to 20'000 and more is far from proportionate for most SME's.

We propose the following differentiation, also in line with 2012-01 c SMS in 145. Such differentiation would grant safe operation AND promote economical organisations:

Definition: an organisation unit is either a Flight Operation, a ATO, part 145, a component shop, a line station, a CAMO etc.

shift-work (with a 3 shift system) 365x24 counts for 2 organisation units, a 2 shift system for 1 orga unit.

1) For organisation with only one organisational unit, no shift work < 200 => **not complex**

a) Organisations with 2 org units > 150 complex (if shift-work, limit is next lower)

b) Organisations with 3 org units > 100 complex

c) Organisations with 4 org units > 50 complex

d) Organisations with 5 or more org units > 20 complex





response

2) For part M/G there should be given a similar differentiation.

Noted.

It is not advisable to define very granular degrees of complexity. The proposed degrees of complexity are in fact elements to be considered under the organisation's safety risk management (e.g. shift work, existence of multiple organisation certificates).

Following a recommendation made by the Focused Consultation Group, the application of complexity criteria for the determination of applicable AMCs (**complex/non-complex organisations**) will not be maintained for the new Part-CAMO.

Consequently, there will be a single set of management system AMCs to be used by all Part-CAMO approved organisations. Specific needs may be addressed through alternative means of compliance.

The Focused Consultation Group further recommended that this change in management-system-related AMCs and GM be also considered for the other domains.

comment

36

comment by: René Meier, Europe Air Sports

2.1. Issue which the NPA is intended to address and sectors concerned  
p 18/31

The second sentence of 2.1 is a gross understatement: The systems mentioned have not only been able to achieve "relatively good" safety results, with these systems good safety results were achieved, but the systems were not identical. The text the Agency proposes as first part of 2.1 is of great importance to all operators and to all competent authorities. We read about "additional resources necessary to be deployed", but we do not read about reductions in other fields.

Rationale:

We did not find out, at least not up to now, where these additional resources could come from, and, even more important, how such increases could be financed, sports and recreational aviation organisations excepted, as we mostly rely on unpaid volunteers.

Reading the second part of 2.1 about the potential for hazards we would like to add in our view it is far more the selection of the right people than the uniform implementation of a single safety management framework that maintains the high level of safety of today's aviation. Flight hours count, not paperwork done after flight hours.

As regards the last part of 2.1 we are confronted with the fact that all what we read before is to be considered "provisional" at this stage, pending the outcome of the actions recommended to the Agency by the European General Aviation Safety Strategy Group. Should we now continue to work on this NPA or should we stop here, considering our scarce resources? Sorry for that one, but everything related to Part-M tend to transform it into a perfect perpetuum mobile.

response

Noted.

The traditional view of SMS is that a balance between safety and production must exist that results in either a high safety level at the expense of production or high productivity at the expense of safety. This could be true when taken to extremes, but from a 'big picture' perspective, safety is not in opposition with production. In fact, investments made in safety management activities often yield both direct and indirect benefits to an organisation's



productivity. An investment in safety makes good business sense even in the absence of accidents and serious incidents.

Considering a quality management system, it is relatively easy to identify cost and benefits; for example, a lower component rejection rate directly results in increased profitability. Similarly, direct financial benefits can be attributed to the effective implementation of SMS. Safety actions, such as controlling or eliminating the risk associated with a hazard that may result in not only an accident and/or incident, but also in production inefficiencies with financial impact (e.g. flights cancelled, higher component rejection rates or cases requiring rework), will have a positive effect on profitability.

Regarding the provisional nature of the changes to Subpart F and the continuing airworthiness management organisations not involved in continuing airworthiness management of CAT aircraft (licensed air carriers) or CMPA, the concerns are acknowledged. The objective to include those proposed changes was to obtain stakeholder feedback that was subsequently discussed with the Focused Consultation Group and the Part-M General Aviation Task Force, which resulted in the final decision to not require SMS for organisations not involved in continuing airworthiness management of CAT aircraft or CMPA.

comment

44

comment by: *FNAM-French Aviation Industry Federation*

The FNAM emphasises the importance to well proportionate the requirements of the implementation of the new management system according to various factors, such as the number of employees, number of certificates held, number of bases, different types of equipment operated as well as the operational environment, must be considered .

It can not just be proportionate to the number of FTE.

Futhermore, the FNAM is recommending to exclude the organisations belonging to General Aviation maintenance activities from the perimeter of the SMS requirements added through this NPA in the Commission Regulation (EC) No 2042/2003 (Part-M/F and Part-M/G). Indeed, it would be far too complicated for these organisations to implement the SMS requirements as requested by the NPA. It would involve heavy economic consequences without proven safety efficiency. At least, some major alleviation are requested.

response

Partially accepted.

In line with performance-based regulations' principles only those management system elements essential to meet the main safety objectives are included at IR level, with details included at AMC level. Following a recommendation made by the Focused Consultation Group, the application of complexity criteria for the determination of applicable AMCs (complex/non-complex organisations) will not be maintained for the new Part-CAMO. The Focused Consultation Group further recommended that this change in management-system-related AMCs and GM be also considered for the other domains. Consequently, there will be a single set of management system AMCs to be used by all Part-CAMO approved organisations. Specific needs may be addressed through alternative means of compliance. In this way, 'scalability' and related complexity markers are no longer defined through the AMCs, and organisations will need to demonstrate effective implementation of the management system that takes account of their specific size, nature and complexity. Competent authorities will define criteria in order to assess organisations in line with performance-based oversight principles. In addition, they should be supported by agreed



methods and tools to assess the effectiveness of the management system. The RAG group 'cross-domain SMS assessment' is currently developing such tool. It will focus on what effective implementation would mean for the different SMS elements.

Regarding the comment on General Aviation maintenance activities, the comment is accepted:

Opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on **General Aviation CAMOs** (CAMOs that are not involved in CAT aircraft and are not managing any CMPA).

Those CAMOs will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements, meaning no requirements on safety risk management.

comment

47

comment by: CAA-NL

We fully agree with the possibility to qualify certain organisations as non complex. We could not find arguments in the text to explain the differences in FTE staff numbers for Part M Subpart G and Part 145, 10 versus 20.

response

Noted.

The number of FTEs alone may not be a reliable indication of the complexity of activities and risks entailed.

Following a recommendation made by the Focused Consultation Group, the application of complexity criteria for the determination of applicable AMCs (complex/non-complex organisations) will not be maintained for the new Part-CAMO. The Focused Consultation Group further recommended that this change in management-system-related AMCs and GM be also considered for the other domains. Consequently, there will be a single set of management system AMCs to be used by all Part-CAMO approved organisations. Specific needs may be addressed through alternative means of compliance. In this way, 'scalability' and related complexity markers are no longer defined through the AMCs, and organisations will need to demonstrate effective implementation of the management system that takes account of their specific size, nature and complexity.

comment

71

comment by: Luftsport Verband Bayern / Germany

We understand, that it is the intention of EASA, that the European General Aviation Safety Strategy Group may change/adopt the regulation/AMC material again to align this with the results of their own review. We appreciate this approach.

response

Noted.

comment

89

comment by: European Sailplane Manufacturers



It is true that parallel existing safety/management system frameworks in organisations holding several approvals makes things more complicated.

In the case of a typical sailplane manufacturer this could look like that:

20 years ago this was a manufacturer holding only one approval: manufacturer.

The covered and approved activities where:

...development of products (new and changed)

...production of these products

...maintenance of these products

...annual inspection of these products

For all of these activities the staff was in many cases the same, because such companies have not more than 50 - 100 persons and the high qualified persons (management, engineers, inspectors) are not more than 5 - 10 people.

Then 10 years ago with introduction of European rules as written mainly by EASA the very same manufacturer is now forced to hold several organisation approvals:

...DOA

...POA

...MOA (M/F or 145)

...CAMO approval

But still the same people do work at this company - especially as in this sector of aviation it is financially impossible to have more persons in the organisation as long as no increase of the production has been made.

Now within NPA2013-01 it is proposed to simplify things by creating a streamlined SMS system to avoid the possibility errors due to the parallel safety/quality systems.

This is the wrong approach for small companies!!!

Do allow a simple approval possibility for a manufacturer including all activities as listed above (which were perfectly possible 20 years ago).

This would be a real simplification avoiding possible errors due to parallel systems.

Therefore the sailplane manufacturers oppose introduction of SMS procedures as this would only be an even more complicating measure to overcome problems introduced by an already too complicated system.

response

Partially accepted.

The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on **General Aviation CAMOs** (CAMOs that are not involved in CAT aircraft and are not managing any CMPA).

Those CAMOs will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements, meaning no requirements on safety risk management. This new Part-CAO may create the basis for a combined approval covering both initial and continuing airworthiness.



comment	91	comment by: <i>European Sailplane Manufacturers</i>
	<p>As commented in sections above, it should be a decision by the General Aviation Part-M Task Force and the General Aviation Group appointed by the management board to introduce SMS procedures.</p> <p>Even proposing such an introduction as "provisional" is already too onerous.</p>	
response	<p>Noted.</p> <p>The objective to including those proposed changes was to obtain stakeholder feedback that was subsequently discussed with the Focused Consultation Group and the Part-M General Aviation Task Force, which resulted in the final decision to not require SMS for organisations not involved in continuing airworthiness management of CAT aircraft or CMPA.</p>	

**Explanatory Note V. Regulatory Impact Assessment 2. Issue analysis and risk assessment 2.2.**  
**What are the risks (probability and severity)?**

p. 20-22

comment	22	comment by: <i>SVFB/SAMA</i>
	<p>2.2</p> <p>The evidence for this in regards to aircraft up to 5.7T is not available. From the "Annual Safety Recommendations Review 2011" which refers to selected accidents leading to a safety recommendation between 1997 to 2011 (<a href="https://easa.europa.eu/safety-and-research/safety-recommendations.php">https://easa.europa.eu/safety-and-research/safety-recommendations.php</a>) our research has shown that:</p> <p>Maintenance caused fatalities out of this report have been as follows:</p> <p>Maintenance driven            9 Heli 9            12 5.7 T to 30 Pax 0            13 2250 kg to 5.7 T 0            14 up to 2250 9</p> <p>Total 18 fatalities compared to a total of 891 which is 2.02 %.            Most fatalities due maintenance have been caused by aircraft &gt; 80 Pax within accident reports with safety recommendation.            The others had no safety recommendation !</p>	
response	<p>Noted.</p> <p>Arguments for rule changes cannot be based on the numbers of fatalities only — this would</p>	



be a purely reactive approach. In addition, while elimination of the risk of fatal accidents remains the ultimate goal, the number of fatalities is not an accurate indication of the level of risk in a system.

comment

23

comment by: SVFB/SAMA

2.2 what are the risks page 20/30 bottom  
quote:

**Aircraft maintenance personnel play an important role in aviation safety by ensuring that aircraft are maintained and repaired to safely carry passengers and cargo.**

Apart from EASA regulators, NAA regulators, SM staff managements and so on.

**It's nice that the one who directly is involved in safety honoured with one sentence in this NPA**

response

Noted.

comment

24

comment by: SVFB/SAMA

pg 20 bottom and top pg 21 v 30

quote.

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.

endquote

Not underestimating the value of fatigue control, but is EASA is going to demotivate this workforce ?

response

Noted.

Fatigue risk management will be reassessed in Phase II of RMT.0251 (MDM.055). Requiring Part-145 organisations to adopt schemes that minimise risks related to maintenance staff fatigue should rather be seen positively, and not as something that would negatively affect staff motivation.



comment

37

comment by: René Meier, Europe Air Sports

## 2.2. What are the risk (probability and severity)

p 19ff

The answer is easy: It is highly probable that people not really fit and suited for a career in aviation are selected and then employed. No safety management system in the world fights this fact.

The Agency believes very much in organisations, we think, however, many incidents and accidents are caused to a very great extent by e.g. misjudgement, bad decisions, wrong assumptions by individuals. Safe operations have much more to do with selecting the right people for the job to be done.

We therefore propose to the Agency to become even more active in this field, first of all as regards flight operations, secondly only as regards aircraft maintenance. When writing these lines we were thinking the following:

- a) Why was the unhappy AF 447 where it was?
- b) Why do airlines operate twin-jets with one reverser inoperative?
- c) Why go-arounds regularly are initiated too late?
- d) Why is it possible to insert an actual take-off weight wrong by 100 tons?
- e) Why to PPL holders disregard urgently required anti-ice measures?

and also of the tragedy that happened to the Polish Air Force Tu-154 that crashed at Smolensk killing dozens of the Polish elite.

The general picture the texts of 2.1. and 2.2 propose lets us think aircraft maintenance being a trade sector full of stressed staff, plagued by fatigue and adverse labour conditions, with customers applying pressure on organisations, facing IT problems, unacceptable time constraints, lack of staff, excessive working hours, poor planning, poor shift scheduling, working in an environment with no proper control of temperature, humidity or noise.

Three simple questions of the author of these lines:

- 1) Where are we?
- 2) Ever been at an airport and in a maintenance environment, actively working?
- 3) What number of working hours is in your eyes correct?

Just the two safety recommendations given on page 21 do in no way justify the text proposed by the Agency.

response

Noted.

Fatigue risk management will be reassessed in Phase II of RMT.0251 (MDM.055). The safety recommendations referenced in the RIA are directly relevant to the issues addressed by the rulemaking task. They are not the only arguments for the rule changes.

Misjudgement, bad decisions, and wrong assumptions made by individuals in critical situations may be addressed through better training and qualification; however, it is important to recognise that human performance is highly context-specific and does not solely result from the knowledge, skills and expertise of the individual. One important aspect of SMS is to create a proper framework for managing human-factors-related risks in particular by considering the organisational and systemic influences on front-line staff.

comment

76

comment by: AIR FRANCE

AFR comments : Considering the personnel fatigue risk management as already covered by



	<p>the initial and recurrent training related to "Human factor" and by the National regulation related to work duration, we propose to remove the notion of personnel fatigue risk from this paragraphe.</p>
response	<p>Noted.</p> <p>Fatigue risk management in Part-145 will be reassessed in Phase II of RMT.0251 (MDM.055). With or without explicit requirements on the introduction of a fatigue risk management scheme, any organisation subject to safety management requirements should identify fatigue-related hazards and manage the associated risks.</p>
comment	<p>94 <span style="float: right;">comment by: <i>European Sailplane Manufacturers</i></span></p> <p>The sailplane manufacturers would appreciate to see a clear proof that we have such problems in CAMOs and/or maintenance organisation in our sector and that such factors have lead to a safety problem in the gliding community.</p> <p>Due to the fact that most manufacturers have a very close connection to the sporting communities and are conducting maintenance themselves we do not see such an indication.</p> <p>Therefore we strongly oppose any rulemaking activity and associated rule change which tries to cure a problem, which does not exist.</p>
response	<p>Accepted.</p> <p>The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on <b>General Aviation CAMOs</b> (CAMOs that are not involved in CAT aircraft and are not managing any CMPA).</p> <p>Those CAMOs will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements, meaning no requirements on safety risk management.</p>
comment	<p>98 <span style="float: right;">comment by: <i>GE Aviation</i></span></p> <p>The past approach of managing risks based on the past causes of accidents has been highly effective in driving down the accident rate. Accidents continue to occur for these same past causes, in geographical/operational areas where the known risk reduction measures have not been implemented. Further reduction of the worldwide accident rate can be done most effectively by continuing to implement these known solutions. The contribution to the accident rate from unique, "random" causes is very small. It is critically important that the introduction of proactive systems to discover and address the new, unique accident risk (very small) not detract from the ongoing effort to reduce accident risk from "known causes" (relatively large.) The introduction of SMS must therefore take great care not to disrupt existing safety systems.</p>
response	<p>Noted.</p> <p>Known causes of accidents are typically systemic in nature, and once addressed system-wide,</p>



result in a new, lower baseline. A succession of improvements in technology, oversight/regulations, and training has brought about the improvements that can be seen in the accident rate curves.

Common cause hazards are the ones that are most effectively addressed with equally broad and sometimes prescriptive countermeasures such as upgrades in technology, training, or regulations. Once solutions are found, they are applied to the entire population, often resulting in significantly lowering the accident rate. These types of countermeasures are the ones that make up the steep declining trend in the accident rate over the last decades. At some point though, most of the significant common causes are brought under control.

The flattening of an occurrence curve is generally regarded as indicative of a situation more under the influence of random or unique causes. While small segments of the overall population may still have systemic causes, their influence on the overall population response is swamped by their uniqueness in the larger group. After event rates plateau, causes of future events typically take on a more random characteristic, with causes becoming more unique to given operators, aircraft, events, regions, etc. Fewer accidents are related to broadly distributed exposure factors. Further gains in safety will depend on identification and control of hazards in a more nuanced fashion using strategies that help managers of individual aviation organisations identify and control hazards in the context of their unique configuration, business model and type of operations.

This is where SMS is important: control of unique problems is best ensured by the processes incorporated in an SMS. SMS requires a service provider to identify hazards in their systems and operational environment, assess these hazards for their degree of risk, and take action to control those that pose an unacceptable degree of potential harm. While the SMS processes may be a subject of regulations, the specific threats ('harms') that are addressed through the SMS processes are not themselves the subject of prescriptive regulations.

This is not to say that continued attention to maintenance, training, and compliance with prescriptive standards ceases to be important. On the contrary, these are the basis of maintaining the baseline of hard-won safety improvements. Relaxation of the controls that provided the safety improvements can easily reverse the process resulting in a return to original, higher event rates. Thus measurement of implementation and compliance with basic safety standards must be part of the safety management strategy.

comment 99

comment by: GE Aviation

Identification of potential areas of human error is a welcome beginning to the development of means to control these risks. Currently the industry has no accepted means to assess the presence, absence or relative importance of risks introduced by management structure, organizational factors, human/system interface, and so on. In the absence of agreed methodologies, mandating risk management as part of SMS is likely to be ineffective at best, and possibly generate unreconcilable differences of opinion and diversion of safety resources from more soluble problems.

Since the NPA does not help identify a path to controlling risk, or to using the risk classification table proposed on page 22, no benefit should be claimed in the RIA for human factors risk reduction.



response

Noted.

Specific implementation support and guidance material on safety risk management in maintenance and continuing airworthiness management will be provided in the framework of the EASA safety promotion programme (a safety promotion task will be proposed for the planning cycle 2017–2021). This may entail templates for manuals, implementation guidelines, etc.

It is not the intention, however, to impose specific methodologies for assessing the presence, absence or relative importance of risks introduced by management structure, organisational factors, human–system interface. Organisations normally start implementing SMS based on a detailed description and subsequent analysis of their systems and processes. Organisations certified to quality management system standards should be familiar with this approach.

comment

121

comment by: GAMA

A.V.2.2 The risk classification table is EASA's proposed version of James Reasons's Risk Matrix which differs from the FAA's version and Transport Canada's version of the matrix. Considering that the NPA is to ensure maximum flexibility by defining core requirements of the management system rather than prescriptive requirements, GAMA questions if other versions of the risk matrix would be acceptable.

response

Noted.

This risk matrix is solely used for the EASA RIA. Organisations are free to adopt any risk matrix of other approach to assess safety risks as they see fit.

<b>Explanatory Note V. Regulatory Impact Assessment 6. Analysis of the impacts 6.1. Safety impacts</b>	<b>p. 22-23</b>
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comment

72

comment by: Cengiz Turkoglu - City University London

While it is inevitable to mandate implementation of SMS in CAMO's & AMO's in EU member states due to ICAO SARPs and the need for harmonisation with other ICAO member states, introducing a new regulation requires an effective oversight and enforcement when necessary. This inherently and inevitably creates a 'compliance culture' in some organisations and the resources are used to demonstrate compliance rather than achieving real process and safety improvements. Also due to the subjectivity of risk management processes (the core element of SMS), it will be extremely difficult for the NAA's to challenge certain (risk prone) organisations' decisions in relation to risk assessments, risk tolerability as well as safety culture (already stated), which will again question the efficacy of SMS rule making. Nevertheless it is hoped that the NAA's across Europe will recognise the delicate balances in terms of auditing SMS processes.

response

Noted.



EASA acknowledges the need to support the introduction of SMS with sound methodologies for authorities to assess the effectiveness of SMS and implement performance-based oversight. EASA facilitates the development of NAAs' best practices in the area of risk- and performance-based oversight, and participates in the RAG group developing a method and tools to assess SMS effectiveness (first results should be available in the summer of 2016). These initiatives are ultimately intended to support the development towards focusing on effective compliance with regulations (as opposed to formal compliance) and to support stakeholders to take responsibility for their own risks and develop effective methods to manage them.

comment 100

comment by: *European Sailplane Manufacturers*

Here within the "safety impacts" section it is already explained, that a safety culture cannot be engineered through regulations.

For small organisations, which are the typical case within sport and recreational aviation this is even worse:

The more and more complicated rules create additional workload and friction for such companies that the real important tasks (e.g. maintaining / repairing / inspecting aircraft) could even suffer.

Introduction of SMS procedures for such small companies is the wrong approach.

Less complicated regulations and clear definition of responsibilities is the only way out of this situation.

Therefore the European sailplane manufacturers oppose introduction of SMS procedures and instead propose to create a set of simple rules allowing for non-complicated organisation approvals.

Then the persons involved could concentrate on their real important tasks: maintaining / repairing / inspecting aircraft.

response Note.

The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on **General Aviation CAMOs** (CAMOs that are not involved in CAT aircraft and are not managing any CMPA). Phase II will focus on Part-145, Design and Production Organisations.

Those CAMOs and Subpart F organisations will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements, meaning no requirements on safety risk management.

comment 101

comment by: *GE Aviation*

The NPA suggests "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



	<p>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."</p> <p>As discussed above, the actual implementation of the basic principles will vary considerably according to the inherent constraints of each sphere of operations. There will be minimal commonality in practice. Consider the example of an organization which designs products and holds type certificates, and also offers a part 145 service conducting overhauls of those products. Hazard identification and risk assessment for the type design might flow naturally from the certification process and the execution of safety analyses for certification. Once the product enters service, hazard identification would be supported by problems reported from the fleet and also from the production (Quality) system. Hazard identification in the part 145 sector would likely have a very different focus, being concerned with the activities in overhauling the product, rather than the design and construction of the product itself. The nature of the data would be very different, and the means of analyzing and understanding the data in support of risk assessments would be completely different.</p>
response	<p>Noted.</p> <p>The related opinion suggests that for multiple certificate holders the management system <b>may</b> be integrated; it is not obligatory. Integration is particularly relevant in terms of information flow, allocation of responsibilities, and layout of reporting lines. Integration does not necessarily imply that unified procedures are used for all areas. Even within a single certificate holder there may be different risk assessment methodologies for different products or services, and nothing in the rules would prevent to adopt different methods for different needs.</p>
comment	<p>102 <span style="float: right;">comment by: GE Aviation</span></p> <p>GE Aviation concurs that the safety impact of this NPA will be too small to measure.</p>
response	<p>Noted.</p> <p>The RIA did not precisely state this; it stated that it is much easier to quantify costs of implementing SMS than to measure the related benefits. Cost-benefit analysis for SMS is more challenging due to the very nature of 'safety'. Intangible benefits, such as improved safety culture, effective regulatory compliance, management commitment to safety, shareholder value, and public confidence are difficult to quantify. Also, an effective SMS results from the interactions of many different organisational elements, actions, and processes that are ideally embedded within the organisation's existing system. Therefore, the effects of individual elements of the SMS framework are not always easy to isolate for the purpose of cost-benefit analysis. In particular, the overall impact of effective SMS implementation on the organisation's safety culture may be significantly greater than a sophisticated cost-benefit analysis may suggest.</p> <p>The potential of SMS is not only related to addressing the risks of major occurrences, but also to identifying and tackling production inefficiencies, improving communication, fostering a better company culture, managing changes more effectively, and better controlling contractors and suppliers. In addition, through an improved relationship with the competent authorities through the introduction of performance-based oversight, implementation of an effective SMS should result in a reduction of oversight burden.</p>



**Explanatory Note V. Regulatory Impact Assessment 6. Analysis of the impacts 6.2. Social impacts**

p. 23

comment	38	comment by: <i>René Meier, Europe Air Sports</i>
	6.2 Social impacts page 23 No negative social impacts are expected? This is in our view not true. Rationale: What about the aircraft maintainers that stopped the activities during recent years, and will stop from now on, because of all the restrictions and regulatory burdens put on them?	
response	Noted.  This point will be reassessed for the RIA to be provided with the related opinion.	

comment	69	comment by: <i>FNAM-French Aviation Industry Federation</i>
	The FNAM reminds that the European Union has already established work and rest time limits and their minimum standard in the "Directive 2003/88/EC" and in the "Directive 2000/79/EC". It is not from the scope of the EASA to establish social requirements but it belongs to the States sovereignty. The FNAM is requesting to remove those principles from the SMS requirements.	
response	Noted.  Fatigue risk management will be reassessed in Phase II of RMT.0251 (MDM.055).	

**Explanatory Note V. Regulatory Impact Assessment 6. Analysis of the impacts 6.3. Economic impacts 6.3.1 Industry**

p. 23-24

comment	5	comment by: <i>Austro Control Ltd.</i>
	Comment: Considering the fact that most of the Part-M Subpart F approved organisations are mostly smallest organisations and/or related to flight clubs (even less than 10 FTE) Austro Control Ltd. considers that such organisations will not be able to implement a SMS as it is described for non complex organisations in this NPA. Also the improvement of safety if such organisations have to implement a SMS is considered to be very low compared to the efforts for the implementation to be made by such organisations. Justification: There are many Part-M Subpart F approved organisations with even less than 5 FTE involved	



	<p>in the activity of the approved organisation and/or work for e.g. flight clubs only. Additional the scope of approval of such organisations is very limited in types and complexity therefore it should be considered that the already required Quality system with the existing focus on compliance and safety issues is enough. No additional management system changes (SMS) should be required by the NPA 2013-01 for such Part-M Subpart F approved organisations by default the existing compliance monitoring is considered to be enough.</p> <p>Proposal: Paragraph M.A.616 should be revised to exclude such organisations from the SMS requirement completely.</p>
response	<p>Accepted.</p> <p>The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on <b>General Aviation CAMOs</b> (CAMOs that are not involved in CAT aircraft and are not managing any CMPA), nor on Subpart F organisations (Phase II will focus on Part-145, Design and Production Organisations). Those CAMOs and Subpart F organisations will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements, meaning no requirements on safety risk management.</p>
comment	<p>39</p> <p>comment by: <i>René Meier, Europe Air Sports</i></p> <p>6.3.1 Industry page 24/31</p> <p>"Once organisations have demonstrated effective implementation...they should see a reduction in the amount and costs associated with competent authority oversight": Thank you for this sentence. We shall show it to our competent authorities each and any time required. We would have preferred the formula "Once organisations have demonstrated effective implementation competent authorities have to reduce oversight activities to keep costs down and, in doing so, to maintain a high level of productivity and efficiency of all stakeholders operations.</p> <p>Rationale: Not much will happen when there will be no obligation to reduce oversight activities, within well defined rules, of course.</p>
response	<p>Noted.</p> <p>The related opinion proposes oversight requirements that support an evolution towards more performance-based oversight and that provide more flexibility to organisations to manage changes without prior approval by the competent authority. This should contribute to the reduction of the oversight burden for organisations having demonstrated an effective management system for safety.</p> <p>Nevertheless, EASA cannot directly regulate the fees and charges applied by competent authorities.</p>
comment	<p>43</p> <p>comment by: <i>FNAM-French Aviation Industry Federation</i></p>



	<p>In the following quote from part 6.3.1. "More importantly, effective fatigue risk management will improve the productivity of maintenance personnel, and reduce the number of errors and incidents that together will <b>provide return on investment for the organisation</b>", the EASA is mentioning that the organisation, through the implementation of its FRMS, will gain return on investment.</p> <p>The FNAM reminds that the European Union has already established work and rest time limits and their minimum standard in the "Directive 2003/88/EC" and in the "Directive 2000/79/EC". It is not from the scope of the EASA to establish social requirements but it belongs to the States sovereignty. The FNAM is requesting to remove those principles from the SMS requirements.</p>
response	<p>Noted.</p> <p>Fatigue risk management in Part-145 will be reassessed in Phase II of RMT.0251 (MDM.055). With or without explicit requirements on the introduction of a fatigue risk management scheme, any organisation subject to safety management requirements should identify fatigue-related hazards and manage the associated risks.</p>

comment	48	comment by: CAA-NL
	<p>Middle paragraph of page 24 of 30: In the text the use of an alternative means of compliance by an organization is related to the demonstration of an equivalent safety level. The organization however has to demonstrate compliance to the related rule. An equivalent safety level is related to the BR article 14.6 derogations, whereby the organization does not comply to the rule.</p>	
response	<p>Noted.</p> <p>The point is noted and the text will be corrected in case it is reused.</p>	

comment	73	comment by: Cengiz Turkoglu - City University London
	<p>1.While it is welcomed that this NPA introduces the need for FRMS implementation in AMO's, it could not be understood why FRMS implementation was not considered in Part M. In the past, HF related requirements were introduced first in Part 145 and then proposed to be incorporated in Part M by this NPA. Considering that many maintenance related issues can be addressed by CAMO personnel by carefully designing task cards and/or planning maintenance, equally fatigued CAMO personnel may also present significant risks by generating and issuing inadequate or inaccurate maintenance instructions. Also fatigue - by definition - is not only caused by lack of sleep but also due to workload and task complexity; therefore personnel working with sophisticated IT systems dealing with AD/SB assessment and/or maintenance forecasting may also be subject to fatigue. Finally personnel, who may be part of CAMO and working in 'Maintenance Control Centres' usually work around the clock and can make important safety decisions related to dispatching aircraft but also subject to fatigue.</p> <p>2.Complying with the European Working Time Directive may not necessarily assure an</p>	



response

acceptable level of safety in airworthiness management and maintenance environment and furthermore EU members states can opt out of certain requirements. In some cases, FRMS (data driven decisions) may enable the organisations to develop new work schemes/rosters, which may not necessarily be compliant with European Working Time Directive but present a strong safety argument.

Noted.

In response to comment 1, following a recommendation from the Focused Consultation Group it was agreed not to introduce formal requirements for a fatigue risk management scheme in Part-CAMO. This does not mean, however, that the organisation would not need to address any fatigue-related hazards and manage the related risk. The Focused Consultation Group in cooperation with the European Human Factors Advisory Group (EHFAG) further recommended to introduce HF-related knowledge and training provisions in the new Part-CAMO to improve the management of any HF-related issues. Finally, a requirement has been added for a man-hour plan to be maintained by the CAMO.

In response to comment 2, please note that fatigue risk management in Part-145 will be reassessed in Phase II of RMT.0251 (MDM.055). With or without explicit requirements on the introduction of a fatigue risk management scheme, any organisation subject to safety management requirements should identify fatigue-related hazards and manage the associated risks. EASA agrees with the statement that compliance with the EU's Working Time Directive (2003/88/EC) alone is not sufficient to address fatigue-related hazards, which are necessarily company-specific.

comment

74

comment by: Cengiz Turkoglu - City University London

1. While this paragraph presents a strong argument, it should also be noted that the implementation cost of SMS may be significant in organisations, which may have reasonably good reporting culture. Because high number of internal safety reports will require significant resource to investigate, identify hazards, risk assess and then implement necessary mitigating measures. I believe this is often underestimated in terms of cost implications.

2. With regards to risk management and trade-offs between commercial pressure and operational risks, it is often argued that by making the appropriate risk decisions, the organisation can achieve the necessary safety objectives without overspending; however in reality, due to the (as an executive from a major legacy carrier recently described) 'brutal competition', many organisations are driven to take risks. Furthermore, some of them encourage their employees (operational staff such as pilots, engineers) to take risks as well by offering incentives (i.e. bonuses mainly based on operational/commercial performance without considering safety performance)

response

Noted.

The comment on the number of reports will be considered for the RIA provided with the related opinion. The investment in analysing potential safety issues raised in the reports should be offset by the ensuing safety benefits, in terms of improved risk management and safety culture.

Regarding the second comment, the introduction of a management system for safety will





require the organisation to clearly define authority and accountability for any decisions made on risks and to provide evidence of the results of risk assessment. The introduction of SMS should also lead the organisation to assess the potential negative outcomes linked with bonus systems for certain expected performance.

comment 103

comment by: *European Sailplane Manufacturers*

Here in the RIA it is tried to create the impression that the proposed alleviations are good enough for smaller / non-complex organisations.

This is not the case - it is still additional effort which will neither lead to a safety improvement nor to a better financial situation of these companies.

The typical outcome could be a designated safety / compliance-monitoring manager which has to take over these roles additionally by working over-time.

This poor guy might work on the fatigue risk management scheme late in the evening (as he/she is also the accountable manager) as only then the day-to-day business will allow to complete this additional job.

The typically small companies will not have the possibility to hire additionally staff for these tasks and therefore in the end the economic impacts will be:

...much more work for an already lean staff

...motivation taken away to do something useful for safety

...less productivity

...in the worst case: normal work will suffer

The financial impact will be negative - for no real safety benefit as explained earlier.

Therefore the sailplane manufacturers oppose the proposal to introduce SMS procedures for such small companies.

response Accepted.

The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on **General Aviation CAMOs** or maintenance organisations (organisations not involved in CAT aircraft and not managing any CMPA).

Those organisations will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements, meaning no requirements on safety risk management.

comment 104

comment by: *GE Aviation*

Adaptation of an organizations management system to comply with the revolutionary approach proposed by EASA is likely to introduce significant costs. GE Aviation will supply a detailed cost analysis if requested by EASA, provided that proprietary/competition-sensitive information can be appropriately protected.



The presence of an existing voluntary SMS within the organization will not help with the costs of complying with this rule package, since the “management system” proposed by EASA is far beyond the ICAO framework requirements, when AMCs are considered.

It is GE Aviation’s understanding that for this package, the AMC material must be complied with unless the organization gets acceptance from EASA to deviate from the AMC. Since acceptance is not guaranteed, it appears appropriate to assess the regulatory impact on the assumptions that the AMCs are enforced without deviations being permitted.

The proposed path to agreement, of demonstrating an equivalent level of safety, is likely to be highly opinion based and therefore potentially contentious. It is GE Aviation’s assessment that in practice this path could be practicable for a very small number of departures from the AMCs, but that the burden of debating the issue would become unmanageable for more than a few deviations, and that the AMCs will be, in practice, “requirements”.

GE Aviation points out a single example here of how AMC material will introduce great costs: AMC1 145.a. 48b states that independent inspection is now required for flight safety sensitive maintenance tasks including engine overhaul or rigging and engine installation.... This appears to require independent inspection for every stage of every task in an engine overhaul shop. The time spent on each engine will therefore double, and the number of people required to do the work will double (one inspector for every shop technician). GE Aviation recommends a critical review of the accident dataset to establish whether this process, if introduced in engine overhaul shops, would have avoided accidents. If this turns out not to be the case, the NPA will have introduced significant cost into the industry for no apparent safety benefit.

response

Noted.

EASA disagrees with the statement that the proposed EASA requirements are far beyond the ICAO framework requirements ‘when AMCs are considered’. The management system builds upon the existing quality system, therefore it maintains all the requirements on compliance monitoring, which are not explicitly addressed in the ICAO framework. This may suggest that the EASA management system is far more demanding than the ICAO framework.

EASA also disagrees with the assumptions that the AMCs are enforced without deviations being permitted. AMC illustrate a means to comply with the rule, but not the only means: they are non-binding by definition.

Nevertheless, EASA proposes to reassess the set of management-system-related AMCs in Phase II of the rulemaking task RMT.0251 (MDM.055).

Please refer also to the response to comment #102.

comment

105

comment by: GE Aviation

The NPA suggests that implementing this NPA will benefit overall productivity and efficiency. GE Aviation, like most major manufacturers, has existing systems in place to manage productivity and efficiency. It is not clear that these systems, which are based on easily measured metrics and relatively frequent events, will be made more effective by substituting measurement of “safety” – which is notoriously difficult to achieve real-time.



response

As noted above, exposure to accidents and serious incidents in the aviation industry is dominated by known causes with identified and validated risk management strategies, which are still in the process of reducing global safety risk. Introduction of SMS will have a very small effect on overall safety risk and is therefore unlikely to reduce insurance costs and commercial success as suggested in the RIA.

Noted.

Considering a quality management system, it is relatively easy to identify cost and benefits; for example, a lower component rejection rate directly results in increased profitability. Similarly, direct financial benefits can be attributed to the effective implementation of SMS. Safety actions, such as controlling or eliminating the risk associated with a hazard that may result in not only an accident and/or incident, but also in production inefficiencies with financial impact (e.g. higher component rejection rates or cases requiring rework), will have a positive effect on profitability. Both safety risk management and financial 'return on investment' management require proactive consideration of the 'what if' scenarios and the ability to quantify potential loss. There are additional indirect and sometimes non-monetary benefits that should be considered with regard to SMS. These may materialise in areas other than safety, such as security, health, or environmental protection, which will directly benefit from the organisation's efforts to foster its capability to manage risks and maximise opportunities.

Please refer also to the response to comment #98.

**Explanatory Note V. Regulatory Impact Assessment 6. Analysis of the impacts 6.3. Economic impacts 6.3.2 Authorities**

p. 25

comment

40

comment by: *René Meier, Europe Air Sports*

6.3.2 Authorities

page 25/31

Up to now and as far as we know not one measure introduced by the legislator reduced any oversight activity of any competent authority.

The Agency writes "This shall form the legal basis for ensuring that all additional tasks can be financed". Looking at the financial state of many of the member states we think this is wishful thinking. We are eagerly awaiting to read the comments of the country representatives on this idea.

Rationale:

Reallocation of resources are impossible when the commitment of the national politics oppose to it. Not one of the additional tasks will be financed, simply because the financial means in many cases will not be available.

response

Noted.

The new article on oversight capabilities is necessary to support adherence to the ICAO Critical Elements of an Oversight System. All ICAO Contracting States committed to adhere to those under the Chicago Convention. This article also supports the EASA standardisation



function as it allows raising finings against competent authorities in case of non-compliance with the elements introduced.

**Explanatory Note V. Regulatory Impact Assessment 6. Analysis of the impacts 6.3. Economic impacts 6.5. Proportionality issues**

p. 26

comment

70

comment by: *FNAM-French Aviation Industry Federation*

EASA has recognized that the approach has to be different for complex and non-complex organisations. The FNAM welcomes this approach. Therefore, some changes may be required.

The FNAM noticed that the new requirements issued under the Implementing Rules between the non-complex organisations and the complex organisations are not so different. Too many requirements are imposed to the non-complex organisations which will be not economically affordable and where the efficiency of the flight safety in terms of costs it will require is not proven.

First of all, the FNAM is recommending to exclude the organisations belonging to General Aviation maintenance activities from the perimeter of the SMS requirements added through this NPA in the Commission Regulation (EC) No 2042/2003 (Part-M/F and Part-M/G). Indeed, it would be far too complicated for these organisations to implement the SMS requirements as requested by the NPA. It would involve heavy economic consequences without proven safety efficiency. At least, some major alleviation are requested.

Secondly, the boundaries between complex and non complex organisations are far too narrow. Only two classifications (complex and non-complex) of organisations are not enough. There is a too high gap in the organisations described as a complex organisation. It can go from an organisation having 20 FTE for Part-M Subpart F and Part-145 organisations or 10 FTE for Part-M Subpart G to 20,000 FTE or more for the major organisations.

The FNAM emphasises the importance to well proportionate the requirements of the implementation of the new management system according to various factors, such as the number of employees, number of certificates held, number of bases, different types of equipments operated as well as the operational environment, must be considered. It can not just be proportionate to the number of FTE. Thus the FNAM is asking to create three categories of organisations (small, medium and large ones) which will depend on the factors just described above and which will allow a better differentiation on the number and consistence of requirements.

response

Partially accepted.

The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on **General Aviation CAMOs** (CAMOs that are not involved in continuing airworthiness management of CAT aircraft or CMPA). **General Aviation CAMOs** will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements, meaning no requirements on safety risk management.



Regarding organisational complexity, EASA agrees that the number of FTEs alone is not a good marker. The proposed complexity markers (number of certificates held, number of bases, different types of equipment operated as well as the operational environment) are in fact elements to be considered under the organisation's safety risk management. Including a detailed set of complexity markers in the EASA rule material would pose the risk of preventing organisations from determining what makes sense for their particular case. The general principle should be that organisations take responsibility for ensuring and demonstrating that their management system is commensurate with their size, nature and complexity.

Following a recommendation made by the Focused Consultation Group, the complexity criteria for the determination of applicable AMCs (complex/non-complex organisations) will not be maintained for the new Part-CAMO. Consequently, there will be a single set of management system AMCs to be used by all Part-CAMO approved organisations. The set of management-system-related AMCs that will be included in the new Part-CAMO will be reviewed to ensure it does not include any overly prescriptive elements. In addition, specific needs may be addressed through alternative means of compliance.

The Focused Consultation Group further recommended that this change in management-system-related AMCs and GM be considered for the other domains.

comment

106

comment by: *European Sailplane Manufacturers*

The sailplane manufacturers do not consider that the proposed rules are taking into account proportionality issues sufficiently.

It is neither explained, how and why the proposed changes will improve safety within the gliding community, nor is a better suited system being proposed.

This proposal within NPA2013-01 is NOT proportionate and therefore the sailplane manufacturers oppose this proposal for their sector in aviation. Even more so it may be suspected that similarly all organisations dealing with ELA2 aircraft might be affected in an unproportionate fashion.

response

Accepted.

Please refer to the response to comment #111.

**Explanatory Note V. Regulatory Impact Assessment 6. Analysis of the impacts 6.3. Economic impacts 6.6. Impact on regulatory coordination and harmonisation**

p. 26

comment

25

comment by: *SVFB/SAMA*

6.6 Impact pg 26/30



response

We understand and support the need to uniform regulation, however we cannot accept ICAO Annex 19 without reservations.  
The same representants who are driving regulation (up) are as well driving ICAO regulation. The problem of proportionality is addressed. However SME Organisations are due to lack of funding always underrepresented.  
So the problem is always the problem of proportionality.

Noted.

The EASA management system framework is less prescriptive than the ICAO Annex 19 SMS framework.

comment

26

comment by: SVFB/SAMA

#### 7. Conclusion and preferred option :

Who could not support this statement.

What is missing is conclusive and readable, comparable DATA in order to KNOW:

- is there a need for it?
- why ?
- what exactly ?
- in what priority order ?
- what effect is expected?
- how to measure

Before this is established we are NOT SUPPORTING this NPA: major MRO's all have in addition to applied present regulation , several other systems, like EN ISO or OHSAS in place

**The first step is a EU wide accident and occurrence database who delivers true material for action in the proper order.**

**Until such data are available, all rule making is comparable to blind flight.**

We see the underlying principle to change to a performance based regulation, less strictly glued to compliance but to a true Safety Management, we request to establish first a trustworthy Horizon, before we undertake this journey.

This concludes ECOGAS comment to NPA2013-01a v130511-0138

response

Noted.

An EU-wide occurrence database exists already (European Coordination Centre for Accident and Incident Reporting Systems (ECCAIRS)), and its potential will be enhanced through the implementation of Regulation (EU) No 376/2014 on the reporting, follow-up and analysis of occurrences in civil aviation.

Regarding the comment on major MROs already applying ISO9001/EN9110 industry standards, it should be noted that these standards have been (ISO 9001:2015) or will be (EN



9100 series) reviewed to introduce risk management.

comment

107

comment by: *European Sailplane Manufacturers*

The stated ICAO Annex 19 and EASAs participation in the SMICG are no valid reasons to introduce SMS procedures with General Aviation.

Therefore such an introduction within General Aviation should only be taken into account if all stakeholders in that sector have agreed to do so.

It could and should be the role of the General Aviation Part-M Task Force and the General Aviation Group appointed by the management board to start such an activity.

And it must be the case that NPA2013-01 will be resulting into such a deep change for General Aviation.

response

Noted.

It was stated in NPA 2013-01(A) that all changes proposed to Part-M Subpart G for organisations not involved in the continuing airworthiness management of CMPA or aircraft used in CAT as well as to Part-M Subpart F **were to be considered 'provisional'**.

The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on **General Aviation CAMOs** (CAMOs that are not involved in CAT aircraft and are not managing any CMPA). Those CAMOs will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements, meaning no requirements on safety risk management.

The **Part-M General Aviation Task Force** was represented by ECOGAS in the Focused Consultation Group, which was established to assist EASA with the drafting of the related opinion for RMT.0251 (MDM.055) Phase I. In addition, it was consulted on the applicability of SMS and its recommendations were considered for the final opinion: the implementation of an SMS will not be required for General Aviation CAMOs (CAMOs that are not involved in CAT aircraft and are not managing CMPA). They will be eligible to the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements.



## Explanatory Note V. Regulatory Impact Assessment 7. Conclusion and preferred option

p. 26

comment

41

comment by: René Meier, Europe Air Sports

## 7. Conclusion and preferred option

p 26

In other words: There is no option! Interesting to read: "...is supported on the grounds of safety, increased efficiency, and international harmonisation". We would like to know how efficiency will be increased by SMS. We believe the contrary is true: Efficiency of any organisation will decrease.

Rationale:

SMS will be time-consuming thus add costs to the product. No rise in efficiency will occur, at least not on the manufacturers and maintainers side: More staff, more time, more money has to be invested in non-productive activities.

We see at least one option: All operations and activities with aircraft below 5700 kg MTOM not engaged in commercial air transport will be exempt from SMS.

Rationale:

We do not live in the world SMS was intended for.

response

Noted.

SMS has been successfully implemented in many industries outside aviation. Insurance companies increasingly consider the effectiveness of SMS implementation to determine the insurance premium. In addition, ISO9001/EN9110 industry standards have been (ISO 9001:2015) or will be (EN 9100 series) reviewed to introduce risk management, as effective risk management is recognised as an essential element of any management system.

The related opinion for RMT.0251 (MDM.055) Phase I (Part-M) will not impose the implementation of an SMS on **General Aviation CAMOs** (CAMOs that are not involved in CAT aircraft and are not managing any CMPA). Those CAMOs will be eligible for the new Part-CAO, which will mostly consider the existing Part-M Subpart F and G requirements, meaning no requirements on safety risk management.

## Draft Opinion - 2. Article 2

p. 27-28

comment

59

comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)

**Article 2**

The definition of GM is missing?

response

Noted.





## Draft Opinion - 3. A new article 7

p. 28-29

Comment	42	comment by: René Meier, Europe Air Sports
	<p>New Article 7 - Oversight capabilities page 29/31</p> <p>We do not see how smaller competent authorities could cope with all these new tasks: There will not be enough funds available nor will there be enough sufficiently trained staff as required by the provisions proposed by the Agency.</p> <p>Question: What would the Agency propose to do when an NAA asks for support or for the permission to out-source tasks to an NAA of another country?</p>	
Response	<p>Please refer to the response to comment #40.</p> <p>The possible 'outsourcing' of oversight tasks to other NAAs or to EASA is currently being assessed in the context of developing the next issue of the EASA Basic Regulation (<b>Regulation (EC) No 216/2008</b>).</p>	
Comment	60	comment by: Swedish Transport Agency, Civil Aviation Department (Transportstyrelsen, Luftfartsavdelningen)
	<p>· <b>Article 2 (i)</b> Should not "Large aircraft" be changed to "Complex Motor Powered Aircraft"? For example in NPA 2013-01(B) mention "Complex Motor Powered Aircraft" (Page 110 AMC1 M.A.712(b)).</p>	
Response	<p>Noted.</p> <p>The definition of 'large aircraft' is no longer included in Article 2, as last amended.</p>	
Comment	108	comment by: European Sailplane Manufacturers
	<p>The sailplane manufacturers propose an introduction of an official abbreviation for the "alternative means of compliance" in this definition.</p> <p>This phrase will be used rather often in the future and use of such an abbreviation will be of help.</p> <p>So why not ALMC or AIMC?</p>	
Response	<p>Noted.</p> <p>An abbreviation (e.g. AltMoC) could be added as part of the GM to be produced for</p>	



Part-CAMO.

**Draft Opinion - Entry into force**

p. 29-30

Comment

49

comment by: CAA-NL

**Cover regulation Article 1** At Article 7.1 the statement is made to ensure compliance with this regulation, where as in the operational regulations a reference to regulation 216/2008 and its implementing rules would be more appropriate.

response

Noted.

The reference to 'this Regulation' is appropriate as the Article explicitly addresses oversight capabilities for continuing airworthiness.

Comment

50

comment by: CAA-NL

**Cover regulation Article 2 – Entry into force**

We propose a new (e) to be added to point (3):

Organisations approved in accordance with Annex II to Commission Regulation (EC) No 2042/2003 'Part-145' not involved in the maintenance 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 Annex I to this Regulation three years after its entry into force at the latest.

Several Part-145 organisations do not maintain aircraft used in CAT or are classified as non-CMPA. As such, CAA-NL propose that the Opt-Out period is aligned with the similar Part-M subpart-G and Part-M Subpart F organizations. And as such provide the organizations and CAA's sufficient implementation time.

Response

Noted.

This comment will be considered in Phase II.

Comment

61

comment by: Baines Simmons Limited

**Article 2 – Entry into force**

We support the transition timescales proposed.

Member States/Competent authorities have to meet their Oversight Capabilities requirements as required by Article 3 of Regulation 965/2012 already, so a year's transition to accommodate these in the continuing airworthiness domain appears reasonable.

CAT operators will have to meet the new requirements for Management Systems, etc. by October 2014, so the transition period of 2 years appears generous. Although those



response	<p>standalone organisations, i.e. those managing non-CAT CMPA, and Part-145 organisations, will need the proposed 2-year transition period.</p> <p>The 3-year transition period for non-CAT and non-CMPA CAMO and Subpart F organisations proportionately reflects the significant changes required and the lower risk to safety in these sectors.</p> <p>Noted.</p>
comment	<p>109 <span style="float: right;">comment by: <i>European Sailplane Manufacturers</i></span></p> <p>As explained earlier, the sailplane manufacturers oppose automatic introduction of SMS procedures after 3 years.</p> <p>This is too fast and it should be only introduced if regarding bodies, representing General Aviation properly will propose to do so.</p> <p>As NPA2013-01 has not been written taking the needs of General Aviation properly into account we oppose introduction of these changes into our sector of aviation and propose to alleviate all organisations dealing (only) with ELA2 aircraft.</p>
response	<p>Please refer to the response to comment #107.</p>
comment	<p>129 <span style="float: right;">comment by: <i>DGAC FRANCE</i></span></p> <p>DGAC, based on all general issues highlighted in our technical general comments, would suggest to extend the application period of this new regulation: two years after the entry into force for authorities, as is the case for other IR AR already published, and three years after the entry into force for all organisations.</p>
response	<p>Noted.</p> <p>The applicability dates and possible opt-outs to be adopted will ultimately be decided in the EASA Committee, and EASA can only make recommendations in this respect</p>

### 3. Appendix A — Attachments

 [M13011843 v1 AIRBUS COMMENTS NPA2013-01.pdf](#)

Attachment #1 to comment [#64](#)

 [AIA Response on NPAs 2013-01.pdf](#)

Attachment #2 to comment [#75](#)

