Terms of Reference

for a rulemaking task

Embodiment of Level of Involvement (LOI) and Safety Management System (SMS) requirements into Part-21

RMT.0262 & RMT.0611 and RMT.0550 & RMT.0612 (MDM.060 project) — Issue 1 — 27/08/2013

Applicability		**Process map**	
Affected regulations and decisions:	Commision Regulation (EU) No 748/2012 and its Annex I (Part-21), ED Decision 2012/020/R (AMC & GM to Part-21).	Rulemaking lead:	R4
		Concept Paper:	Yes
		Rulemaking group:	No*
		Review group:	No*
Affected stakeholders:	Applicants for EASA Part-21 design approvals, Part-21 Design and Production organisations, NAAs of EU Member States performing POA oversight	**RMT.0262 — LOI NPA 1 (IR):**	
		RIA type:	Light
		Technical consultation during NPA 1 drafting:	Yes
		Publication date of NPA 1 (IR):	2013/Q3
		Duration of NPA 1 consultation:	2 months
		Focussed consultation:	Yes
		Publication date of the Opinion:	2014/Q2
Driver/origin:	Legal obligation	**RMT.0611 — LOI NPA 2 (AMC/GM):**	
		RIA type:	Light
		Technical consultation during NPA 2 drafting:	Yes
		Publication date of NPA 2:	2014/Q2
		Duration of NPA 2 consultation:	3 Months
		Focussed consultation:	Yes
		Publication date of the Decision:	2015/Q2
Reference:		**RMT.0550 & RMT.0612 — SMS NPA (IR + AMC/GM):**	
		RIA type:	Full
		Technical consultation during NPA 3 drafting:	Yes
		Publication date of NPA 3:	2014/Q4
		Duration of NPA 3 consultation:	3 Months
		Focussed consultation:	Yes
		Publication date of the Opinion:	2015/Q4
		Publication date of the Decision:	2016/Q4
		** NOTE: While the working method is formally 'Agency', the Agency will be supported by two groups (for LOI and SMS) with industry/NAA representatives to steer and monitor a set of pilot projects to test the concepts.*	

1. Issue and reasoning for regulatory change

In order to further improve the already good safety records of the civil aviation industry ICAO developed and adopted between 2001 and 2009 in a number of ICAO Annexes the concept of 'Safety Management' (SM). These new SM provisions require implementation of a State Safety Programme (SSP) by the Contracting States and a Safety Management System (SMS) by aviation industry organisations (service providers). As part of its SSP, each State shall require that service providers under its authority implement an SMS in their organisation.

On 25 February 2013, ICAO adopted a new Annex for 'Safety Management' (Annex 19, Edition 1). Annex 19 consolidates all the general SSP and SMS provisions currently spread across Annexes 1, 6, 8, 11, 13 and 14. Annex 19 has adopted the frameworks for SSP and SMS which are generally applicable to all aviation domains, including the domain of Annex 8 'Airworthiness of aircraft'. Annex 19 will become applicable in all aviation domains on 14 November 2013. EU MS will be requested to notify ICAO of any differences that will exist on 14 November 2013 between their national regulations or practices and the provisions of the Standards in Annex 19. Such notifications are to be made before 14 October 2013, and, thereafter, the States shall notify ICAO of any further differences that arise.

To reflect these ICAO developments and in line with the generally accepted EASA principle of Total System Approach, the Agency is in the process of implementing, in a modified form, the ICAO provisions for Safety Management in all the aviation domains within the scope of the Regulation (EC) 216/2008[1] (hereinafter referred to as the 'Basic Regulation'). It is an obligation that stems from the provision of the Basic Regulation which requests to ensure that the provisions of the ICAO Chicago Convention and its Annexes are duly taken into account (ref. Article 2(2)(d)). In addition, the Basic Regulation in its essential requirements for airworthiness, pilot licensing, air operations, ATM/ANS, and aerodromes (see the annexes to the Basic Regulation) requires aviation organisations to implement and maintain a Management System relating to safety, and aim for continuous improvement of this system. The Agency has, recognising its potential for safety improvement, endorsed the Safety Management concept and is actively introducing it across all the aviation domains. Related actions were introduced into the European Aviation Safety plan (EASp) in order to support the Member States to implement their SSPs and foster implementation of SMS by industry.

The domain of initial airworthiness is the last domain for which rulemaking for the implementation of the Safety Management provisions has to be launched, and EASA Part-21 implementing rules have to be amended accordingly. Related rulemaking tasks RMT.0262 & RMT.0611 and RMT.0550 & RMT.0612 (formerly all under the MDM.060 project) are part of the EASA 2014-2017 Rulemaking Programme to address the EASp actions SYS1.3a and SYS.2.2a.

2. Objectives

The principal objective of this rulemaking project is to ensure a full compliance of Part-21 with the framework of Safety Management provisions of ICAO Annex 19. This means to check the existing Part-21 rules and add, as necessary, the missing Safety Management provisions so that the Design & Manufacturing (D & M) organisations approved under EASA Part-21 are ICAO SMS compliant; and the competent authorities granting them approvals and performing their continuing oversight are supported with the regulatory provisions to meet their ICAO SSP obligations.

[1] Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79, 19.03.2008, p. 1). Regulation as last amended by Commission Regulation (EU) No 6/2013 of 8 January 2013 (OJ L 4, 9.1.2013, p. 34).

Closely linked with the above objective related to Part-21 organisations and their approvals is the objective of implementation of performance-based oversight in product certification. This means introduction in Part-21 of a risk-based approach and setting clear criteria for the determination of the Level of Involvement (LOI) of the Agency when it verifies the applicant's demonstrations of compliance of the product with the applicable type certification basis.

The ultimate objective is to further improve the safety performance in the field of initial airworthiness, among others, through:

— systematic risk management (hazard identification, risk assessment and mitigation);

— safety performance measurement of the management system in support of its continuous improvement;

— safety performance-based oversight allowing to focus on areas of greater risk;

— safety awareness and promotion among all staff involved; and

— improved effectiveness and efficiency of Part-21 implementing rules achieved by their streamlining and improved consistency.

Besides the objective of improved safety for D & M organisations and the competent authorities, the other objective is to reduce, in the long term, the cost of the product certification processes and the cost of maintaining the Part-21 organisation approvals.

3. Activities

In the course of the project conduct, the following activities are envisaged:

— Set up steering groups with stakeholders tasked to select, launch, and monitor a number of pilot projects to test the LOI and SMS concepts, and get experience to support the Agency in its related rulemaking activity for Part-21 and AMC/GM material;

— Conduct a thorough gap analysis between the existing Part-21 implementing rules and ICAO Annex 19 SM framework to identify those SM elements currently missing in Part-21. In completion of this action, take into account the EASA SM model framework as implemented (or going to be implemented) in other domains, in particular Air Crew/Air Operations and Continuing Airworthiness (task RMT.0251 (MDM.055));

— Evaluate and improve as much as possible and without resulting excessive administrative cost the overall consistency of Part-21 organisation approvals; take into consideration the recommendations of Advance-NPA 15-2006 and related CRD on 'Consistency of Organisation Approvals' (COrA);

— Evaluate and, if practicable, improve Part-21 implementing rules to better reflect the EASA generally accepted principle of performance-based rulemaking with rules focussed on safety objectives, leaving prescriptive implementation means and interpretations to the AMC/GM level;

— Introduce into Part-21 Human Factors as adapted from the other aviation domains to fit D & M organisations;

— Draft amendments (NPAs) to Part-21 rules and related AMC/GM material to implement the LOI and SMS concepts while providing flexibility, by means of application of the

concept of Alternative Means of Compliance (AltMoC), and proportionality, by means of AMCs/GMs tailored to complex and non-complex D & M entities; and

— Develop Regulatory Impact Assessments (RIA) for LOI and SMS implementation.

Due account should be taken of the experience gained from SMS implementation in the other aviation domains as well as the lessons learned from the previous Agency's attempts to implement LOI and SMS in the domain of initial airworthiness.

4. Deliverables

— **NPA 1** with draft amendments to Part-21 rules to implement LOI;

— **NPA 2** with draft amendments to AMC/GM to Part-21 to support implementation of LOI;

— **NPA 3** with draft amendments to Part-21 rules and AMC/GM to Part-21 to support implementation of SMS;

— **Opinion 1 + CRD** with resulting draft amendments to Part-21 rules to implement LOI;

— **ED Decision 1** with amendments to AMC/GM to Part-21 to support implementation of LOI;

— **Opinion 2 + CRD** with resulting draft amendments to Part-21 rules to implement SMS; and

— **ED Decision 2** with amendments to AMC/GM to Part-21 to support implementation of SMS.

5. Interface issues

— Interface with the other EASA Safety Management related activities, namely with rulemaking under RMT.0251 (MDM.055) task to embody Safety Management System (SMS) requirements into Regulation (EC) No 2042/2003 with the purpose to ensure consistency in principles and frameworks of the SM implementation in both domains; and

— Interface with the international and national Safety Management related activities (ICAO Safety Management Panel (SMP), ICAO Airworthiness Panel (AIRP), Safety Management International Collaboration Group (SM ICG), FAA 21/SMS Aviation Rulemaking Committee (ARC) project etc.) in order to assure equivalency of EASA Part-21 SM concept implementation with corresponding concepts of non-EASA ICAO Contracting States to facilitate mutual understanding and support mutual recognition of related organisation approvals.

6. Focussed consultations

— Consult RAG/TAG and D & M SSCC advisory bodies (meetings and/or written consultations).

— Hold technical workshops as felt appropriate.

7. Profile and contribution of the rulemaking group

As explained above, RMT.0262 & RMT.0611 and RMT.0550 & RMT.0612 are 'Agency' tasks so formal rulemaking groups will not be set up. However, the Agency will ensure proper stakeholder's involvement by other, more flexible means using pilot projects (one set for

LOI and one set for SMS) monitored by their dedicated steering groups composed of the involved Agency staff and representatives of stakeholders (D & M organisations and NAAs).

The profile of these pilot projects and participating D & M organisations will ideally include fields as follows:

— CS-25 aeroplane (TC/significant/major change project);

— CS-23/VLA/LSA aeroplane (TC/ significant/major change project);

— Engine (TC/ significant/ major change project);

— Rotorcraft (TC/ significant/ major change project)

— Non-TC holder major change (STC project);

— Part or Appliance project.

8. Annex I: Reference documents

8.1. Affected regulations

Commission Regulation (EU) No 748/2012 and its Annex I (Part-21)

8.2. Affected decisions

AMC & GM to Part-21 (ED Decision 2012/020/R)

8.3. Reference documents

— EASA Concept Paper 'Embodiment of Level of Involvement (LOI) and Safety Management System (SMS) requirements into Part-21' (RMT.0262 & RMT.0611 and RMT.0550 & RMT.0612 (MDM.060 PROJECT))

— ICAO Annex 19;

— ICAO Annex 8;

— ICAO Doc 9859 (Safety Management Manual);

— ICAO Doc 9734 (Safety Oversight Manual);

— ICAO Doc 9760 (Airworthiness Manual);

— Annex III (Part-ORO) to Commission Regulation (EU) No 965/2012 of 28 October 2012 and ED Decision 2012/017/R;

— Annex II (Part-ARO) to Commission Regulation (EU) No 965/2012 of 28 October 2012 and ED Decision 2012/016/R;

— Annex VI (Part-ARA) to Commission Regulation (EU) No 290/2012 of 30 March 2012 and
ED Decision 2012/006/R;

— Annex VII (Part-ORA) to Commission Regulation (EU) No 290/2012 of 30 March 2012 and ED Decision 2012/007/R;

— Commission Regulation (EC) No 2042/2003 of 20 November 2003 and its Annexes I & II (Part-M, Part-145);

— NPA 2013-01 (A, B, C) Embodiment of Safety Management System (SMS) requirements into Commission Regulation (EC) No 2042/2003;

— Advance NPA 15-2006 and related CRD on 'Consistency of Organisation Approvals' (COrA);

— FAR Part 5;

— FAR Part 21; and

— Guidance documents of the Safety Management International Collaboration Group (SM ICG).

European Aviation Safety Agency

Annex to ToR RMT.0262 & RMT.0611 and RMT.0550 & RMT.0612 (MDM.060 PROJECT)

CONCEPT PAPER

Embodiment of Level of Involvement (LOI) and Safety Management System (SMS) requirements into Part-21

EXECUTIVE SUMMARY

This Concept Paper presents a top-down, systemic approach to the issues related to the adaptation of the implementing rules for initial airworthiness in order to comply with the Safety Management principles introduced by ICAO Annex 19. It deals with two closely related topics – Level of Involvement (rulemaking tasks RMT.0262 & RMT.0611) and Safety Management System (rulemaking tasks RMT.0550 & RMT.0612). The tasks aim at amending Commission Regulation (EU) No 748/2012 and its Annex I (Part-21), as well as related AMC & GMs in order to add the missing, ICAO compliant Safety Management provisions for applicants for EASA design approvals as well as applicants/holders of Part-21 organisation approvals. The tasks have been classified as complex. Both tasks, formally separated, are seen as parts of one project which aims at :

(a) introducing a risk-based approach to determine Level of Involvement (LOI) of the Agency in product certification; and

(b) reviewing Part-21 to check its compliance with the Safety Management provisions of ICAO Annex 19 and add, as necessary, the requirements for Design & Manufacturing (D & M) organisations related to the Safety Management System (SMS), as well as requirements for competent authorities granting them approvals and performing their continuing oversight to support their State Safety Programme (SSP).

The key elements of the ICAO Safety Management concept which are new to Part-21 regulation are:

— safety risk management (hazard identification, risk assessment and mitigation);
— safety performance measurement and continuous improvement;
— performance-based oversight; and
— safety promotion.

Implementation of Safety Management principles in product certification and D & M organisations has a potential to bring significant safety and cost benefits to both D & M organisations and competent authorities due to better allocation and use of resources and rigorous universal application of a proactive/predictive approach to safety allowing focus on safety critical issues. It will also help maintain a level playing field with competitors since the ICAO Safety Management principles are going to be implemented worldwide in all aviation domains. However, Safety Management implementation will certainly require investment from stakeholders.

The domain of initial airworthiness is the last domain within the scope of Regulation (EC) 216/2008 (hereinafter referred to as the 'Basic Regulation'[2]) where the compatibility of existing implementing rules with the Safety Management principles laid down in Annex 19 still needs to be assessed and full compliance needs to be established, as needed.

This Concept Paper is intended to facilitate discussion, among all parties involved, in order to find the best way forward.

[2] Regulation (EC) No 216/2008 of the European Parliament and of the Council of 20 February 2008 on common rules in the field of civil aviation and establishing a European Aviation Safety Agency, and repealing Council Directive 91/670/EEC, Regulation (EC) No 1592/2002 and Directive 2004/36/EC (OJ L 79, 19.3.2008, p. 1). Regulation as last amended by Commission Regulation (EU) No 6/2013 of 8 January 2013 (OJ L 4, 9.1.2013, p. 34).

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1. Identification of the issue

The Agency is in the process of implementing the ICAO provisions for 'Safety Management' (SM) in all the aviation domains within the scope of the Basic Regulation. This stems from the provision in the Basic Regulation related to the Chicago Convention (and its Annexes) which requests to ensure that '…. its provisions are duly taken into account in this Regulation and in the rules drawn up for its implementation' (Article 2 (2) (d)).

The ICAO 'Safety Management' (SM) concept, which was introduced in the past years in several Annexes to the Chicago Convention, consists of two main components - the State Safety Programme (SSP) with safety management responsibilities of Contracting States, and Safety Management System (SMS) to be implemented by specified aviation service or product providers in support of the safe operation of aircraft.

Based on the ICAO SSP/SMS frameworks, the Agency has developed its own EASA SM framework which is the adaptation of the ICAO frameworks to fit the specific needs of EU/EASA rules and EU legal environment. The implementation of the EASA SM framework has been completed in the domains of Air Crew and Air Operations. These two domains are fully ICAO compliant[3]. The process has been completed for the domain of ATM/ANS, but additional rulemaking effort will be needed to bring this domain into full compliance with the ICAO SM provisions in Annex 19. The rulemaking process has been launched and is in various levels of progress in the domains of Aerodromes and Continuing Airworthiness.

Initial airworthiness is the last remaining domain in which SM implementation has to be evaluated for compliance with ICAO Annex 19. Certain rulemaking attempts were made in the past but they were unsuccessful (details below). The main issue and objective of this remaining rulemaking task is, therefore, to amend Commission Regulation (EU) No 748/2012 and its Annex I - Part-21 in order to introduce therein the ICAO compliant EASA SM framework.

This rulemaking activity will build on the results achieved and experience gained from the SM implementations in the other domains, in particular the domains of Continuing Airworthiness, Air Crew and Air Operations. The EASA SM framework developed and adopted there will be considered as a model for SM implementation in the field of Initial Airworthiness.

However, its implementation in this domain will require adaptations to fit the specific needs of Part-21. Many organisations already hold a Design Organisation Approval (DOA) and/or a Production Organisation Approval (POA) issued under Part-21. These organisations have already embedded a number of the SM principles, as required by Part-21, and this approach has resulted in a good safety record from these organisations. It is, therefore, important that the introduction of the full SM principles does not detract from the current effective framework or result in unnecessary costs for no safety benefit. Previous attempts to change the current Part-21 system proved difficult due to misunderstandings and resulting opposition on the side of both stakeholders and some of the Agency staff involved. Therefore, we considered useful to describe and explain now, before the rulemaking starts, all the main issues and their possible solutions. Then the subsequent rulemaking activity needs to be embedded into a well-managed change management process to support a smooth SM full implementation. The main

[3] Since EU is not an ICAO Contracting State, the Agency can neither produce on behalf of the EU MS a common EU State Safety Programme (SSP), nor can it mandate from EU MS the full content of such SSP. The MS are accountable to ICAO to adopt and implement their own SSP. In that, they are supported by EU/EASA aviation rules, namely those for MS competent authorities, and also by the EASA Safety Aviation Programme (EASP) and Plan (EASp) developed for that purpose.

reason for and objective of this Concept Paper is to facilitate a discussion between all parties in order to define the best solution and implementation plan.

This Concept Paper:

— identifies the core issues driving this rulemaking effort (see Section 1);

— provides background to ICAO developments in the Safety Management domain (see Section 2);

— provides background on the EASA approach to the introduction of the ICAO Safety Management principles in all the domains within the scope of the Basic Regulation (see Section 3); and

— identifies specific implementation issues in the domain of initial airworthiness, and describes parameters and open issues on the concepts of implementation of LOI (Section 4) and SMS (Section 5).

2. ICAO background

In order to further improve the already good safety record of the civil aviation industry, between 2001 and 2009, ICAO developed and adopted for a number of ICAO Annexes the new concept of Safety Management (SM).

These new SM provisions require the implementation, from a date specified in each applicable Annex, of a State Safety Programme (SSP) by the Contracting States and of a Safety Management System (SMS) by aviation industry organisations (service providers). As part of its SSP, each State shall require that service providers under its authority implement an SMS in their organisation. This involves the following service/product providers:

— Approved training organisations and medical assessment centres (Annex 1);

— Operators of aeroplanes or helicopters (Annex 6);

— Approved maintenance organisations (Annex 6);

— Air traffic services providers (Annex 11);

— Accident investigation bodies (Annex 13)[4]

— Organisations of certified aerodromes (Annex 14); and

— Organisations responsible for type design or manufacturers of aircraft (Annex 8).

The SSP/SMS provisions, including their frameworks, were originally developed and adopted separately in each of the above ICAO Annexes (except framework for SMS in Annex 8) and made applicable only within the scope of each Annex. The required applicability/compliance dates were different for each Annex.

Annex 19

In 2010 the ICAO High-Level Safety Conference decided that a new annex should be developed on Safety Management. This new annex - Annex 19 'Safety Management' - has been developed in a very short time by the Safety Management Panel (SMP) consisting of

[4] Annex 13 in reality does not require accident investigation bodies to implement a full SMS but requires States to establish, as part of their SSP, a mandatory and voluntary incident reporting system and an incident database to facilitate effective analysis of safety data and ensure a prompt exchange of safety information to promote accident prevention.

representatives of a number of Contracting States as well as representatives of some international industry organisations (e.g. ICCAIA) and the EU. The Agency, representing the EU, participated (and continues to participate) in the SMP work.

The new Annex 19 (Edition 1) that was adopted by the ICAO Council on 25 February 2013, becomes effective in July 2013 and shall be applicable in all aviation domains on 14 November 2013.

Annex 19 consolidates all the general SSP and SMS provisions currently spread across Annexes 1, 6, 8, 11, 13 and 14 and adds elements on the collection and use of safety data and State safety oversight duties. Annex 19 defines two frameworks, one for SSP (see Attachment A of Annex 19) and one for SMS (see Appendix 2 of Annex 19). These frameworks are generally applicable to all aviation domains, including the domain of Annex 8 'Airworthiness of aircraft'.

The general SM provisions of Annex 19 will be complemented, as necessary in each Annex, by domain specific SM provisions. The Annexes will contain appropriate cross references to the general provisions of Annex 19. All affected annexes will shortly undergo revisions to remove the general provisions now contained in Annex 19 in order to avoid duplications. By creating Annex 19 with Safety Management provisions applicable to all aviation domains, ICAO has created a new hierarchical structure of SSP/SMS provisions.

Immediately after the new Annex becomes effective (July 2013), the Contracting States, including the EU MS, will be requested by the Secretary General to notify ICAO of any differences that will exist on 14 November 2013 between their national regulations or practices and the provisions of the Standards in Annex 19. Such notification is to be made before 14 October 2013, and thereafter the States shall notify the Organization of any further differences that arise.

Further, the Contracting States will also be invited to notify ICAO of any differences between their own practices and those established by the ICAO Recommended Practices, when the notification of such differences is important for the safety of air navigation. The Contracting States will also be requested to notify ICAO, before 14 October 2013, of the date or dates by which they will have complied with the provisions of the Standards in Annex 19.

3. EASA background

3.1. General

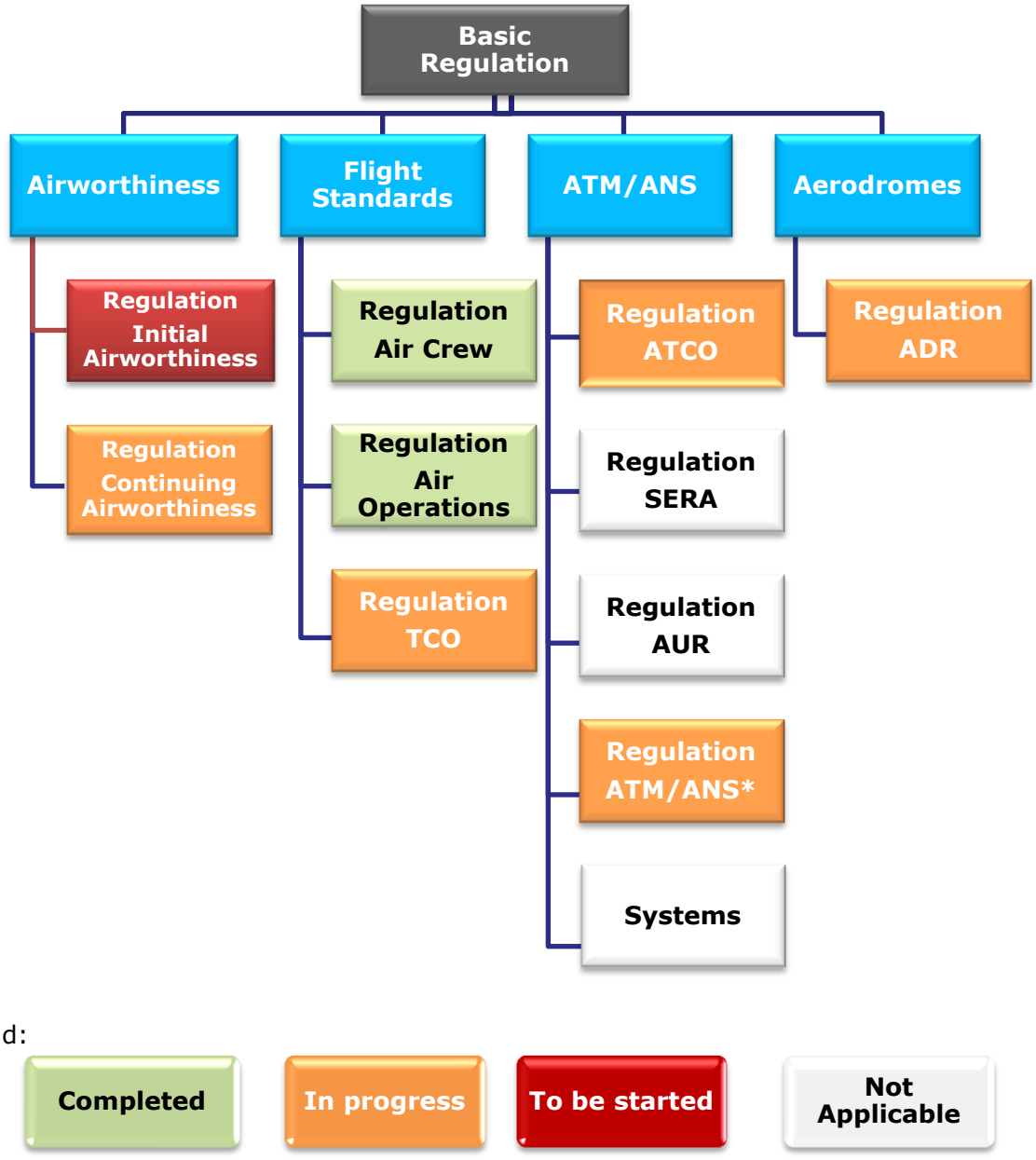
As explained in section 1 above, the Agency, being responsible for aviation rulemaking in the EU, is obliged to ensure that all the implementing rules within the scope of the Basic Regulation take due account of ICAO provisions, including the provisions for Safety Management specified in Annex 19 and the other affected Annexes.

In addition, the Basic Regulation itself, in its essential requirements for airworthiness, pilot licensing, air operations, ATM/ANS and aerodromes (see the annexes to the Basic Regulation) requires aviation organisations to implement and maintain **a Management System** relating to safety, and aim for continuous improvement of this system.

To implement the above provisions of the Basic Regulation, the Agency has developed its own concept and model framework for Safety Management which is fully ICAO compliant and adapted to the specific EU legal environment.

This model, adapted in its form to fit each domain, is gradually being introduced into the implementing rules for all the domains within the scope of the Basic Regulation. In different domains, the work is in different status of progress (see Figure 1). Below you can find brief information on the implementation status in each domain.

Figure 1: The status of SMS implementation in EU/EASA implementing rules



3.2. Air Crew

The rulemaking process has been completed with the adoption of Commission Regulation (EC) No 290/2012[5] which defines, among other things, the Authority and Organisation Requirements for civil aviation aircrew.

Requirements for competent authorities are contained in **Annex VI 'Part –ARA', Authority Requirements for Air Crew.** The SSP related provisions are contained in Sections I (General), II (Management), & III (Oversight, certification and enforcement). Supporting AMC

[5] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:100:0001:0056:EN:PDF

and GMs are contained in ED Decision 2012/006/R[6] (**AMC and GM to Part-ARA**), Subpart GEN, Sections I, II, and III.

The organisation requirements are contained in **Annex VII 'Part ORA', Organisation Requirements for Air Crew.** The SMS related provisions are contained in Sections I (General) and II (Management). Supporting AMCs and GMs are contained in ED Decision 2012/007/R[7] (**AMC and GM to Part-ORA**), Subpart GEN, Sections I and II

The organisation requirements, encompassing the SMS elements apply to:

— approved training organisations (ATOs), i.e. all organisations providing training for commercial and/or private licences in accordance with the EASA rules on flight crew licensing, as well as organisations engaged in flight test training;

— all holders of a Flight Simulation Training Device (FSTD) qualification certificate; and

— all aero-medical centres (AeMCs).

A text comparison between the ICAO Annex 6 SMS framework and the EASA management system provisions is available in the Explanatory Note to the Decision 2012/007/R (AMC and GM to Part-ORA)[8] .

3.3. Air Operations

The rulemaking process for implementing rules for Air Operations has been completed with the adoption of Commission Regulation (EU) No 965/2012_of 5 October 2012 defining Authority, Organisation and Technical Requirements for air operations. It entered into force on 28 October 2012.

Requirements for Competent Authorities are contained in **Annex II 'Part-ARO' Authority Requirements for Air Operations.** The SSP related provisions are contained in Subpart GEN, Section I (General), Section II (Management) and Section III (Oversight, certification and enforcement). Supporting AMC and GMs are contained in ED Decision 2012/016/R[9], Subpart GEN, Sections I, II, and III.

The SMS related provisions for organisations of air operators are contained in **Annex III 'Part-ORO' Organisation Requirements for Air Operations,** Subpart GEN, Sections I (General) and II (Management). The supporting AMC and GMs are contained in ED Decision 2012/017/R[10], Subpart GEN, Sections I and II .

The organisation requirements, encompassing the SMS elements, apply to:

— all operators who are required to hold an AOC/organisation certificate under the new EU rules for air operations; and

— all operators who will be required to declare their activity under the new EU rules for non-commercial operations of Complex Motor Powered Aircraft .

3.4. ATM/ANS

SM related requirements have been adopted and are contained in:

6 http://easa.europa.eu/agency-measures/docs/agency-decisions/2012/2012-006-R/Annex%20to%20ED%20Decision%202012-006-R.pdf
7 http://easa.europa.eu/agency-measures/docs/agency-decisions/2012/2012-007-R/Annex%20to%20ED%20Decision%202012-007-R.pdf
8 http://easa.europa.eu/agency-measures/docs/agency-decisions/2012/2012-007-R/Explanatory%20Note%20to%20Decision%202012-007-R.pdf (starting on page 8)
9 http://easa.europa.eu/agency-measures/docs/agency-decisions/2012/2012-016-R/Annex%20to%20ED%20Decision%202012-016-R.pdf
10 http://easa.europa.eu/agency-measures/docs/agency-decisions/2012/2012-017-R/Annex%20to%20ED%20Decision%202012-017-R.pdf

— Commission Implementing Regulation (EU) No 1034/2011[11] of 17 October 2011 on 'Safety oversight in air traffic management and air navigation services' with the corresponding requirements for competent authorities in the field of ATM/ANS. This Regulation sets out specific requirements for annual safety oversight reporting and monitoring and assessment of the levels of safety achieved.

— Commission Implementing Regulation (EU) No 1035/2011[12] of 17 October 2011 on 'Common requirements for the provision of air navigation services', which mandates Air Traffic Services and Communication, Navigation and Surveillance (CNS) providers to have a Safety Management System and all Air Navigation Service providers to implement a Quality Management System (QMS). For the QMS requirement, the Regulation recognises an EN ISO 9001 certificate covering the air navigation services of the provider as a sufficient means of compliance. Under this Regulation, service providers may integrate safety, security and quality management systems.

However, the SM requirements contained in these Regulations are not compliant with ICAO Annex 19. Therefore, it is necessary to align Safety Management Systems (SMS) requirements in Commission Implementing Regulation (EU) No 1035/2011 with SMS requirements within the ICAO SMS framework, and to align Management Systems requirements in Commission Implementing Regulation (EU) No 1034/2011 with SSP requirements required by ICAO. NPA 2013-08[13] on 'Requirements for ATM/ANS providers and the safety oversight thereof' was published on 10 May 2013.

3.5. Aerodromes

The draft implementing rules on 'Authority, Organisation and Operations Requirements for Aerodromes' have been published in Opinion 01/2013[14]. The rules foresee that aerodrome operators shall implement and maintain a management system that includes a safety management system. The organisation and authority requirements of Opinion 01/2013 are largely based on the organisation and authority requirements developed for air crew and air operations, but inconsistencies exist.

3.6. Continuing Airworthiness

The rulemaking process under task RMT.0251 (MDM.055) was recently started by publication on 21 January 2013 of NPA 2013-01 'Embodiment of Safety Management System (SMS) requirements into Commission Regulation (EC) No 2042/2003'. The NPA was published in 3 parts - 2013-01 (A)[15] (Explanatory Note), 2013-01 (B) (Part-M)[16], and 2013-01 (C)[17] (Part-145). The main objective is to amend Commission Regulation (EC) No 2042/2003[18] and the implementing rules of Part-145 and Part-M to incorporate the ICAO SMS framework and support the implementation of SSP/EASP by the EU Member States. The frameworks of the SMS/SSP requirements for Commission Regulation (EC) No Regulation 2042/2003 are based

[11] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:271:0015:0022:EN:PDF
[12] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:271:0023:0041:EN:PDF
[13] http://easa.europa.eu/rulemaking/docs/npa/2013/2013-08/NPA%202013-08%20(A).pdf
[14] http://easa.europa.eu/agency-measures/docs/opinions/2013/01/Opinion%2001-2013%20-%20Explanatory%20Note.pdf
[15] http://easa.europa.eu/rulemaking/docs/npa/2013/2013-01/NPA%202013-01%20(A)%20EN%20-%20RIA%20-%20Cover%20Regulation.pdf
[16] http://easa.europa.eu/rulemaking/docs/npa/2013/2013-01/NPA%202013-01%20(B)%20Part-M.pdf
[17] http://easa.europa.eu/rulemaking/docs/npa/2013/2013-01/NPA%202013-01%20(C)%20Part-145.pdf
[18] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2003:315:0001:0165:EN:PDF

on the EASA Management System framework originally developed with a view to be generally applicable across all aviation domains and which was later adopted for Air Crew and Air Operations (Parts ARX/ORX). The embodiment respects the existing structure of Part-145 and Part-M. The changes are extensive and address, as part of SMS/SSP implementation, some specific subjects such as Human Factors and consider the recommendations of the Consistency of Organisation Approvals (COrA) Report (see Advance-NPA No 15-2006[19] and the related CRD.) A second NPA containing changes to Part-147 and Part-66 is expected to be published in the second quarter of 2013. The objective is to apply the same basic management system provisions and authority requirements for all certified organisations within the scope of Commission Regulation (EC) No 2042/2003. The Opinion & draft Decision is planned for the first Quarter of 2014 (the regulation one year later).

3.7. Initial Airworthiness

Implementation of SM principles in Initial Airworthiness is focussed on two core Part-21 processes:

(1) The product certification process with the idea of introducing a risk–based approach for the determination of the Level of Involvement (LOI) of the Agency in product certification projects.

(2) The process of approval and oversight of Design & Manufacturing (D & M) organisations with the idea of complementing the related organisation requirements with ICAO compliant SM elements, as well as adding these elements to the requirements for the competent authorities granting them approvals and conducting continuing oversight.

Both the LOI and SMS issues are interrelated because the Agency, the design organisation, and the production organisation participate in the same certification and post-certification activities. The organisation SMS requirements and the requirements for performance-based oversight by the competent authorities are complementary with each other and support implementation of SMS and LOI. Therefore, the LOI and SMS frameworks should be compatible and apply the same SM principles.

3.7.1 History of LOI

One of the key elements of the SM concept is the performance-based oversight supported by a performance-based regulatory system. Performance-based oversight can be applied by authorities in various aviation domains for the initial approval, as well as the continuing oversight of aviation organisations, which provide 'service' (aircraft operation, maintenance, ATM/ANS, aerodromes, etc.). In the domain of initial airworthiness, it can be also applied by the authorities when granting the initial design approval to the product itself (i.e. a type certificate) as well as when approving post –TC design changes and repairs during the life cycle of the product. The term 'Level of Involvement' (LOI) has been chosen for product related performance-based oversight.

The implementation of this approach has now been discussed within the Agency for several years. The work started as early as 2004 under task 21.024 ' Subpart J'. The original objective of this task was to remove the conflict between the privileges of the DOA holder (see 21.A.263(b)) and the rights of the Agency (see 21.A.257(b) and 21.A.33 (c) and (d)) in respect of the Agency's involvement in the certification process. Under the 21.A.263(b) privileges, the DOA holders' compliance documents shall be accepted by the Agency without

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

further verification. At the same time, the applicant for design approval is (under 21.A.257(b) and 21A.33 (c) and (d)) obliged to allow the Agency to review any report, make any inspection, perform or witness any flight and ground test necessary to check the validity of the DOA compliance statements. The task aimed to resolve this conflict and provide upfront, at the stage of approval of the certification programme, a greater legal certainty on the level of Agency involvement in the certification process.

The task was contentious from the outset, with different views being expressed both internally within the Agency and in the wider aviation community. Following the publication and comments received on NPA No 16/2006, some fundamental changes in the concept were introduced, requiring significant internal debate. The ISC participated to this debate on many occasions between the period 04 May 2007 – 06 May 2008. The external Review Group set up in accordance with the rulemaking procedure did not support the proposal.

Even the amended proposal, covered by CRD No 16/2006, which attempted to establish a balance between the organisation and product approval processes by adopting a risk-based approach with a clearer demarcation of responsibilities between the applicant and the Agency, was not agreed. Among the main concerns were:

— The lack of clarity regarding the respective roles and responsibilities of design approval applicants/holders, DOA, product certification teams and DOA oversight teams may lead to overlaps or gaps in the overall certification role of the Agency;

— The perception that the approach will reduce safety (product certification considered more efficient in safety terms than auditing organisations). Experience has shown that compliance documentation may not always be of the standard expected by the Agency. This has led to a general lack of confidence in DOA by certification teams who view DOA as too remote and that assessing a design organisation should be in addition to and not a substitute for assessing the product itself;

— The limited confidence in some DOAs (due to reorganisations, instability and lack of resources);

— The concern that a limited Agency involvement will lead to a loss of Agency technical competence, product specific knowledge, standardisation between projects and credibility;

— The concern that the proposal requires greater coordination between the DOA team and specific PCMs and certification experts. Procedures would need to be developed to ensure this coordination is effective; and

— The possible impact on bilateral agreements which could result in the need for an increased level of involvement from the validating authority…..

The final outcome of the rulemaking activity was contained in Opinion No 01-2010 which only addressed the non-controversial part of the proposal. This part, later adopted into Commission Regulation (EU) No 748/2012, introduced limited changes to Part-21 related to the obligation of the applicant for a design approval to present to the Agency a certification programme detailing the means of compliance demonstration, and to keep this document updated as necessary during the certification process. Additionally, DOA holders were given the privilege to approve minor revisions to the Aircraft Flight Manual and its supplements. The rest of the proposal on LOI was put on hold. This sequence of events emphasised the need for proper change management for such a rule change.

However, the effort to progress the subject of LOI was pursued. Since the first rulemaking attempt, the situation has evolved, as the risk-based approach has been promoted worldwide. Consequently, the concept of LOI is viewed positively today.

3.7.2 Start of MDM.060

MDM.060 task has also faced a series of difficulties since its start. MDM.060 was first introduced in the EASA rulemaking programme for 2009-2012 under the title 'New structure for Commission Regulation (EC) No 1702/2003' (later amended to add introduction of SMS). The title suggested that the primary objective of this task was to reorganise the existing structure of Commission Regulation (EC) No 1702/2003 (predecessor of Commission Regulation (EU) No 748/2012) and its Annex - Part-21 in order to align it with the new, 'horizontal structure' of EASA/EU aviation rules proposed by the draft authority and organisation requirements for Air Crew and Air Operations. This was in line with the ICAO direction (Annex 19 was being drafted) and the FAA direction (Part-5 was being drafted) to have the SM related provisions in the 'horizontal structure'.

AGNA and the SSCC were consulted on the Pre-RIA and TOR Issue 1 developed in 2010 (at that time the LOI issue was not highlighted in the scope of the task but the subject was included under 'performance-based oversight') and both industry and NAA groups provided feedback as follows:

(1) The proposed 'horizontal structure' of the EASA/EU aviation rules was seen to lead to no safety benefit whilst imposing a great administrative burden. On the other hand, the structure and content of the existing Part-21 was considered good, providing good safety results. There were concerns about an envisaged adverse impact of SMS implementation on DOA and POA holders who had invested a lot of resources in the implementation of existing and well-performing systems (Quality and Design assurance systems). There were concerns that the existing systems were to be abandoned when the full SMS would be implemented.

(2) SMS implementation in D & M was not at all clear at the ICAO level. Because of a strong opposition from D & M Industry, no framework for SMS was adopted for Annex 8. Discussions on the very need to implement SMS in D & M were under way between the ICAO secretariat and some D & M Industry associations for a long time.

(3) There was disagreement with the proposed working method and a strong recommendation to change it from 'Agency' to 'Group' in order to properly involve industry and NAA stakeholders.

(4) There were complaints that too many rule changes were under way in many aviation domains and that time should be given to stakeholders to first 'digest' the first extension rules.

(5) It was clear from the comments that there was a lack of confidence that the safety benefits, the new SM approach was designed to produce, would, in fact, result.

The above comments led to the decision to postpone the start of MDM.060 task until the issues were clarified. Early in 2011, the task was put on hold, following the decision not to implement the horizontal rule structure.

In March 2012, the MDM.060 task was re-started after the issue of rule structure was definitively clarified with the adoption of Commission Regulation (EU) No 290/2012 and Commission Regulation (EU) No 965/2012.

A new version of the ToR (version 2) was prepared. This time the LOI element was explicitly stated in the ToR and seen as a benefit by all. The AGNA and SSCC were again consulted on the revised ToR. Preliminary regulatory material was drafted by the Rulemaking Directorate accompanied with a concept for LOI. The decision to proceed was taken. The deliverables for the LOI topic were due for December 2012.

The new feedback on the ToR showed, however, the following:

(6) The stakeholders were concerned that Part-OR/ORO, Subpart GEN requirements, although designed with a view to ensuring general applicability, were tailored to operators and not suitable for Part-21 organisations.

(7) Opposition was expressed against combining the LOI and SMS issues under the umbrella of a single task. They were seen as two separate processes, one related to the product, the other to the organisation.

(8) A request was made to review and clarify DOA privileges with the possibility to extend them if justified by the results of the risk/performance based oversight. A wish was expressed to grant stakeholders the DOA privilege to issue STCs and major changes approvals if in the approved scope.

(9) A request was made to harmonise the EASA SM framework with the FAA and TCCA and accept assistance from D & M associations (ICCAIA).

(10) A request was made to address Human Factors.

(11) Stakeholders disapproved of the Agency's rejection of the proposal to change the working method from 'Agency' to 'Group'.

At this stage (June 2012), the issue was transferred to the Certification Directorate to develop a new concept and test it in pilot projects. However, there were no convenient pilot projects available. The Certification Directorate concentrated on developing the new concept with support material provided by the Certification Strategy Group which has D&M industry participation.

4. LOI concept for Part-21

4.1. LOI concept parameters

In collaboration with industry and the EASA DOA Section, the Certification Directorate has developed a concept for LOI which addresses the majority of the issues not progressed during the previous rulemaking attempts. The concept has been agreed internally within the Agency and the initial discussions with stakeholders have been favourable.

The key elements of the concept for LOI are :

(a) It builds on the introduction of the certification programme by Commission Regulation (EU) No 748/2012;

(b) It formally introduces a risk-based approach both in product certification and design organisation approvals;

(c) It enables the Agency to determine its level of involvement in product certification on the basis of consistent clear criteria, associated with safety risk, linked to:

  (1) the novelty and criticality of the certification item, including means of compliance, and

(2) the level of performance of the design organisation;

(d) It introduces the possibility of extending, under certain conditions, the DOA privileges to approve major changes to the Type Design (including changes to associated required manuals/data), major repairs and STC;

(e) It establishes product certification and design organisation approvals as two processes sharing the same common risk-based elements;

(f) It improves the clarity of the Part-21 text, by separating the requirements applicable to product certification and those applicable to design organisation approvals;

(g) It clarifies the responsibilities of the applicant and the Agency in the product certification process. The applicant remains fully responsible for the compliance of its design with the certification basis;

(h) It better defines the responsibilities of the Agency in product certification. In particular, the contradiction of the present text in 21.A.33 (d), 21.A.257 (b) and 21.A.263 (b) is resolved. The current privilege 'compliance documents shall be accepted by the Agency without further verification' is replaced by a risk-based determination of the level of involvement;

(i) It is consistent with and extends the current DOA concept with all the new elements introduced, as appropriate, including the description of the privileges;

(j) It supports innovations by enabling the industry to safely discharge their responsibilities in a manner appropriate with the extended supply chain models used by industry;

(k) It introduces a consistent and proportionate demonstration of capability for all design organisations (including those applying for ETSOA).

(l) It has the potential to make the DOA concept attractive and proportionate for Small and Medium Enterprises (SMEs), in terms of complexity and privileges.

It is assumed that the LOI concept will be applicable to -

— applicants for TCs and APU ETSOA; and

— applicants for major/minor changes and major/minor repairs, STCs (Subparts D, M, and E) and ETSOAs (Subpart O).

In the first phase, the focus will be on LOI implementation in certification projects of DOA applicants/holders. The applicants for/holders of design approvals designing under Alternative Procedures to DOA (APDOA) and under certification programme only will be addressed later.

The concept does not change the accountability of the applicant for demonstrating full compliance with the type-certification basis. It also does not change the respective roles and division of work in the certification process within the Agency team (i.e. between the Certification staff and DOA staff) or within the applicant team (i.e. between their Certification staff & DOA staff) but should improve the collaboration between the teams, the exchange of information and encourage timely interaction.

For further details about the LOI concept by the Certification Directorate, see Attachment A to this Concept Paper. The concept is accompanied with the detailed initial proposal for Part-21 rule changes.

4.2. Rulemaking process for LOI

The first step is to initiate rulemaking for Part-21 to introduce there the necessary rule changes for the implementation of LOI. The draft rule changes developed by the Certification Directorate will be used as an input for the content of the first NPA (NPA 1). The draft rule changes will be accompanied by an Explanatory Note and a light qualitative RIA only. The draft NPA proposal will undergo focussed internal consultation and immediately after that it will be published for external comments. This first phase will be progressed as fast as possible, leading to an Opinion.

In the meantime, the second phase will be launched with the objective of developing AMC/GM material. This material will be published in the second NPA (NPA No 2) leading to a draft Decision. The development of AMC/GM material will be supported by pilot projects.

4.2.1 Working method

The working method will formally be 'Agency', so that a rulemaking group will not be set up, but adequate involvement of the industry will be assured by other means, namely by direct monitoring of the pilot projects (see below) and participation in the development of AMC/GM material. In addition, consultations with the D & M Sub-SSCC and TAG advisory bodies, workshops, focussed consultations, etc. will take place as necessary.

4.2.2 Pilot projects

To avoid similar difficulties to those experienced in the first attempt, it was agreed to use several current certification projects as pilot projects to test and validate the LOI concept as proposed by the Certification Directorate. The pilot projects will also inform the drafting of AMC/GM material to the proposed rules to allow a smooth implementation of LOI. The LOI pilot projects are ready to start. In April 2013, a Steering Group for LOI pilot projects (LOI SG) was set up. It consists of the Agency staff involved and representatives from leading D & M industry companies. The role of the LOI SG will be to monitor the pilot projects, collect experience and exchange views between the Agency and industry to achieve a good mutual understanding to facilitate smooth implementation. The main group's deliverable will be draft AMC/GM material and, if necessary, a proposal for further adaptations of the implementing rules drafted in phase one.

The profile of these pilot projects and participating design organisations will ideally include fields as follows:

— CS-25 aeroplane (TC/significant/major change project);

— CS-23/VLA/LSA aeroplane (TC/significant/major change project);

— Engine (TC/ significant/major change project);

— Rotorcraft (TC/significant/ major change project)

— Non-TC holder major change (STC project); and

— Part or Appliance project.

4.2.3 Deliverables

The main deliverables will be an Opinion with draft rule changes to Part-21 and a draft Decision with AMC/GM material. If needed, a proposal for further adaptations of the implementing rules drafted in phase one will be delivered.

4.2.4 Time schedule for LOI

4.2.4.1 Time schedule for implementing rules

The time schedule for the IRs is proposed as follows:

April 2013	Start of the LOI SG for pilot projects
May 2013	Adoption of this Concept Paper (both on LOI and SMS) by ISC/IETC
June 2013	RAG/TAG/SSCC are consulted on the Concept Paper + draft ToR
June/July 2013	TOR is published, NPA 1 (IRs only) internal consultation
August 2013	NPA 1 (IRs only) is published (shortened consultation period will be considered)
Q2/2014	Opinion (+ CRD + draft Commission Regulation) is published
Q4/2015	Commission Regulation is adopted (estimate)

NOTE: *Full implementation of LOI is planned to be synchronised with SMS implementation expected in 2017. However, in individual certification projects LOI can be applied earlier, based on Certification Memos and updated certification procedures. Before the applicability date of the Part-21 rule changes, certain details, such as the envisaged extended DOA privileges, cannot be applied.*

4.2.4.2 Time schedule for AMC/GM material

The time schedule for AMC/GM is proposed follows:

Q2/2013	Start of pilot projects, the Concept Paper and ToR are approved
Q3/2013	Start drafting NPA 2 (for AMC/GM material) based on the output from pilot projects
Q2/2014	NPA 2 published
Q1/2015	Draft Decision ready
Q4/2015	Decision adopted (concurrent with Commission Regulation adoption)

4.3. LOI concept open issues

4.3.1 Applicability issue

It needs to be considered whether and how the LOI concept should be applied to SMEs designing and modifying ELA 2 and ELA 1 aircraft under the Alternative Procedures to DOA

(APDOA) or, for ELA 1 only, by presenting the certification programme. The issue also includes applications for ETSOAs.

4.3.2 Content of AMC/GM material

The Certification Directorate envisages in their concept for LOI that a significant amount of AMC and GMs will need to be produced, in particular in the following domains:

— Content and level of detail of the certification programme;

— Criteria for determining the level of performance of design organisation;

— Criteria for determining the criticality of an item of the certification programme; and

— Criteria for determining the novelty of an item of the certification programme.

There are other candidates for AMC/GMs such as :

— Definition of a mechanism which will ensure a smooth cooperation of and timely interactions between the different parties involved in the product certification activities to be established (applicant, EASA DOA team, and EASA Product certification team);

— Definition of a mechanism for the management of certification programmes (how they are established, on what basis, in which form, how they are approved, how they can be amended, etc.);

— Criteria for the determination of the depth of involvement. For a specific item of the certification programme, the determination of the LOI may not be just 'Yes/No' but 'How deep';

— Criteria and conditions for granting the privilege to a DOA holder to approve major changes, major repairs and/or STC under their DOA;

NOTE: Before formal adoption of the Commission Regulation with the related LOI Part-21 rules and synchronised adoption of related ED Decision with supporting AMC/GM material, Certification Memos may be used to allow the LOI process to be applied to individual certification projects. However, DOA holders will only be entitled to the LOI related privileges after the Commission Regulation is formally adopted.

— Access of the Agency certification team to all compliance documents whether or not the agency is involved in the task;

— Reporting obligations of the Applicant for significant events that occur during the certification process; and

— Criteria and procedure for reconsidering the LOI for a specific item or items of the certification programme.

4.3.3 Output from FAA 21/SMS ARC project

The details of the LOI concept may be influenced by the outcome of the FAA 21/SMS Aviation Rulemaking Committee (ARC) project which has been set up to provide FAA with recommendations on how to amend FAR Part-21 and Part-5 to implement performance-based oversight (Level of Involvement) in product certification and SMS in D & M organisations. There is a need to align the results of the work on each side to support harmonisation and mutual recognition of performance-based oversight (Level of Involvement) based on their equivalency.

4.4. Interfaces

4.4.1 Interface with tasks RMT.0550 & RMT.0612 (SMS)

The activity under tasks RMT.0262 & RMT.0611 on LOI should be closely coordinated with the activity under tasks RMT.0550 & RMT.0612 for the implementation of SMS, in particular to address the design organisations whose safety performance will be a factor considered when determining a LOI in certification projects.

4.4.2 Interface with the FAA 21/SMS ARC project

The LOI SG should establish contacts with and monitor the work of the FAA 21/SMS ARC group on the implementation of the performance-based oversight and SMS in FARs.

5. SMS concept for Part-21

5.1. SMS concept parameters

5.1.1 Part-21 SMS and compliance with ICAO

The framework of the SMS implementation in Part-21, including its oversight, must be ICAO compliant. This will be assured by conducting a thorough gap analysis between the criteria of Annex 19 and Part 21 to identify SMS/SSP elements that will need to be added.

5.1.2 Part 21 SMS framework and its consistency with other domains

The framework of the SMS implementation in Part-21 should be consistent with the EASA model framework as implemented (or going to be implemented) in the other domains within the scope of the Basic Regulation. This is required by the principle, generally accepted in EASA, of a Total System Approach. This system requires that aviation system components (organisations, systems, services, products, regulations, etc.) are addressed in a uniform or, at least, consistent way as they are all part of a single aviation network. Such system facilitates interoperability of the system components and improves its overall performance. It eliminates or minimises room for safety gaps, conflicting or overlapping requirements, confused responsibilities misinterpretations etc. Applied to a single organisation holding multiple EASA organisation approvals, it supports smooth integration of these approvals under their company integrated management system. Therefore, internally (within Part-21) and externally (against the other EASA domains) the SMS/SSP frameworks should be consistent. However, a consistent approach does not mean that all implementation aspects must be the same. Differences, where supported by an appropriate rationale, can be accommodated. It is not intended to rigorously enforce a specific framework aspect where it is inappropriate for D&M (see also 5.3.1 below).

5.1.3 Structure

When introducing the SMS/SSP requirements into Part-21, its existing structure (its division to Sections and Subparts) will be respected as far as possible, unless justified otherwise.

5.1.4 No stand-alone SMS organisation approval

The existing organisation and authority requirements of DOA and POA approvals will be amended to embody those SMS/SSP elements which are currently missing there. The existing approvals will be amended but the Agency does not foresee a separate 'SMS' approval.

5.1.5 EASA SMS scope vs ICAO SMS scope for D & M

The ICAO SARPs, as in Annex 19, apply to organisations designing or manufacturing aircraft only. ICAO has already communicated its plan for Edition 2 of Annex 19 to extend its scope to include engines, propellers, and some other safety critical aircraft components. The Agency's approach is based on the essential requirements of the Basic Regulation and requires implementation of a Management System with safety aspects from all holders of or applicants for EASA organisation approvals while applying it to the full scope of these approvals. In the initial airworthiness domain, the implementation of SMS will be required from design organisations designing under DOA and production organisations producing under POA and will cover their full approved scope which may cover :

— products and/or their changes and repairs; and

— parts and appliances (including ETSO articles)

SM principles will also need to be implemented, in some proportionate form to be explored, by those designing under Alternative Procedures to DOA (APDOA) or under presentation of certification programme only. In the manufacturing field, the SM principles will need to be implemented by holders of or applicants for a letter of agreement under Subpart F of Part-21 to produce products, parts, or appliances without POA. But how exactly SMS will be implemented in these fields is an open issue.

5.1.6 Consistency of SMS frameworks between DOA and POA

It is recognised that organisations wholly or partly involved in aviation D&M are likely, as with the Agency, to have a total system approach to safety management and as such will have one Management System framework for their complete organisation, which may extend beyond D&M and, indeed, beyond aviation. It is a principle of the EASA SM implementation rulemaking that every attempt will be made to allow easy integration of Part-21 SM processes into a broader framework, while making no compromises on adhering to the ICAO Annex 19 requirements (see also 5.1.2 above).

Consequently, as far as their contents is concerned, the resulting DOA and POA SMS/SSP frameworks need to be consistent. The exact way how these frameworks will be incorporated in the relevant Part-21 Subparts (J, G, F) is an open issue. Another open issue is if and how to improve, apart from SMS, the overall consistency of the DOA an POA requirements (see also 5.4.1 below).

5.1.7 Regulation of State Safety Programme (SSP)

SSPs of the EU MS fall within their authority and are currently not directly regulated by the EU/EASA aviation rules, and there is no plan to change this. This decision has been taken for all aviation domains and it is due to legal reasons as well as due to a wish not to interfere with the current SSPs recently implemented in the MS. Certainly the SSPs of the EU MS need to reflect the existing EU/EASA aviation legislative framework as well as the European Aviation Safety Programme (EASP) and plan (EASp) designed to support the SSPs of the MS. Consequently, the requirements for competent authorities (for Section B of Part-21) will not directly refer to the SSP but will support their implementation by the States .

5.1.8 Alternative Means of Compliance

The SMS/SSP concept for D & M organisations will incorporate the EASA concept of voluntary use of alternative means of compliance (altMoC) with the Implementing Rules, as adopted in other domains within the scope of the Basic Regulation (e.g. Air Crew and Air Operations). This is to offer D& M organisations the same flexibility as provided to the other service providers (Total System Approach). However, as in case of the alternative MoC proposed by the applicant for a design approval (an alternative to the AMC published in CS), these altMoCs must be found acceptable by the approving competent authority (the Agency for DOA, the applicable NAA for POA). Therefore, the published Part-21 AMC remain 'the only means of compliance' with the corresponding rule unless an altMoC is approved by the competent authority. To be approved, it must provide an equivalent level of safety. The requirements for Section B of Part-21 will specify for the competent authorities the procedure and conditions for the use of altMoCs.

5.1.9 Human factors

The scope of MDM.060 task will include the embodiment into Part-21 of Human Factors as adapted from the other aviation domains(e.g. Part-145) to fit Part-21 and the D & M

organisations. Human Factors are currently missing in Part-21 and their inclusion is in response to comments on the initial ToR and a recommendation of the European HF Advisory Group.

5.2. Rulemaking process for SMS

5.2.1 Working method

The working method will formally be the 'Agency' but adequate involvement of the industry and NAA stakeholders will be assured by various means. The Agency will set up an SMS Steering Group with industry and NAA representatives which will be primarily tasked to launch and monitor a number of the SMS pilot projects (see below) and gather implementation experience. Based on the pilot projects results, the SMS SG or its dedicated sub-groups will prepare draft SMS rules for Part-21and related AMC/GM material. In addition, consultations of the TAG & D & M Sub-SSCC, workshops, focused consultations etc. will be considered as necessary. This will be stated in the project ToR.

5.2.2 Pilot projects for SMS

In a similar way to LOI, the Agency plans to launch a set of pilot projects for testing the implementation of SMS in D & M organisations. The pilot projects are means for development of the rules and AMC/GM material, and the SMS SG in charge of the pilot projects will support the Agency in their drafting. The exercise will require involvement of the Agency's POA and Standardisation (Initial Airworthiness) expert staff. Because national POAs in the EU MS are within the remit of EU NAAs, their staff will also be invited to participate in the pilot projects.

The profile of these pilot projects and participating D & M organisations will ideally include fields as follows:

— CS-25 aeroplane (TC/significant/major change project);

— CS-23/VLA/LSA aeroplane (TC/significant/major change project);

— Engine (TC/ significant/major change project);

— Rotorcraft (TC/ significant/major change project)

— Non-TC holder major change (STC project); and

— Part or Appliance project.

5.2.3 Deliverables

One Opinion for Part-21 implementing rules and one Decision for AMC/GM material will be delivered. The draft rule changes and related AMCs/GMs will be developed simultaneously to be contained in a single NPA leading to the Opinion and Decision.

5.2.4 Time schedule for SMS

The time schedule proposal for the SMS implementation is as follows:

May 2013	Adoption of the Concept Paper by ISC/IETC
June 2013	TAG/SSCC consulted on the Concept

	Paper + draft ToR
June/July 2013	TOR published
Q3/2013	Start of pilot projects for SMS
Q1 /2015	NPA (both IR & AMC/GM) published
Q1 /2016	Opinion + CRD + draft Commission Regulation + draft ED Decision published
Q2/2017	Commission Regulation adopted (estimate) + ED Decision adopted
2017	Full implementation of SMS (synchronised with LOI implementation).

5.3. SMS concept open issues

5.3.1 Form of SMS implementation in Part-21

The form of implementation of SMS into Part-21 may differ from other domains because of the specific structure of Part-21. Since DOA and POA already contain a number of elements upon which to build SMS (e.g. competent and trained personal, facilities, a feedback to accountable manager, compliance monitoring system, etc.) the embodiment must be such that there will be no superfluous or contradicting requirements. To ensure this, a thorough gap analysis will be performed with the Annex 19 framework. It will need to be decided whether to only complement the existing requirements of the relevant Part-21 Subparts (J, G, and F) with missing SMS/SSP provisions piece by piece or to introduce (e.g. into Subpart A – General Provisions common for all the other Part-21 Subparts) a full set of basic high-level requirements on the Management System and adapt Subparts J, G, and F to avoid obvious duplications.

5.4. Other open issues

5.4.1 Consistency of Part-21 organisation approvals

The need for SMS implementation in DOA and POA organisations offers again the opportunity for implementation of the old JAA initiative of restoring consistency of various aviation organisation approvals. In the framework of Part-21 field, it would apply to the requirements of DOA & POA approvals and production without POA (contained currently in Subparts J, G, and F). The aim would be to make these three approvals more consistent in terms of their structure, contents and terminology. These approvals were originally developed for JAR-21 by the JAA progressively and more or less independently (as were the other organisation approvals for other JARs) so that the regulatory material varies in many aspects. Inconsistencies in organisation approvals became apparent while implementing them. The JAA recognised this issue by setting up a WG to address this issue. The WG produced a final report 'Consistency of Organisation Approvals' (COrA report) and the Agency later, based on the COrA report, progressed the issue with an Advance-NPA (A-NPA No 15-2006) followed by a

CRD. However, the implementation of the idea was deferred. For the purpose of this rulemaking project there are two options:

Option 1: Use the opportunity of RMT.0550 task with the aim to introduce the SMS related requirements in a consistent way and amend also the existing remaining requirements in Subparts J, G, and F to achieve the overall consistency of the DOA and POA approvals.

Advantages of Option 1

Consistency, well implemented, should improve transparency and clarity of requirements and reduce room for misinterpretations. Both the D & M industry and the competent authorities may profit if the potential for safety and cost benefits is realised, particularly where organisations hold more than one approval. It is likely to support integration of both design and production management systems as consistent pillars under a single 'integrated management system' of the organisation.

Disadvantages of Option 1

It extends the scope of the tasks and scope of the necessary changes to Part-21. When not implemented sensitively, it could have an administrative impact on DOA and POA communities for both stakeholders and the competent authorities.

Option 2: Limit the task to strictly necessary changes to Part 21 for introduction of SMS principles.

Advantages of Option 2

It might simplify conduct of MDM.060 task and limit changes to Part-21 to what is strictly requested by ICAO Annex 19. It might avoid industry stakeholders having to make changes in their established organisations based on administrative rather than safety related reasons.

Disadvantages of Option 2

Leaving the issue of consistency of organisation approvals for (a) future rulemaking task(s) might result in more work for D&M organisations to align their internal single SMS with inconsistent requirements. It might result in a situation not optimised for safety, given that Option 1 was seen as having potential to improve safety.

5.4.2 Part-21 review to introduce performance based rulemaking principles

The need to introduce rule changes and potentially transfer rules within the structure of Part-21 to implement SMS raises the question of whether to use the opportunity to make a full review of Part-21 and related AMC/GM in order to check and, if needed, improve its quality by introducing the principles of performance-based rulemaking (Option 1). The objective would be to clearly distinguish between the essential safety elements to be kept in Part-21 and the non-essential implementation aspects that should be transferred to the AMC/GM to Part-21. The alternative option (Option 2) would be to defer this exercise to (a) future rulemaking task(s).

Preferred option:

Option 1, including Part-21 review, to introduce performance-based rulemaking principles.

The extra work for organisations with existing DOA and POA approvals needs to be mitigated by ensuring the revised, consistent rule and guidance material is no more prescriptive than it needs to be. The basic style and approach of Part-21 should not be changed.

5.5. Interfaces

5.5.1 Interface with tasks RMT.0262 & RMT.0611 (LOI)

The activity under tasks RMT.0550 & RMT.0612 on SMS should be closely coordinated with the activity under tasks RMT.0262 & RMT.0611 on LOI. For example the level of involvement of the Agency in certification projects of Design Organisations that have achieved SMS compliance is relevant to both tasks.

5.5.2 Interface with task RMT.0251 (MDM.055) - SMS for Commission Regulation (EC) No 2042/2003 organisations)

The activity under tasks RMT.0550 & RMT.0612 on SMS implementation should be coordinated with the activity under task MDM.055 on implementation of SMS by organisations within the scope of Commission Regulation (EC) No 2042/2003. The aim is to implement consistent SMS systems, in particular, in organisations having multiple approvals and to allow competent authorities to streamline and rationalise their procedures.

5.5.3 Interface with the FAA 21/SMS ARC project

The future SMS SG should establish contacts and monitor the work of the FAA 21/SMS ARC group on the implementation of SMS and performance-based oversight in FAR Part-21. European D & M industry will profit if both the US and EU SMS systems (and ultimately the SMS systems of other countries) are as close as possible, providing that the consistent systems are appropriate.

6. Conclusions

(To be completed with conclusions for the open issues and, if needed, changes to the assumptions.)

7. Attachments

A. Level of involvement (LOI) project - Descriptive note

B. Comparison of the Annex 19 SMS framework with EASA SMS framework

ATTACHMENT A

LEVEL OF INVOLVEMENT (LOI) PROJECT DESCRIPTIVE NOTE

1. Rationale for the proposed changes

The recent publication of the revised Part-21 included as the Annex to Commission Regulation (EU) No 748/2012 has clarified the duties of applicants in product certification activities (type certificates, restricted type certificates, changes to TC, supplemental type certificates, repair design approvals, European technical standard orders).

The proposed revision of Part-21 aims at improving the current regulation in the following domains:

— Formal introduction of a risk-based approach both in product certification and design organisation approvals;

— Enabling the Agency to determine its level of involvement in product certification on the basis of consistently tangible criteria, based on safety risk;

— Introduction of the possibility to approve major changes, major repairs, and STC under a DOA privilege, under certain conditions;

— Establishment of product certification and design organisation approvals as two separate processes sharing the same common risk based elements; and

— Improvement of the clarity of Part-21 text, by separating the requirements applicable to product certification and design organisation approvals.

2. Scope of the proposed changes

2.1. Principle of the proposed changes

The proposed changes do not change the roles and repartition of the tasks between the applicant and the Agency for product certification activities when an EASA certificate has to be issued.

The principle is that the Agency will review and verify the demonstrations of compliance proposed by the applicant according to a predefined level of involvement (LOI):

— When the Agency does not verify, or, alternatively, when it is satisfied after its verification (which may need completion of several iterations), it does not issue any statement, nor any endorsement. The applicant proceeds with its final declaration of compliance, in response to which the Agency issues the approval certificate. This is the current Part-21 process and it is not modified; and

— When, on the other hand, the Agency is not satisfied after its verification, it shall issue a formal rejection of demonstration of compliance, which automatically results in a DOA finding and blocks the issuance of the certificate until the demonstration is modified and can be accepted by the Agency. This element is new.

Additionally, to avoid unnecessary administrative burden without any added technical value, a new privilege is introduced to allow design organisation approval (DOA) holders to issue themselves major design change or repair approval or STC, when the Agency has decided not to be involved in the verification of the demonstrations of compliance.

2.2. Impact on the chronology of certification projects

Certification projects typically comprise the following chronological phases:

(1) Familiarisation,

(2) Establishment of the type certification basis,

(3) Establishment of the certification programme,

(4) Compliance demonstration,

(5) Declaration of compliance, and

(6) Final report and issuance of the certificate.

The LOI project builds on the introduction of the certification programme by Commission Regulation (EU) No 748/2012. It does not, therefore, modify the chronology except for the establishment of the certification programme phase which also includes the determination of the LOI by the Agency.

2.3. Scope of the changes in Part 21

This project fully takes advantage of the structure of Part-21 and essentially comprises two main symmetrical paragraphs:

— Elements related to requirements set on the applicant for product certification are essentially contained in paragraph 21.A.20. For this purpose, two new clauses have been added, one of which coming from an existing paragraph, and

— Elements related to requirements set on the Agency for product certification activities are essentially contained in a new paragraph 21.B.20B.

An additional clause is added to paragraph 21.A.21 to prevent the issuance of the certificate when the Agency is not satisfied with the demonstrations of compliance.

Another additional clause has been added to 21.A.258 to introduce an automatic link (a DOA finding) between type certification and design organisation approval when a demonstration of compliance is formally rejected by the Agency.

Finally, paragraph 21.A.263 has been modified to introduce the new DOA privilege, and adaptations are proposed to paragraphs 21.A.103, 21.A.115 and 21.A.437.

2.4. Acceptable means of compliance and guidance material

A significant amount of AMC and GM will need to be produced, in particular in the following domains:

— Content and level of detail of the certification programme;

— Criteria for determining the level of performance of design organisation;

— Criteria for determining the criticality of an item of the certification programme; and

— Criteria for determining the novelty of an item of the certification programme.

This soft law material is likely to be dependant on the type of product and the experts' discipline (or group of disciplines). It is proposed to develop the soft law material in cooperation with industry. It will be based on the current best practices augmented by the results of 'pilot projects'. These may consist of elements of ongoing projects on which the concepts are retrospectively tested, or completely new projects (or elements of projects) on which the LOI concept will be applied.

2.5. Compatibility with OSD

The proposed changes have been tested and found compatible with the OSD requirements which are on the process to be incorporated in Part-21 according to the most recent version of the OSD opinion.

3. Proposed changes to Part-21

Section 3.1 contains the typographical conventions used to describe the proposed changes to Part-21. The following sections respectively address:

— changes to section A implementing the LOI concept for type certificates and restricted type certificates;

— changes to section B implementing the LOI concept for the Agency;

— changes to section A extending the LOI concept to Subparts D, E, M, and O; and

— changes to section A implementing the additional privilege described in the proposed modified paragraph 21.A.263(c) (8).

3.1. Typographical conventions

The following conventions are used in this part of the document:

— Unchanged text is in this font,

— *Changed or additional text is in this font,* and

— `Editorial comments are in this font.`

3.2. Proposed changes to section A implementing the LOI concept for TC and RTC

21.A.20 Compliance with the type-certification basis and environmental protection requirements

(a) The applicant for a type-certificate or a restricted type-certificate shall demonstrate compliance with the applicable type-certification basis and environmental protection requirements and shall provide the Agency with the means by which such compliance has been demonstrated.

(b) The applicant shall provide the Agency with a certification programme detailing the means for compliance demonstration. This document shall be updated as necessary during the certification process.

(c) The applicant shall record justification of compliance within compliance demonstration documents according to the certification programme established under point (b).

(d) The applicant shall declare that it has demonstrated compliance with the applicable type-certification basis and environmental protection requirements, according to the certification programme established under point (b).

(e) Where the applicant holds an appropriate design organisation approval, the declaration of point (d) shall be made according to the provisions of Subpart J.

(f) The Applicant shall timely allow the Agency to review any report and make any inspection and perform or witness any flight and ground test necessary to check the validity of its compliance demonstrations and to determine that no feature or characteristic makes the product unsafe for the uses for which certification is requested, as defined by the level of involvement specified under point 21.B.20B (b).

(g) The Applicant shall regularly inform the Agency of the progress and of any significant difficulty encountered whilst demonstrating compliance.

21.A.21 Issue of a type certificate

The applicant shall be entitled to have a product type-certificate issued by the Agency after:

(a) demonstrating its capability in accordance with point 21.A.14;

(b) submitting the declaration referred to in point 21.A.20(d); and

(c) demonstrating that:

(1) the product to be certificated meets the applicable type-certification basis and environmental protection requirements designated in accordance with points 21.A.17 and 21.A.18;

(2) any airworthiness provisions not complied with are compensated for by factors that provide an equivalent level of safety;

(3) no feature or characteristic makes it unsafe for the uses for which certification is requested; and

(4) the type-certificate applicant has expressly stated that it is prepared to comply with point 21.A.44.

(d) In the case of an aircraft type-certificate, the engine or propeller, or both, if installed in the aircraft, have a type-certificate issued or determined in accordance with this Regulation.

(e) <Reserved for OSD>

(f) All demonstrations of compliance subject to Agency verification according to point 21.B.20B (b) have been verified to the satisfaction of the Agency.

21.A.23 Issue of a restricted type certificate

(a) <No change>

(b) <No change>

(c) All demonstrations of compliance subject to Agency verification according to point 21.B.20B (b) have been verified to the satisfaction of the Agency.

21.A.33 Inspections and tests

(a) <No change>

(b) <No change>

(c) <No change – conformity inspection>

(d) <Deleted: moved to 21.B.20B (d)>

(e) For tests performed or witnessed by the Agency *to verify the demonstration of compliance of the applicant according to point 21.B.20B (b):*

(1) <no change>

(2) <no change>

21.A.257 Investigations

The design organisation shall make arrangements that allow the Agency to make any investigations, including investigations of partners and subcontractors, necessary to determine compliance and continued compliance with the applicable requirements of this Subpart.

(a) <Text moved up in same paragraph with no change>

(b) <deleted>

21.A.258 Findings

(a) <No change>

(b) <No change>

(c) <No change>

(d) <No change>

(e) The rejection of a demonstration of compliance made by the Agency in accordance with 21.B.20B (e) shall result in a DOA finding classified according to point (a) and (b).

21.A.263 Privileges

(a) <No change>

(b) <Deleted>

(c) (1) to (7) <No change>

<Additional privilege for approval of major design changes and STC>:

(8) When, pursuant to 20.B.20B(b), the Agency has concluded that it is not involved, the design organisation approval holder shall be entitled to issue the design approval.

3.3. Proposed changes to section B implementing the LOI concept

21.B.14 Level of performance of the design organisation

When acting in accordance with Subparts B, D, E, M and O, the Agency shall establish the level of performance of the design organisation.

21.B.20B Level of involvement

When acting in accordance with Subparts B, D, E, M, and O:

(a) The Agency shall notify the applicant once it has accepted the certification programme provided according to 21.A.20(b).

(b) For each item in the certification programme established under point 21.A.20 (b), the Agency shall determine its level of involvement in the verification of the demonstration of compliance and in determining that no feature or characteristic makes the product unsafe for the uses for which certification is requested, based on a combination of:

(1) the novelty and criticality of the certification item, including means of compliance, and

(2) the level of performance of the design organisation, as established under 21.B.14,complemented as necessary by elements resulting from the circumstances listed under 21.B.20B (c).

(c) The following circumstances may be used by the Agency to complement or revise its level of involvement:

(1) accident, incident or unsafe condition related to the concerned item of the certification programme, or its technology, on any product, or

(2) change in the performance of the design organisation, or

(3) demonstration of compliance rejected by the Agency whilst verifying the demonstrations of compliance provided by the Applicant, for any ongoing certification project with this applicant, or

(4) revision of the certification programme established under point 21.A.20 (b), or

(5) technical or operational evolution in the field of the concerned item of the certification programme, its technology, or in the means of compliance identified in the certification programme, or

(6) information provided by the applicant under 21.A.20 (g).

(d) According to point (b), the Agency shall verify the demonstrations of compliance submitted by the applicant and determine that no feature or characteristic makes the product unsafe for the uses for which certification is requested. For this purpose, it may require further clarifications from the applicant.

(e) When the Agency is not satisfied with the demonstration of compliance of the applicant and all attempts to resolve the situation have failed, it shall notify the rejection of the demonstration of compliance to the applicant, and the reasons thereof.

3.4. Proposed changes to section A extending the LOI concept to Subparts D, E, M, and O

3.4.1 Extension to major changes and STC

21.A.97 Major changes

(a) <no change>

(1) <no change>

(2) <no change>

(3) comply with points 21.A.20 (b), (c), *(d), (f) and (g);* and

(4) <no change>

(5) <no change>

(b) <no change>

Note: no changes to Subpart E (STC) are needed because 21.A.114 refers to 21.A.97.

3.4.2 Extension to repair design approvals

21.A.433 Repair design

(a) <no change>

(1) <no change>

(2) comply with points 21.A.20 (b), (c), *(d), (f) and (g);* and

(3) <deleted>

(b) <no change>

3.4.3 Extension to ETSO

21.A.605 Data requirement

(a) <no change>

(b) <no change>

(c) <no change>

(d) <no change>

(e) <no change>

(f) for all other articles, the procedures referred to in point 21.A.602B(b)(2*) and the certification programme referred to in 21.A.20(b)*.

21.A.615 Verification by the Agency

The applicant for an ETSO approval shall comply with 21.A.20(f) and (g).

3.5. Proposed changes to section A resulting from the new privilege

Changes are introduced to 21.A.103, 21.A.115 and 21.A.437 to introduce approval by DOA holder when the Agency has concluded that it is not involved.

3.5.1 Extension to major changes

21.A.103 Issue of approval

(a) <No change>

(b) <No change>

(c) By derogation to this paragraph, a major change to the type design may be approved by the appropriately approved design organisation of the applicant under a procedure agreed with the Agency, when the Agency has concluded that it is not involved according to 21.B.20B(b) and given that conditions (a) and (b) of this paragraph are met.

3.5.2 Extension to STC

21.A.115 Issue of a supplemental type certificate

(a) <No change>

(b) <No change>

(c) <No change>

(d) <No change>

(e) By derogation to this paragraph, the supplemental type certificate may be issued by the appropriately approved design organisation of the applicant under a procedure agreed with the Agency, when the Agency has concluded that it is not involved according to 21.B.20B(b) and given that conditions (a) to (d) of this paragraph are met.

3.5.3 Extension to repair design approvals

21.A.437 Issue of a repair design approval

(a) <No change>

(b) <No change>

(c) for minor repairs only, by an appropriately approved design organisation under a procedure approved by the Agency, *or* <"or" added at the end>

(d) For major repair design approval, by the appropriately approved design organisation of the Applicant under a procedure agreed with the Agency, when the Agency has concluded that it is not involved according to 21.B.20B(b).

ATTACHMENT B

COMPARISON OF ANNEX 19 SMS FRAMEWORK WITH THE EASA SMS FRAMEWORK

ICAO Annex 19 SMS Framework	EASA SMS Framework
1. Safety policy and objectives 1.1 – Management commitment and responsibility 1.2 – Safety accountabilities 1.3 – Appointment of key safety personnel 1.4 – Coordination of emergency response planning 1.5 – SMS Documentation **2. Safety risk management** 2.1 – Hazard identification 2.2 – Risk assessment and mitigation process **3. Safety assurance** 3.1 – Safety performance monitoring and measurement 3.2 – The management of change 3.3 – Continuous improvement of the SMS **4. Safety promotion** 4.1 – Training and education 4.2 – Safety communication	– **Safety policy, organisation and accountabilities** • Organisational commitments for safety • Lines of responsibility and accountability • Key safety personnel and units • Safety objectives and performance standards • Resources for safety implementation • Organisation management system documentation • Emergency response plan (ERP) – **Safety risk management** • Hazard identification • Risk assessment and mitigation – **Safety assurance** • Compliance monitoring system • Safety reporting principles • Internal occurrence reporting scheme

	• Internal safety investigation • Safety performance and measurement • Management of change • Continuous improvement – **Personnel - Safety promotion** • Safety training • Safety communication
ICAO Annex 19 SMS Standards	**EASA Management System Implementing Rules**
1. Safety Policy and Objectives **1.1 Management commitment and responsibility** The service provider shall define its safety policy in accordance with international and national requirements. The safety policy shall: (a) reflect organizational commitment regarding safety; (b) include a clear statement about the provision of the necessary resources for the implementation of the safety policy; (c) include safety reporting procedures (d) clearly indicate which types of behaviors are unacceptable related to the service provider's aviation activities and include the circumstances under which disciplinary action would not apply; (e) be signed by the accountable executive of the organization;	**ORX.GEN.200 Management System** (a) The organisation shall establish, implement and maintain a management system that includes: (1) clearly defined lines of responsibility and accountability throughout the organisation, including a direct safety accountability of the accountable manager; (2) a description of the overall philosophies and principles of the organisation with regard to safety, referred to as the safety policy; (3) the identification of aviation safety hazards entailed by the activities of the organisation, their evaluation and the management of associated risks, including taking actions to mitigate the risk and verify their effectiveness;

(f) be communicated, with visible endorsement, throughout the organization; and

(g) be periodically reviewed to ensure it remains relevant and appropriate to the service provider.

1.2 Safety accountabilities

The service provide shall:

a) identify the accountable executive who, irrespective of other functions, has ultimate responsibility and accountability, on behalf of the organization, for the implementation and maintenance of the SMS;

b) clearly define lines of safety accountability throughout the organization, including a direct accountability for safety on the part of senior management;

c) identify the accountabilities of all members of management, irrespective of other functions, as well as of employees, with respect to the safety performance of the SMS;

d) document and communicate safety responsibilities, accountabilities and authorities throughout the organization; and

e) define the levels of management with authority to make decisions regarding safety risk tolerability.

1.3 Appointment of key safety personnel

The service provider shall appoint a safety manager who is responsible for the implementation and maintenance of an effective SMS.

1.4 Coordination emergency response planning

The service provider shall ensure that an emergency response plan is properly coordinated with the emergency response plans of those organizations it must interface with during the provision of its products

(4) maintaining personnel trained and competent to perform their tasks;

(5) documentation of all management system key processes, including a process for making personnel aware of their responsibilities and the procedure for amending this documentation;

(6) a function to monitor compliance of the organisation with the relevant requirements. Compliance monitoring shall include a feedback system of findings to the accountable manager to ensure effective implementation of corrective actions as necessary; and

(7) any additional requirements that are prescribed in the relevant Subparts of this Annex or other applicable Annexes.

(b) The management system shall correspond to the size of the organisation and the nature and complexity of its activities, taking into account the hazards and associated risks inherent in these activities.

ORX.GEN.205 Contracted activities

(a) Contracted activities include all activities within the organisation's scope of approval that are performed by another organisation either itself certified to carry out such activity or if not certified, working under the organisation's approval. The organisation shall ensure that when contracting or purchasing any part of its activity, the contracted or purchased service or product conforms to the applicable requirements.

(b) When the certified organisation contracts any part of its activity to an organisation that is not itself certified in accordance with this Part to carry out such activity, the contracted organisation shall

and services.

1.5 SMS documentation

1.5.1 The service provider shall develop an SMS implementation plan, formally endorsed by the organization that defines the organization's approach to the management of safety in a manner that meets the organization's safety objectives.

1.5.2 The service provider shall develop and maintain SMS documentation that describes its:

a) safety policy and objectives;

b) SMS requirements;

c) SMS processes and procedures;

d) accountabilities, responsibilities and authorities for SMS processes and procedures; and

e) SMS outputs

1.5.3 The service provider shall develop and maintain an SMS manual as part of its SMS documentation.

2. Safety risk management

2.1 Hazard identification

2.1.1 The service provider shall develop and maintain a process that ensures that hazards associated with its aviation products or services are identified.

2.1.2 Hazard identification shall be based on a combination of reactive, proactive and predictive methods of safety data collection.

2.2 Risk assessment and mitigation

The service provider shall develop and maintain a process that ensures

work under the approval of the organisation. The contracting organisation shall ensure that the competent authority is given access to the contracted organisation to determine continued compliance with the applicable requirements.

ORX.GEN.210 Personnel requirements

(a) The organisation shall appoint an accountable manager, who has the authority for ensuring that all activities can be financed and carried out in accordance with the applicable requirements. The accountable manager shall be responsible for establishing and maintaining an effective management system.

(b) A person or group of persons shall be nominated by the organisation with the responsibility of ensuring that the organisation remains in compliance with the applicable requirements. Such person(s) shall be ultimately responsible to the accountable manager.

(c) The organisation shall have sufficient qualified personnel for the planned tasks and activities to be performed in accordance with the applicable requirements.

(d) The organisation shall maintain appropriate experience, qualification and training records to show compliance with point (c).

(e) The organisation shall ensure that all personnel are aware of the rules and procedures relevant to the exercise of their duties.

ORX.GEN.215 Facility requirements

The organisation shall have facilities allowing the performance and management of all planned tasks and activities in accordance with the applicable requirements.

ORX.GEN.220 Record keeping

(a) The organisation shall establish a system of record keeping that

analysis, assessment, and control of the safety risks associated with identified hazards. **3. Safety assurance** 3.1 Safety performance monitoring and measurement 3.1.1 The service provider shall develop and maintain the means to verify the safety performance of the organization and to validate the effectiveness of safety risk controls. 3.1.2 The service provider's safety performance shall be verified in reference to the safety performance indicators and safety performance targets of the SMS. 3.2 The management of change The service provider shall develop and maintain a process to identify changes which may affect the level of safety risk associated with its aviation products or services and to identify and manage the safety risks that may arise from those changes. 3.3 Continuous improvement of the SMS The service provider shall monitor and assess the effectiveness of its SMS processes to enable continuous improvement of the overall performance of the SMS. **4. Safety Promotion** 4.1 Training and education 4.1.1 The service provider shall develop and maintain a safety training programme that ensures that personnel are trained and competent to perform their SMS duties 4.1.2 The scope of the safety training programme shall be appropriate to	allows adequate storage and reliable traceability of all activities developed, covering in particular all the elements indicated in ORX.GEN.200. (b) The format of the records shall be specified in the organisation's procedures. (c) Records shall be stored in a manner that ensures protection from damage, alteration, and theft. FOR GUIDANCE, PLEASE SEE ED Decision 2012/017/R, SUBPART GEN, SECTIONS I AND II

each individual's involvement in the SMS. 4.2 Safety communication The service provider shall develop and maintain a formal means for safety communication that: a) ensures personnel are aware of the SMS to a degree commensurate with their positions; b) conveys safety-critical information; c) explains why particular safety actions are taken; and d) explains why safety procedures are introduced or changed. **FOR GUIDANCE, PLEASE SEE SAFETY MANAGEMENT MANUAL DOC 9859** **(213 PAGES)**	