

Interactive session on SMS oversight

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Workshop on SMS for Design and Production Organisations

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Applicable Regulations and AMC/GM

REGULATIONS

- Commission Delegated Regulation 2022/201 (DOA & POA organization requirements and DOA authority requirements for EASA)
 - Amended by Commission Implementing Regulation 2022/1253 (derogations for certain production organisations and for certain organisations producing products, parts or appliances without an approval certificate)
- Commission Implementing Regulation 2022/203 (POA authority requirements for EASA and NAAs)

ACCEPTABLE MEANS of COMPLIANCE / GUIDANCE MATERIAL

- ED Decision 2022/021/R (first package AMC/GM) issued on 19th December 2022
- 2nd ED Decision 2023/014/R (second package AMC/GM) issued on 20th October 2023

Oversight policy: List of topics

1. Flexibility period and surveillance approach
2. SM-0001 Issue B is an Acceptable Means of Compliance for DOA and POA.
3. Maturity assessment: expected level for SMS compliance
4. Proportionality
5. Significant changes
6. Length of oversight cycle
7. Key organisation personnel
8. Findings and finding level escalation policy
9. Unannounced inspections
10. DOA/POA alignment

Topic 1: Flexibility period and surveillance approach

- Applicability date: 7 March 2023
- Deadline for closure of related findings: 7 March 2025
- **For DOAs:**
 - For new applications submitted after 7 March 2023: SMS implementation mandatory before DO approval.
 - For new applications submitted before 7 March 2023 and not yet approved on that date:
 - Case by case: for very advanced investigations, SMS implementation not required before approval
 - No generic finding was issued on 7 March 2023. Findings (if any) are raised as discussions progress with the DOAs regarding the implementation of the novel requirements. Initially findings are more general (e.g. lack of SMS...). Later, findings become more specific.
 - EASA inspectors are merging the oversight of SMS within the existing oversight plans for each DOA.

Topic 1: Flexibility period and surveillance approach

➤ For POAs:

- For new applications submitted after 7 March 2023: SMS implementation is mandatory before POA approval.
- For new applications submitted before 7 March 2023 and not yet approved on that date:
 - SMS implementation mandatory before POA approval (Regulation (EU) 2022/1253 does not offer flexibility).
- A generic transition finding was issued on 7 March 2023 for all approved organisations to ensure appropriate tracking.
- This finding, if not closed, will be the basis for an EASA negative decision pre-consultation letter that will be sent to the POA before end of implementation period.
- If generic transition finding is not closed as of 7 March 2025, EASA will take negative decision
 - Suspension: if not application for SMS Significant Change has been received
 - Limitation: If SMS significant change application has been received but not processed in time.
- EASA inspectors are merging the oversight of SMS within the existing oversight plans for each POA after having received the SC for SMS implementation.

Topic 2: SM-0001 Issue B is an AMC for DOA and POA.

- The Standard was developed with the intention to be an Internationally Accepted Means of Compliance with ICAO Annex 19 and SMS regulations from Aviation Authorities or for voluntary SMS implementation.
- It is accepted as a Means of Compliance to 21.A.139(c) and 21.A.239(c) (safety management elements of the production and design management systems).
- If used, its implementation is also subject to EASA/NAA oversight.
- Alternatively, a parallel set of AMC and GM other than the SM-0001 Issue B has been developed by EASA. These AMC and GM can also be used by organisations to demonstrate compliance against SMS-related requirements.

Topic 3: Maturity assessment - expected level for SMS compliance

- EASA has developed and published a Management System Assessment Tool. Internal tool for Competent Authorities. Can be used as a “self-assessment” tool by organisations.
 - Contains 4 levels of SMS implementation: Present, Suitable, Operating, Effective (PSOE)
- SM-0001 Issue B:
 - Contains 5 levels of SMS implementation (maturity scale): Present, Suitable, Operating, Effective, Excellence
- **For EASA DOA oversight:**
 - Step 1 (“Present” and “Suitable”):
 - Adequate organisation structure (e.g. safety manager, reporting structure)
 - Safety policy
 - Safety risk management established as a process (see 21.A.239(c) and related 21.A.243 and 21.A.245)
 - ISM should provide feedback on SMS compliance
 - Step 2 (“Operating”):
 - SMS in place, producing results and generating output that enhances safety.
 - Check SMS 4 pillars and 12 elements
 - Step 3 (“Effective”):
 - Is SMS maturing? What is the maturity level on a certain topic? Is there a continuous improvement?

Topic 3: Maturity assessment - expected level for SMS compliance

➤ For EASA POA oversight

- Step 1: Initial technical investigation of safety management element (before 07 March 2025)
 - No Findings are issued if the system is not Present or Suitable => existing transition finding.
 - Desktop/remote audit is the preferred option (POE and nominated personnel).
 - Safety Management system is established as a process to 21.A.139(a) and (c)
- Step 2: Continuous compliance with Safety management element
 - Oversight to evaluate MS remains present, suitable, operating, and efficiency is assessed.
 - L2 findings are issued if MS found not present, suitable or operational
 - Observations are issued if MS found not efficient
- Step 3: Effective management system implementation
 - Effective safety management system + satisfactory compliance history
 - Oversight cycle of 36 Months
- Step 4: Effective management system implementation
 - Effective safety management system + satisfactory compliance history + effective reporting system
 - Oversight cycle of 48 Months

Topic 4: Proportionality.

- The SMS should be created taking into account the size, scope, nature and complexity of an organisation – NOT one size fits all.
- Part 21 allows for a proportional implementation, both in the case of embedding POA/DOA requirements in an existing corporate SMS or as stand-alone.
- Flexibility provisions contained in the AMC & GM, which allow different scenarios that are proportionate to the size and complexity of the operations (e.g. a full-time equivalent safety manager is not required as long as the function of a 'safety manager' is properly discharged by another person. The same applies for a formal safety review board.)
- The changes for Part 21 are limited to the introduction of the ICAO SMS framework based on an analysis of the gap between the ICAO SMS framework and the previous Part 21 requirements.
- Team Leaders are trained to take a proportional approach IAW 21.B.222(b) or 21.B.432(b)

Topic 5: Significant Changes.

➤ For DOAs (21.A.247):

- Incorporation of SMS may be significant to a DOA's DMS.
- This determination is the responsibility of DOA-Holder (based on gap analysis). To be agreed with DOATL.
- Some organisations may have already a **functioning** SMS (e.g, because of other approvals, etc)
- With the Significant Change on-going, and under agreement with DOATL, the organisation can start implementing SMS processes and procedures.

➤ For POAs (21.A.147):

- Incorporation of SMS is always a Significant Change
- An application for Significant Change is required for all POAs (EASA Form 51 + POE + Implementation Plan)
- While some organisations may have already a functioning SMS (e.g., because of other approvals, etc), the Significant Change investigation is focused in ensuring such existing SMS is compliant with EASA requirements.
- With the Significant Change on-going, and under agreement with POATL, the organisation can start implementing SMS processes and procedures.
- Once the investigation is completed, the Significant Change will be approved through a formal letter.

Topic 6: Length of oversight cycle.

For DOAs:

- Standard oversight cycle is 2 years per the rule.
 - Initial cycle length may be influenced by previous oversight experience (DOAs coming from 3-year cycle). Also depends on TOA, activity of the DOA (complexity and number of staff), oversight results, and DOA performance (rationale of 21.B.432(c) and (d))
 - To be reviewed at the end of each year, and identified in the Annual Report.
 - May be increased up to a maximum of 4 years under certain conditions.
 - May be shortened in cases of reduced performance. For example, if findings in previous year reflect a decrease of the overall safety performance

For POAs:

- Oversight cycle currently 2 years (24 months) for all organisations.
 - Under certain conditions, the oversight planning cycle might be extended to 3 years (36 months), or 4 years (48 months).
 - The NAA may decide to implement shorter oversight cycles in case the safety performance of the organization has decreased.

Topic 7: Key organisation personnel - DOA

- DOA key personnel (21.A.245) (may differ for smaller organisations – proportionality):
 - HDO (head of the design organisation)
 - COA (chief of the airworthiness function)
 - CISM (chief of the independent monitoring function)
 - **SM (safety manager)**
- Form 4 is deleted from the AMC/GM and thus from the Agency website.
- Depending on the size, scope, and applicability in a given organisation:
 - COA may be performed by HDO for DOAs with only minor changes/minor repairs or for a limited period of time;
 - SM may be done by CISM;
 - CISM may not be done by HDO or COA;
 - There may be more than one office of airworthiness as long as there is a “unique focal point for the entire design organisation (DO)” nominated as the COA. Each airworthiness office may have their own manager and should report to the COA.

Topic 7: Key organisation personnel - POA

- POA key personnel (21.A.145)
 - POA Accountable Manager
 - POA Quality Manager
 - **Safety Manager**
 - Other nominated personnel, as per size, complexity of the organization.

- EASA Form 4 will be deleted from the AMC/GM. EASA POA will maintain a similar form to record applications, including minimum requirements for nominated personnel.

- Depending on the size, scope, and applicability in a given organization, the functions may be subdivided under individual managers (and in fact may be further subdivided) or combined in a variety of ways, for example:
 - POA Quality Manager and Safety Manager under the same person
 - Subject to a risk assessment and the competent authority's agreement, with due regard to the size of the organisation, and the nature and complexity of its activities, the functions of the quality manager and the safety manager may be performed by the accountable manager

Topic 8: Findings and finding level escalation policy.

- **Findings and corrective actions; observations:**
 - Redefined criteria in 21.B.433 for DOAs and 21.B.225 for POAs.
- **Observations (instead of Level 3 findings).**
 - Not to be used for “small” non-compliances (these shall be Level 2)
 - No need to rename existing Level 3 findings as observations.
- **Safety significance of findings:**
 - For DOAs: The DOA Team discusses with PCMs/Experts (current normal practice)
 - For POAs: Discussed with POA Section Manager
- **Escalation from level 2 to level 1:**
 - Rule provides sufficient flexibility to agree on corrective action plans with longer corrective periods without escalating to Level 1.
 - If escalated to Level 1, rule does not differentiate provisions for escalated Level 2 findings and findings initially raised as Level 1.
 - Certain action needs to be taken by EASA if the Level 1 finding is not corrected within the deadline.
 - However, the action will be proportional to the safety risk caused by the finding. Actions may cover suspension, partial limitations, minor restrictions to certain privileges, temporary exclusion of further organizational changes...

Topic 9: Unannounced inspections.

- Unannounced inspections can be planned or Ad-Hoc.
- Unannounced inspections may cover different topics, such as:
 - Whistleblowers and response to safety concerns
 - Safety priorities of a State Safety Programme
 - Regular oversight elements
- Unannounced inspections may include:
 - For DOAs, sampling of minor change, minor repair, FC, Compliance Documents not part of EASA LOI, etc. initiated ad-hoc;
 - Questionnaire with a limited number of questions (could be even one) with short due date;
 - Queries;
 - Unannounced topic during a scheduled audit.
- For DOAs an activity at a company premises will not be scheduled completely unannounced.
For POAs, completely unannounced inspections should be a very rare case (linked to product audit)

Topic 10: DOA/POA alignment.

- 21.A.139(f) and 21.A.239(f) *“If the production/design organisation holds one or more additional organisation certificates within the scope of Regulation (EU) 2018/1139, the production/design management system may be integrated with that required under the additional certificate(s) held”*
- An approved organization holding both DOA and POA approvals (and potentially other approvals) can make use of a single SMS covering both domains
- Coordination between DOA and POA inspectors should be promoted– for example, by means of shared audits, sharing of audit reports between inspectors, etc.
- In addition, Competent Authorities must establish procedures for the participation in mutual exchange of information among themselves (21.B.25(c))

Thank you for attention.

Any questions?



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