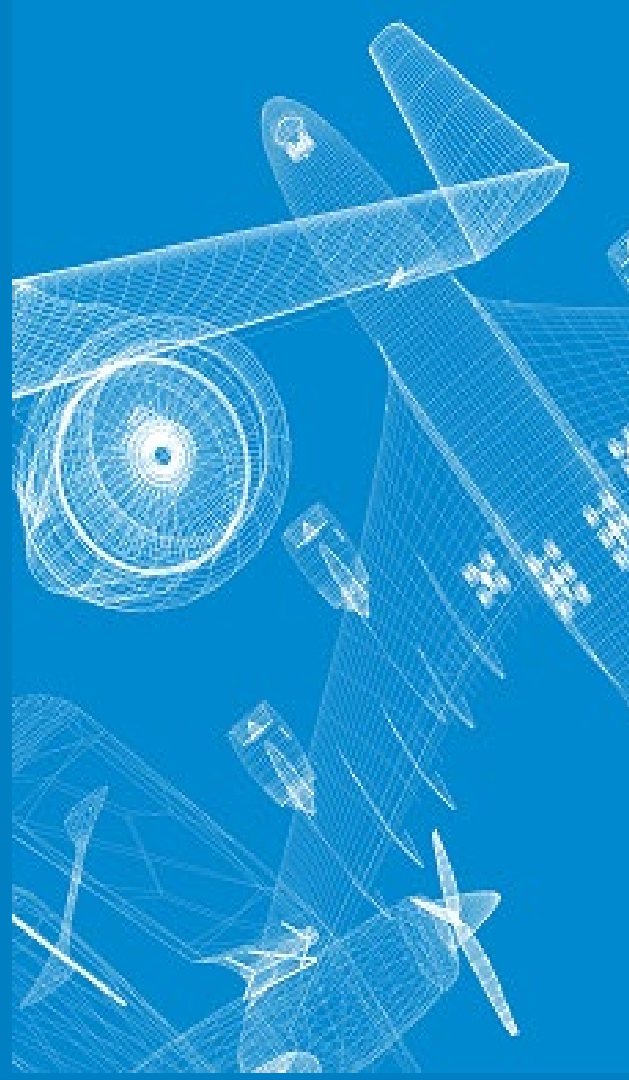


2024 SMS Workshop

Outstanding topics from the previous workshop

C. Bosso, Section Manager - Design Organisations & Policy Issues
R. Boersma - Senior DOA Team Leader, SMS Network Representative



Outstanding topics from the previous workshop



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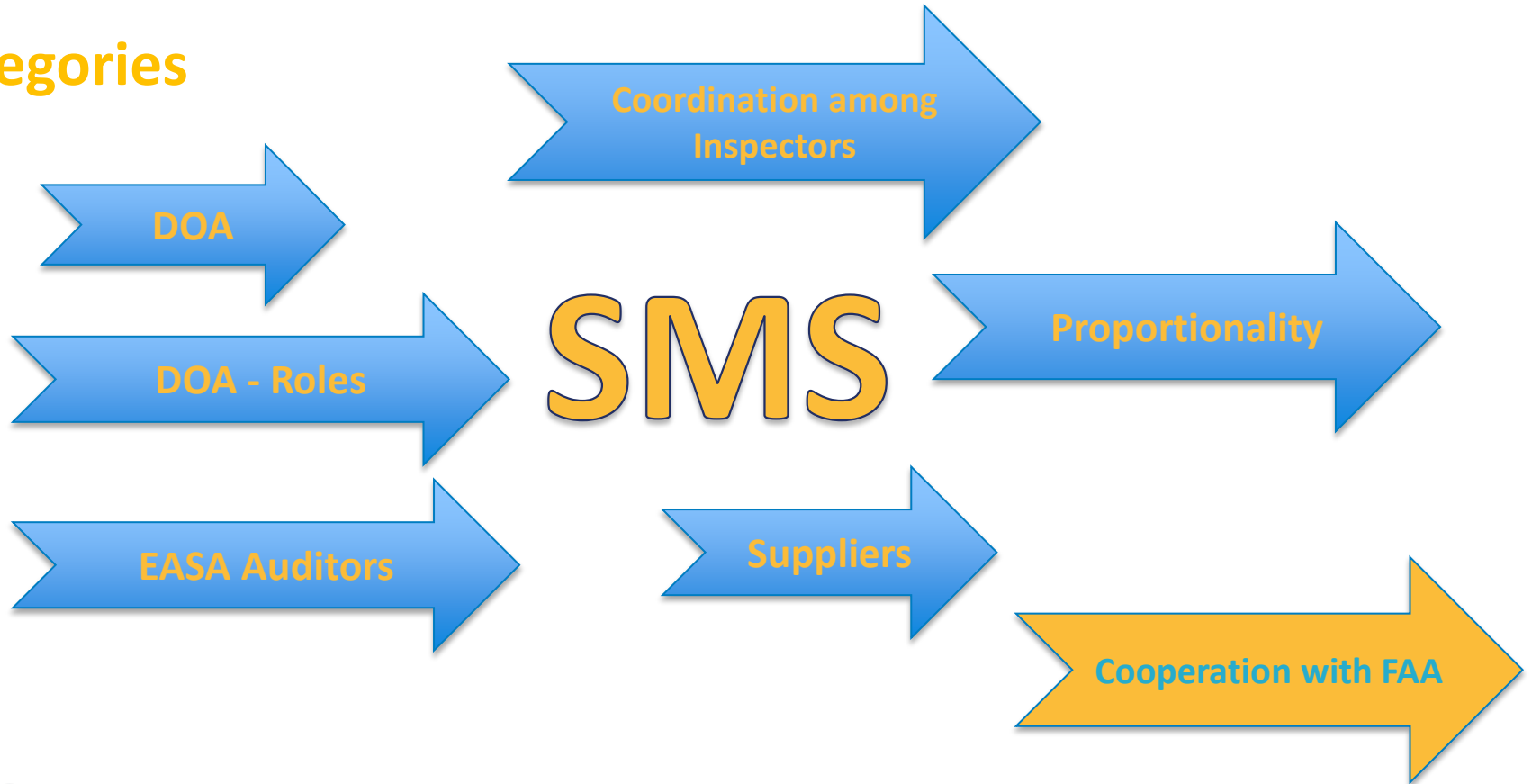


“There are many interesting questions in SLIDO that were not replied due to lack of time. Should be helpful to get a FAQ with answers in the MoM of this event. Do you intend to do it ? “



Outstanding topics from the previous workshop

Categories



Outstanding topics from the previous workshop

Suppliers (1)



Is there any requirement for the design organisation to make arrangements with the design suppliers related to SMS?

What about suppliers that we work with but they don't have an SMS? Shall we include them in our SMS?

We are Design Supplier not DOA because, we are a component company. We would like to know as supplier of DOA what we need to do for SMS in our company?

What is the expectation to flow down SMS requirements to suppliers? Is this expectation harmonized across regulators to avoid disruption to the supply chain that is common to all the OEMs?

You mentioned suppliers, does EASA expect DO and PO to require their suppliers to have an SMS?

What kind of impact will the SMS system have on subcontractors who develop software and hardware compliant with RTCA DO-178C and RTCA DO-254 but do not have DOA and POA approval? What will subcontractors be expected to integrate into their existing quality systems?

How about subcontractors/ suppliers we work with but who has not an SMS and/ or not required to have one? Shall we include them in our SMS?

Should DOA POA organisations flow down SMS requirements to subcontractors?

How have you ensured the successful SMS working with your suppliers & sub-contractors?

How a subcontractor can classify a risk : it shall be performed at TC level?

We are a DOA supplier of components, not DOA, EN9100 certified, which impact we should consider in our organisation in terms of SMS implementation?

It will also be interesting to learn more on how external supplier and subcontractor are brought under DOA SMS, because not all supplier understand Part 21 SMS requirement? How was those cases are handled?

For integration of suppliers 'SMS in TC Holder SMS, do we ask the suppliers to report hazards only to TC holder and the TC holder manages the associated aviation safety risk?

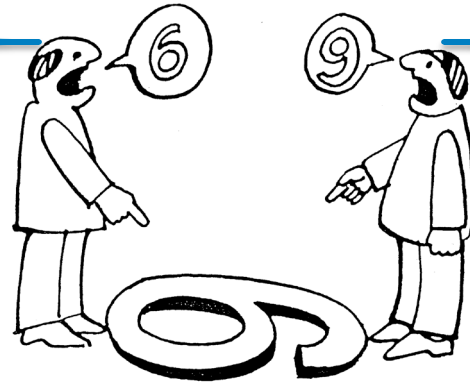
Outstanding topics from the previous workshop

Suppliers (2)

DOA Holders,
affected by SMS
requirements

Integration,
Cascade

Two perspectives



Suppliers not
affected directly
by SMS
requirements,
as not holding a
DOA
Impact

Outstanding topics from the previous workshop

Suppliers (3)

Scenario 1:

the design supplier has an EASA DOA, SMS applies directly to them.

Example:

TCH
Design supplier for landing gear.
Supplier DOA for approval of minor changes.
The Design supplier performs also design activities under the TCH-DOA umbrella.



Interfaces between SMSs.

Does the design supplier SMS cover the subcontracted activities?



A DMS should be proportionate to the size and scope of a DOA; the subcontractor arrangements can follow the same principles.

Outstanding topics from the previous workshop

Suppliers (4)

Scenario 2:

the design supplier has not an EASA DOA, SMS requirements need to be extended/cascaded to the design supplier by the Design Holder



Integration of the design supplier into the SMS of the Design Holder DOA.



Scalability considerations are still possible.

Outstanding topics from the previous workshop

Suppliers (4)

Scenario 3:

the design supplier has not an EASA DOA and subject to Third Authority SMS requirements



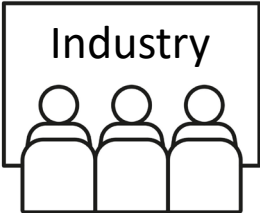
1. Design suppliers should not be seen as stand alone entity; they are following Safety Management principles within the system(s) that they are operating.

2. Again, is the subcontracted activity covered by the design supplier SMS?

Outstanding topics from the previous workshop

Suppliers (5)

How external supplier and subcontractor are brought under DOA SMS, because not all supplier understand Part 21 SMS requirement?



Outstanding topics from the previous workshop

EASA Auditors



Discussions with colleagues from other companies, we showed differences of understanding of the ways to implement SMS from different EASA auditors. Do you have intention to standardize the understanding from EASA auditors ?

All organisations are different. Their safety management systems are designed to work within the specific needs and management system of the organisation. Are EASA surveyors able to test whether a system works, even if it doesn't look like the AMC?

In the absence of specific rule/requirements of SMS, how could we avoid subjective evaluation during regulatory audit.

Maturity assessment neither in regulation nor in EASA AMC/GM. Why is now mandatorily requested by EASA DOATLs?

Why not create a common question database with the expectations of an SMS audit (questionnaire used by EASA and NAAs)? Who would be available on the EASA website? Are we not all looking for an optimum level of security? Let us not waste time with differences of interpretation.

Which referential the EASA DOA team leader will use during her/ his audit ?

If SM is part of EASA annual surveillance (say once per year), will EASA provide DOATL availability /proactively support DOA in closing the findings before 7th march 2025.

Outstanding topics from the previous workshop

EASA Auditors (2)



- (1) Mandatory Training
- (2) Development of Policies
- (3) Coordination with SMS Focal Point
- (4) Development of tool for SMS procedural system review
- (5) Development of tool for maturity assessment (audit mode)
- (6) Continuous exposure to DOAs implementing SMS
- (7) Sharing of experience
- (8) Workshops

Collective journey



Outstanding topics from the previous workshop

EASA Auditors (3)



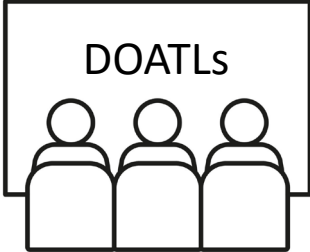
All DOATLs have included SMS assessment in their surveillance plan (regardless, it was classified as significant/non significant change)

Guidelines have been developed in order to tailor the depth of the assessment to the scope of the DOA; priority on those DOAs having a higher risk.

Outstanding topics from the previous workshop

EASA Auditors (4)

Maturity assessment neither in regulation nor in EASA AMC/GM. Why is now mandatorily requested by EASA DOATLs?



Outstanding topics from the previous workshop

DOA roles



To EASA: The current ISM in DOA can be the same person responsible for SM? Please define what is the interface between ISM and SM? For organisation which has Part 145 and Part 21 approval, can the SMS be managed by the same department / personnel?

Can the Safety Manager work in other roles of the company? (design engineer, CVE, auditor, etc.)

Will EASA plan to do interview for SM as per HoA and HDO?

To what extent does the safety manager involve themselves in the design or production projects conducted within the organization?

To EASA: the current ISM (Independent System Monitoring) in DOA is responsible for auditing SM? Please define what is the interface between ISM and SM (Safety Management)?

A person, covering the Role of Quality Manager (POA) and the role of ISM (DOA), can be appointed also as safety manager for both POA and DOA? Is there a conflict (like auditing himself)?

Can you clarify how you intend external Safety Manager?

Is acceptable that Head of Airworthiness could be also the Safety Manager ?

Is DOA's current Independent System Monitoring (ISM) responsible for SM audits? Define what is the interface between ISM and SM (Safety Management)

Outstanding topics from the previous workshop

DOA roles (2)

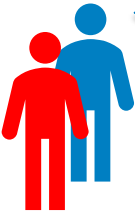


CoIMF

Who does what?



Safety Manager



One person for both roles?

Outstanding topics from the previous workshop

DOA roles (3)

AMC1 21.A.245(b) Resources

(d) Allows the head of independent monitoring function to be also the safety manager



If the same person is designated to manage both the independent monitoring function and safety-management-related processes and tasks, **the head of the design organisation (HDO)**, in order to discharge their safety accountability, should ensure that sufficient resources are allocated to both functions, taking into account the size of the organisation, and the nature and complexity of its activities.

Outstanding topics from the previous workshop

DOA roles (4) AMC1 21.A.245(b) Resources



CoIMF

PSOE?



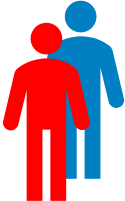
Safety Management Element

Design Assurance Element



Safety Manager

PSOE?



Independent auditor for the Safety Element (PSO)?

Outstanding topics from the previous workshop

DOA roles (5)

Can the Safety Manager work in other roles of the company? (design engineer, CVE, auditor, etc.)



Safety Manager should be a Management Position



Will EASA plan to do interview for SM as per HoA and HDO?



EASA will assess the nomination process of the SM. Until 07.03.2025, the strategy may vary upon complexity of the organisation. Then standard oversight applies.

Outstanding topics from the previous workshop

Proportionality



Is **any proportionality strategy** applied by DOATLs to the various organisations? E.g. minor changes DOA
What will be considered a simple non-complex organisation with respect to the SMS for a multiple approval holding organisation ? (organisation size? range of activities? (no flight or ground aircraft operations), or other measure?

Would it not be better that EASA creates a risk matrix for organisations **to identify if certain organisation need to implement SMS or not**. In that way, the DOA and POA creating parts with almost no risk for aviation are exempted for SMS.

Will EASA be able to provide guide lines to implement SMS for DOAs, **depending on size of DOA or Scopes or involvements or only for organisations with minor changes/repairs?** This request is not to prepare industrial type of SMS procedures for small DOAs at least at the beginning

Great presentations today but mostly focusing on **multiple-approval holders and larger organizations**. I would like to ask EASA if practical implementation for **smaller organizations** including those with only a single approval (ie DOA) would be addressed in subsequent workshops?

For a small DOA (<10 heads) can the organisation be considered as small and non-complex with respect to developing the safety management system?

Does Authorities have a perspective in near future **like SMS-Light** for especially other than A/C design and production organisations...

You just mentioned the implementation requirement with respect to large complex organisations, what criteria is to be used to classify the organisation itself as small/non-complex or large/complex?

How is a new application for (small) PO for parts/appliances handled because of the lack of useful and practicable **SMS requirements (AMC/GM) depending on size/scope?**

Outstanding topics from the previous workshop

Proportionality (2) 21.A.239(c)

21.A.239 Design management system

- (a) The design organisation shall establish, implement and maintain a design management system that includes a safety management element and a design assurance element with clearly defined accountability and lines of responsibility throughout the organisation.
- (b) The design management system shall:
 1. correspond to the size of the organisation and to the nature and complexity of its activities, taking into account the hazards and associated risks inherent in those activities;

GM1 21.A.239(c) Design management system

The safety management capability of an organisation should be commensurate with the safety risks to be managed, which can be at the product, part, and appliance level or at the organisational level. The risks that are inherent in a complex structure require a robust safety risk management process (e.g. complex interfaces with different partners that participate in the design of a product may pose hazards that are complex to mitigate). As a consequence, scalability and suitability of the safety management element should be a function of the inherent safety risk capability of the organisation. For instance, for organisations with a lower risk level:

- (a) the risk assessment model that is used may be very simple in cases in which the identified hazards are easy to mitigate;
- (b) expert judgement might be sufficient to measure the efficiency of safety barriers;
- (c) the collection of data, safety information, and occurrences might be very limited;
- (d) there might be no need for software or tools to manage the SMS; and
- (e) the communication policy might be limited.

AMC1 21.A.239(c)(2) Design management system

ORGANISATION AND ACCOUNTABILITY

- (a) The management system should encompass safety by including a safety manager and a safety review board in the organisational structure. The functions of the safety manager are defined in [AMC1 21.A.245\(b\)](#).
- (b) Safety review board

Safety objectives.

- (d) Notwithstanding point (a), if justified by the size of the organisation and the nature and complexity of its activities, and subject to a risk assessment and/or mitigation measures, as well as the competent authority's agreement, the organisation may not need to establish a board. In that case, the tasks that are normally allocated to the board should be allocated to the safety manager.

GM1 21.A.239(c)(2) Design management system

SAFETY ACTION GROUP

- (a) Depending on the size of the organisation and the nature and complexity of its activities, a safety action group may be established as a standing group or as an ad hoc group to assist, or act on behalf of, the safety manager or the safety review board.
- (b) More than one safety action group may be established, depending on the scope of the task.

The Safety Management system is proportionate to the safety risk inherent to the organisations

Outstanding topics from the previous workshop

DOA



To EASA: Please describe clearly the boundary between Design Assurance Element and Safety Management Element. It seems there are some overlaps.

What does the phrase "compliance with regulations" refer to in the SMS internal audit conducted by the safety manager? Is compliance with regulations also verified for every project undertaken within the organization through SMS?

Pragmatically, what have you done or will do, to make the speak-up as natural mindset

For the DOA oversight, must all steps be checked before 07 march 2025?

Is there a DOA that has just implemented SMS?


Steps means three audits till march 2025?

Concretely how to measure the effectiveness of the SMS?


Can EASA provide a generic SMS manual mentioning what is really required just to help the industry?

Outstanding topics from the previous workshop


DOA (2)



No artificial separation between DAS element and SM element



No generic SMS manual, to enable the proportionate approach to the maximum extent.

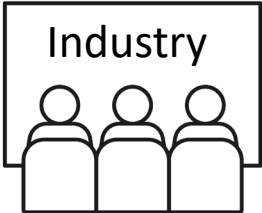


Oversight: Guidance have been provided to the DOATLs to accomplish those steps which are considered mandatory based on the complexity/size of the organisation

Outstanding topics from the previous workshop

DOA (2)

Pragmatically, what have you done or will do, to make the speak-up as natural mindset?



Outstanding topics from the previous workshop

Coordination Among Inspectors



For organisations with multiple approvals and a corporate SMS which includes AOC, CAMO, MRO DOA and POA. **How will be the management of the Audits?** Due the fact that DOA is Audited by EASA and is not the case for the rest.

Already existing SMS: which Authority will be responsible to approve the new version of the SMM (Safety Management Manual), knowing that the current version is already approved by DSAC, and that the new one will includes parts under the responsibility of OSAC for Part 21G, and of EASA for Part 21J?

Can companies that have DO, PO and MO approval under a group EN 9100 certificate **combine EASA and NAA audits to the SMS or how are EASA and NAA auditors aligned?**

Outstanding topics from the previous workshop

Coordination Among Inspectors (2)



No extensive coordination during implementation.

Outstanding topics from the previous workshop

Coordination Among Inspectors (3)

TL allocations across DOA/POA/MOA

Feasibility, cross domains competences

Non homogenous complexity across domains

Different level of complexity across domains.

Short term initiatives

- For POA organizations under EASA TL, DOATL and POATL can coordinate internally
- For POA organizations under NAA TL, EASA instructed POATL to contact DOATL and suggest aligned assessment of SMS as much as practicable possible.

Thank you!

Slido Event Code #: **SMSEASA**

Passcode: **SMS2024**

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