

## **SMS Overview Compliant with 21.A.239 Design Management System - Regulation (EU) 2022/201**

Sofema Aviation Services (SAS) [www.sassofia.com](http://www.sassofia.com) considers the key features and requirements found in a fully compliant Design Management System -Safety System Function)

### **Introduction – EU 21.A.239**

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.

The design management system shall:

- 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;
- Be established, implemented and maintained under the accountability of a single manager appointed pursuant to point 21.A.245

### **21.A.245 Resources - Regulation (EU) 2022/201**

The organisation shall appoint a head of the design organisation with the authority to ensure that, within the organisation, all design activities are performed to the required standards and that the design organisation is continuously in compliance with the requirements of the design management system referred to in point 21.A.239 and the procedures specified in the handbook referred to in point 21.A.243.

- The head of the design organisation shall nominate and specify the extent of authority of:
  - A chief of the airworthiness function;
  - A chief of the independent monitoring function;

Note 1 - Depending on the size of the organisation and the nature and complexity of its activities, any other person or group of persons that are required to ensure that the organisation complies with the requirements of this Annex.

Note 2 - By way of derogation the airworthiness function may be performed under the direct supervision of the head of the design organisation in either of the following cases:

- Where the scope of activities of/of work of the design organisation, as identified in the terms of approval issued under point 21.A.251, is limited to minor changes and/or minor repairs.
- For a limited period of time when the design organisation does not have a nominated chief of the airworthiness function and the exercise of that function

under the direct supervision of the head of the design organisation is commensurate with the scope and level of the organisation's activities.

### **Safety manager - AMC1 21.A.245(b) Resources ED Decision 2022/021/R**

If more than one person is designated for the development, administration, and maintenance of effective safety management processes as defined in point 21.A.239(c)(2), the HDO should identify the 'safety manager' as the unique focal point.

The role of the safety manager should be:

- To facilitate hazard identification, as well as risk assessment and management;
- To monitor the implementation of action taken to mitigate risks, as listed in the safety action plan, unless action follow-up is addressed by the independent monitoring function;
- To provide periodic reports on safety performance to the safety review board (the functions of the safety review board are defined in AMC1 21.A.239(c)(2));
- To ensure the maintenance of safety management documentation;
- To ensure that there is safety training available, and that it meets acceptable standards;
- To provide advice on safety matters; and
- To ensure the initiation and follow-up of internal investigations of occurrences.

### **The design organisation shall ensure that:**

- The staff in all technical departments are of sufficient numbers and experience and have been given the appropriate authority to be able to discharge their allocated responsibilities and the facilities, equipment and accommodation that are adequate to enable the staff to fulfil the airworthiness, operational suitability data and environmental protection requirements as regards the product;
- There is full and efficient coordination between the departments and within the departments in respect of airworthiness, operational suitability data and environmental protection matters.

### **Design Management System - Safety Management Element**

As part of the safety management element of the design management system, the design organisation shall:

- Establish, implement and maintain a safety policy and the corresponding related safety objectives;
- Appoint key safety personnel in accordance with AMC1 21.A.245(b)

- Establish, implement and maintain a safety risk management process that includes
  - The identification of aviation safety hazards entailed by its activities,
  - Their evaluation and
  - The management of the associated risks,
  - Including taking actions to mitigate the risks and
  - Verify their effectiveness;
- Establish, implement and maintain a safety assurance process that includes:
  - The measurement and monitoring of the organisation's safety performance;
  - The management of changes
  - The principles for the continuous improvement of the safety management element;
- Promote safety in the organisation through:
  - Training and education;
  - Communication;
  - Establish an occurrence reporting system in order to contribute to continuous improvement of safety.
- As part of the design assurance element of the design management system, the design organisation shall:
  - Establish, implement and maintain a system for the control and supervision of the design,
  - and of design changes and repairs, of products, parts and appliances covered by the terms of approval;
- that system shall:
  - Include an airworthiness function responsible for ensuring that the design of products, parts and appliances, or the design changes and repairs, comply with
    - the applicable type-certification basis,
    - the applicable operational suitability data certification basis and
    - the environmental protection requirements;
  - ensure that the design organisation properly discharges its responsibilities in accordance with this Annex and with the terms of approval issued under point 21.A.251;

## **Organisational Competence & Training**

To implement a Design Management System (DMS) that complies with 21.A.239 and integrates safety management principles from ICAO Annex 19, organizations need to ensure that their workforce is properly trained and competent in both the technical and safety management aspects. Here's a detailed approach, focusing on manpower training and competence:

## Training Needs Assessment

- **Objective:** Identify the necessary skills and knowledge required by personnel to comply with **EASA AMC1 21.A.239(c)**, which mandates the integration of Safety Management Systems (SMS) into the design processes.

## AMC1 21.A.239(c) Design Management System ED Decision 2022/021/R

### SAFETY MANAGEMENT ELEMENT

Demonstration of compliance with the international industry standard SM-0001 'Implementing a Safety Management System in Design, Manufacturing and Maintenance Organisations', Issue B, 31 March 2022, is an acceptable means to demonstrate compliance with the safety management element of the design management system.

(See Sofema Library download area to view this document)

### Key Areas to Address:

- Product certification and compliance with environmental protection regulations.
- Risk identification and assessment processes related to design and production.
- Safety performance monitoring and use of Key Performance Indicators (KPIs).
- Procedures for continuous improvement and corrective actions.

**Action:** Conduct a gap analysis to determine what SMS knowledge or specific technical training (e.g., risk management in design, safety auditing) is currently lacking among personnel.

### Developing a Comprehensive Training Program

The training program must be aligned with both the technical certification specifications and the principles of ICAO Annex 19 related to structured safety management.

- **SMS Training:** Focus on SMS concepts, including risk management, hazard identification, and reporting systems. Personnel need to understand how safety risk management is applied throughout the design and production phases.
- **Design & Environmental Regulations:** Ensure that staff understand the specific certification and environmental protection regulations, including

compliance with Part 21 Subpart J requirements, particularly in areas like the continuing structural integrity of aircraft.

- **DMS Procedures Training:** Personnel should be trained on the organization's internal DMS procedures, particularly how safety data is reported, tracked, and how continuous improvement measures are implemented.

**Action:** Create modular training courses to address both technical certification knowledge and SMS implementation in design processes.

### Competency Development and Maintenance

- **Competency Framework:** Develop a framework outlining the necessary competencies for each role within the organization. This framework should include both technical skills (related to design and airworthiness certification) and safety management competencies (aligned with Annex 19 and EASA's AMC1 21.A.239(c)).
- **Continuous Competency Evaluation:** Competence should not only be developed through initial training but maintained and evaluated through ongoing performance assessments. Implement regular competency assessments to ensure that staff remain up-to-date with regulatory changes and risk management practices.
- **On-the-Job Training (OJT):** Use OJT to complement theoretical training. This ensures that personnel can apply safety management principles in real-world design tasks, particularly in the areas of compliance verification, environmental certification, and risk-based decision-making.

**Action:** Implement a system for regular competency evaluations, integrating feedback from DMS performance metrics and audit results.

### Risk Management and Reporting Systems

Personnel must be trained to actively participate in the reporting system, as outlined in 21.A.3A. This involves recognizing and reporting failures, defects, and non-compliances that may affect safety.

- **Risk Identification and Assessment:** Train design staff to identify risks early in the design process. This includes risks to airworthiness, environmental protection, and overall safety.
- **SMS Reporting Tools:** Staff should be familiar with the organization's SMS tools for logging hazards, monitoring safety performance, and tracking corrective actions. The training should also cover how to integrate feedback into design changes.

**Action:** Set up workshops that include case studies and practical exercises in risk identification, reporting, and applying corrective measures to improve design safety.

### **Audit and Feedback Loops**

- Train employees to conduct internal audits and participate in DMS performance evaluations.
- Personnel involved in safety audits should understand how to assess the effectiveness of risk controls, how to evaluate the implementation of corrective actions, and how to use findings to improve safety performance in design processes.

**Action:** Provide audit training courses and certification for relevant staff, ensuring they are proficient in conducting safety audits in compliance with both EASA and ICAO Annex 19 requirements.

### **Safety Culture and Leadership Training**

- Foster a proactive safety culture by providing leadership training for managers and team leaders. Leaders should be trained to encourage reporting, transparency, and continuous improvement.
- Emphasize that safety is not just a compliance issue but a core part of the organization's values, aligning with the Safety Policy principles in ICAO Annex 19.

**Action:** Run safety leadership programs that train management on how to lead safety initiatives, mentor staff, and build a culture of accountability and continuous improvement.

### **Implementation of Continuous Improvement Mechanisms**

- As EASA AMC1 21.A.239(c) requires ongoing safety performance monitoring, employees should be trained to use safety data for improving design processes. This includes understanding how Key Performance Indicators (KPIs) are used to measure safety outcomes and implementing continuous improvement processes.

**Action:** Provide advanced training for key personnel on data analysis and performance monitoring, enabling them to identify trends and implement changes that enhance safety.

### **Next Steps**

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