EASA Part 21 J Developments & Organisational Considerations

Sofema Aviation Services (SAS) www.sassofia.com considers the key roles and responsibilities within the EASA Part 21 J Organisation

Introduction

The following guidance is provided related to the key roles and responsibilities within an EASA Part 21 J organization, as outlined under Regulation (EU) 2022/201 reference – 21.A.239 Design Management System.
By adhering to these roles and responsibilities and addressing the issues of concern with proactive and structured approaches, EASA Part 21 J organizations can effectively manage safety and design assurance, thereby ensuring compliance with regulations and the safety of aviation products.

Key Roles and Responsibilities

Head of the Design Organization (HDO)

- Accountability: The HDO is ultimately accountable for establishing, implementing, and maintaining the design management system.
- Oversight: Ensure that the design management system corresponds to the organization's size, nature, and complexity, considering the inherent hazards and risks.
- Integration: If applicable, integrate the design management system with additional organization certificates as per Regulation (EU) 2018/1139.

Safety Manager

- Policy and Objectives: Establish, implement, and maintain the organization's safety policy and related safety objectives.
- Safety Risk Management: Oversee the identification, evaluation, and management of aviation safety hazards and associated risks.
- Safety Assurance: Implement a safety assurance process, including monitoring safety performance and managing changes.
- Safety Promotion: Promote safety within the organization through training, education, and communication.
- Occurrence Reporting: Establish and maintain an occurrence reporting system to contribute to the continuous improvement of safety.

Design Assurance Manager

- Design Control: Establish a system for the control and supervision of design, changes, and repairs, ensuring compliance with applicable certification bases and environmental protection requirements.

- Independent Verification: Maintain an independent verification function to demonstrate compliance with airworthiness, operational suitability, and environmental protection requirements.
- Subcontractor Oversight: Ensure the acceptability of parts or tasks performed by partners or subcontractors.

Key Safety Personnel
Appointed in accordance with point 21.A.245(b), these individuals support the safety manager in implementing the safety management element of the design management system.

Independent Monitoring Function
- Compliance Verification: Verify the organization’s compliance with relevant requirements and the adequacy of the design management system.
- Feedback Mechanism: Provide feedback to key safety personnel and the HDO, facilitating the implementation of corrective actions where necessary.

Issues of Concern and Guidance
- Clear Definition of Roles: Ensure that all roles and responsibilities are clearly defined, documented, and communicated within the organization to avoid overlaps and gaps in the safety management and design assurance processes.
- Training and Competency: Regularly assess and address the training needs of all personnel involved in the design management system to ensure they have the requisite skills and knowledge to perform their roles effectively.
- Change Management: Incorporate a robust Management of Change (MoC) process to handle changes in organizational structure, processes, or external conditions, ensuring that safety and compliance are not compromised.
- Continuous Improvement: Foster a culture of continuous improvement by regularly reviewing and updating the design management system in response to feedback, audit findings, and evolving regulatory requirements.
- Integration and Coordination: For organizations holding additional certificates, ensure seamless integration of the design management system with other management systems to enhance efficiency and effectiveness.
- Stakeholder Engagement: Engage with all stakeholders, including employees, regulatory authorities, and partners, in the development and implementation of the design management system to ensure buy-in and compliance.

Part 21 J SMS Introduction

In today’s aviation landscape, Safety Management Systems (SMS) play a vital role within Part 21J Design Organizations, ensuring that safety considerations are integrated into all aspects of design and development.

• The implementation of SMS is not merely a regulatory requirement but a strategic approach to proactively identify and mitigate potential risks associated with the design and production of aviation products.
Part 21J SMS and Compliance with ICAO Annex 19 and EASA Obligations
ICAO Annex 19 underscores the necessity of SMS for a globally harmonized approach to safety, promoting a risk-based, data-driven method to support modern aviation design's complexities.

• By fostering a safety culture of reporting, accountability, and continuous improvement, SMS allows organizations to address potential issues early in the design phase, where even small oversights can significantly impact downstream safety.

• Part 21 Subpart J organizations, also known as Design Organisation Approval (DOA) holders, are responsible for compliance with EASA Regulatory Requirements (Based on conformity with ICAO Annex 19)

• Mandating Safety Compliance with EASA regulations that incorporate these principles within the European regulatory framework.

Consider the following regarding how Part 21J organizations can ensure alignment with these obligations:

Establishment of a Design Management System (DMS)

The Design Management System (DMS), as mandated by 21.A.239, ensures compliance with applicable requirements, including safety management principles from ICAO Annex 19. This system structures safety management by integrating risk identification, safety performance monitoring, and continuous improvement into the organization’s processes.

Risk Management and Safety Reporting

Part 21 organizations are required to maintain a system for reporting occurrences of non-compliance or unsafe conditions, as per 21.A.3A.
• This aligns with Annex 19’s focus on safety data collection, analysis, and sharing, enabling organizations to identify and address risks proactively.

Safety Audits and Continuous Monitoring
Continuous monitoring and safety audits are integral to the DMS. These activities, guided by AMC1 21.A.139(d), enable organizations to verify compliance with EASA and

ICAO standards, foster a culture of continuous improvement, and implement corrective actions as needed.

Training and Competency
Part 21J organizations must ensure that personnel have the necessary training and competencies to effectively execute SMS-related duties, as required by 21.A.245.
• This includes safety management training aligned with ICAO Annex 19 to enhance awareness of risks and encourage proactive safety behaviours.

Integration of SMS with Design Activities

The DMS requires SMS integration directly within design processes, ensuring that safety is embedded throughout the product lifecycle.
• This includes conducting safety risk assessments during design changes, repairs, or modifications to address any new risks.

Communication with Authorities
Coordination with EASA is essential for compliance, as outlined in AMC1 21.B.15. Part 21J organizations must report significant changes or safety concerns and share safety performance data, contributing to broader safety objectives.

Management of Safety Data
EASA's occurrence reporting aligns with Annex 19's emphasis on managing safety data.

• Collected data is used to identify trends, measure safety performance, and address potential risks, thereby supporting the State Safety Programme (SSP) and Safety Performance Indicators (SPI) objectives under Annex 19.

Adoption of Corrective Actions
Part 21J organizations must implement corrective actions to mitigate identified risks, as per AMC1 21.A.125B.
• These actions are tracked to ensure safety issues are effectively resolved, maintaining alignment with both EASA and ICAO standards.

Unique Challenges of SMS Integration in Part 21J

Implementing SMS in a Part 21J environment requires balancing safety with other key factors, including cost, performance, and innovation. Effective SMS integration demands a nuanced understanding of safety management and consistent communication across teams, alongside managing evolving regulatory compliance and a robust risk assessment process. This course will guide participants through embedding SMS within a design organization, promoting a proactive safety culture, and addressing the unique challenges associated with Part 21J compliance.

Balancing Safety with Cost, Performance, and Innovation

- Safety vs. Cost: Ensuring robust safety features can lead to increased costs due to additional testing, certification requirements, and the implementation of safety controls.
- Safety vs. Performance: Achieving safety goals can sometimes limit performance characteristics, particularly in cases where lighter, high-performance materials may be less proven in terms of safety.
- Safety vs. Innovation: Innovation drives competitive advantage, but in aviation, innovative approaches must be balanced with the need to adhere to strict safety protocols.

Developing a Nuanced Understanding of Safety Management

Understanding SMS in Context: SMS requires more than a general understanding of safety; it demands that safety principles are applied specifically to design practices, with the entire product lifecycle in mind.

Proactive Safety Analysis

- Safety is not static, and in complex design environments, emerging risks can develop as designs evolve.

- Part 21J organizations need to integrate proactive hazard identification, where risk assessments and safety impact analyses are embedded throughout the design process.

Establishing a Robust Risk Assessment Process

- Comprehensive Hazard Identification: Identifying hazards requires a proactive approach, where potential safety concerns are anticipated and evaluated at the early design stages.

- Risk Mitigation Through Design: The goal of SMS in design is to prevent safety issues before they arise.

- This requires designing layers of safety redundancies, such as fail-safe mechanisms and fault-tolerant systems, and conducting design reviews to assess risk mitigations.

- Risk Assessment for Design Changes: Design is often an iterative process, and each iteration brings potential new risks.

- Part 21J organizations must be diligent in performing safety reviews for all design changes, particularly as regulatory requirements may also mandate additional compliance checks for design modifications.

Theoretical Foundations of Hazard Identification in Part 21J

Hazard identification (HAZID) under Part 21J is anchored in theoretical safety concepts, primarily driven by a proactive risk management approach.
The main theories include:

- Reason’s Swiss Cheese Model: Emphasizes that hazards result from multiple latent conditions within organizational processes, each representing a “slice” in the “cheese” where weaknesses may align to create risk.

- Risk-Based Approach (RBA): Promotes risk prioritization by focusing on high-impact and high-likelihood hazards, thus facilitating efficient resource allocation.

- System-Theoretic Process Analysis (STPA): Uses a system perspective to examine design process controls, helping to identify potential hazards that may arise from control failures within the design process. (See Sofema Download Library Area – Part 21 SMS)

- The Structured What-If Technique (SWIFT): A proactive hazard analysis approach that uses structured brainstorming with guidewords and prompts to identify potential risks efficiently.

    - It is designed to be faster than more comprehensive methods like Failure Mode and Effects Analysis (FMEA), making it adaptable to various sectors, including the aerospace industry.
    - For EASA Part 21J Design Organization Safety Management Systems (SMS), SWIFT offers a valuable method to identify design and operational risks early in the development process.
    - Its structured approach enables the design organization to assess potential safety issues systematically, facilitating timely and targeted mitigations.

Note – Like other methods such as FMEA, SWIFT may not provide comprehensive risk coverage when used in isolation. Integrating SWIFT into a broader SMS framework enhances its effectiveness, as it supports proactive risk identification while aligning with EASA’s safety objectives for design assurance and continuous safety monitoring.

Practical Solutions for Hazard Identification within Part 21J

Note the relationship between the cost of design changes and the evolution of development.

Integration of Hazard Identification within Design Stages

- Early Design Review: Conducting hazard identification during initial design reviews can help identify system-level hazards before they evolve into complex issues.
- Use of HAZID Tools: Techniques such as Failure Modes and Effects Analysis (FMEA), Preliminary Hazard Analysis (PHA), and Hazard and Operability Studies (HAZOP) can be embedded into routine design assessments.
- Cross-Functional Teams: Involving engineers, safety specialists, and quality assurance staff in hazard identification activities facilitates diverse perspectives, promoting comprehensive hazard assessment.

Leveraging Digital Solutions for Hazard Tracking

- Digital Tracking and Reporting Systems: The use of digital tools like safety dashboards to track hazards and monitor their mitigation status in real-time enhances accountability.
- Data Analytics for Trend Analysis: Trend analysis of past incidents and non-conformities helps to recognize recurring patterns that might indicate latent hazards.

Embedding Safety Culture and Reporting Mechanisms

- Speak-Up Culture: Encouraging employees to report potential hazards without fear of negative consequences strengthens the identification process.
- Incident and Hazard Reporting Systems: Implementing easy-to-use reporting systems that are accessible to all employees within the 21J environment increases the likelihood of early hazard identification.

Challenges in Hazard Identification for Part 21J

- Complex and Rapidly Evolving Design Environments
- Complex System Interactions: As systems become more integrated and complex, identifying hazards related to these interactions is increasingly challenging.
- Dynamic Regulatory and Technological Landscape: Rapid advancements in technology and evolving regulations make it difficult to continuously update hazard identification processes.

Resource Constraints

- Time and Budget Limitations: Organizations often face time and budget constraints that may limit the extent and frequency of hazard assessments.

- Skilled Personnel Shortage: The need for specialized knowledge in hazard identification, coupled with a limited workforce, can constrain SMS effectiveness.

Best Practices for Part 21J Hazard Identification – Developing a Structured Hazard Identification Program

- Defined Roles and Responsibilities: Clarifying roles within the hazard identification process ensures accountability and engagement from all levels.

- Regular Safety Audits and Reviews: Conducting routine safety audits focused on hazard identification strengthens the proactive identification process.

- Collaborative Workshops and Brainstorming Sessions: Engaging cross-functional teams in hazard identification workshops can foster collaboration and uncover hidden hazards.

Safety Training Programs Tailored to 21J Environments

- Initial and Recurrent Training: Regularly updated training programs should cover theoretical aspects of hazard identification, familiarizing employees with tools like FMEA, PHA, and other HAZID methodologies.
- Scenario-Based Training: Using real-life case scenarios in training allows participants to apply hazard identification techniques in controlled, relevant situations.
- SMS Competency Assessments: Assessing employee competence in SMS processes ensures they retain necessary hazard identification knowledge and skills.

Detailed Training Considerations for Hazard Identification in Part 21J

Theoretical and Practical Components
- Fundamentals of Hazard Identification: Training should emphasize the core theories, such as risk-based approaches, the Swiss Cheese Model, and STPA.
- Application of HAZID Techniques: Providing hands-on training in FMEA, PHA, and root cause analysis methods prepares employees for real-world applications.

Training on Advanced Risk Assessment Techniques
- Advanced Risk Analysis: Training on advanced risk assessment techniques, like bow-tie analysis and fault tree analysis, enables in-depth hazard examination.

- Systemic Thinking Skills: Developing systemic thinking abilities equips employees to view hazards within the broader context of the design process.

Next Steps

please see www.sassofia.com for Classroom or Webinar Training & www.sofemaonline.com for online training - for comments & questions please email team@sassofia.com