

Conducting Risk Assessments Based on Identified Hazards

Sofema Online (SOL) www.sofemaonline.com considers the key elements within an EASA Part 21 J SMS to include in a Risk Assessment Process to address multiple hazard types.

Introduction

Conducting risk assessments based on identified hazards involves systematically evaluating the potential safety risks posed by those hazards to mitigate or control them effectively.

- Hazard identification should be both proactive and reactive, focusing on potential nonconformities of products or components during design, production, or operational processes typically include the following elements:

Risk Categorization

- **Human Impact (Severity):**
 - Evaluate how hazards can affect human life or health, including potential injuries, fatalities, or exposure to harmful conditions.
 - **Categories:**
 - Minimal: No significant injury or health impacts.
 - Moderate: Reversible injuries or short-term exposure to risks.
 - Severe: Irreversible injuries or fatalities.
- **Environmental Impact:**
 - Assess the potential for environmental damage, such as pollution, noise, waste generation, or ecosystem disruption caused by identified hazards.
 - **Categories:**
 - Negligible: No measurable environmental impact.
 - Moderate: Limited or short-term environmental impacts, mitigated with minor controls.
 - Major: Significant, long-term environmental degradation requiring substantial mitigation efforts.
- **Technical Impact:**

- Analyze the consequences of technical failures, such as system downtimes, functional loss, or operational interruptions.
- **Categories:**
 - Low: Minor technical malfunctions with no operational interruption.
 - Medium: Malfunctions that affect operations but are recoverable.
 - High: Critical failures that cause operational cessation or safety hazards.
- **Organizational Impact:**
 - Evaluate the consequences of process failures, mismanagement, non-compliance with regulatory standards, or inadequate resource allocation.
 - **Categories:**
 - Low: Minor disruptions to internal processes.
 - Medium: Noticeable disruptions that affect service delivery or compliance.
 - High: Systematic failures that lead to regulatory non-compliance or significant operational disruptions.

Risk Evaluation

- **Human Risk Tolerance:**
 - Assess the organization's tolerance for human risk, focusing on occupational safety, staff competence, and adherence to safety protocols.
 - **Benchmark:** Ensure risk to human life and safety is minimized to "as low as reasonably practicable" (ALARP).
- **Environmental Risk Tolerance:**
 - Evaluate the acceptable level of environmental risk based on the organization's sustainability commitments and regulatory environmental requirements.
 - **Benchmark:** Compliance with local and international environmental regulations (e.g., emissions, noise levels).
- **Technical Risk Tolerance:**

- Establish the acceptable level of risk associated with system or component failure based on criticality and operational redundancy.
- **Benchmark:** Ensure technical risks align with industry standards and reliability thresholds (e.g., MTBF – Mean Time Between Failures).
- **Organizational Risk Tolerance:**
 - Define the acceptable level of risk related to operational inefficiencies, delays, or management failures.
 - **Benchmark:** Conformance with regulatory requirements (e.g., airworthiness, safety management system compliance).

Control Measures

- **Human-Focused Controls:**
 - Implement training programs, improve communication, and enforce safety protocols to reduce human error.
 - **Benchmark:** Regular safety training, safety culture assessments, and ergonomic interventions to minimize human-related hazards.
- **Environmental Controls:**
 - Introduce measures to mitigate environmental hazards, such as waste management, emission controls, and sustainable operational practices.
 - **Benchmark:** Compliance with ISO 14001 environmental management standards or equivalent.
- **Technical Controls:**
 - Modify designs, implement redundancy systems, and conduct regular maintenance to prevent or mitigate technical failures.
 - **Benchmark:** Application of industry standards like DO-178C (software), ARP4761 (safety assessment), and regular preventive maintenance schedules.
- **Organizational Controls:**
 - Enhance processes, improve resource allocation, and introduce better safety governance and communication strategies to prevent organizational lapses.

- **Benchmark:** Conformance with ICAO Annex 19 (Safety Management System) and organizational change management best practices.

Compliance with Regulatory Requirements

- **Human-Centered Compliance:**
 - Ensure that personnel qualifications, training programs, and occupational health & safety protocols meet or exceed regulatory standards.
 - **Benchmark:** ICAO Annex 6 (Operational Safety Requirements) and applicable labor laws.
- **Environmental Compliance:**
 - Verify that environmental risk controls comply with all relevant aviation and environmental protection regulations.
 - **Benchmark:** Conformance to EU environmental protection laws (e.g., noise regulations, emissions standards).
- **Technical Compliance:**
 - Ensure all technical systems, including design, production, and operational processes, meet airworthiness certification requirements.
 - **Benchmark:** Compliance with **Part 21** for design, manufacturing, and modification approval processes.
- **Organizational Compliance:**
 - Implement procedures to ensure organizational practices are aligned with aviation authority standards and internal governance policies.
 - **Benchmark:** Compliance with **ICAO Annex 19** for SMS and organizational risk management practices.

Residual Risk Assessment

- **Human Residual Risk:**
 - Reassess risks after implementing controls to determine if residual human risks remain acceptable.
 - **Benchmark:** Adhere to safety culture principles, ensuring ongoing training and compliance monitoring.
- **Environmental Residual Risk:**

- Evaluate if environmental impacts have been adequately mitigated post-control.
- **Benchmark:** Ensure that environmental impacts are reduced to within permissible legal limits.
- **Technical Residual Risk:**
 - Verify that technical systems function effectively after modifications and that failures are within acceptable thresholds.
 - **Benchmark:** Residual technical risks should align with failure modes and effects analysis (FMEA) tolerances.
- **Organizational Residual Risk:**
 - Ensure organizational risks, such as management inefficiencies or procedural errors, are minimized post-implementation of controls.
 - **Benchmark:** Continuous audit and assessment of organizational performance against **ISO 9001** or **ISO 45001** standards.

Continuous Monitoring and Review

- **Human-Focused Monitoring:**
 - Continuously monitor human performance, stress levels, and adherence to safety protocols.
 - **Benchmark:** Implement human performance monitoring tools and regular safety audits.
- **Environmental Monitoring:**
 - Ensure that environmental monitoring systems are in place to track emissions, waste management, and compliance.
 - **Benchmark:** Adhere to **ISO 14001** environmental standards for ongoing monitoring.
- **Technical Monitoring:**
 - Implement technical monitoring systems, such as predictive maintenance and failure tracking, to detect issues early.
 - **Benchmark:** Use predictive maintenance tools like condition-based monitoring and adherence to reliability-centered maintenance (RCM) principles.

- **Organizational Monitoring:**

- Establish review processes and feedback loops to capture lessons learned and improve organizational performance.
- **Benchmark:** Conduct regular internal and external audits in line with **ICAO** and **EASA** standards.

Documentation and Traceability

- **Human Records:**

- Maintain documentation of training records, human performance assessments, and compliance with safety protocols.
- **Benchmark:** Keep detailed training logs, compliance checks, and incident reports, ensuring data is updated regularly.

- **Environmental Documentation:**

- Ensure all environmental impact assessments, emissions reports, and waste management records are maintained.
- **Benchmark:** Follow environmental reporting regulations, maintaining compliance with EU environmental directives.

- **Technical Documentation:**

- Maintain records of all design changes, technical inspections, maintenance logs, and system modifications.
- **Benchmark:** Detailed maintenance and modification logs in compliance with **Part 21** and **EASA** guidelines.

- **Organizational Documentation:**

- Document all procedural changes, safety assessments, risk management actions, and organizational audits.
- **Benchmark:** Use **ISO 9001** quality management systems for continuous improvement and documentation.

Next Steps

Please see the following Training Course - EASA Part 21 Subpart J Safety Management System Implementation – 2 Days or visit www.sassofia.com or email team@sassofia.com