Management of Change in Design Management Systems - Considerations

Review and considerations by Sofema Aviation Services (SAS) www.sassofia.com

Introduction

The management of change (MoC) within an EASA Part 21J Organisation is a critical element in ensuring that any alterations within an organization, particularly those related to a design management system, do not inadvertently introduce new hazards or compromise existing safety controls.

Changes to the design management system may pose new hazards or decrease the effectiveness of existing safety risk controls.

The organisation should manage any safety risks that are related to change in that organisation.

- The management of change should be a documented process to identify external or internal change that may have an adverse effect on safety.
- The management of change should use of the organisation's existing processes for hazard identification, risk assessment, and risk mitigation.
- According to AMC1 & GM1 - 21.A.239, changes within the design management system (DMS) must be approached with caution to mitigate potential risks.

The Importance of Managing Change

Organizational changes—whether they involve:

- Personnel,
- Facilities,
- Policies, or
- Work processes

Introduce the possibility of new hazards. These changes, if unmanaged, can increase risk levels, jeopardizing not only the safety of operations but also the integrity of the design processes.

- Therefore, the MoC process is integral
  - o To identifying risks,
  - o Assessing potential impacts, and
  - o Implementing necessary safety controls to prevent adverse outcomes.

Key principles of managing change in the Design Management System (DMS) ensure emphasis on a structured framework to mitigate risks associated with change.

Documenting and Implementing a Management of Change Process

- An essential first step in any management of change process is to ensure it is well-documented and integrated into the organization's overall safety management system.
- The process should be part of the organization's procedural controls, aligned with the existing mechanisms for
  - Hazard identification,
  - Risk assessment, and
  - Risk mitigation.

Proactive Consideration of Safety Implications

Any organizational change should be evaluated for its potential safety implications.

- This involves a thorough risk assessment process that considers
  - The magnitude of the change,
  - Its safety criticality, and
  - The potential impacts on human performance (HP).
  - Non-complex changes, such as minor administrative adjustments, may not require additional safety assessments. However, for more substantial changes, special attention must be given to ensure that new risks are not introduced.

Human Performance Considerations

In the context of a Part 21 J Design Organization, it is critical not only to focus on organizational processes but also to account for the product being designed and the potential exposure that could affect future users

- Operators,
- Maintainers, and
- Ultimately the passengers and crew who depend on the safety of the aircraft.

The quality of human performance in a design organization directly impacts the integrity of the product and introduces potential risks that may manifest in future operational environments.

Key Aspects of Human Performance Impacting the Product and Users

- Task Execution and Product Safety The performance of individuals and teams within the design process directly influences the safety of the final aircraft or component.
- Poor execution in areas such as design calculations, compliance documentation, or testing oversight can introduce latent defects that may not be immediately obvious but could surface during operational use.
  - These defects can lead to safety incidents, aircraft downtime, or catastrophic failures in extreme cases.

o The exposure to future users (pilots, maintenance personnel, airlines) arises if these performance gaps result in compromised product integrity.

- Design Adaptability and User Requirements Human performance also affects the extent to which the product meets the specific needs of future users.

- Impact of Design Errors on Future Users Human errors during the design phase, can have long-term consequences.
    o When human performance fails to ensure comprehensive testing or overlooks potential failure modes, the exposure to future users increases, potentially leading to safety hazards during operation.

- Long-Term Product Lifecycle Performance The human performance of the design team affects not only the initial certification of the aircraft or component but also its performance throughout its operational lifecycle.

- Poor performance in the development phase can result in products that experience more frequent defects, require extensive maintenance, or have shorter service lives than anticipated.

- Human Performance shortfalls in identifying and mitigating potential hazards in the design phase that could affect the product's future users. Weak performance in risk identification, analysis, or mitigation can leave unaddressed hazards in the final product.
    o These hazards could manifest during aircraft operation, leading to incidents or accidents. The inability of a design team to foresee user-related risks, such as the misuse of systems or unexpected operational stresses, can significantly increase future exposure for users.

Human Factors Consideration:

- Changes in technology, work processes, or organizational structure may raise human factors issues such as increased workload, unfamiliarity, or reduced communication.
    o These factors must be considered in the MoC process to ensure that human performance remains optimized, and safety risks are mitigated.

Risk Assessment and Safety Cases: The management of change process should include comprehensive safety cases and or risk assessments.

- These assessments need to focus specifically on the impact of change on aviation safety.

- Reviewing past risk assessments and existing hazards is essential for determining if new or exacerbated risks will arise due to the changes.

Transition Period Management: Any transition period following the implementation of change poses specific risks.

- This period requires careful monitoring to ensure that any unforeseen hazards are identified and addressed promptly.
- Special consideration should be given to the human factors involved in transitioning to new systems, processes, or personnel arrangements, ensuring that safety-critical functions remain unaffected.

Continuous Improvement and Monitoring

- Beyond managing specific changes, organizations should strive for continuous improvement in their safety performance and the effectiveness of their DMS.

- Continuous improvement should be built into the MoC process, allowing organizations to learn from past experiences and implement best practices.

Summary

The management of change process is an essential component of any design management system.

- It ensures that organizations can adapt to internal and external changes without compromising safety.
- By integrating risk assessments, human factors considerations, and continuous improvement mechanisms into the change management process, organizations can effectively manage new hazards, minimize safety risks, and maintain the integrity of their safety systems.

Next Steps

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