U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION

ORDER
AM 1110.155A

Effective Date:
12/09/2020

SUBJ: Aerospace Medicine Safety Management Council (SMC)

1. Purpose of this Order. This order establishes the operational requirements for the Office of Aerospace Medicine's (AAM) Safety Management Council (SMC). The order outlines the roles and responsibilities of the SMC and supports the Federal Aviation Administration's (FAA) and Aviation Safety (AVS) organization's commitment to the continuous improvement of a Safety Management System (SMS). Safety Risk Management (SRM) and Safety Assurance (SA) are integral parts of a SMS.

2. Audience. All AAM Employees.

3. Where You Can Find this Order. You can find this order on the Orders & Notices website: https://employees.faa.gov/tools_resources/orders_notices.

4. Explanation of Changes. This revision does the following:

a. Includes additional definitions and acronyms in Appendices A and B.

b. References to Risk Based Decision Making Strategic Initiative removed; and those outputs incorporated into the FAA's SMS.

c. Changes language to reflect continuous improvement of the SMS rather than implementation.

d. Changes the references from Significant Safety Issues to safety issues to align with the continuous identification and management of safety issues rather than as an annual process.

5. Background.

a. The FAA's mission is "to provide the safest, most efficient aerospace system in the world". To support this mission, the FAA implemented an agency-wide SMS. FAA's SMS integrates managing safety risk into business planning, operations, and decision making to enhance the safety of the flying public and strengthen the FAA's worldwide leadership in aviation safety.

b. This order establishes the AAM SMC in support of AAM's continued improvement of the SMS. The SMC will assess AAM safety policy, SRM and SA activities. The SMC will assist in promoting SA in AAM's regulatory and organizational responsibilities.

c. The International Civil Aviation Organization (ICAO) has established frameworks for a State Safety Program in member states and SMS in product/service provider organizations. Because AAM consists of regulatory and product/service provider programs, the organization meets the tenets of both the State Safety Program and SMS ICAO framework.

6. Scope. This order supports FAA Order 8000.369, Safety Management System, which describes the process, scope, and responsibilities of an SMS. The SMC's role in continued improvement of the SMS will be leading efforts in identifying hazards, analyzing and assessing safety risk, and when required, implementing risk controls. The SMC will ensure AAM's safety risk decision making is consistent and meets the requirements in FAA Order VS 8000.367, AVS Safety Management System Requirements.

7. Structure.

a. The Deputy Federal Air Surgeon shall serve as the Council Chairperson, and only the Federal Air Surgeon (FAS) can delegate another AAM director to this position.

b. The SMC core structure shall consist of the following positions:

(1) Deputy Federal Air Surgeon,

(2) Deputy Director, Civil Aerospace Medical Institute (CAMI),

(3) Senior Regional Flight Surgeon,

(4) Director, Medical Specialties Division, and

(5) A representative from the Systems Analysis Branch.

c. The Council Chairperson may choose to supplement this core structure with additional short or long-term members based on the needs of sustaining AAM's SMS.

8. Roles and Responsibilities. The roles within the SMC are as follows:

a. Chairperson. Gives oversight to the council, represents the overall mission of AAM through an executive and leadership point of view, and takes into account both internal and external factors when assessing the effectiveness of AAM SMS actions. The duties of the chair include:

(1) Lead Council meetings as needed to conduct preliminary safety risk analyses and assessments of identified hazards, and to determine the level of safety risk,

(2) Assign safety risks/hazards to the appropriate division responsible for mitigating and conducting SRM,

(3) Lead collaboration within AAM and with external stakeholders to address and mitigate identified risks/hazards,

(4) Ensure AAM Divisions with identified safety risk/hazards conduct SRM to mitigate the risk to an acceptable level,

(5) Collaborate with SMC members and other AAM program managers to identify and submit candidate safety issues for possible inclusion as an AVS or FAA level safety issue,

(6) Approve comments associated with council recommendations,

(7) Present written findings to the Federal Air Surgeon,

(8) Appoint subject matter experts to the council as needed, and

(9) Gather consensus of council recommendations.

b. Council Members. Supports AVS' SMS by participating in AAM's SMS. The duties of the SMC members include:

(1) Each fiscal year, AAM Divisions will establish measurable safety objectives and Acceptable Levels of Safety Performance (ALoS) for their respective areas of responsibilities, and submit through the SMC to the Federal Air Surgeon for approval:

a) The CAMI Representative will facilitate the provision of objectives/ALoS for CAMI based organizations.

b) The Medical Specialties Division representative will facilitate the provision of objectives/ALoS for HQ organizations.

c) The Senior Regional Flight Surgeon will facilitate the provision of objectives/ALoS for regional operations.

(2) Analyze potential hazards and risks identified by or submitted to the SMC,

(3) Assist the Chairperson with identifying the office of primary responsibility (which may be outside of AAM) for risks/hazards identified within AAM,

(4) Conduct independent safety risk analyses on identified risks/hazards,

(5) Identify and submit potential candidate safety issues to the Chairperson,

(6) Attend meetings as needed to assess the severity and likelihood (probability) of the potential outcomes of identified hazards and to make safety risk determinations of hazards,

(7) Vote on determinations/recommendations, and

(8) Recommend subject matter experts to the SMC as needed to support determining/mitigating the severity of an identified hazard.

c. Systems Analysis Branch (AAM-110). Supports the SMC through administrative and logistical actions. The duties of the branch include:

(1) Facilitate the administrative and logistical needs for Council meetings and other requirements of the SMC,

(2) Serve as SMS subject matter experts giving analytical support, advice and guidance to the SMC,

(3) Update the SMC on AVS SMS initiatives,

(4) Capture results of the Council's actions for historical purposes,

(5) Monitor the organization's safety objectives and ALoS, and report potential or actual issues to the Council,

(6) Document SRM processes, recommendations, and dispositions,

(7) Update the Council on the status of any hazards classified as a red/high safety risk,

(8) Conduct SMS program evaluations and assessments, and report results back to council for action, and

(9) Collect and maintain information on SMS activities and update the SMC members on new or open actions.

9. Council Operations. An important goal of the SMC is to minimize logistical and administrative requirements while providing maximum value to AAM. The Council operates as follows:

a. Ensure AAM's safety policy establishes an interface between AAM's SRM process and the requirements outlined in FAA Order 8000.367,

b. Ensure the organization's SRM and safety assurance processes are in accordance with requirements outlined in FAA Order 8040.4,

c. Meet quarterly, or as needed, to conduct assessments and identify hazards/risks,

d. Review select hazards and risks to assess their safety risk level, and submit any red/high hazards to the Federal Air Surgeon for adjudication as soon as possible for risk/hazard acceptance,

e. Conduct safety assurance by monitoring and reviewing hazards/risks to ensure AAM divisions are compliant in their mitigation recommendations,

f. Submit requests for additional analysis and support, including, but not limited to, CAMI SMS teams and Program Management Division program evaluation/auditing resources,

g. The SMC will leverage AAM's current Quality Management System to focus on continued improvement. Management Reviews, Analysis of Data, corrective actions, and internal audits are established processes to ensure compliance with SMS principles,

h. Establish processes to measure the effectiveness of safety risk controls to resolve safety problems,

i. Communicate council findings through the chair to the Federal Air Surgeon at the AAM Management Review and/or through written reports,

j. Identify stakeholders when new requirements or mandates impact AAM operations,

k. Assist AAM-110 with developing metrics to measure the effectiveness of AAM's SMS.

10. Council Recommendations. At each meeting, the council will review AAM's SMS actions and may make recommendations on identified risks/hazards. The Federal Air Surgeon will review the recommendations for approval, with a courtesy copy to AAM managers, identified stakeholders, and the hazard submitter. In all recommendations, the council must be unanimous in its findings. For each specific safety performance metric, hazard identification, SRM, or risk acceptance action, the council can choose to make one of three recommendations:

a. No Recommendation - the council has determined there are no recommendations to provide on the action or hazard. This is not necessarily a statement of approval or acceptance. In some cases, the council may provide no recommendation due to the inability to reach consensus. A "No Recommendation" finding for red/high risk hazards does not imply the group has a specific position on the hazard itself, but does indicate that the hazard/risk case presented meets the minimum requirements for some level of safety risk assessment.

b. Deferred - the council has placed the action back into the queue until the next review. Recommendations regarding red/high level risks or hazards shall not be deferred,

c. Recommendation for Further Investigation - the council has reviewed the action and finds there may be value in investigating the action. This finding is based on the type of action being reviewed.

(1) **Safety Performance Metrics** - the council recommends the system owner may find value in reconsidering if, for example:

a) The action demonstrates the system is establishing, monitoring and continuously improving the acceptable levels of safety performance for its

operational systems,

b) The action demonstrates the system is adequately expressing the required safety performance of AAM systems through a range of mutually supporting and descriptive set of safety metrics,

c) The action demonstrates the system is adequately addressing the complexities of the operational environment.

(2) **Identification of Hazards** - the council recommends the hazard submitter or system owner may find value in reconsidering if, for example:

a) system is actively being explored for potential threats,

b) system is effectively reporting potential threats,

c) hazard is adequately described and documented to support the initial safety risk assessment,

d) system protects reporters of threats from inappropriate disciplinary and/or administrative action.

(3) **Safety Risk Management (SRM) of Hazards** - The Council recommends the hazard submitter or system owner may find value in reconsidering if, for example:

a) system or hazard was adequately analyzed,

b) appropriate stakeholders participated in the SRM process,

c) assessment is in accordance with the safety risk tolerances or control limits of the system,

d) planned mitigations and safety assurance are appropriate and adequate.

(4) **Acceptance of Safety Risk**- the council recommends the hazard submitter or system owner may find value in reconsidering, if for example:

a) system is proactively addressing potential threats,

b) system is effectively managing safety for its areas of operational responsibility,

c) system is considering and balancing the resources available to AAM against the desired level of safety performance,

d) system is monitoring the effectiveness of risk controls and the continuing risk acceptance.

11. Additional Council Actions. For all recommendations, the council may direct other AAM resources to support these efforts, including:

a. AAM-110 investigation of opportunities for improving the AAM SMS,

b. CAMI SMS team analysis to support safety system owners in hazard identification, risk analysis, and/or safety risk assessment,

c. Program Management Division and/or program office management studies and evaluations to assess the implementation and performance of safety systems in AAM, and

d. Initiating follow-on efforts through an SMS/SRM project statement-of-work.

12. Documentation of Council Actions. AAM-110 staff will record council recommendations in writing and forward recommendations with cross-organizational impact to the AVS SMS Coordination Group as necessary. Other SMC internal safety recommendations will be captured in management documents such as Analysis of Data and Management Review.

13. Authority to Change This Order. This order may be changed or canceled by the Federal Air Surgeon.

14. Who Should I Contact. Contact the AAM-110 Manager with any questions or comments.

15. Distribution. Distributed electronically to all AAM divisions, centers, and regions.

Brett Arlo Wyrick

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Brett A. Wyrick, D.O., MPH, FACOS
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Aviation Safety

Appendix A. Definitions

1. Acceptable Level of Safety (ALoS) - The safety goals of an oversight authority, operator, or a service provider. From the perspective of the relationship between oversight authorities and operators/service providers, it provides the minimum safety objective(s) acceptable to the oversight authority to be achieved by the operators/services providers while conducting their core business functions.

2. Aerospace System - U.S. airspace, all manned and unmanned vehicles operating in that airspace, all U.S. aviation operators, airports, airfields, air navigation services, pilots, regulations, policies, procedures, facilities, equipment, and all aviation-related industry.

3. Aircraft Accident - An occurrence associated with the operation of an aircraft, which takes place between the time a person boards the aircraft with the intention to fly and when person(s) have disembarked, and in which any person suffers death or serious injury, or the aircraft receives substantial damage.

4. Corrective Action - Action to eliminate or mitigate the cause or reduce the effects of a detected nonconformance, noncompliance, or other undesirable situation.

5. Hazard - A condition that could foreseeably cause or contribute to an aircraft accident.

6. Likelihood - The estimated probability or frequency, in quantitative or qualitative terms, of a hazard's effect or outcome.

7. Mitigation - A means to reduce or eliminate the effects of hazards. See Safety Risk Control. The terms control, mitigation, and safety risk control are used synonymously.

8. Noncompliance - Conduct that is contrary to a statute, regulation, or order issued under a statute or regulation.

9. Nonconformance - Non-fulfillment of an organization's requirements, policies, and procedures, as well as requirements of safety risk controls developed by the organization.

10. Performance Assurance - The function of ensuring that product/service provider's performance meets safety objectives and that their risk controls are effective.

11. Product/Service Provider - An organization engaged in the delivery of aviation products or services.

12. Safety - The state in which the risk of harm to persons or property damage is acceptable.

13. Safety Assurance (SA) - Processes within the SMS that function systematically to ensure the performance and effectiveness of safety risk controls and that the organization meets or exceeds its safety objectives through the collection, analysis, and assessment of information.

14. Safety Culture - The shared values, actions, and behaviors that demonstrate a commitment to safety over competing goals and demands.

15. Safety Management System (SMS) - The formal, top-down, organization-wide approach to managing safety risk and assuring the effectiveness of safety risk controls. It includes systematic procedures, practices, and policies for the management of safetyrisk.

16. Safety Objective - A measurable goal or desirable outcome related to safety.

17. Safety Oversight - A function by means of which the FAA ensures effective implementation of the safety-related laws, regulations, policies, and procedures. Safety oversight also ensures the national aviation industry provides a safety level equal to or better than the acceptable level defined by theFAA.

18. Safety Performance - Realized or actual safety accomplishment relative to the organization's safety objectives.

19. Safety Policy - The documented commitment to safety of an FAA line of business or staff office, or an aviation service/product provider, organization, or certificate holder, which defines its safety objectives and the accountabilities and responsibilities of its employees with regard tosafety.

20. Safety Promotion - A combination of training and communication of safety information to support the implementation and operation of an SMS in anorganization.

21. Safety Risk - The composite of predicted severity and likelihood of the potential effect of a hazard. The terms risk and safety risk are usedsynonymously.

22. Safety Risk Control - A means to reduce or eliminate the effects of hazards. The terms control, mitigation, and safety risk control are usedsynonymously.

23. Safety Risk Management (SRM) - A process within the SMS composed of describing the system; identifying the hazards; and analyzing, assessing, and controllingrisk.

24. Severity - The consequence or impact of a hazard's effect or outcome in terms of degree of loss or harm.

25. SMS Outputs - The result or product of an SMS process. In this context, the result of a process, which is intended to meet a requirement described in this order (e.g., results of safety data analyses, safety audits, and SRMresults).

26. System - An integrated set of constituent elements combined in an operational or support environment to accomplish a defined objective. These elements include people,hardware, software, firmware, information, procedures, facilities, services, and other support facets.