U.S. DEPARTMENT OF TRANSPORTATION
FEDERAL AVIATION ADMINISTRATION

Aerospace Medicine National Policy

ORDER AM 1110.155

Effective Date: 10/20/17

SUBJ: Aerospace Medicine Safety Management Council

1. Purpose of this Order. This order establishes the operational requirements for the Office of Aerospace Medicine (AAM) Safety Management Council; outlines the roles and responsibilities of the Safety Management Council (SMC); and supports the FAA's and the Aviation Safety (AVS) organization's commitment to implement Risk Based Decision Making (RBDM), Safety Risk Management (SRM), and Safety Assurance (SA) as integral parts of a Safety Management System.

2. Audience. All AAM Employees

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

4. Background.

a. The FAA's mission is "to provide the safest, most efficient aerospace system in the world." To support this mission, the FAA is using a Safety Management System (SMS) to integrate the management of 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 Safety Management Council (SMC). This order will support the AAM's implementation of SMS by providing the AAM SMC the ability to consistently assess potential hazards, provide safety risk determinations, and ensure mitigation of the organization's identified hazards. The SMC will assist AAM in ensuring hazards are identified and risks are managed, and in promoting safety compliance in the areas of AAM's regulatory responsibilities.

c. The International Civil Aviation Organization (ICAO) has established frameworks for a State Safety Program (SSP) in member states and SMS in product/services provider organizations. Because AAM contains regulatory as well as product/services provider's programs, AAM has implemented an SMS which meets the tenets of both the SSP and SMS ICAO framework.

5. Scope. This order supports FAA Order 8000.369, Safety Management System, which describes the process the scope and responsibilities of the Safety Management Councils (SMC) role to support SMS efforts by identifying hazards, analyzing safety risk, assessing safety risk, and developing and implementing risk controls. The SMC will enhance safety risk decision making by ensuring hazards are identified, and managed to acceptable levels throughout the aerospace system.

6. Safety Management Council Structure

a. The Deputy Federal Air Surgeon shall serve as the chairperson, and only the Federal Air Surgeon can delegate another AAM manager to this position,

b. The Safety Management Council (SMC) core structure shall consist of the following positions:

(1) Deputy Federal Air Surgeon (Council Chairperson);

(2) Deputy Director, Civil Aerospace Medical Institute;

(3) Senior Regional Flight Surgeon;

(4) Director, Airmen Medical Certification Division;

(5) Director, Medical Specialties Division; and

(6) A representative from the System Management Branch, AAM-110.

c. The Federal or Deputy Federal Air Surgeon may choose to supplement this core structure with additional short or long-term members based on the needs of AAM SMS

7. Roles and Responsibilities – The roles within the Safety Management Council are as follows:

a. The Chairperson – Provides 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 quarterly, or more frequently if needed, SMC meetings to conduct preliminary safety risk analyses and assessments of identified hazards, and determining the levels of safety risk,

(2) Assign safety risks/hazards to the appropriate division that will be responsible for mitigating and conducting safety risk management (SRM) for the identified safety risks/hazards,

(3) Lead collaboration within AAM, and 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 Significant Issues (SSIs) for inclusion as a AVS or FAA level SSI list,

(6) Conduct voting on recommendations,

(7) Approve comments associated with council recommendations,

(8) Present written findings to AAM-1, and

(9) Appoint subject matter experts to the council as needed.

b. Safety Management Council Members are responsible for supporting risk-based decision making efforts under the AAM SMS, and providing safety risk determinations for safety risk hazards identified. The duties of the SMC members include:

(1) By October of each fiscal year establish measurable safety objectives for the respective areas of responsibilities, and submit through the SMC to the Federal Air Surgeon for approval,

(2) Determine the acceptable level of safety performance for product/service providers for which AAM has oversight responsibilities,

(3) Analyze potential hazards and risks identified by or submitted to the Council,

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

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

(6) Identify and submit potential candidate safety significant issues (SSIs) to the SMC Chairperson,

(7) Attend quarterly, or as needed meetings, to assess the severity and likelihood (probability) of the potential outcomes of identified hazards and to provide safety risk determinations on safety risk hazards,

(8) Vote on determinations/recommendations, and

(9) Recommend subject matter experts to the council as needed to provide support associated with the specific hazards.

c. System Management Branch AAM-110 is responsible for supporting the Safety Management Council (SMC) through administrative, clerical, and logistical actions. The duties of the branch include:

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

(2) Serve as SMS subject matter expert providing 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 safety objectives and report potential or actual issues to the Council,

(6) Ensure documentation of SRM processes conducted,

(7) Provide the Council with updates for issues within HIRMT that are classified as Red/ high safety risk, and

(8) Collect information on activities in the SMS program and provide updates of all new or open activities over the past quarter to the Council members.

8. Council Operations. The SMC is designed to minimize logistical and administrative requirements while providing maximum value to AAM leadership. The council operates as follows:

a. Ensure the AAM Safety policy establishes an interface between AAM Safety Risk Management process and the requirements outlined in *Order 8000.367*,

b. Ensure the organization's SRM and safety assurance processes are in accordance with requirements outlined in the current version of *FAA Order 8040*,

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

d. Review all hazards and risks to assess their safety risk level, and submit all "red/high" hazards to AAM-1 for acceptance of the risk/hazard within 7-business days of receipt from AAM-110,

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

f. Submit to AAM-1 recommendations to provide additional analysis and support, including, but not limited to, the CAMI SMS team and AAM-100 program evaluation and auditing resources,

g. Investigate other areas of concerns related to identified hazards/risks,

h. Communicate, through the council chair, findings to AAM-1 at the AAM Management Review (MR) meeting and though written reports,

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

j. Assist AAM-110 with developing metrics to measure the effectiveness of AAM SMS.

9. Council Recommendations. At each meeting, the council will review AAM SMS actions and may make recommendations. Meetings also may be called to make recommendations on identified risks/hazards. These recommendations are provided to AAM-1, with a courtesy copy provided to AAM managers, to identified stakeholders, and, in the case of hazards, the 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 SMC 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 recommendations due to the inability to reach consensus. A "**No Recommendation**" finding for High Risk/RED hazards does not imply that 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 management assessment.

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

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

(1) Metrics describing safety performance- The council recommends that the system owner may find value in reconsidering if, for example:

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

(b) The action demonstrates that 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 that the system is adequately addressing the complexities of the operational environment.

(2) The identification of hazards- The council recommends that the hazard submitter or system owner may find value in reconsidering if, for example:

(a) The action demonstrates that the system is actively exploring systems for potential threats.

(b) The action demonstrates that the system is effectively reporting potential threats.

(c) The action demonstrates that the hazard is adequately described and documented to support the initial safety risk assessment.

(d) The action demonstrates that the system protects reporters of threats from inappropriate disciplinary and/or administrative action.

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

(a) The action demonstrates the system or hazard has been adequately described or analyzed.

(b) The action demonstrates that appropriate stakeholders have participated in the SRM process.

(c) The action demonstrates that the assessment is in accordance with the intended safety risk tolerances or control limits of the system.

(d) The action demonstrates that planned mitigations and safety assurance are appropriate and adequate.

(4) The acceptance of hazard safety risk- The council recommends that the hazard submitter or system owner may find value in reconsidering if, for example:

(a) The action demonstrates that the system is proactively addressing potential threats.

(b) The action demonstrates that the system is effectively managing safety for its areas of operational responsibility.

(c) The action demonstrates that the system is considering and balancing the resources available to AAM against the desired level of safety performance.

(d) The action demonstrates that the system is monitoring the effectiveness of risk controls and the continuing risk acceptance.

10. Additional Council Actions. For all recommendations, the council may direct various other AAM resources to participate in the support of these efforts, including:

a. AAM-110 investigation of opportunities to improve the AAM SMS,

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

c. AAM-100 and/or program office management studies and evaluations to assess the implementation and performance of safety systems in AAM, and

d. A recommendation to AAM-1 to initiate a follow-on effort through an SMS/SRM project statement-of-work.

11. Documentation of Council Actions. The recommendations of the council are formally captured in writing by AAM-110 staff. Recommendations related to hazards are captured in the Hazard Identification, Risk Management Tracking (HIRMT) tool, while recommendations outside of HIRMT are captured in AAM Safety Management Council documents, through the Analysis of Data and Management Review process, and through SMS/SRM project statements of work.

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

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

14. Distribution. Distributed electronically to all AAM Divisions and Regions.

Michael A Berry, M.D.,
Federal Air Surgeon, AAM-1

Appendix A. Definitions

1. Acceptable Risk – The level of risk that individuals or groups are willing to accept given the benefits gained. Each organization will have its own acceptable risk level, which is derived from its legal and regulatory compliance responsibilities, its threat profile, and its business/organizational drivers and impacts.

2. Accident – An unplanned event or series of events that results in death, injury, or damage to, or loss of, equipment or property.

3. 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.

4. Aircraft Accident – An occurrence associated with the operation of an aircraft which takes place between the time any person boards the aircraft with the intention of flight and all such persons have disembarked, and in which any person suffers death or serious injury, or in which the aircraft receives substantial damage.

5. Corrective Action – Action to eliminate or mitigate the cause or reduce the effects of a detected nonconformity, noncompliance, or other undesirable situation.

6. Design Assurance – The function of ensuring that the safety of product/service provider's designs are in compliance with established requirements and standards and the designs include the appropriate safety risk controls to meet safety objectives.

7. Hazard – A condition that could foreseeably cause or contribute to an aircraft accident.

8. Incident – An occurrence other than an accident that affects or could affect the safety of operations.

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

10. 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.

11. Noncompliance – Conduct that is contrary to a statute, regulation, or order issued under a statute or regulation.

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

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

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

15. Risk – See Safety Risk. The terms *Risk* and *Safety Risk* are used synonymously.

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

17. Safety Assurance – 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.

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

19. 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 safety risk.

20. Safety Objective – A measurable goal or desirable outcome related to safety.

21. 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 the FAA.

22. Safety Performance – Realized or actual safety accomplishment relative to the organization's safety objectives.

23. 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 to safety.

24. Safety Promotion – A combination of training and communication of safety information to support the implementation and operation of an SMS in an organization.

25. Safety Risk – The composite of predicted severity and likelihood of the potential effect of a hazard.

26. Safety Risk Control – A means to reduce or eliminate the effects of hazards. The terms *Control*, *Mitigation*, and *Safety Risk Control* are used synonymously.

27. Safety Risk Management (SRM) – A process within the SMS composed of describing the system; identifying the hazards; and analyzing, assessing, and controlling risk.

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

29. 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 SRM results).

30. System – An integrated set of constituent elements that are 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.

Appendix B. Acronyms

a. **ASIAS** – Aviation Safety Information Analysis and Sharing

b. **AVS** – Aviation Safety Organization

c. **HIRMT** – Hazard Identification, Risk Management and Tracking

d. **ICAO** – International Civil Aviation Organization

e. **LOB** – Line of Business

f. **OPR** – Office of Primary Responsibility

g. **NAS** – National Airspace System

h. **NTSB** – National Transportation Safety Board

i. **SMS** – Safety Management System

j. **SPAS** – Safety Performance Analysis System

k. **SMC** – Safety Management Council

l. **SRM** – Safety Risk Management

m. **SSI** – Significant Safety Issue

n. **SSP** – State Safety Program

Appendix C. FAA Form 1320-19, Directive Feedback Information

Please submit any written comment or recommendation for improving this directive, or suggest new items or subjects to be added to it. Also, if you find an error, please tell us about it.

Subject: FAA Order AM 1110.155 - Aerospace Medicine Safety Management Council

To: Directives Management Officer AAM-1

(Please mark all appropriate line items.)

☐ An error (procedural or typographical) has been noted in paragraph Click here to enter text. on page Click here to enter text.

☐ Recommend paragraph Click here to enter text. on page Click here to enter text. be changed as follows:
(Attach separate sheet if necessary.)

Click here to enter text.

☐ In a future change to this Order, please cover the following subject:
(Briefly describe what you want added.)

Click here to enter text.

☐ Other comments:

Click here to enter text.

☐ I would like to discuss the above. Please contact me.

Submitted by: _____ Date: _____

FAA Form 1320-19 (10-98)