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Federal Aviation Administration
William J. Hughes Technical Center
Aviation Research Division
Atlantic City International Airport
New Jersey 08405

# Survey of Performance-Based and Risk-Based Oversight Strategies and Methods

August 2025

InterimTechnical report

U.S. Department of Transportation
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16. Abstract


Recent changes in aviation safety oversight in the Federal Aviation Administration (FAA) and globally have incorporated performance-based oversight (PBO) which assess organization management system effectiveness in achieving defined safety objectives. PBO is intended to be complementary to traditional compliance-based oversight which examines conformance to prescriptive rules and regulations as well as risk-based oversight (RBO) which aligns oversight focus and frequency with risk. To address FAA’s Future of Oversight research objectives, this report documents results of a literature survey and catalog of current oversight mechanisms in aviation and other industries, focusing on performance-based and risk-based oversight. Findings inform potential areas for additional research or improvements under the FAA’s Future of Oversight research program. This report describes the literature survey approach and interviews conducted with FAA aviation safety experts that identified current challenges and future considerations for adapting oversight approaches for PBO and performance-based regulations regarding safety management in aviation. A survey of safety management systems across industries including aviation, nuclear energy, oil & gas, and public transit, among others is documented along with literature review results and findings on PBO and RBO concepts, methods, and implementation as well as lessons learned.


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## Acronyms

| Acronym | Definition |
|---|---|
| AAC | Approval, Acceptance, and Concurrence |
| AAM | FAA Aerospace Medicine |
| AFS | Flight Standards |
| AIR | Air Certification |
| AME | Aviation Medical Examiner |
| AOV | Air Traffic Safety Oversight |
| API | American Petroleum Institute |
| ATO | Air Traffic Organization |
| AVP | Office of Accident Investigation and Prevention |
| AVS | Aviation Safety |
| BSEE | Bureau of Safety and Environmental Enforcement |
| CDER | Center for Drug Evaluation and Research |
| CFR | Code of Federal Regulations |
| COS | Continued Operational Safety |
| CS | Certification Specifications |
| CTO | Control Tower Operator |
| DCT | Data Collection Tool |
| DOE | Department of Energy |
| DOT | Department of Transportation |
| EASA | European Union Aviation Safety Agency |
| EI | Effective Implementation |
| FAA | Federal Aviation Administration |
| FDA | Food & Drug Administration |
| FSMA | Food Safety and Modernization Act |
| IATA | International Air Transport Association |
| ICAO | International Aviation Civil Organization |
| INC | Incident of Noncompliance |
| IOSA | IATA Operational Safety Audit Program |
| ISA | Integrated Safety Analysis |
| ISARP | IOSA Standards And Recommended Practices |
| ISM | Integrated Safety Management |

| **Acronym** | **Definition** |
|---|---|
| MMS | Minerals Management Service |
| MSAD | Monitor Safety/Analyze Data |
| NAS | National Airspace System |
| NPRM | Notice of Proposed Rulemaking |
| NRC | Nuclear Regulatory Commission |
| NTSB | National Transportation Safety Board |
| OCS | Outer Continental Shelf |
| OEP | Oversight and Enforcement Program |
| PBO | Performance Based Oversight |
| RBO | Risk Based Oversight |
| RBRT | Risk Based Resource Targeting |
| ROP | Reactor Oversight Process |
| SEMS | Safety & Environment Management System |
| SM ICG | Safety Management International Collaboration Group |
| SMC | Safety Management Council |
| SMS | Safety Management System |
| SOC | Safety Oversight Circular |
| SRM | Safety Risk Management |
| USOAP | Universal Safety Oversight Audit Program |

## Executive summary

The National Airspace System (NAS) and aviation industry are continually evolving with innovative aircraft technologies and vehicles, emerging operations such as advanced air mobility, and increasing complex and global infrastructure to produce and maintain aerospace products. To meet these challenges, the FAA launched a research initiative, Future of Oversight, to inform the implementation of performance-based oversight, including regulations and associated systems; proactive monitoring of safety performance and risks for aviation operating sectors; and adaptation of oversight plans and actions accordingly, in alignment with public expectations for safety. The future of FAA oversight, according to the FAA's vision described in a 2014 Aviation Rulemaking Committee report, encompasses principles for both traditional, compliance-based oversight and performance-based oversight, which "focuses FAA resources on areas of higher risk in the aviation system and moves the FAA from a total dependence on compliance findings, audits, and inspections to a more effective approach of monitoring safety and compliance performance data from the aviation industry." (FAA, 2014).

To achieve the highest levels of aviation safety, the U.S. State Safety Program presents goals for performance-based and compliance-based oversight. Per the State Safety Program, the FAA will apply a performance-based approach in safety regulation and industry oversight activities and measure and monitor aviation safety performance, which is informed by safety indicators and results from oversight activities, both compliance-based and performance-based (FAA & NTSB, 2021). A key enabler for this approach is the aviation industry implementation of Safety Management Systems and associated FAA safety oversight models and risk-based decision making.

As a first step of the Future of Oversight research initiative, FAA Aviation Safety (AVS) sponsors tasked the William J Hughes Technical Center Aviation Research Division (ANG-E2) with conducting a literature review and stakeholder engagement to catalog and benchmark current oversight mechanisms used in aviation and other industries, focusing on performance-based and risk-based oversight strategies, to help identify potential areas for FAA focused research. To address this objective, interviews were conducted with AVS safety experts, leaders, and stakeholders between December 2023 and April 2024, and over two hundred reference sources on safety management system regulations and performance-based and risk-based oversight strategies were surveyed across aviation, public transit, nuclear energy, and oil and gas industries, among others. This report synthesizes the results and findings from interviews and literature reviews and provides key findings and recommendations for Future of Oversight research focus areas.

Certain themes emerged during stakeholder interviews, highlighting ongoing challenges and considerations for adapting oversight approaches for performance-based regulations for safety management and performance-based oversight:

- Regulatory framework changes necessitate changes in oversight methods and tools
- Future oversight strategies must incorporate surveillance on changing operations and technology
- Cross-organization oversight integration and industry collaboration are needed for effective and efficient risk-based oversight
- Workforce development and safety culture investments are needed to facilitate performance-based and risk-based oversight

These themes were applied to refine the literature research across aviation, energy, oil and gas, and food safety industries for associated safety management regulations and oversight methods. Several key findings derived from both research interviews and the literature surveyed are outlined below:

- Performance-based and risk-based oversight methods are not intended to replace compliance-based oversight; instead, these methods are part of a comprehensive oversight regime that allows regulatory authorities to not only verify compliance through audits and inspections, but also assess safety performance and evaluate the suitability of risk management processes in place.
- Oversight process changes should be piloted in a limited area and assessed for issues, effectiveness, and lessons learned, as well as scalability and resource needs for broader implementation. Follow-up evaluation of pilot oversight process changes, and broader implementation should be incorporated in recurring oversight effectiveness evaluations.
- Oversight mechanisms designed to gather information on ongoing and planned regulated entity changes to systems, processes, tools, and technologies are needed for forward oversight planning and as data points to verify and validate that Safety Risk Management (SRM) and safety assurance are being applied appropriately and consistently for such changes.
- A positive safety culture and a workforce that is trained and confident in their work functions and their safety impacts are important elements for a positive and effective adoption of performance-based oversight.
- Safety performance goals and measures can be specific to hazards and outcomes but there is an opportunity to apply measures at additional points in a risk model (e.g., barrier

performance), including the influence of oversight actions throughout the model, which supports proactive safety action.

- Safety performance indicators should build in threshold progressions with margins of safety that allow time for both regulated entity and regulatory oversight intervention and escalation as needed.

To further improve the FAA's performance-based oversight, the following topics are proposed for further research:

**(1)** **Safety Objectives.** Define clear, measurable safety objectives for performance-based oversight by the aviation sector and for communication within FAA oversight organizations and with industry.

**(2)** **SMS Effectiveness Objectives and Indicators**. Explore whether a minimum set of safety objectives and safety performance indicators can be standardized across regulated entities for SMS effectiveness evaluation to reduce regulatory burden in tailoring oversight guidance for each regulated entity's SMS implementation.

**(3)** **Applying Performance Thresholds**. Determine how to incorporate safety objectives into recurring baseline inspections that are risk-based with thresholds for performance that inform forward planning for future oversight activities.

**(4)** **Safety Benefit Validation**. To validate the safety benefits of effective SMS implementation for Part 121 and other federal aviation regulation parts with sufficient implementation history, compare safety performance results by regulated entity before and after SMS implementation phases, including voluntary implementation (where applicable) and mandatory. Results may help promote aviation industry investment in continued safety improvements and safety culture or point out SMS components that need improvement.

**(5)** **Applying Performance-Based Regulation Lessons**. Identify historical (non-FAA) oversight effectiveness problems with safety-related, performance-based regulations and what the regulator did afterward to improve regulations and oversight methods and procedures. Determine how these lessons learned can be incorporated into FAA performance-based oversight implementation approaches and guidance for developing performance-based regulations.

**(6)** **Safety Culture Evaluation**. Develop actionable safety culture evaluation criteria and guidance with thresholds for additional evaluation or oversight responses.

**(7)** **Stress Testing Oversight Processes**. Explore opportunities for safety improvements in FAA oversight processes for assessing quality and safety management effectiveness, leveraging data collected from observing inspections/audits in the field and table-top experiments to assess the inspection/audit process effectiveness in detecting and characterizing quality and safety management process lapses.

**(8)** **Risk Barrier Modeling and Evaluation**. Research the use of risk barrier models to understand how oversight methods can be applied as risk mitigations and determine if such models can provide a framework for recurring evaluation of oversight effectiveness in reducing risk.

**(9)** **Risk Interdependencies**. Research methods and means to identify and manage risk interdependencies across regulated entities and topics such as safety and security and align reporting approaches to foster government/industry cooperation and collaboration.

**(10)** **SMS Implementation Knowledge Sharing**. Research joint industry/government forums to establish and guide information exchanges on SMS implementation, including issues and best practices developed in a collaborative manner.

This report summarizes the results of the initial research task focused on a review of performance-based and risk-based oversight methods. An update to this report planned for September 2024 is intended to incorporate the results from a follow-up, targeted literature review to address findings from oversight stakeholder interviews and additional considerations for benchmarking performance-based oversight methods and features. The following research task, also due by September 30, 2024, is to conduct a review of oversight systems and tools currently used in aviation to understand to what extent regulators or aviation companies have automated their oversight processes on product/service providers including oversight of both prescriptive regulations and performance-based regulations.

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# 1 Introduction

The aviation industry and National Airspace System (NAS) are continually evolving with innovative aircraft technologies and vehicles, emerging operations such as advanced air mobility, and increasing complex and global infrastructure to produce and maintain aerospace products. To meet these challenges, the FAA launched a research initiative, Future of Oversight, to inform implementation of performance-based oversight, including regulations and associated systems; proactive monitoring of safety performance and risks for aviation operating sectors; and adaptation of oversight plans and actions accordingly, in alignment with public expectations for safety. Traditional oversight within the FAA assures that regulated entities comply with regulations, standards, and associated procedures (FAA, 2017). The future of FAA oversight, according to the FAA's vision described in a 2014 Aviation Rulemaking Committee report, encompasses principles for both traditional, compliance-based oversight and performance-based oversight which "focuses FAA resources on areas of higher risk in the aviation system and moves the FAA from a total dependence on compliance findings, audits, and inspections to a more effective approach of monitoring safety and compliance performance data from the aviation industry" (FAA, 2014).

To achieve the highest levels of aviation safety, the U.S. State Safety Program presents certain policy goals for performance-based and compliance-based oversight. Per the State Safety Program, the FAA will apply a performance-based approach in safety regulation and industry oversight activities and measure and monitor aviation safety performance which is informed by safety indicators and results from oversight activities, both compliance-based and performance-based (FAA & NTSB, 2021). A key enabler for this approach is aviation industry implementation of Safety Management Systems and associated FAA safety oversight models and risk-based decision making.

As a first step of the Future of Oversight research initiative, FAA AVS sponsors tasked the William J Hughes Technical Center Aviation Research Division (ANG-E2) to conduct a literature review and stakeholder engagement to catalog and benchmark current oversight mechanisms used in aviation and other industries, focusing on performance-based and risk-based oversight strategies, to help identify potential areas for focused research or improvements for the FAA. To address this objective, interviews were conducted with AVS safety experts, leaders, and stakeholders between December 2023 and April 2024, and over two hundred reference sources on performance-based safety management system regulations and oversight strategies were collected and surveyed across aviation, public transit, nuclear energy, and oil & gas industries, among others. This report synthesizes the results and findings from interviews and literature reviews and provides key findings and recommendations for Future of Oversight research focus areas.

## 1.1 Purpose of report

This report is intended to catalog and benchmark current oversight mechanisms in aviation and other industries, focusing on performance-based and risk-based oversight, to identify potential areas for research or improvements under the FAA's future of oversight research program.

## 1.2 Definitions

The following definitions of performance-based and risk-based oversight are adapted from International Civil Aviation Organization (ICAO) safety terminology (ICAO SM ICG, 2022) and Nuclear Regulatory Commission (NRC) guidance (NRC, 2024).

- **Performance-Based Oversight** – Assessment of an organization's management system effectiveness in achieving defined safety objectives. PBO identifies and assesses safety performance measures that ensure an adequate safety margin and offer incentives to improve safety without formal regulatory intervention.
- **Performance-Based Regulation** – A regulatory approach that focuses on desired, measurable outcomes, rather than prescriptive processes, techniques, or procedures. Performance-based regulation leads to defined results without specific direction regarding how those results are to be obtained.
- **Prescriptive Regulation** – A regulatory approach that specifies the means of compliance such as particular features, actions, and or programmatic elements to achieve a desired objective.
- **Risk-Based Oversight (RBO)** – An approach where oversight surveillance activities are prioritized based on the risk involved in regulated entity scope, operations, products, and processes.
- **Safety Performance Indicator** – A measurable, data-based parameter used to assess and monitor a regulated entity's safety achievement relative to a planned or desired outcome or service for a given time period.

# 2 Approach

This section provides an explanation of the approaches taken to review relevant literature, conduct and document results of interviews, and develop a methodology for benchmarking the relative capability of aviation safety oversight organizations.

## 2.1 Literature review

A literature review was initiated in December 2023 based on a compilation of 215 documents and other media addressing safety regulations, safety management systems, and oversight approaches provided by the FAA WJTHC technical monitor for this task. The compiled reference sources were categorized by industry and topic and prioritized for review based on authority and relevancy with respect to the purpose of this report in cataloging current aviation and other industry oversight methods with a special attention to performance-based and risk-based oversight applications. A list of the initial surveyed literature not cited as direct references herein is provided as an annex to this report.

The literature review was refined to focus on material that addresses key themes and guidance from FAA Aviation Safety (AVS) research interviews conducted in February and March 2024 as described in Section 2.2. As a result, literature from the initial survey was down-selected resulting in the 82 citations referenced throughout this report and summarized in in Section 11.

## 2.2 Interviews

Interviews were conducted with FAA aviation safety leads and stakeholders with deep experience across the spectrum of oversight roles and responsibilities in the FAA AVS community. FAA representatives from Flight Standards (AFS), Aircraft Certification (AIR), and the Office of Accident Investigation & Prevention (AVP) organizations participated in research interviews in February and March 2024 and provided insights, recommendations, and references in response to a series of interview questions. In addition, AFS stakeholders conducted a demonstration on the use of FAA's Safety Assurance System for oversight planning, data collection, and analysis. Representatives from the FAA Air Traffic Safety Oversight Service (AOV) and Office of Aerospace Medicine (AAM) also provided responses to research questions and background material incorporated in this report. Lastly, AVS representatives with prior experience in safety management leadership roles in the airline and aircraft maintenance industries as well as in nuclear safety under the Nuclear Regulatory Commission provided additional insights into oversight successes and challenges from those industry and regulatory perspectives.

FAA oversight needs across AVS and anticipated future challenges for oversight based on the research interviews conducted for this report are as follows:

**1. Regulatory framework changes necessitate changes in oversight methods and tools**

**(a)** Oversight resources, methods, and tools need to accommodate oversight of both prescriptive and performance-based regulations, as regulatory changes expand to incorporate more performance-based elements such as a Safety Management System (SMS) while retaining prescriptive regulations for safety critical operations and systems (multiple AVS organizations).

**(b)** Risk-based oversight strategies should include both compliance-based and performance-based elements, where compliance issues and safety performance, including SMS effectiveness issues, inform risk-based priorities for oversight focus areas, frequencies, and regulated entities (AFS).

**(c)** Specific approaches to defining safety objectives, measuring safety performance, and evaluating safety management effectiveness must be defined and validated along with strategies to assure industry self-correction is occurring and effective (AIR).

**(d)** Oversight methods and approaches should be agile and mature over time – for example, initially focusing on assessing the implementation and application of specific processes such as SMS and later focusing on measures that reflect effectiveness of safety risk management processes (AIR).

**(e)** Oversight of SMS effectiveness will require a "look-back" approach similar to root cause analyses, where the approach to issue identification and corrective action are supplemented by an approach to determine which SMS or other management system gaps and process lapses allowed the failure to occur (AIR).

**2. Oversight strategies must incorporate surveillance on changing operations and technology**

**(a)** Aviation industry and technologies are changing quickly, and as new and modified technologies and operations are introduced in the National Airspace System (NAS), the FAA needs to develop a comprehensive and independent understanding of those new technologies and operations, and especially safety-significant changes, to provide effective oversight (multiple AVS organizations).

**3. Cross-organization oversight integration and industry collaboration is needed for effective and efficient risk-based oversight**

**(a)** Oversight methods and tools that can be tailored for specific oversight needs within AVS organizations can also adapt to address provisions for performance-based oversight as related oversight processes are expanded and matured. As oversight tools become more integrated to meet needs across AVS, there is a greater need for data sharing among oversight organizations to realize the benefits of those integrated tools in risk-based oversight planning and prioritization (AIR).

**(b)** Oversight should take a holistic approach that accounts for how activities of different AVS organizations impact one another and the same regulated entities engaged in multiple oversight activities (AIR).

**(c)** Some regulated entities lack knowledge and understanding of SMS, certification, and FAA continued operational safety policy and processes; the FAA will need to improve and expand resources for industry education and collaboration, as this area currently consumes many oversight resources (multiple AVS organizations).

**4. Workforce development and both FAA and industry safety culture investments are needed to facilitate successful performance-based and risk-based oversight implementation**

**(a)** An evolution of the oversight workforce is needed, focusing on expanding knowledge, experience, and confidence in applying performance-based oversight (multiple AVS organizations).

**(b)** Expectations for the required workforce development timeframe to adopt performance-based oversight need to be realistic in planning for expected outcomes and benefits (AIR).

**(c)** Workforce training needs to address changes in approach and mindsets between compliance-focused and performance-based oversight (AFS), including the use of systems-level thinking to evaluate the effectiveness of the regulated entity management systems and to interpret and respond to collected oversight data (multiple AVS organizations).

**(d)** Actions focused on achieving desired transparency and information sharing are needed both within the FAA and between FAA and regulated entities; this could include inputs to specific oversight methods as well as other activities to drive a positive safety culture (AVP, AIR). Success cases and lessons-learned can also be documented and shared as part of this activity (AFS).

**(e)** When the aviation system appears to be safe, it can be difficult to motivate industry to invest in continued safety improvements and to fully promote SMS and safety culture principles within its operations and processes (multiple AVS organizations)

These themes for AVS oversight needs and challenges were used to guide aspects of the literature research to catalog aviation and other industry oversight methods and strategies with a focus on performance-based and risk-based elements of most benefit for future FAA oversight research.

## 2.3 Benchmarks

The concept of benchmarking is useful for establishing a frame of reference to gauge existing capabilities and identify potential areas of improvement. Initial investigation into non-aviation regulatory agencies within the United States has led to identification of several attributes that are relevant to aviation safety oversight. This information could be used as the basis for developing benchmarks to reflect the relative maturity of an oversight organization's capability. As with other benchmarking schemes, this would allow identification of strengths and weaknesses and provide a roadmap to more effective oversight practices that lead to the achievement of benchmark capabilities.

In reviewing current regulations, as well as proposals and recommendations for oversight, themes emerge across a variety of regulatory agencies who have demonstrated maturity in their capabilities over time. One clear theme is a migration away from sole reliance on prescriptive regulations and towards performance-based regulations that specify what must be achieved, but not how it must be achieved. Another theme is transitioning away from audits limited to verification of compliance documentation and binary pass/fail checklists in favor of more comprehensive inspections by personnel with expertise and experience in the field, with inspectors interacting with employees on site at company facilities to gauge process effectiveness (e.g., in controlling risk). Additionally, the ability of the regulator to understand and conduct its own independent risk analysis to verify the results submitted by regulated organizations has improved over time and migrated to a more objective, data-driven analysis. Finally, the most robust oversight methods are holistic in nature and include analysis supporting oversight decisions that simultaneously protect personnel, assets, and the environment from any safety hazard or security threat.

With these observations in mind, a set of benchmarks could be created to allow any aviation regulatory organization to evaluate its capabilities, gain insight into the nature of improvements that would be needed for its oversight capabilities to mature, and for measuring progress over time as the agency advances to higher levels, supporting the achievement of organization-level objectives. Table 1 presents one possibility for such a set of benchmarks at five different levels of performance.

Table 1: Benchmarks for aviation regulatory oversight

| ***Level*** | **Attributes** |
|---|---|
| *1* | Prescriptive requirements<br>Yes/No inspection checklists<br>Remote audits of documentation<br>Limited insight into regulated entity changes<br>No risk analysis capability at regulatory level |

| *Level* | **Attributes** |
|---|---|
| *2* | Categorical severity & likelihood scales<br>Reliance on qualitative analysis and consensus<br>On site audits and inspections<br>Required reporting of regulated entity changes<br>Non-punitive whistleblower program |
| *3* | Performance-based requirements & regulations<br>Measurable safety metrics & objectives<br>Discrete probabilistic risk analysis<br>Consistent, repeatable method for establishing acceptability of risk<br>Independent means of identifying regulated entity changes<br>On site expert inspections of facilities and processes |
| *4* | Standardized taxonomy & analytic framework<br>Integrated data collection and analysis<br>Statistically valid performance targets & risk validation<br>Independent means for identifying and assessing safety criticality of regulated entity changes<br>Risk-informed, performance-based requirements & regulations |
| *5* | Automation tools for ease of data access & analytics<br>Continuous severity & likelihood scales<br>Continuous probabilistic risk analysis<br>Independent means for identifying and assessing safety criticality of regulated entity changes with associated oversight criteria and guidance<br>Holistic, integrated safety, security, and environmental risk management<br>Risk-informed decision analysis |

## 2.4 Limitations

Development of this report was scoped as a five-month effort and is necessarily broad based on schedule and the objective to catalog performance-based oversight approaches across multiple industries. Also, since FAA interviews were conducted later during this survey, additional literature collection and review for the performance-based oversight topics and challenges cited during interviews was limited by the remaining time to complete the initial report. An update to this report by September 2024 is intended to incorporate the results from additional, targeted literature surveys to address interview findings as well as a survey of oversight systems and tools currently used in aviation.

For aviation, this report does not address Organization Designation Authorization (ODA) nor Designee Management Systems, and whether findings and recommendations may differ for ODA or designee responsibilities vs. FAA Aviation Safety oversight organizations.

Lastly, this report also does not catalog oversight workforce competencies, development, and training methods nor workforce or organizational safety culture, since the focus is on oversight methods.  However, this report does note where surveyed literature and stakeholder interviews identified such topics as key for successful performance-based oversight implementation.

# 3 Survey of safety management systems

ICAO and other regulatory organizations generally describe safety management systems as a methodical approach to managing safety, including organizational structures, accountability, responsibilities, policies, and procedures.  Safety management systems may be specified as performance-based, prescriptive, or a hybrid of both.  Examples of each were found in a survey of systems across industries presented in this section.

## 3.1 SMS in aviation

### 3.1.1 ICAO Annex 19 Safety Management

ICAO Annex 19 Safety Management establishes Standards and Recommended Practices (SARPs) for member state safety programs (e.g., regulatory oversight) and aviation product and service provider safety management systems (ICAO, 2016).  In addition to establishing state safety policies and objectives, member states and aviation product / service providers are responsible for safety risk management, safety assurance, and safety promotion, which are components of a safety management system.  For member states, critical elements for a state safety oversight systems include: operating regulations; qualified technical personnel; technical guidance, tools, and provision of safety-critical information; licensing, certification, authorization, and approval obligations; surveillance obligations; and resolution of safety issues, among others.  For aviation product and service providers, ICAO's Safety Management Manual provides guidance for "organizational structures, accountability, responsibilities, policies and procedures" that comprise safety management systems (ICAO, 2018).  ICAO Annex 19 safety management system SARPs for aviation product/service providers apply to operator, training, and maintenance organizations; design and manufacturing organizations; and air traffic service providers and tower operators, among others.

As noted in the U.S. State Safety Program, the FAA has both regulatory oversight organizations and aviation product/service provider organizations.  Accordingly, the FAA chose to implement and harmonize agency-level and organization-level safety management systems, addressing both of these roles.

### 3.1.2 US air carrier and commercial operators SMS – FAR Part 5

Title 14 CFR Part 5, published in 2015, required air carriers and commercial operators (Part 121) to implement an SMS that meets the requirements of the rule by 2018, with implementation plans subject to FAA approval by 2016. To align with ICAO Annex 19 requirements, the FAA's 2021 Notice of Proposed Rulemaking updated and expanded the Part 5 rule to Part 135 operators, Part 91 air tour operators, and certain certificate holders under Part 21.

Part 5 defines SMS as "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" (Code of Federal Regulations, 2023). The SMS includes four components: safety policy, safety risk management, safety assurance, and safety promotion.

Safety policy must be documented and communicated in the certificate holder's organization and specify measurable safety goals or desirable outcome (i.e., safety objectives), meaning that the holder determines the objectives. The policy addresses SMS-related roles and responsibilities, including a single accountable executive who must sign the safety policy and is responsible for the certificate holder's safety performance and resource control (financial and human). Other safety roles and responsibilities include management members responsible for implementing, facilitating, and updating the four safety process components and a management member who is authorized to accept safety risk. The policy must address employee reporting of safety concerns and prescribe disciplinary action for unacceptable behavior such as substance abuse or employee criminal activity, among others. Finally, safety policy must cover emergency response authority, employee responsibilities during emergencies, and coordination with interfacing organizations involved in emergency response plans. Per the Notice of Public Rulemaking (NPRM) for Part 5, the accountable executive and management members with SMS responsibilities are not required to be dedicated roles, i.e., they may perform other non-SMS duties.

Per Part 5 (Subpart C), SRM is required for certain situations. These include implementation of new systems, modification of existing systems, development of operational procedures, and outputs of the safety assurance process that identify hazards or ineffective risk controls. Processes for analyzing and assessing risk must be developed, allowing the certificate holder to compare its forecasted risk to its own standard for acceptability, and to inform decisions regarding the need for additional safety risk controls. The rule does not explicitly require that proposed risk controls themselves be evaluated for potential risks (e.g., unintended consequences).

Safety assurance (Subpart D) requires certificate holders to develop processes, systems, and data acquisition and analysis to monitor the organization's safety performance and operating environment changes along with data to support such monitoring. Safety assurance provisions also require processes for auditing and evaluating the effectiveness of the SMS, accident/ incident investigation, and reported non-compliance with regulatory standards or certificate holder-identified safety risk controls. A confidential employee reporting system to express safety concerns and hazards along with candidate solutions and safety improvements is required. Safety assurance also involves risk validation, comparing the organization's observed safety performance to its predicted performance, and to its safety objectives. Lastly, as part of assurance, the certificate holder is required to have processes in place to identify gaps in the SMS and to allow for continuous improvement or maturity of the system.

Safety promotion (Subpart E) requires provision of training to ensure competency in SMS for specific personnel who provide safety accountability and authority – namely, the accountable executive, all management members involved in SMS implementation, and employees who support SMS activities. Promotion also addresses required safety information communications to ensure employee awareness of the certificate holder's SMS provisions (relevant to their role), disseminate hazard information, and explain implemented safety actions and rationale for modified safety procedures.

SMS documentation and recordkeeping (Subpart F) requires that the certificate holder document and update safety policy and SMS processes and procedures. Records are required for SRM and safety assurance process outputs, training, and communications with differing retention schedules. For example, training records must be retained while personnel are still employed, and safety promotion-related communications must be retained for 2 years.

The Part 5 rule is performance-based, permitting certificate holders to use existing programs, policies, or procedures to meet the requirements. The certificate holder's SMS must be appropriate to the size, scope, and complexity of that holder's operations. The rule does not define which systems are subject to SRM but has provisions for systems analysis of functions, operating environment, and operating resources as context for hazard identification. Of note, the rule permits the certificate holder to define the acceptable level of safety risk but provides no guidance on how to do so, though the Notice of Proposed Rulemaking that preceded the final Part 5 rule noted that determining acceptable risk is predicated on corresponding regulatory requirements and technical or performance standards. where "use of severity / likelihood is one method of analyzing hazard risk." How the certificate holder develops or documents a manual for its SMS is not specified, and air carriers may address SMS in pre-existing FAR 121.133

requirements for manuals on the use and guidance of flight, ground operations, and management personnel in conducting its operations. Recordkeeping formats or media are not specified, and no requirements for minimum scope and frequency of audits or reporting audits to the regulator are specified. Similarly, the scope, frequency, and methods for training are not specified by the rule.

### 3.1.3 EASA commercial air transport SMS

For European commercial air transport operators, EASA explains that "EU requirements for a safety management system (SMS) are embedded into the [EU] management system framework. Such framework addresses the core elements of the ICAO SMS as defined in Appendix 2 to ICAO Annex 19 (EASA, 2024)." The EU management system framework encompasses not only SMS, but also other management systems required for air transport operations such as training, crew resource management systems, inspections, and security, among others. Some of the provisions for managements systems relevant to safety as outlined by EASA include:

- Defined accountability and responsibility
- Safety policy and related safety objectives
- Occurrence reporting
- Internal safety reporting per "just culture" principles
- Identification, evaluation, and risk management of aviation safety hazards based on operator activities
- Verification of risk mitigation action effectiveness
- Compliance monitoring
- Trained, competent, and informed personnel with awareness of significant safety issues
- Documentation for all management system key processes

### 3.1.4 SMS for use of US government aircraft

Title 41 Public Contracts and Property Management 102-33.180 applies to US government executive branch agencies that use government aircraft for official business with exemptions for armed forces among others. The rule requires an SMS compliant with FAA's current advisory circular (not identified in 102-33.180) or an internationally recognized SMS by 2015. The rule specifies qualifications for aviation safety managers and safety officers responsible for an agency's aviation safety program, including pilot, crew, maintenance, or aviation management experience and graduation or certification from an aviation safety officer course. An accident prevention program is required with provisions for measurable accident prevention procedures (with examples cited for safety reviews, proficiency evaluations, and hazard analyses), a safety award program, and compliance with GSA's Gold Standard Program. Of note, 41 CFR 102-33.180 requires "policies that require the use of independent, unbiased inspectors to verify compliance with the standards called for in this [SMS]." Standards for acceptable safety behavior are required (in contrast with other SMS rules that specify misconduct and unacceptable behavior). A security program is also required within the provisions for aviation safety management.

### 3.1.5 Airports SMS

Tite 14 Part 139 Certification of Airports Part E Airport Safety Management System requires SMS implementation for large, medium, and small hub airports, ports of entry, designated international airports, and others. The SMS applies to aircraft operation in movement areas (e.g., taxiways) and non-movement areas (e.g., ramps) and other airport operations covered by Part 139. A data sharing and reporting plan is permitted between airport tenants subject to both the Part 5 SMS rule and the Part 139 certificate holder, while the Part 139 holder has final responsibility for compliance with its developed airport SMS. SMS requirements are organized by the four pillars. Under safety promotion, a safety awareness orientation (including hazard identification and reporting) is required for anyone authorized to access the airport areas regulated under Part 139. Training for SMS participants is required at least every 2 years. SMS implementation plans are generally due to FAA between 2024 – 2025 and fully implemented SMS within 3 years after FAA approval of its implementation plan. The rule requires that certificate holders provide any changes to the airport SMS Manual annually or when requested by the FAA.

## 3.2 SMS in public transit

Title 49 Part 673 Public Transportation Agency Safety Plans Subpart C Safety Management Systems, which took effect in 2019, specifies SMS requirements organized by the four SMS pillars (policy, SRM, assurance, promotion). Applicability of assurance requirements is risk-based, accounting for the exposure of the transit operation such as a public rail fixed guideway system vs. a small transportation provider. No risk matrix or maximum acceptable risk is defined here, but SRM provisions require an assessment of the likelihood and severity of hazard consequences as part of risk assessment. Subpart B addresses a broader Public Transportation Agency Safety Plan which includes SMS implementation, and for fixed rail guideway systems, that plan must be approved by a State Safety Oversight Agency. Annual certification of compliance with 49 CFR Part 673 is required from a transit agency, direct recipient, or State. Subpart D addresses Safety Plan Documentation and Recordkeeping with a requirement to maintain documents at least 3 years after creation.

## 3.3 SMS in nuclear industry

Title 10 CFR 70 establishes federal regulations for domestic licensing of special nuclear material. Subpart H of this regulation provides for licensees to maintain a safety program, with sections 70.61 establishing performance-based requirements and 70.62 adding prescriptive requirements for the program. These prescriptive aspects effectively require licensees to apply probabilistic risk management techniques that are more fully described on the NRC website and through employee training.

Section 70.61 establishes a foundation for the Commission to apply performance-based oversight of a licensee's safety program. This part of the regulation establishes three quantifiable levels of severity for the degree of exposure to radiation that may be the result of either an internally or externally initiated event. The severity categories are high, intermediate, and low. Radiation doses are expressed on the Sievert (Sv) scale, but the regulation also addresses the possibility of uranium intake in soluble form as well as chemical exposure that could injure or kill a worker. This part also establishes terminology for probabilistic risk, providing the term "highly unlikely" for an acceptable probability of a high-consequence event and "unlikely" for intermediate-consequence events. The corresponding probability for these categories is not included in the federal regulations but is presumably determined by NRC.

In addition to establishing performance-based requirements that identify safety objectives but do not specify how those objectives may be met, section 70.61 includes some prescriptive requirements. Specifically, it states that all mitigation strategies for controlling the risk of *nuclear criticality accidents* must be based on preventive controls rather than approaches that would be responsive. Additionally, all nuclear processes must be subcritical and must meet an approved margin of subcriticality for safety. Similar to its probability categories, this margin is established by NRC and may be updated over time as necessary.

With the safety objectives established, section 70.62 provides regulations for a safety program and an Integrated Safety Analysis (ISA). This part identifies and describes three elements of a safety program: process safety information, integrated safety analysis, and management measures. The term ISA is defined in 70.4 as

"a systematic analysis to identify facility and external hazards and their potential for initiating accident sequences, the potential accident sequences, their likelihood and consequences, and the items relied on for safety. As used here, integrated means joint consideration of, and protection from, all relevant hazards, including radiological, nuclear criticality, fire, and chemical. However, with respect to compliance with the regulations of this part, the NRC requirement is limited to consideration of the effects of all relevant hazards on radiological safety, prevention of nuclear criticality accidents, or chemical hazards directly associated with NRC-licensed radioactive material. An ISA can be performed process by process, but all processes must be integrated, and process interactions considered."

An ISA summary documents the results of the analysis. Section 70.62 adds more detailed requirements for the ISA, specifying types of hazards that must be documented, potential accidents that may be caused by the hazards, and the range of severities that may be associated with those accidents. Additionally, it requires safety mitigations to be identified as being relied upon to achieve the safety objectives described in 70.61. This part also provides requirements for ISA team members and management measures that contribute to the achievement of the safety objectives.

Another integral part of NRC's oversight is its inspection program, outlined in 70.55. This part requires licensees to afford the Commission opportunity to inspect nuclear material as well as the premises and facilities they are used on. The regulations also call for reasonable inspection of all records required under Part 70, including those associated with safety programs.

## 3.4 SMS in oil & gas industry

Title 30 of the Code of Federal Regulations (CFR) establishes the regulatory framework for the offshore oil and gas industry. Chapter II Subpart 250.1900 – 1933 provides requirements for a Safety & Environmental Management Systems (SEMS) program at each facility (30 CFR 250, 2024). This subpart is similar in nature to 14 CFR 5, where requirements for aviation SMS are addressed. While this part includes safety management-related definitions, key terms associated with risk management such as risk, hazard, likelihood, and severity are not defined.

Within this section, 250.1911 prescribes hazard analysis as the technique that must be used to manage risk. There are no requirements for methodology or guidance on how to conduct a hazard analysis, however. Instead, the guidance only requires the individual(s) conducting the hazard analysis to be familiar with the technique.

Section 250.1912 provides requirements for change management and requires change procedures to be included within the SEMS program. These procedures apply to changes or modifications to equipment, operating procedures, personnel, materials, or operating conditions. Included in the guidance is a requirement to assess the "Impact of the change on safety, health, and the coastal and marine environments." However, there is no guidance connecting this requirement to the hazard analysis requirements in the previous subsection. Additionally, there is no requirement to notify BSEE of any changes nor is the operator required to provide results of the assessment on the impact of the change except when requested as part of an audit or inspection.

Subsequent sections focus on operations and incident investigation.  Section 250.1920 provides requirements for audits, with a standard interval of 3 years between audits.  Section 250.1924 describes how the regulator determines SEMS program effectiveness per prescriptive requirements and inspections of SEMS program documentation.

# 4 Aviation safety oversight approaches

## 4.1 International Aviation Civil Organization (ICAO)

The International Civil Aviation Organization (ICAO)'s role in aviation safety includes establishing global standards and regulations addressing the safety, security, efficiency, and sustainability of international civil aviation. One of ICAO's core functions is safety oversight, which includes regulating and monitoring safety programs and performance of member states.

ICAO has developed Standards and Recommended Practices (SARPs) related to safety oversight through its Safety Oversight Manual (Doc 9734) which cover aspects of safety oversight, including the establishment of a civil aviation authority, licensing and certification of personnel and organizations, aircraft operations, airworthiness, aerodromes, and air navigation services. ICAO Annex 19, Amendment 1 defines specific safety management requirements including member state safety management responsibilities; safety management systems; and safety data collection and management.

ICAO has established several programs specific to safety oversight.  These include:

- Universal Safety Oversight Audit Program (USOAP): a program to assess member states' safety oversight capabilities and ensuring compliance with ICAO SARPs; this program includes the conduct of audits called Universal Safety Oversight Audit Program Continuous Monitoring Approach which are used to assess regulatory frameworks, organizational structures, and operational practices for oversight.
- ICAO Collaborative Assistance and Support Program: this program assists member states in improving safety oversight capabilities and address deficiencies identified through ICAO audits.

ICAO collaborates with various aviation industry stakeholders, including airlines, airports, aircraft manufacturers, and aviation associations, to promote positive safety management and safety culture.  The Safety Management International Collaboration Group (SM IGC) was established as part of this collaboration and is comprised of approximately eighteen Air Navigation Safety Provider organizations (including FAA, the Office of Aviation Safety (AVS)) and ICAO as an independent observer. In recent years, the SM IGC has released several guidance documents addressing safety oversight and SMS within safety oversight including:

- SM IGC Industry Engagement Group Product Use Survey Results (March 2024)
- Safety Oversight Following the Implementation of Safety Management Systems (November 2022)
- Risk-Based and Performance-Based Oversight – Guidance (May 2022)
- Safety Management Terminology (March 2022)
- Attitudes and Behaviors for Effective Safety Management Systems (March 2021)
- Sector Safety Risk Profiling at the State Level (May 2020)
- Guidance for Comprehensive Safety Performance Management in a State Safety Programme (July 2019)
- Safety Management System Evaluation Tool Version 2 (April 2019)
- Industry Safety Culture Evaluation Tool and Guidance (April 2019)
- Organizational Culture Self-Assessment Tool and Guidance for Regulatory Authorities (March 2019)
- Training Program Outline for Inspector SMS Competency (March 2017)
- Measuring Safety Performance Guidelines for Service Providers (July 2013)

ICAO also collects and analyzes safety data through its Global Aviation Safety Plan (GASP) and Global Aviation Data Management (GADM) programs, where data is used to identify emerging safety trends, assess safety performance indicators, and prioritize areas for improvement in global aviation safety.

The subsections below provide additional information on ICAO safety oversight concepts and methods, as defined in SM IGC documentation. With respect to the material below, it should be noted that ICAO Safety Terminology equates “a measurement of the effectiveness of a system’s safety based on the probability of tolerable incidents that can occur” as the “degree of safety of a system” which is defined as the “Level of Safety.” While this definition is not explicitly “SMS effectiveness” it is useful in understanding the broader objective of safe system.

### 4.1.1 Guidance on performance-based and risk-based oversight

#### *4.1.1.1 SM ICG, Risk-Based and Performance-Based Oversight – Guidance, May 2022*

The focus of this document is to offer guidance on how legacy compliance-based oversight activities may be augmented by performance-based oversight and risk-based oversight (RBO)

(ICAO SM ICG, 2022). The document defines and describes each of these terms (i.e., PBO, RBO) and offers guidance on how safety data should be gathered, grouped by sectors, and used to assess an organization's performance to support decisions regarding allocation of resources.

A driving theory in this document is the establishment of an organizational risk profile based on several indicators that are intended to be measures of effectiveness for the organization. An approach to development of qualitative methods to convert observations to an ordinal scoring system for evaluation is defined; it is also noted that this scoring approach can provide consistency across organizations and the results can be used to facilitate oversight planning. While the document focuses on RBO and PBO, it is noted explicitly that these oversight methods are not intended to be replacements for compliance-based oversight. Rather, these new tools are additions that allow regulatory authorities to not only verify compliance through audits and inspections, but also assess performance and evaluate the suitability of risk management processes in place. This is expected to allow regulators to challenge the organization's processes as needed, and tailor the scope and frequency of surveillance activities.

#### *4.1.1.2 SM ICG, Guidance for Comprehensive Safety Performance Management in a State Safety Programme, July 2019*

While this document pre-dates the SM ICG definitions for risk-based or performance-based oversight, it does focus on identifying clear safety objectives and the assessment of a State's performance in terms of achieving those objectives and maintaining an acceptable level of risk. The document is focused on providing guidance on what to do (rather than how to do it).

A cornerstone of the document is the *Safety Performance Management Framework*, depicted as a type of flow chart with explanations as to the various processes described in the framework. These include development of a risk picture, safety objectives, and measurements of system risk. It is suggested that risk is measured through a set of safety indicators and defines these by example, citing accidents, incidents, and regulatory violations as indicators. The document explains that safety performance should be "determined by measuring the *impact of safety management processes on the actual results achieved*." Similarly, the document explains that the State should establish an acceptable level of safety performance and periodically review its safety performance in order to determine whether it has achieved its objective.

The document discusses a range of other topics including safety data; risk matrices; and application of risk models (such as the bow-tie model). It is suggested that for safety data, accident/incident data is the richest source of information. Specific to development of a risk picture, it is noted that a risk matrix can be used to define regions of acceptable versus unacceptable risk.

#### *4.1.1.3 SM ICG, Measuring Safety Performance Guidelines for Service Providers, July 2013*

This document describes two types of indicators: lagging and leading. Lagging indicators are associated with historic occurrences such as accidents, though the document also describes non-accident outcomes, or *precursors*. Leading indicators are subjective, and based on a belief that some policy or procedure may have an influence on a safety objective. An example provided in the text is the “percentage of change to Standard Operating Procedures that have been subject to hazard identification and safety risk management” (SM ICG, 2013, p. 6). A graphical representation of the process for defining and reviewing safety performance indicators is provided, with an explanation of each phase. The document also provides an extensive list of indicators for systemic, operational, and external issues. Of specific interest is section 3.2, providing a table of high severity outcomes to be prevented and metrics that serve as indicators. This section clearly establishes the belief that controlling the metrics identified as indicators will result in a desired effect on the associated occurrences. For example, the table suggests that controlling the indicator “number of trainees per instructor” (SM ICG, 2013, p. 19) could reduce the number of accidents and incidents that cite training as causal.

### 4.1.2 Universal Safety Oversight Audit Program

The ICAO Safety Management Manual (SMM) (Document 9859) defines guidance addressing the implementation of SMS in aviation. The document includes an introduction to safety management concepts, principles, and objectives, noting the importance of proactive safety culture, risk management, safety performance monitoring, and continuous improvement. The document also provides a regulatory framework for implementing SMS within a member state organization, including requirements and guidance for implementing safety policies, safety risk management processes, safety assurance activities, and safety promotion actions. The SMM notes in 8.7.3.2 that a regulatory State Safety Programs needs to be assessed for how effective it is in achieving its objectives and that “effectiveness is achieved when the outcome produces the desired result each time.”

The ICAO USOAP identifies how ICAO would evaluate a State’s Safety Program oversight effectiveness. This includes a Continuous Monitoring Approach where oversight is achieved through a combination of on-site audits, off-site validation activities and analysis of safety data. Per the USOAP Continuous Monitoring Approach Results SAFETY REPORT for 2019 – 2021, the audit focused on several areas, including aircraft operations, airworthiness of aircraft (AIR), air navigation services (ANS), and aerodromes and ground aids among others. During audits, various aspects of a safety oversight system are assessed including the regulatory framework, organization structure, licensing and certification processes, surveillance and inspection activities, accident investigation capabilities, and safety management systems implementation.

Questions for the audit areas are distributed across 8 critical elements, such as CE-2 Specific operating regulations for standard operating procedures, services, and infrastructure conformance to applicable ICAO Annexes; and CE-6 Licensing, certification, authorization and/or approval obligations. ICAO auditors use an Effective implementation (EI) indicator as a measure of a regulator's safety oversight capability. A higher EI indicates that a State's safety oversight system and accident/incident investigation capabilities has a greater degree of compliance with ICAO provisions. The EI is calculated for up to 790 protocol questions as a percentage representing the number of satisfactory questions vs. the total number of applicable questions. While this EI definition is quantitative and specific, it is more a measure of compliance level rather than effectiveness of an oversight program in meeting that oversight program's safety objectives. This approach is likely necessary given that ICAO's global scope cannot feasibly tailor assessments to each State-specific safety objectives and must seek a broader standard to apply across States.

When an audit is complete, findings and observations for each assessment element are defined and documented. Findings identify areas of compliance and non-compliance. An audit report is created and shared with the audited state. For areas of non-compliance, a state is expected to develop a State Action Plan to identify corrective actions that will be applied to address identified deficiencies.

USOAP incorporates feedback from its member states, auditors, and other stakeholders to continuously improve audit processes, guidance material, and training programs. Lessons learned from audits are shared to facilitate knowledge exchange and best practice information sharing.

## 4.2 Federal Aviation Administration (FAA)

This section presents the combined survey of literature and observations and recommendations obtained from interviews conducted with FAA Aviation Safety (AVS) representatives presented in Section 2.2. The AVS interviews identified current oversight challenges and considerations for future, strategic oversight planning for each organization in this section. Interviews and literature surveyed also offered background and context for the oversight scope and approach captured for each AVS organization's areas of safety oversight responsibility herein.

### 4.2.1 Flight Standards (AFS)

The FAA's Flight Standards organization establishes standards for certification and oversight of airmen, air operators, designees, and air agencies, including aircraft dispatcher, flight engineer, and flight navigator-approved schools (FAA AFS-200, 2024). AFS also conducts certification, inspection, surveillance, and other oversight activities with offices for air carrier and general aviation safety assurance, safety standards, and foundational business.

AFS's Office of Air Carrier Safety Assurance oversees air carrier and commercial operator certification and operations under 14 CFR Part 121. This includes oversight of operator compliance with operator-specific flight procedures, airmen qualifications and proficiency, and aircraft maintenance among other areas of oversight (FAA, 2024). AFS also develops domestic aircraft maintenance and manufacturing standards for airworthiness and standards for aeronautical products according to FAA Order 1100.1H. The Air Carrier Safety Assurance Office also includes AFS Certificate Management Offices organized by airline- and cargo-specific oversight offices as well as regional offices for aur carrier certification, surveillance, and inspection plus 14 CFR Part 142 training center programs and instructor qualifications (FAA, 2024).

Flight Standards District Offices, under the Office of General Aviation Safety Assurance, manage certification and oversight of numerous non-Part 121 operators, air carriers, and airmen (e.g., pilots, mechanics, repairmen, dispatchers) (FAA, 2024).

Both Air Carrier and General Aviation Safety Assurance Offices plays a key role in in AFS's application of risk-based decision-making when managing oversight resources as well as implementing safety assurance responsibilities per the Flight Standards Service Safety Management System.

AFS's Office of Safety Standards develops standards and guidance for "operations, repair and alteration of aircraft and operations, the use of designees or delegation, flight technologies, safety promotion, and international operations." The Safety Standards office works with other AFS and external stakeholders to examine and communicate "trends impacting aviation safety" and encompasses a Safety Analysis & Promotion Division that manages the implementation of the Safety Assurance System, a key resource used within AFS and other AVS counterparts to provide risk-based, data-supported, proactive oversight. The Office of Safety Standards also includes the Aircraft Evaluation Division (among other divisions) that disseminate continued operational safety issues and information to AFS and AIR. The Aircraft Evaluation Division examines aircraft engines, propulsion, and other technologies for applicability to operating rules;

continued airworthiness and requirements for flight crew type ratings among other areas (FAA, Aircraft Evaluation Division Duties and Responsibilities, n.d.).

The Office of Foundational Business provides quality control and quality assurance for internal oversight of AFS's SMS implementation as well as program management for aircraft registration and airmen certification among other AFS mission support services.

Flight Standards' oversight approach is based on a tiered structure with a three-level model of the air transportation system, namely the Aviation System Level, the Organizational Level, and the Individual Level according to FAA Order 8000.368A (FAA, 2012):

- At the ***aviation system level***, "AVS and AFS oversee activities in the NAS and major components or classes within that system, such as: air carrier and commercial aviation; General Aviation [including Air Tour operations and airworthiness; fractional ownership operations and airworthiness; pilot training systems; [Instrument Flight Procedure] IFP service providers; maintenance, repair, and overhaul."…
- At the ***organizational level***, AFS's objective is safety assurance, focused on design assurance and performance assurance, both of which is supported by AFS Safety Assurance System. "Specifically, this means to assure that the certificate holders are properly implementing the safety risk controls that AFS has developed and promulgated at the national level, and that these risk controls are also effective. This includes both certification activities and ongoing operational oversight. In addition, safety assurance efforts at the organization level identify changes in the environment that could result in additional hazards not previously examined."
- At the ***individual level***, AFS also certifies pilots, mechanics, and other individuals that are not certificated by the FAA (e.g., corporate flight departments, certain flight schools, certain maintenance facilities, instrument flight procedure service providers).

According to interviews with AFS representatives, oversight approaches differ for General Aviation and Air Carriers. Oversight for General Aviation remains compliance-based, with prescriptive methods for evaluations and associated schedules. On the other hand, oversight of Air Carriers is very performance-based

Although the AFS approach does not specifically use the terminology *performance-based oversight*, FAA Order 8000.368 describes AFS safety assurance functions that incorporate performance-based and risk-based oversight:

- ***Design Assurance*** – Air carrier / commercial operator and training organizations [management] systems' design is assessed during initial certification and later on during program approvals or acceptance (e.g., of changes). AFS inspectors also conduct Design

Assessments of organization-specific operational systems' effectiveness to meet regulations and safety standards and provide an acceptable level of safety.

- ***Performance Assurance*** – AFS conduct surveillance, inspections, and other oversight to verify whether certificate holder systems are used as designed and whether such systems demonstrate continued effectiveness in meeting applicable regulations and safety standards and provide an acceptable level of safety.
- ***Safety Risk Management*** – To evaluate and verify air carrier SMS effectiveness, AFS identifies and analyzes certificate holder-specific safety risks and may provide SRM assistance to certificate holders. As noted in Order 8000.36, however, "the primary responsibility for SRM rests with the certificate holder." As part of risk-based oversight, AFS also applies SRM results to target and align its internal oversight resources with risk-based priorities.

Details for the safety assurance processes above are described in AFS's Certificate Holder Evaluation Process, FAA Order 8900.1 Volume 10 (FAA, 2023). The objectives for the Certificate Holder Evaluation Process are to: "1) Verify certificate holder compliance with applicable regulations, 2) Evaluate whether the certificate holder is effectively managing safety; and 3) Identify hazards, assess risk, and provide documentation for the Certificate Management Team to mitigate associated risks." The Certificate Holder Evaluation Process applies to certificate holders for air carrier and commercial operators, repair stations, pilot schools, training centers, and aviation maintenance technician schools.[1] Certain for certificate holder conditions (similar to safety performance measures or leading indicators) may prompt an evaluation as outlined in Table 2.

Table 2: Conditions for certificate holder evaluation

| | | |
|---|---|---|
| • Substantial change in certificate holder management<br>• Substantial turnover in personnel or reduction in force<br>• Labor dispute<br>• Rapid expansion or growth<br>• Merger, takeover, or change in ownership<br>• Enforcement actions<br>• Noncompliant attitude | • Accidents/ incidents/ occurrences<br>• Department of Defense reviews<br>• Department of Transportation (DOT)/ Office of the Secretary of Transportation economic authority/ insurance requirements<br>• Change in fleet type<br>• Substantial change in outsourcing<br>• Financial distress | • Substantial customer or employee complaints<br>• Cargo Focus Team evaluation of a certificate holder /applicant's Weight and Balance Control Program<br>• Hotline complaints<br>• Certificate transfer |

FAA Order 8000.368 also explains a PBO-related concept under the heading of "quantifying levels of risk" through the use of performance indicators and targets. The order identifies

[1] 14 CFR parts 121, 135, 145, 141, 142, 147

performance indicators as metrics that are associated with aircraft accidents, such as accidents per million passenger miles. Performance targets are tied to safety objectives, such as a percentage reduction in a performance indicator.

The Safety Assurance System is the FAA's oversight tool to "perform certification, surveillance, and continued operational safety" and, for Flight Standards, it supports oversight of CFR parts 121, 135, and 145 certificate holders and applicants (FAA, 2022). Among other regulatory areas, the Safety Assurance System provides Data Collection Tools (DCTs) provide insight into AFS's current oversight of SMS effectiveness.

While this report does not address oversight tools specifically, it is informative to examine Data Collection Tools (DCTs) managed within the Safety Assurance System that provide insight into AFS's current oversight of SMS effectiveness. DCTs provide questionnaires to determine if a certificate holder or applicant follows procedures, controls, and process measures for each element of a given regulation or standard. The current DCTs incorporate compliance-based oversight for certificate holder SMS elements, among others. AFS noted during interviews that the Safety Assurance System is being adapted to ascertain whether certificate holders are using SMS and using it correctly. AFS representatives also noted that safety inspectors are asked to evaluate the effectiveness of a certificate holder's SMS program, and that AFs would prioritize oversight focus on certificate holders that lack an effective SMS since there is a lower degree of confidence their risk management.

A sample of current DCT objectives and questions for SMS evaluation are reproduced in Table 3. Questions sampled do not provide thresholds for ranges of compliance, effectiveness, or quality and are framed for yes / no / not applicable responses with codes to capture certain issues the inspector observes. These codes are used to note unclear or conflicting procedures; use of workarounds; skipped process steps; personnel failure to perform tasks or follow processes; unavailable, outdated, undocumented, or inconsistent procedures/guidance; missing information; process oversight failure; inadequate, unavailable, or uncalibrated equipment/tools; and inadequate facilities.

Table 3: Sample Data Collection Tools (DCTs) for SMS evaluation

| Data Collection Tool | Example Questions |
|---|---|
| **Title:** SMS-Safety Risk Management Design Validation (Airworthiness)<br><br>**Objective:** Validate that the CH has effectively designed an SMS which incorporates a process to identify, | Q1. Does the certificate holder's SMS require that the organization apply the Safety Risk Management process when any of the following conditions occur:<br>#1 Implementation of new systems;<br>#2 Revision of existing systems;<br>#3 Development of operational procedures; and |

| Data Collection Tool | Example Questions |
|---|---|
| analyze, and assess the hazards, to mitigate the associated risks<br><br>DCT Revision: 2.0 on 01/15/20<br>Accessed March 29, 2024 | #4 Identification of hazards or ineffective risk controls through the safety assurance processes contained in subpart D?<br>Q7. Does the certificate holder's SRM include specific processes for conducting risk assessment that allows for the determination of acceptable safety risk? |
| **Title:** SMS-SRM (Organizational) Design Demonstration (Operations)<br><br>**Objective:** Confirm through design demonstration, the CH is capable of conducting integrated Safety Risk Management when multiple departments are affected by a system change.<br><br>DCT Revision: 3.0 on 01/15/20<br>Accessed March 29, 2024 | Q3. Does the certificate holder have documentation showing the individuals or group who complete the organizational safety risk management related process steps have the competencies (i.e., qualification, training, knowledge, and experience) to properly perform those activities?<br>Q4. When the organization has identified hazards or ineffective risk controls, can the SRM process documentation be traced to ensure the following recording requirements are met:<br>#1 Record(s) of identified hazards or lack of hazards;<br>#2 A list of risks associated with each existing hazard;<br>#3 Analysis of each risk;<br>#4 Record of mitigation (controls) for unacceptable risks;<br>#5 Record of safety risk acceptance decision(s) by authorized individual/group; and<br>#6 Verification of safety risk control effectiveness prior to final risk acceptance?<br>Q5. When multiple departments are affected by a system change, is there clear documentation that affected process owners or their proxies participate in a collective (organizational) risk assessment? |
| **Title:** SMS-SRM (Process/Department Owner) Design Demonstration (Airworthiness)<br><br>**Objective:** Confirm through design demonstration, that the CH can effectively apply the organization's Safety Risk Management process to all safety critical processes within the process owner's department.<br><br>DCT Revision: 4.0 on 01/15/20<br>Accessed March 29, 2024 | Q1. Do individuals or groups that accept supplier guidance materials into their process area(s) understand that updates or changes to these materials requires safety risk management be conducted before it is used in the system?<br>Q2. Do individuals or groups that have the authority to draft and approve new or revised process and procedural changes for their process area(s), understand their responsibility to conduct safety risk management on those changes/ materials before they are used in the system?<br>NOTE: Changes and updates from suppliers and vendors may result in new or revised operational<br>procedures. New or revised procedures may also be required as a result of the Safety Assurance Process. SRM may need to be conducted when new or revised procedures are presented for approval. |
| **Title:** SMS–Safety Assurance Design Validation (Operations)<br><br>**Objective:** Validate that the CH has effectively designed processes that ensure effective safety risk controls which meet or exceed safety objectives through the collection, analysis, and assessment of data.<br><br>DCT Revision: 6.0 on 01/15/20 | Q6. Does the certificate holder's SMS have procedures to analyze data acquired from their safety assurance processes, described in part 5.71(a)(1 through 7), and any other relevant data with respect to its operation, products, and services, including at a minimum:<br>#1 Monitoring of operational processes;<br>#2 Monitoring of the operational environment to detect changes;<br>#3 Auditing of operational process and systems;<br>#4 Evaluations of the SMS and operational processes and systems;<br>#5 Investigations of incidents and accidents; |

| Data Collection Tool | Example Questions |
|---|---|
| Accessed March 29, 2024 | #6 Investigations of reports regarding non-compliance with regulations or risk controls established under<br>subpart C, SRM; and<br>#7 Confidential safety reporting from employees on hazards, concerns, incidents, etc.?<br>Q7. Does the certificate holder's SMS require the organization to regularly review and report on the system's<br>safety performance and does the Accountable Executive review these reports to:<br>#1 Ensure compliance with their established safety risk controls;<br>#2 Evaluate the performance of the SMS;<br>#3 Evaluate the safety risk control effectiveness established under 5.55(c) with identification of ineffective controls;<br>#4 Identify changes to the organization's operational environment that may introduce new hazards; and<br>#5 Identify new hazards? |

According to interviews with Flight Standards representatives, AFS has been gradually adopting performance-based oversight objectives over the last 10 years. This gradual implementation allows AFS to use an approach that "meets AFS inspectors where they are" in terms of workforce experience with compliance-based oversight approaches and associated skills and training. Culturally, one of the biggest challenges AFS representatives noted is helping inspector shift mindsets from compliance-based to performance-based oversight, and AFS facilitates this transition by clearly explaining why performance-based approaches are needed. During interviews it was noted that AFS recognizes that it is comparatively easy for inspectors to evaluate a specific list of items at a defined inspection intervals as part of a compliance-based approach vs. interpreting and using data to formulate surveillance actions in response to that data as part of a performance-based approach.

### 4.2.2 Aircraft Certification (AIR)

The FAA's Aircraft Certification Service (AIR) manages and oversees design, production, and airworthiness standards, approval, and certifications for civil aircraft and aeronautical products and aircraft continued operational safety (COS). AIR also participates in intra-agency and industry efforts for international air transportation system safety improvements. FAA Order 8100.5E describes AIR's organizational structure and functions for Policy & Standards, Safety & Performance Integration, Certificate Management, Compliance & Airworthiness, System Oversight, and Enterprise Business Operations.

There are aspects of risk-based oversight and some internal performance-based oversight in AIR's division roles described in FAA Order 8100.5E. For example, AIR's Policy & Standards division is responsible for "enabling system solutions to improve effectiveness of risk-based safety management and oversight." Also, AIR's Compliance & Airworthiness Division has a role in disseminating product safety information (e.g., for fleet safety) "to enable risk-based decision making for each division" of AIR. AIR's Safety & Performance Integration Division assesses the effectiveness of AIR oversight services by analyzing associated performance measures and recommending improvements (FAA, 2023).

AIR reviews industry applicant requests for aircraft and other product design approvals and issues Type Certificates for products that demonstrate compliance with applicable regulations. To modify a product from its original design, an applicant must obtain a Supplemental Type Certificate from the FAA. When an applicant seeks to manufacture a product under either a type or supplemental type certificate, AIR also evaluates and issues production approvals. According to FAA Order 8120.22A, a production approval allows production of a product or article in accordance with its approved design and quality system. It can take the form of a Production Certificate, a Parts Manufacturer Approval, or a Technical Standard Order authorization. The FAA uses Technical Standard Orders for minimum performance standards for specified materials, parts, and appliances used on civil aircraft.

AIR's current production certification oversight activities entail compliance-based evaluation of Quality Management Systems and quality processes for manufacturing, building, assembly, and resulting products. 14 CFR 21 provides prescriptive regulations for Quality Management System elements and was amended in 2016 to improve quality standards to ensure products and articles are produced consistent with their designs and are safe to operate. Examples of required elements are controls for design data, suppliers, and manufacturing processes; inspections and testing; handling of non-conforming parts and articles; corrective and preventive actions; and internal audits. AIR's compliance-based evaluation of a production approval holder's quality system and associated quality manual are addressed in FAA Order 8120.22A, CHG 1.

Risk-based oversight analyses for quality systems are in development according to AIR interviews conducted for this research. There are groups within AIR developing bow tie models for requirements of quality systems to evaluate risk barriers and ensure the design of quality system is robust enough to preclude hazardous escapes.

Also, as part of risk-based oversight, AIR uses a systematic approach for assessing product or service provider organizational and technical risk and determining corresponding oversight resource activities and frequencies. This process is called "Risk Based Resource Targeting

(RBRT)” and is applied as part of AIR (and broader FAA AVS) decision making for allocating oversight resources to standards development and authorization, type and production certifications, parts manufacturer approval, certificate management, and designee management (FAA, 2007). According to an interview with AIR representatives, criteria considered in RBRT include the scope of the product and its associated risk (for example, an aircraft sidewall panel is considered lower risk than a flight control system); the stability of the product (e.g., whether new, novel, or mature and unchanged); the stability of suppliers; the amount of work performed in-house by the approval holder; the approval holder’s relationship with the FAA and compliance history; and the approval holder’s company growth among others. For AIR, RBRT is part of the Air Carrier Activity Information System and leverages data collected by FAA aviation safety inspectors to assess risk. An initial assessment for RBRT is performed during the production certification process and then updated periodically as part of AIR’s certificate management of production approval holders. FAA Order 8120.23, Certificate Management of Production Approval Holders, describes a risk assessment process for categorizing the overall risk level for a given production approval holder according to three tiers. The highest level, Level 1, is assigned for Production Approval Holders whose manufacturing involves 2+ product models, high production rates (i.e., more than 100 aircraft, 500 engines, or 1500 propellers), and extensive outsourcing (i.e., 20+ external suppliers or 33%+ outsourced for critical parts). If a Production Approval Holder’s manufacturing process does not meet all 3 criteria for Level 1 but the holder manufactures a critical article or items on a category parts list, Level 2 is assigned. Otherwise, Level 3 is assigned when criteria for Levels 1 and 2 are not met. Based on the assessed risk level and RBRT process, a baseline risk is assigned which determines the interval of audits (e.g., annually or another frequency).

AIR uses a process called Monitor Safety/Analyze Data (MSAD) for safety risk management and safety assurance as described in FAA Order 8110.107B (FAA, 2023). The MSAD process is used for hazard identification and risk assessment, structured causal analyses, corrective action reviews, risk mitigation evaluation, and continuous trending and monitoring of in-service risk data. Sources for in-service risk data include product faults, failures, and defects; voluntarily reported safety issues (e.g., by manufacturer employees); and Service Difficulty Report (SDRs) from operators and repair stations among others. Per the MSAD process, structured causal analyses examine the sequence of events and contributing factors that lead to safety effects and are required when risks have potentially fatal outcomes, ineffective mitigations, and complexity or uncertainty in cause identification and interrelationships among other criteria. Based on risk analysis and causal analysis (when required), results of the MSAD process may be used to recommend corrective actions. Those corrective actions include Special Airworthiness

Information Bulletin (SAIBs) to disseminate advisories on product safety improvements and enforceable Airworthiness Directives (ADs) to correct an unsafe product condition in an aircraft, aircraft engine, propeller, or appliance (FAA, 2013).

In 2016, AIR explored a performance-based oversight model and associated safety performance indicators for product manufacturing (FAA, 2016). The model incorporated the use of risk, safety performance, and quality performance in determining minimum audit scope and where to conduct audits in terms of high-risk manufacturing facilities. The premise of the model is that onsite oversight at production approval holder facilities could be reduced if controls for production approval holder manufacturing and quality systems are effective, since effective controls "produce high performance." To evaluate safety performance, performance data agreements between FAA and PAH are needed for continuous monitoring of performance relative to thresholds that prompt corrective action when exceeded. Examples of performance data examined as part of the 2016 PBO prototype effort included Service Difficulty Reports (SDRs), internal audit results, material reviews, quality escapes, supplier part rejections, and engineering change requests, among others. Thresholds are defined by agreement between the FAA and PAH on what is acceptable performance, though it was noted that "thresholds cannot replace compliance to regulations." Seven companies participated in a prototype evaluation of the PBO model and discussion of PBO indicators. Example performance-based oversight indicator topics considered for the prototype are reproduced in Table 4. Though some elements of the PBO indicator topics appear to be present in the current MSAD process, it is not clear if MSAD or other AIR tools, work instructions, or oversight practices were modified to adopt the outcomes from this 2016 effort.

Table 4: AIR performance-based oversight prototype indicators

| Indicator Topic | Examples |
| --- | --- |
| **Quality Performance Indicators** | Repeated occurrences - i.e., missed drilled holes in multiple structures, supplier parts consistently being rejected, drawings consistently being corrected to match part. |
| **Quality Escapes** | Nonconformances that affect Fit, Form or Function<br>Multiple quality escapes is an indicator of a quality system that is not being maintained.<br>Multiple quality escapes by a direct ship supplier may be an indicator of inadequate source or delegated source inspections. |
| **Internal audit findings** | High level of audit findings over a short period of time may indicate:<br>o new audit system / criteria that is finding non-compliances and improving the quality system.<br>High level of audit findings over a long period of time may indicate:<br>o Quality system not maintained<br>o Trends not being addressed<br>o Corrective actions not fixing the root cause |

| Indicator Topic | Examples |
|---|---|
| | o lack of commitment to quality and compliance, etc.<br>Repetitive audit findings in may indicate:<br>o ineffective corrective actions<br>o failure to follow-up or determine the effectiveness of C/A<br>o lacking internal compliance mechanisms and not tracking repetitive findings |
| **Materials Review Board** | Significant and or continued high numbers of nonconformances may indicate:<br>o Unrepeatable manufacturing process(s)<br>o Tooling problems<br>o Inadequate training<br>o lack of or unsuccessful FAI<br>o Ineffective corrective action system<br>o Unrealistic engineering (drawing/ specification) tolerances or inadequate drawing definition (ambiguous)<br>o Turnover of people (training levels)<br>o Too much variability in the process<br>Repetitive “Use-as-is” dispositions may indicate:<br>o De-facto changes to the type design<br>o All the above |
| **Service Difficulty Reports / COS reports** | Increased levels of safety reported events may indicate potential or significant problems with design, quality or reliability systems.<br>May also indicate effectiveness of the safety risk controls and or how risk controls are evaluated.<br>A certain level of untimely responses to problem reports may indicate resources issues, system issues. |
| **Supplier Part Rejections** | High level of rejections at receiving inspection may indicate:<br>o Poor quality /design requirements flow down to supplier<br>o Source delegation poorly implemented<br>o Supplier not understanding flow down requirements<br>o Poorly written supplier control system requirements<br>o Supplier not capable to produce conforming parts<br>o Lack of an FAI at the supplier<br>o Poor root cause analysis / corrective action verification<br>High level of quality escapes from supplier may indicate:<br>o Direct shipment to users without a define requirement from the PAH on delegated source inspection<br>o Lacking inspections of critical part and or critical characteristics<br>o Improper oversight |
| **Multiple drawing changes after design approval** | Multiple drawing changes may indicate drawings that inadequately define the configuration, material, and or production processes necessary to produce each part in accordance with the certification basis of the product.<br>Multiple drawing changes may indicate inadequate drawing verification methods, inadequate or nonexistent FAI/conformity inspections to validate repeatability of the design in production. |

AIR will oversee implementation of Safety Management Systems for certain design and production organizations that will be required within 3 years after final rule issuance. Per 2023 Notice of Proposed Rulemaking 88 FR 5812, Safety Management System implementation will be required for organizations with aircraft / product design and manufacturing roles for the same product issued under 14 CFR (i.e., certain type certificate and production certificate holders) (FAA, 2023). As a result, AIR is developing policy and work instructions for oversight of SMS elements applicable to AIR's oversight responsibilities and coordinating with related AFS oversight activities, according to interviews with AIR, especially since large manufactures (e.g., Bell, GE, and Boeing) have manufacturing processes and repair stations subject to AIR and AFS oversight, respectively.

It should be noted that NPRM 88 FR 5812 states, "the underlying principles and oversight processes that form the foundation of FAA's approach to compliance would not change under this proposed rule." This does not preclude AIR's use of performance-based oversight (in addition to compliance-based assessment) for Part 21 SMS implementation.

In keeping with FAA goals for PBO adoption, AIR representatives interviewed for this research explained that AIR is examining how to evaluate manufacturer safety risk management and safety assurance processes, including risk management for product changes and measurement of safety performance according to objectives. This includes whether risk controls are functioning as intended and requires coordination and review with manufacturers. Once the manufacturer has been using SMS for a year, AIR plans to assess whether the manufacturer is measuring safety assurance and performance to objectives, evaluating changes in accordance Safety Risk Management (SRM) processes, evaluating whether risk controls are functioning as intended, and keeping training records for SMS, among other processes.

FAA workforce training considerations to enable performance-based oversight was discussed as part of interviews with AIR. It was noted that a strategies for implementing desired workforce changes should be prioritized and done incrementally. Such strategies must account for current workforce culture and experience with compliance-based auditing to develop a means to transition to safety performance measurement with a focus on outcomes and regulated entity "self-correction."

### 4.2.3 Air Traffic Safety Oversight (AOV)

AOV is responsible for safety oversight of the FAA Air Traffic Organization (ATO). As part of its oversight responsibilities, AOV establishes, approves, or accepts safety standards spanning the ATO's air traffic control services, NAS equipment implementation and maintenance, training programs for air traffic and system technical operations, flight procedure development, and flight inspections. FAA Order 1100.161A provides a high-level overview of AOV and ATO organizational responsibilities for air traffic safety oversight (FAA, 2020).

While AOV does not issue performance-based or prescriptive federal aviation federal regulations, it does publish guidance for ATO compliance with FAA AVS directives. AOV provides Safety Oversight Circulars (SOCs), published between 2007 and 2016, that address topics such as AOV Concurrence/Approval at Various Phases of ATO Safety Risk Management, Guidance Regarding the Validation and Verification of the ATO Safety Management System, Guidance Regarding the AOV Voluntary Disclosure Policy, and Corrective Action Plan Development and Acceptance in Response to Safety Compliance Issues. It should be noted that AOV SOC-08-07 regarding ATO SMS Validation and Verification addresses required components for the ATO's SMS but does not provide specific criteria for an independent assessment (by AOV or otherwise) of the ATO's process for SMS effectiveness evaluation (FAA, Policies and Forms: Safety Oversight Circulars, 2024).

According to 1100.161A, the ATO is responsible for assessing its own SMS effectiveness relative to NAS safety. However, AOV may review safety indicators the ATO proposes and tracks to demonstrate SMS safety objectives. Such indicators include air traffic incidents, losses of standard separation, runway incidents, near mid-air collisions, missed equipment preventative maintenance, expired equipment certifications, internal audit results, and other indicators the ATO proposes. Safety data is compared to a historical baseline (where available). If a safety concern arises from safety indicators, then the ATO is required to implement and verify the effectiveness of mitigations. Guidance for evaluating the risk or safety significance of indicator performance issues to determine and prioritize mitigations or corresponding oversight responses and priorities is not discussed in 1100.161A.

AOV has certain mechanisms for independent oversight of elements for ATO SMS effectiveness, such as the effectiveness of risk management. AOV's Monitoring Work Instruction provides AOV safety inspectors with procedures for ensuring that an air traffic service provider (e.g., the ATO) adheres to established safety standards, such as the ATO SMS (among other standards), with an acceptable level of safety (FAA, 2022A). Monitoring is described as a surveillance method that uses organized data collection and analysis where "AOV is responsible for ensuring due diligence is provided while effectively overseeing ATO's system risk management in the NAS." While "due diligence" is not defined in this work instruction nor in 1100.161A, a review of FAA Order 2150.3C Compliance and Enforcement explains concepts for due diligence as ensuring that personnel are always assigned and actively participating in an oversight role (FAA, 2023A). Due diligence may also require work to be fast-tracked and to be given priority over other work assignments, which is an aspect of risk-based oversight resource prioritization. When conducting monitoring oversight, AOV uses three strategies to help safety inspectors monitor the NAS and address safety risks: proactive oversight which focuses on predicting and forecasting unknown issues or risks; preventive oversight which focuses on compliance management to avoid known failures; and reactive oversight which addresses issues, accidents, and incidents and exposes control, mitigation, and prevention program failures. AOV prepares monitoring plans that address safety performance targets defined as the "qualitative or quantitative expected outcome from Monitoring Plan activity" as well as monitoring frequency and duration among other plan elements.

AOV also monitors ATO compliance with safety standards such as the ATO Safety Management System Manual. ATO SMS monitoring and compliance is carried out through audits, access to ATO records to confirm compliance, status reporting of safety occurrences, and corrective action reviews. Per the ATO SMS Manual, the ATO conducts safety risk management to identify hazards and hazard mitigations for changes to air traffic procedures and new and modified NAS systems, among other types of National Airspace System (NAS) changes. According to 1100.161A, ATO is responsible for identifying "safety critical parameters" in risk assessments to validate assessed safety performance of an implemented NAS change. This provision relates to the safety performance targets established in change-specific safety risk assessments addressed in the ATO SMS.

AOV has certain oversight mechanisms for gaining insight into planned and ongoing changes in the ATO's system, procedures, and operations. A challenge for many oversight authorities is situational awareness of safety-significant changes – whether reported by the regulated entity or gained through oversight authority surveillance methods. To address this challenge, AOV's Safety Management Action Review Team is chartered with gathering and disseminating information on NAS changes so that AOV can prepare its oversight plans and resources accordingly. This team collects and briefs programmatic and safety-related information for new and changed systems organized by Communications, Navigation, Surveillance, Automation, and Weather portfolios as wells as new and modified air traffic facility operations and procedures. AOV also receives periodic briefings from ATO on NAS changes as part of the ATO's SRM responsibilities. Once a proposed NAS change is defined, AOV may also participate in planning and conduct of ATO-led safety risk assessments for that change. AOV also has review and approval responsibility for certain types of changes prior to implementation, such as proposed changes to air traffic separation minima in FAA Order 7110.65, NAS equipment availability programs, and the ATO SMS Manual and waivers to safety standards identified in FAA Order 1100.161A.

AOV has oversight processes that serve as gates in reviewing risk mitigations for proposed NAS changes and risk mitigation processes. If a high-risk hazard is identified during SRM for a proposed NAS change, AOV must approve controls to mitigate or eliminate the initial or current high-risk hazard. A NAS change will not be allowed to proceed until all high-risk hazards have been mitigated to a medium or low predicted residual risk. AOV also approves ATO processes for acceptance of medium- and low-risk hazards, and AOV accepts and coordinates the approval of medium- and low-risk mitigations that affect organizations outside of the ATO.

AOV's Approval, Acceptance, and Concurrence (AAC) Work Instruction provides AOV safety inspectors with methodical procedures for AAC-related activities identified in FAA Order 1100.161 and safety risk verification for ATO-submitted AAC requests (FAA, 2022B). AOV's Safety Risk Verification process collects data and assigns a rating that can be used for risk-based oversight of a specific NAS change. The data collected includes the number of risks that a proposed change entails by assessed risk level, whether a proposed change is local vs. NAS-wide in scope, and the characteristics of the change which may impact safety-critical functions or operations (e.g., changes to aircraft separation standards, legacy systems, phase of flight). The process is intended to provide AOV management insight to make informed decisions on post-SRM follow-up oversight activities.

AOV is responsible for the overall management, oversight, and control of credentialing programs for certain type of personnel with safety-related duties, namely Control Tower Operators (CTOs) and ATO air traffic control and airway transportation system specialists. AOV establishes policy and requirements for the CTO certificate program and requirements and guidelines for CTO examiners and managers. Oversight of the Credentialing program is primarily compliance-based via surveillance such as audits and assessments and continuous monitoring. AOV may also issue, amend, withdraw, or remove ATO safety personnel Credentials when deemed necessary (FAA, 2023B). AOV also accepts Flight Standards-approved training of personnel who design or certify instrument flight procedures as well as any changes or revisions to the training, qualification, and certification standards approved by Flight Standards.

AOV is also responsible for reviewing and accepting certain changes made to the FAA flight inspection manual (FAA Order 8200.1) that have been approved by FAA Flight Standards. Such changes include flight inspector authority and responsibilities, facility classification and Notices to Airmen, inspection intervals and tolerances for new equipment or functionality, required inspection checklist items, procedures for evaluating safety of instrument flight procedures, and personnel certification requirements contained in FAA Order JO 8240.3.

### 4.2.4 Office of Accident Investigation and Prevention (AVP)

The Office of Accident Investigation and Prevention (AVP) does not oversee regulated entities that are external to the FAA. Instead, AVP is responsible for coordinating aviation safety and safety data management activities within the FAA and assuring US compliance with ICAO regulation and guidance within Annex 19. AVP's mission is "to make air travel safer through investigation, data collection, risk analysis, and information sharing" (FAA & NTSB, 2021). AVP does not oversee regulated entities that are external to the FAA. Its safety focus areas including conduct and coordination of aircraft accident investigations, including coordination with the National Transportation Safety Board (NTSB); identification of hazards, evaluation of associated risk, and monitoring risk mitigations; and sharing and coordinating safety information with the aviation community in support of continued safety improvement.

The work performed within AVP is allocated to four divisions including:

- AVP-100 ***Accident Investigation***: This division includes investigators that respond to and coordinate with the NTSB on investigation of aviation accidents. While supporting the overall investigation of accidents, this division also identifies risk related to FAA areas of responsibility.
- AVP-200 ***Safety Analytics Services***: This division collects, analyzes, and shares aviation accident and safety data. This includes coordination with the airline industry on collection of aircraft data (e.g., Flight Operations Quality Assurance or Flight Data Monitoring) and pilot data. This division creates and monitors safety metrics, collaborates with other industry safety committees, and leverages data analytics to identify and act proactively on emerging safety risks.
- AVP-300 ***Safety Management and Research***: This division develops and manages the U.S. State Safety Program, and has developed FAA organizational safety regulations, policy, and guidance, including definition of the overall FAA Safety Management System and the AVS-specific SMS. This division also establishes relationships and fosters innovation and ideas that will have positive safety impact.
- AVP-400 ***Management Servies and Recommendations***: This division provides support to the FAA executive team, manages coordination with the NTSB, and supports the identification and implementation of FAA safety recommendations. This division also collects, manages, and responds to FAA employee safety submissions.

Each of the divisions noted above is further organized into branches. For example, the branches of AVP-300 have roles to define FAA and AVP safety policy, which includes development of a SMS, and to fulfill specific pillars of the AVS SMS. AVP-310 has responsibility in the SMS areas of Safety Risk Management and Safety Assurance. AVP-320 focuses on Safety Policy and Promotion. In FAA interviews conducted for this research, it was noted that although individual AVP branches have a specific mission and focus, there is significant collaboration among branches. For example, AVP-310 has overall responsibility for AVP safety assurance activities; however, the work in AVP-200 to collect and analyze aviation data within the FAA and industry, to identify data points of interest and to organize and conduct studies is a significant contribution to overall safety assurance activities.

AVP developed FAA SMS policy, including elements of SMS as reflected in AVS-201503-001 Supporting US State Safety Program and FAA Order 8000.369C Safety Management System.

AVS-201503-001 addresses US support for ICAO establishment of State Safety Programs, with ICAO documentation including Annex 19 Chapter 3 – State Safety Management Responsibilities (including safety risk management, safety assurance and safety promotion) and Annex 19 Chapter 5 – Safety Data and Safety Information Collection, Analysis, Protection and Sharing. The report notes that the US meets most ICAO State Safety Program requirements but has not implemented SMS regulations across all aviation sectors. Some objectives of the State Safety Policy, as applied within the US, include adopting new tools and metrics to further anticipate sources of risk, identify and mitigate accident precursors (and associated barriers), and effectively manage safety resources; taking advantage of safety data and development of additional analytical capabilities; and focusing activities on higher risk areas. Results of FAA performance to specific targets are noted to be provided in the FAA Performance and Accountability Reports. The report addresses safety oversight, documenting activities and tools performed and used within FAA AVS including reviews, evaluations, audits, inspection, data tracking, data analysis and investigations. The application of specific tools within AVS groups, e.g., the Flight Standards Service use of the Safety Assurance System is described, with reference to validation of performance of certificate holders approved programs. There is also reference made to FAA participation in the Safety Management International Collaboration group (SM IGC) and an FAA developed framework called NAS-wide Safety Performance Monitoring Methodology, which was to augment existing risk indicators with additional data and analysis.

FAA Order 8000.369C documents agency-wide SMS requirements for the FAA, including elements of FAA's SMS and basic principles for performance safety management and oversight

(FAA, 2020). For context, the Order addresses FAA responsibilities to define requirements, perform risk-based oversight, verify systems/services meet applicable requirements, and evaluate effectiveness of systems/services with respect to standards and regulations. The applicable regulated entities with which the FAA interact with to perform these functions include air traffic service providers, airports, aviation manufacturers, operations, training organizations, and maintenance organizations.

The SMS activities and responsibilities described in Order 8000.369C are organized into the four primary SMS pillars; the policies and key SMS activities as defined in the order include:

- Safety Policy: defines the need to establish requirements, methods, and commitment to achieve a defined set of safety outcomes.
- Safety Risk Management: Defines the action to analyze performance, identify and evaluate hazards and associated safety risk, and take action to control and monitor hazards. This section references to a more detailed SRM policy in FAA Order 8040.4.
- Safety Assurance: defines the need to establish actions to verify that intended safety performance is met; actions defined include data analysis; employee/stakeholder reporting systems; monitoring/investigation, evaluation, and auditing; corrective action establishment and tracking; and management review.
- Safety Promotion: establishes elements of an organization that need to be evaluated and promoted to ensure the safety mission can be achieved; this includes ensuring the workforce has competencies and training to perform their mission and driving a positive safety culture.

Order 8000.369C also establishes responsibilities for continuous improvement.

### 4.2.5 FAA Aerospace Medicine (AAM)

The Office of Aerospace Medicine (AAM) oversees industry and FAA / DOT drug and alcohol testing programs, airmen medical certification, medical regulations and standards, and the Aviation Medical Examiner (AME) designee system. According to AAM representatives surveyed for this research, the majority of AAM's oversight is focused on establishing medical standards based on Part 67 Medical Standards and Certification, related ICAO practices (which AAM-200 manages), and then certifying pilots (which AAM-300 manages).

Another of AAM's key roles, highlighted by AAM stakeholders, is regulation and oversight of the aviation industry's drug and alcohol programs, performed by the Drug Abatement Division (AAM-800). The Drug Abatement Division assesses the compliance of aviation industry employers, contractors, and service agents with drug and alcohol testing requirements outlined in DOT regulation 49 CFR part 40, FAA regulation 14 CFR part 120, and other relevant FARs. The

FAA's Drug and Alcohol Compliance and Enforcement Surveillance Handbook (Order 9120.1E) is used in conjunction with FAA's Compliance and Enforcement Program Order 2150.3 and SRM Order 8040.4 to ensure inspections, investigations, and voluntary disclosure decisions are conducted consistently and accurately.

Within AAM, the Civil Aerospace Medical Institute supports safety oversight through medical research projects, data collection and analysis, and civil aircraft accident investigations. Their primary concern is the human element (e.g., flight crew, passengers, and air traffic controllers) and human support system in aviation. Its Aerospace Medical Certification Division administers the national medical certification program, including certifications[2] for airline transport, commercial pilots, and private / recreational pilots (among other types of flying) as well as non-FAA air traffic tower controllers and airman medical records.

The Aerospace Medical Certification Division also manages Aviation Medical Examiners (AMEs) that administer physical exams for pilot and non-FAA controller applicants to check for conditions of aeromedical safety significance (auditory, visual, vascular, psychiatric, and others). Depending on the safety significance of the medical condition, medical examiner guidance outlines recommendations on whether to issue a medical certificate, consider special issuance, or seek an FAA decision among other disposition options. Also, the frequency and severity of occurrence of medical conditions is documented among other facts as part of medical examination records.

AAM also oversees the ATC Specialist Health Program which is intended to assure FAA air traffic controllers[3] meet medical qualifications and are medically cleared to perform ATCS duties (FAA, 2023).

AAM uses a compliance-based risk decision analysis process and system for addressing non-compliance issues found during inspection. Following inspections of employer drug and alcohol testing programs, AAM inspectors complete an inspection profile in the Compliance and Enforcement Tracking Subsystem. This process includes an automated risk analysis based on inspection results (including non-compliance), compliance history, corrective actions taken by the employer, and other data. A risk level is calculated consistent with FAA Order 8040.4 SRM principles.

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[2] Flight Standards specifies the class of medical certification that pilots are required to obtain based on type of flight plus medical certifications for non-FAA air traffic control tower operators.
[3] The program excludes contract tower operators and contract flight service station air traffic control specialists.

For each instance of non-compliance, the Compliance and Enforcement Tracking Subsystem provides a recommendation ranging from a compliance action (i.e., to achieve compliance) to an enforcement action.  Compliance actions, subject to inspector review, are recommended when there is no evidence of repeat non-compliance, employer qualification issues, or high risk.  An administrative enforcement action entails a letter of correction or warning.  A legal enforcement action, subject to multiple levels of management and legal review, is recommended for cases of misconduct, failure to implement corrective actions, and conduct that causes significant safety risk for which there is insufficient means to resolve noncompliance and maintain future compliance.

The Office of Aerospace Medicine's (AAM) Safety Management Council (SMC) is responsible for SMS continued improvement, including safety risk management and safety assurance. According to FAA Order 1110.115A, the SMC evaluates AAM's safety policies, SRM program, and safety assurance activities to determine if they satisfy the requirements of FAA Order VS 8000.367, AVS Safety Management System. The SMC oversees all aspects of the SMS process, including the identification of hazards, assessing safety risk, and implementing risk controls.

The SMC is responsible for assessing the effectiveness of AAM SMS actions, defining member roles, and establishing safety objectives.  The safety objectives are then used as the basis for establishing an acceptable levels of safety performance.  The SMC is also responsible for conducting safety risk analysis for identified hazards. The Systems Analysis Branch (AAM-110) assists the SMC in monitoring the organization's safety objectives, maintaining an acceptable level of safety and conducting SMS program evaluations and assessments.

To minimize administrative requirements, the SMC performs reviews of select hazards and their safety risk level for submission to the federal air surgeon for adjudication and acceptance. The SMC also conducts safety assurance by monitoring hazards to confirm mitigation compliance, applying AAM's Quality Management System, and performing management reviews, data analysis, and corrective actions and audits to ensure compliance with SMS principles (FAA, 2020).

AAM uses three categories of performance measures for oversight of AME designee performance according to FAA 8000.95C. These measures span designee knowledge and understanding, interpretation and application of performance standards, and suitability of equipment and materials. The three categories include:

- <u>Technical Performance Measures</u>:  These measures address the knowledge and understanding of a designee including the ability to understand material in FAA orders and regulations;

ability of a designee to interpret and apply applicable performance standards; and ability of the designee to select and apply applicable equipment and tools supporting certification activities.

- Procedural Performance Measures: These measures address alignment with established procedures, including completeness and accuracy. Elements considered in these metrics include the designee performing duties associated with the functions authorized for them; proper capture and submission of written materials; consistently and correctly following FAA procedures during certification, evaluation and providing feedback; and following procedures when issuing certification, test results and findings.
- Professional Performance Measures: these measures address the attitude and conduct of the designee while performing their duties ensuring that their actions (including communications) and manner are representative of FAA standards. Measures include effectiveness of their communications (oral and written); demonstration of a positive reflection on the FAA; demonstration of a positive and cooperative attitude; and execution of actions with good judgment and high ethical standards.

According to AAM representatives surveyed for this research, AAM is conducting research on an aeromedical safety performance management framework, which has elements of risk-based and performance-based oversight. AAM's Concept for a State Safety Program Pilot Medical Fitness Reference Model (FAA, 2023) recognizes a need for both prescriptive and performance-based oversight of pilot medical fitness and performance given that either approach alone is not sufficient to oversee and address vulnerabilities in the pilot medical fitness impacts on flight safety. For prescriptive approaches, there are limits in medical understanding of relationships between the physiological aspects of disease and pilot performance ability which may lead to over-regulation. A challenge in implementing a performance-based oversight approach (and transitioning from prescriptive) is determining a performance goal for adequate and stable pilot performance. This is further complicated by determining what frequency pilot performance must be evaluated to establish performance durability (and whether that frequency is practical).

While there are challenges identified with defining and implementing performance-based oversight, AAM's Concept for a State Safety Program Pilot Medical Fitness Reference Model does describe a safety model that can be used to define performance measures associated with modeled hazards, threats (e.g. triggers) and associated barriers (acting in a role to prevent or mitigation consequences of a realized threat). In the barrier model concept, by way of example in AAM's reference model, a threat such as *hypobaria and/or hypoxia* could lead to the defined "inappropriate or inadequate pilot response" hazard, with preventive barriers for this threat to include “preflight assessment of disease state”, “inflight pulse oximetry...”, and “use of inflight supplemental oxygen”. Root cause analysis performed on realized hazard occurrences can be used to evaluate threat risk (by way of occurrence statistics) and effectiveness of specific barriers (for example, it may identify a barrier that didn’t perform as intended). With a large set of incident data applied to the model, barrier performance assessments can be used to identify specific barriers for oversight focus (e.g., those assessed to have poor effectiveness). For those barriers identified for oversight focus, specific performance measures to monitor performance more closely and to provide opportunities for proactive action can be defined. AAM’s model concept identifies the application of barrier models to both operational risks and process implementation risks.

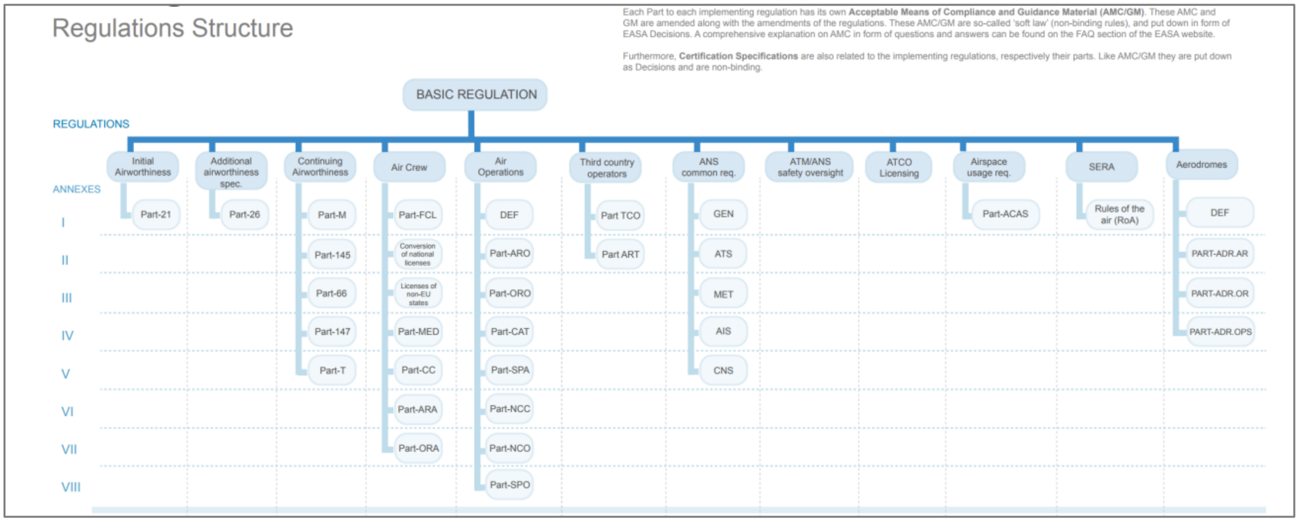
## 4.3 European Union Aviation Safety Agency (EASA)

The European Union Aviation Safety Agency (EASA) is tasked with a regulatory oversight responsibility of ensuring safety, security, environmental protection, and efficiency in civil aviation across Europe. EASA's regulatory scope encompasses a wide array of areas, including:

- *Aircraft Certification*: EASA oversees the certification process for aircraft, ensuring they meet airworthiness and safety standards before operating within European airspace.
- *Airworthiness Standards*: EASA establishes and enforces airworthiness standards for aircraft design, construction, and maintenance.
- *Operations and Flight Crew Licensing*: EASA regulates the operations of aircraft and the licensing of flight crew members, setting requirements for pilot training, qualifications, and operational procedures.
- *Air Traffic Management*: EASA collaborates with air navigation service providers and stakeholders to develop and implement harmonized air traffic management standards and procedures.
- *Airports and Aerodromes*: EASA sets standards and regulations for the design, construction, and operation of airports and aerodromes.
- *Air Navigation Services*: EASA oversees the provision of air navigation services, including air traffic control, navigation aids, and communication systems.

In terms of rulemaking, Basic Regulation is the top of the EASA regulation hierarchy and contains broad objectives for addressing all elements of aviation including airworthiness, flight standards, air traffic management, and airports. The next lower level of regulation is Implementation Rules that identify specific requirements that require compliance. EASA also publishes Certification Specifications with *Acceptable Means of Compliance* and associated

Guidance Material which provide information on how compliance with Implementation Rules can be met. The regulated entity can leverage and apply the *Acceptable Means of Compliance* but also can provide for approval *Alternative Means of Compliance*. The full Regulations Structure is shown in the figure below (EASA, 2017).




The aim of the regulations above is to identify technical requirements and administrative procedures for the subject area.  For example, EU 748/2012 defines the technical requirements and administrative procedures for certification of aircraft airworthiness and environmental performance and certification of associated design and production organizations.  EASA also develops certification specifications (CS) that identify technical requirements to be applied and which are standard means to demonstrate compliance of products or parts to elements of the Regulation requirements.  For example, for Initial Airworthiness, EASA defines many CSs including CS-25 Large Aeroplanes; CS-27 Small Rotorcraft, and CS-31HB Hot Air Balloons.

In 2019, EASA published Notice of Proposed Amendment  2019-05 which addressed the integration of safety management system requirements for Part-145 and Part 21; specifically, the notice proposed amendments to Annex I of EU regulation 748/2012 (Part 21 production and design organizations for aircraft and related products, parts, and appliances) and Annex II of EU 1321/2014 (Part 145).  Phase I of the regulation focused on Continuing Airworthiness domains, while Phase II focused on implementation in approved design and production organizations.  As of January 2023, SMS is mandatory for Part 145 and Part 21 organizations.

EU2018/1139 defines the responsibility for member states to perform task related to certification, oversight, and enforcement (as defined in 2018/1139 Article 62), however a member state can also request that EASA or another member state to carry out these tasks (per 2018/1139 Article 64).  Certification and oversight are performed for a mix of prescriptive requirements and performance-based regulations (e.g., regulation requiring SMS implementation). For prescriptive regulations, certification and oversight is performed via independent assessment of design and confirmation that the products meet safety and environmental protection standards. For example, for a new product the following steps are applied (SOFEMA Aviation Services, 2021):

- A certification team is established and reviews product design material.
- Applicable standards and requirements are identified, and a certification program established and agreed to among all parties.
- The design organizations demonstrate compliance to applicable requirements, which are verified by the certification team.
- A final report is created, and certification issued if all technical requirements are met, and no safety issues are identified.

As noted above, EASA creates and publishes CSs for all certified elements of the aviation system in their purview. For example, CS-27 includes a CS for the certification of Small Rotorcraft. An example is shown in Table 5:

Table 5: Example certification specification with acceptable means of compliance

| **Requirement Number/Name** | **Requirement** | **Acceptable Means of Compliance** |
|---|---|---|
| CS 29.251 Vibration | Each part of the rotorcraft must be free from excessive vibration under each appropriate speed and power condition | Supplements FAA AC 29-2C, § AC 29.251 and should be used in conjunction with that AC when demonstrating compliance with CS 29.251. The applicant should investigate each individual installation of the rotorcraft for compliance with CS 29.251. The absence of coupling with the rotors vibration frequencies has to be demonstrated by a combination of analysis, vibration and flight tests. Qualitative and quantitative flight tests should be performed depending on the extent of the change. For any installation, the failure of which or its attachment would have a catastrophic consequence, a fatigue evaluation should be performed when the vibrations are likely to affect the fatigue strength |

In addition to compliance-based oversight, EASA has published guidance on risk-based oversight. According to *EASA Practices for Risk-based Oversight* (European Union Aviation Safety Agency (EASA), 2016), domains including ATM, Aircrew, Air Operations, and Aerodromes are integrating risk-based oversight. One objective of this report was to offer definitions of terms and standardized approaches supporting risk-based oversight. Of note in this report is a definition of the relationship between performance-based oversight and risk-based oversight (RBO). Specifically, the report notes that “the concept of ‘performance’ conveys the idea of tangibly measuring the health of the system under scrutiny and ultimately assessing its overall performance. Performance indicators, as a means to measure, may specifically help to either identify risks within that system or measure safety risks or monitoring actions mitigating these risks. This means that a PBO can also support the identification of areas of greater risks and serve the risk assessment and mitigation exercise. This is exactly where PBO meets RBO” (European Union Aviation Safety Agency (EASA), 2016). The document defines a framework to organize activities to support RBO, including development of a risk profile and measurement of safety performance to inform planning activities, and where planning activities guide execution activities which include both compliance verification and assessment of risk measurement. This could be performed within the context of the compliance-based oversight activities described above.

The EASA report also highlights limitations of both RBO and PBO. It is noted that an “outcome-based approach focusing on the measurement of safety performance is essential for RBO. However, too much emphasis on safety performance indicators can be counterproductive.” An over-reliance on safety performance indicators may cause regulators to overlook compliance with prescriptive regulations and safe behavior which are essential to safe operations. Also noted is that RBO processes may be unable to identify new and emerging risks in time to proactively mitigate them.

EASA has established the Management System Assessment Tool to collect and manage data during initial certification and continued oversight. Specific focus areas of this tool include “safety management system (SMS) elements, which refers to ICAO Annex 19 and follows its ICAO framework… as per the transition four pillars of SMS” and the “compliance monitoring system as described in the EU system… which is a function to check compliance with the relevant EU requirements” (EASA, 2023). This tool and associated guidance have been established to assess compliance and effectiveness of a management system with ICAO Annex 19 and EASA Management System requirements. The tool leverages “12 elements of the ICAO SMS Framework” as defined in ICAO Annex 19, Appendix 2 and additional EU requirement including those specified in EU 276/2014.

The approach applied is to define each assessed SMS element as meeting the following defined maturity levels (EASA, 2023):

- **Present** – There is evidence that the relevant item is documented within the organization’s Management System Documentation

- **Suitable** – The relevant item is suitable based on the size, nature, complexity of the organization and the inherent risk in the activity
- **Operating** – There is evidence that the relevant item is in use and an output is being produced
- **Effective** – There is evidence that the relevant item is achieving the desired outcome and has a positive safety impact

To assist with making a maturity level assessment, a section on what to look for is provided in the Management System Assessment Tool guidance; although this is not intended to be a checklist, it does provide considerations to inform an assessment rating. The tool guidance (EASA, 2023) explicitly notes that the tool is intended to support both compliance and performance assessments where compliance focuses on ensuring required management system elements are present and functioning whereas performance-based assessment focuses on the management system elements delivering the intended results. Also of note is that the tool's guidance states that while the primary purpose of the tool is to support initial certification and continued oversight, it could also be used to evaluate the effectiveness of the oversight organization.

## 4.4 IATA Operational Safety Audit (IOSA) Program

The International Air Transport Association (IATA) is a global airline industry association, representing passenger and freight carriers. Among other functions, IATA develops and provides an industry accepted approach for evaluating airline operational management and control systems in accordance with approximately 920 Standards and Recommended Practices in the IOSA Standards Manual (ISARPs).

IOSA's Program Manual for Operational Safety Audits outlines high-level processes to evaluate an operator's compliance with ISARPs as well as a new risk-based approach to ascertain the maturity level of an operator's safety related processes and systems (IOSA, 2023). According to IATA's website, "risk-based IOSA increases the effectiveness of the audit and contributes to the overall industry goal of reducing the accident rate" and focuses "on pertinent safety risks, while maintaining a baseline of safety (IATA, 2024)." The risk-based IOSA, planned for full implementation by 2025, applies a three-tier prioritization scheme to identify higher priority ISARPs for periodic audits that are based in part on observed increases in safety occurrence rates such as runway excursions. The criticality of ISARPs to controlling risk specific to an operator is also factored into a risk-based approach for tailoring audit scope and frequency by individual operator along with the operator's audit history.

Like other performance and risk-based oversight approaches, IOSA requires a minimum baseline audit of ISARPs compliance.

To assess the maturity of operator SMS and other safety related management processes, IOSA established a maturity stage cycle. The cycle moves from low and basic maturities to established and then mature, and finally to leading. As of April 2024, IATA reported that criteria to assess maturity levels are shared only with operators planning a risk-based IOSA and that maturity assessment criteria will be released in the future to all operators (IATA, 2024). For SMS, IOSA examine ISARPs for management and control, safety assurance and monitoring, safety risk management, and training and communication. For operational safety, IOSA examine ISARPs for crew training, flight data analysis, and operation control.

EASA accepts IOSA Standards and Recommended Practices as form of compliance with EASA regulations. In contrast with EASA, the FAA does not use industry-led third-party auditor findings or conformance or non-conformance to U.S. Federal Aviation Regulations according to AVP representatives interviewed for this research.

## 4.5 International Civil Aviation Authorities (CAAs)

To align with ICAO safety standards and improve aviation safety oversight methods, many international aviation authorities are implementing and using performance-based oversight for targeted applications within their regulatory areas of responsibility. These organizations apply performance-based oversight in diverse ways, with different levels of early success and evolution toward achieving desired safety outcomes. This section summarizes oversight applications, activities, and outcomes realized within international aviation oversight organizations.

### 4.5.1 United Kingdom's Civil Aviation Authority

The United Kingdom's (UK's) Civil Aviation Authority (CAA) is responsible for establishing regulations, including safety and security standards; performing licensing and certification for UK pilots, maintenance staff, operators, and airports; certifying design, development, and maintenance for UK registered aircraft; and managing and overseeing air traffic management in the UK. The CAA has gradually issued requirements for SMS implementation by operators, aircraft maintenance organizations, and aircraft design and manufacturing organizations. One motivation for this change is an effort to be more proactive in addressing safety incidents. One aspect of this transition is to "examine the [incident] causal factors more closely and transform … regulatory activities to a more risk and performance-based approach" (UK Civil Aviation Authority, 2014).

In concert with changes to regulations to adopt SMS, there is a corresponding transition in the UK CAA's oversight approach. Besides compliance-based oversight, the CAA leverages a risk-based approach to prioritize safety oversight activities based on understanding a regulated entity's performance to requirements. This includes both compliance with prescriptive standards and effectiveness in implementing performance-based regulations (e.g., SMS effectiveness and safety performance indicators).

The UK CAA closely associates risk-based oversight with performance-based oversight where safety risk and safety performance data is used to steer and prioritize regulatory oversight activities (UK Civil Aviation Authority, n.d.). The CAA's oversight approach includes collection and characterization of risk information, including the performance of a regulated entity's capability in managing its safety risks. Of note is that CAA safety inspectors are "asked to consider various aspects of the organization [they are overseeing] and rate the confidence that they have in that particular area's effectiveness" considering factors such as the regulated entity's staff safety awareness, staff turnover, competency level, planning and implementation of performance improvement, and change management, among others (UK Civil Aviation Authority, n.d.).

A recognized challenge of assessing performance-based oversight is oversight workforce guidance on how to assess SMS implementation effectiveness. As a result, the CAA developed an SMS evaluation tool to assess a regulated entity's SMS performance effectiveness (UK Civil Aviation Authority, 2023). This tool applies a maturity level assessment for individual SMS elements, including the following markers and definitions provided tool guidance material:

- **Present:** There is evidence that the 'marker' is clearly visible and is documented within the organization's SMS or MS [Management System] Documentation
- **Suitable:** The marker is suitable based on the size, nature, complexity, and the inherent risk of the activity.
- **Operating:** There is evidence that the marker is in use and an output is being produced.
- **Effective:** There is evidence that the marker is effectively achieving the desired outcome and has positive safety impact.

Since the definitions above are high-level and require interpretation of data provided by the regulated entity, the SMS evaluation tool also identifies "what to look for" as examples that can help to make an assessment. The CAA's SMS evaluation tool also requests that the inspector document how a specific maturity level is achieved and provides an opportunity to capture additional remarks.

### 4.5.2 Transport Canada

Transport Canada is responsible for Canada’s aviation transportation policies and programs. This includes defining, enforcing, and overseeing aviation regulations and standards; pilot licensing; aircraft certification and registration; and oversight of the provision of air traffic and air navigation services in Canada. Transport Canada has gradually shifted regulatory policy towards performance-based specifications and oversight. As defined by Canada in an ICAO 38th Assembly Technical Commission Meeting, performance-based oversight includes assessing a level of compliance/conformance of an “enterprise” with aviation regulations. Specifically, it is noted that Canada is “looking at how effectively the enterprise complies [i.e., conforms] with aviation regulation and not just whether the enterprise complies” (ICAO, 2013). Transport Canada’s performance-based oversight approach assesses the effectiveness of aviation operators and maintenance organizations in their implementation and application of safety management systems.

Recent updates to Transport Canada’s Surveillance Policy (Transport Canada, 2023) define objectives for a systems and risk-based approach to surveillance oversight. Part of this approach takes a holistic evaluation of the entire regulated entity across applicable elements in manufacturing, operations, and maintenance to understand associated risks and performance data. A key reference in this surveillance policy is the use of a “multi-disciplinary teams of inspectors to gather and analyze safety risk information about all parts of an organization’s operations” (Transport Canada, 2023). Although not explicitly stated, recognition that a multi-disciplinary team of inspectors is required to oversee complex enterprises implies that the inspectors must be informed and experienced across the technical and organizational aspects under evaluation.

Transports Canada’s Surveillance Planning Instructions provide guidance and factors for determining the scope and frequency of surveillance (Transport Canada, 2022). The surveillance planning guidance includes routine (e.g., yearly) completion of qualitative questionnaires with additional surveillance actions planned based on a range of factors, including occurrence accident/incidents, inspector judgment, history of non-compliance, complexity of the regulated enterprise, any unwillingness to cooperate, and insufficient production of information, among others (Transport Canada, 2022). An additional input to surveillance planning is data available for defined safety risk indicators. For Transport Canada surveillance planning, these indicators are applied to enterprises subject to oversight and include:

- Time since previous inspection
- Average number of inspection findings

- Number of inspection observations
- Number of occurrence reports

### 4.5.3 New Zealand

New Zealand's Civil Aviation Authority (CAA) is responsible for development of aviation regulations for aircraft airworthiness, aircraft maintenance, airport operations, pilot licensing, and training; certification of airline/air operations; registration of aircraft; assessment of compliance to regulations and other safety oversight actions; and aviation security oversight. New Zealand's regulatory framework recognizes the importance of both prescriptive civil aviation rules, such as technical standards and operating procedures, and performance-based regulations. Safety-related performance-based regulations include measuring safety and security performance outcomes and the CAA's safety rule requiring aviation organizations to implement an SMS (New Zealand CAA, 2024).

The New Zealand CAA describes the transition to SMS as a journey rather than a destination, recognizing that establishing an SMS involves interconnected organizations and systems where each component and everyone's conduct has influential impacts on safety (New Zealand CAA, n.d.). A key objective for SMS implementation and application is to minimize safety risk using proactive actions based on measuring and monitoring systems of interest. The CAA requires air operators, aircraft maintenance organizations, airport operators, training organizations, and air traffic service providers to implement an SMS.

The New Zealand CAA's oversight activities include a combined approach of compliance with prescriptive and performance-based regulations and assessment of performance-based regulatory effectiveness. Together, these elements inform an overall risk-based approach for planning and execution of oversight that considers operational complexity, safety history, compliance performance, and effectiveness assessments to inform the allocation of oversight resources. As part of this approach, the New Zealand CAA uses aviation sector risk profiles aligned with ICAO SM ICG guidance on Sector Safety Risk Profiling at the State Level (ICAO SM ICG, 2020). Sector risk profiles were developed for medium and large transport aircraft, Part 135 commuter and on-demand operations, and agricultural aviation operations. Risk indicators for associated sector risk profiles entail increasing levels of performance for assessed topics. Examples of risk indicators for Part 121 are presented in Table 6.

Table 6: Example Part 121 risk indicators for New Zealand

| **Safety, risk and quality management systems** | **Change in company organization, scope, or size** |
|---|---|
| 1 A comprehensive documented Quality Management system is in place. The | 1 All aircraft have been owned for at least 24 months |

| | |
|---|---|
| Operator/Management has clear visibility of issues confronting them and the quality system in place is designed to sensibly anticipate and/or cope with them. No deficiencies in the QMS were observed during the most recent CAA evaluation. Best practice SMS is evident. Risks are effectively evaluated and mitigated or eliminated. Continual review and improvement. Training in risk management is provided to all relevant staff. Vertical, horizontal and matrix (project orientated) free communications exist between all levels and units.<br>2 A well-designed Management System is in place within the organization. It may contain a documented, comprehensive QA system. No significant deficiencies in the Management, Planning, or QA systems were noted. Process and problem ownership is well defined. SMS in place. Risks are evaluated and routinely dealt with, although not always proactively. Training in risk management is provided to some, but not all affected staff. Clear, well-defined lines of communication exist.<br>3 A basic Management System is in place and it may contain a QA system. There are aspects/facets of the organization's operations that have not been considered. Process and problem ownership is defined but some deficiency noted. A proactive planning system is in place. Some deficiencies in the planning or management system noted. Risks are evaluated but not always dealt with in a systemic formal manner.<br>A general awareness of risk management is evident through informal processes. Lines of communication are defined.<br>4 Management has taken some initiatives towards introducing and implementing a quality approach and systems throughout the organization's operations. However, the system is not comprehensive and/or not clear. Problem or process ownership is not defined. There is a piecemeal/ reactive approach to planning. Safety management is treated as actions to take after a major problem is identified. Risks are<br>ignored when convenient. No risk management training is provided. Lines of communication are not clear.<br>5 There is little or no evidence of a sensible Quality Management System being in place. No evidence of any form of quality system or proactive management/planning system evident. Safety management is ignored in favor of commercial priorities. No evidence of SMS. Risks are deliberately ignored. No training in risk management is provided and discussion about the subject is | 2 All aircraft have been owned for 12 months to 24 months<br>3 Any aircraft have been owned for less than 12 months.<br>4 Any aircraft with a new engine type (turbine, turboprop, piston) has been owned for less than 12 months.<br>5 Any aircraft of a new class (Aeroplane, Helicopter, Balloon, etc.) has been owned for less than 12 months.<br><br>**Staff turnover especially Chief Pilots/supervising staff**<br>1 All senior persons have held positions for > 24 months.<br>2 All senior persons have held positions for > 12 months.<br>3 One senior person has held position < 12 months.<br>4 More than half the senior persons have held their positions < 12 months<br>5 All senior persons have held their positions < 12 months<br><br>**Safety trends**<br>1 Occurrence rate and NCI both decreased in last year (>10% decrease)<br>2 One of Occurrence rate or NCI decreased in last year.<br>3 Occurrence rate and NCI both remained static in last year (<10% increase and/or <10% decrease)<br>4 One of Occurrence rate or NCI increased in last year. (>10% increase)<br>5 Occurrence rate and NCI both increased in last year<br><br>**Attitude to safety and compliance by management**<br>1 An excellent attitude to all aspects of safety within the organization. Safety culture is well embedded and obvious (such as safety teams across organizational lines). Just culture is actively promoted.<br>2 Management is proactive in safety matters and there are only minor/occasional lapses. Safety culture is accepted and understood through the organization. A just culture ethos is in place.<br>3 Management takes the initiative in safety and has safety procedures in place. Safety culture is generally understood but there are minor individual lapses Operational 'risk assessment' does take place.<br>4 Management is reactive. Does on occasion take some initiatives towards implementing policy and procedures to enhance organizational safety, but generally ongoing monitoring is spasmodic. Safety culture is confined to individual initiatives. No operational 'risk assessment' apparent.<br>5 Management is either inactive or actively fosters the development of poor safety culture within the wider |

| | |
|---|---|
| discouraged. Communication regarding safety, risk and quality matters does not take place unless forced to by external reasons. | organization. No evidence of a positive safety culture in either management or in individuals within the organization. Individual responsibilities are not recognized and there does not appear to be any grasp of the 'big picture'. There is no operational 'risk assessment' mechanism. |

For information collected as part of oversight, it is explicitly noted (similar to Transport Canada) that a systems approach is applied, emphasizing the importance of identifying and recognizing all areas of a "system" for assessment. The CAA of New Zealand notes that a range of data from both internal and external sources is needed to "develop intelligence" to shape oversight processes with a need for "high-quality reporting by participants of occurrences (i.e., accidents, incidents, and immediate hazards to the safety of an aircraft operation)" (CAA of New Zealand and Aviation Security Service, 2022). This reference points to the importance of positive and effective safety culture both within an oversight organization but also within the regulated entities where clear, open, trusted, complete, and continued communications are needed to achieve the goal of "high-quality reporting."

In its forward-looking plan for safety, the CAA of New Zealand also recognizes the importance of a purposeful, informed, and integrated workforce. Specifically, New Zealand provides a safety plan to continue development of the CAA's regulatory workforce while recognizing that "not all people can be expected to have specialized knowledge in all areas" (CAA of New Zealand and Aviation Security Service, 2022). This reiterates themes noted from the UK CAA and Transport Canada that a multi-disciplinary team of inspectors is needed with diverse skills and knowledge, assigned to perform in areas where they are trained and effective. As reported in New Zealand CAA's Regulatory Safety and Security Strategy for 2022-2027, five behaviors key to the success in performing safety oversight functions include:

- Systems thinking: recognize components of a system, their interactions, and the implications for system performance.
- Problem solving: Identify, understand, and fix the important problems to ensure the continuous improvement of the aviation system.
- Critical thinking: Use analytical and evaluative techniques to arrive at balanced, evidence-based judgements and decisions.
- Communications and engagement: Interface effectively between internal and external stakeholders to ensure we meet organizational objectives.
- Influencing: Tenaciously pursue aviation safety by motivating participants to behave in a safe and secure way within the aviation system.

# 5 Energy safety oversight approaches

## 5.1 Department of Energy (DOE)

The DOE is responsible for U.S. energy policy, security, advancement, research and development of nuclear energy and related technologies, and management of nuclear weapons programs. The DOE oversees the safety of nuclear facilities' construction and operation (by the DOE itself or a DOE contractor) per 42 U.S.C. 2140; renewable energy technologies; the US energy grid; the production and maintenance of nuclear weapons; and nuclear waste management.

The scope of DOE oversight includes assessment of effective performance and compliance for DOE federal and contractor programs and management processes to DOE requirements and directives. Oversight programs include onsite reviews, assessments, self-assessments, performance evaluations, and other activities to evaluate contractor and federal organizations that operate or manage DOE sites, facilities, or operations (DOE, 2022). DOE's ultimate safety goal is "zero accidents, work-related injuries and illnesses, regulatory violations, and reportable environmental releases" per DOE policy 450.4A Change 1 (2018 update).

To meet DOE's safety goal, controls or mechanisms are implemented across all DOE missions and corresponding lifecycle activities to limit radiological and non-radiological hazard exposure of the public, workers, and the environment to a level that is as low as reasonably achievable. DOE line management is identified as having primary responsibility and accountability for meeting this policy objective, where line management is "the unbroken chain of responsibility" from those that direct the work to those responsible for program execution, including contractors and subcontractors (DOE, 2015).

DOE's Integrated Safety Management Policy (DOE P 450.4A Change 1) defines how DOE meets line management safety responsibility by:

- Defining safety functions and roles: This includes specifying safety roles with defined roles and authorities; for example, safety roles may have *responsibility* authority (ensuring a task or function is completed), and some may have *accountability* authority (ownership of the action and the results achieved)
- Performance measurement: This includes the definition of performance measures (including data collection and processing methods) and evaluation and interpretation of data.
- Development of regulations, contracts, directives, and oversight and enforcement capabilities: This provides the requirements, methods, and tools to meet safety performance objectives considering actions and functions within the DOE and among all contractors.

DOE applies Integrated Safety Management (ISM) across management and work planning and execution based on ISM guiding principles and core functions identified in DOE Order 226.1B. The DOE defines ISM as applying a systematic approach to management of safety risks, emphasizing an integrated approach to safety planning, execution, evaluation, and continuous improvement (generally aligning with the plan, do, check, act approach). ISM core functions include analyzing hazards, implementing controls according to agreed-on standards and within established "safety envelopes", and collecting feedback on control adequacy as part of continuous improvement, among others.

DOE Order 226.1B-CHG1, Implementation of Department of Energy Oversight Policy, establishes requirements for implementing DOE's P226.2 Policy for Federal Oversight and Contractor Assurance Systems. Within P226.2, it is noted that oversight should use "outcomes and information from effective Contractor Assurance Systems" to inform oversight whenever possible, noting these systems should address not only safety, security, environment, but also business and financial systems. This policy document defines high-level attributes of effective assurance and oversight processes which:

> Are tailored to meet the needs and unique risks of each site or activity;
> Include methods to perform rigorous self-assessments;
> Conduct feedback and continuous improvement activities;
> Establish metrics to identify and correct negative performance trends;
> Include independent reviews;
> Assure that corrective actions implemented are effective;
> Share lessons learned (DOE, 2016)

This policy document also notes that DOE oversight activities should be designed and executed with alignment to the level of risk of an activity and where higher oversight priority is given to activities with potentially high consequences.

Within DOE Order 226.1B-CHG1, requirements are defined for oversight processes developed and implemented within DOE line management. These requirements include:

- Evaluation of contractor and DOE management systems for performance effectiveness (explicitly noted to include compliance with requirements) and where the level and mix of oversight is applied based on defined hazards, maturity of a management system and program, and operational performance of a management system and program.
- Written plans and schedules for assessments

- Developing findings which can be organized by risk and priority where issues related to findings should have a root cause analysis and corrective actions

The DOE oversight order also notes that performance expectations must be defined and communicated to contractors.

In 2022, the Defense Nuclear Facilities Safety Board, which oversees 10 active DOE defense nuclear sites and 4 closure project sites (Defense Nuclear Facilities Safety Board, n.d.), conducted a review of DOE Safety Oversight Effectiveness (Defense Nuclear Facilities Safety Board, 2022). The Board found that the DOE integrated regulatory oversight model encompasses key elements of DOE oversight directives; of particular interest in this review was the requirement to assess "effectiveness" of oversight. This includes evaluation of contractor effectiveness and of DOEs performance in its regulatory oversight role. The Defense Nuclear Facilities Safety Board review noted that "assessing 'effectiveness' requires a performance-based assessment in addition to compliance assessment" (Defense Nuclear Facilities Safety Board, 2022). The performance-based element is described as defining and then applying a set of criteria with associated thresholds for making a specific effectiveness assessment. The DOE Safety Oversight Effectiveness review provides examples of DOE requirements, associated guidance to assess compliance and effectiveness, and examples of criteria that could facilitate the effectiveness assessment as reproduced in Table 7:

Table 7: DOE safety oversight effectiveness criteria

| **Requirement** | **Compliance** | **Effectiveness** | **Potential Criteria** |
|---|---|---|---|
| DOE must have effective processes for communicating oversight results and other issues in a timely manner | Does DOE have procedures for communicating oversight results? | Does the procedure clearly define criteria for "timely" and for evaluating how clearly and comprehensively the communication plan identifies issues? | Average time it takes to communicate an issue; number of times the contractor needs additional clarification of the issue |
| DOE must include written plans and schedules for planned assessments. | Does DOE have an annual integrated assessment plan? | Does the plan give criteria for selecting the right mix and rigor of oversight activities and completing them on time? | Number of postponed reviews; negative contractor performance trends in unreviewed areas |
| DOE must have an issues management process that is capable of categorizing findings based on risk and priority, ensuring that problems are evaluated and corrected on a timely basis | Does DOE have an issues management process with risk categories? | Does the process measure whether the issues management process is effective at categorizing findings and correcting them in a timely manner? | Time to closure for correcting high risk issues; recurrence of previously corrected issues |

In the review of DOE Safety Oversight Effectiveness, it was noted that there was opportunity for improvement in the approach for effectiveness assessment. Of note was a lack of consistent and documented evaluation criteria with acceptable thresholds to apply during effectiveness assessments; criteria that did not always include contractor performance elements (which could indicate ineffective safety oversight); and insufficient documented basis to justify a specific effectiveness assessment. An additional issue was the insufficient clarity of responsibilities in DOE's functions, responsibilities, and authorities (FRA) documents and office procedures. These issues, in addition to what the review noted as insufficient frequency of oversight, led to an observation that there was insufficient material to assess the DOE oversight process as effective.

Other safety observations made in the report included a need to ensure that sufficient technical capability is applied to oversight activities; improvement in proactive actions to identify potential safety issues; and managed processes to ensure that identified safety issues are addressed and closed in a timely manner.

The Defense Nuclear Facilities Safety Board's review implies that DOE staffing for baseline oversight was not well defined because baseline oversight requirements were not well defined. As a result, limited oversight staffing resources were applied toward high-risk, reactive oversight at the trade-off of proactive baseline oversight that could provide data for future oversight cycles and insight into potential FRA gaps. Baseline oversight needs a consistent cadence, scope, and level of rigor to facilitate proactive safety oversight.

## 5.2 Nuclear Regulatory Commission

While the DOE oversees nuclear scientific and technological research and innovation for US security and defense, the Nuclear Regulatory Commission is responsible for licensing and overseeing civil nuclear plants, siting, and materials among other facets of nuclear safety and operation.

One of the NRC's oversight roles focuses on nuclear reactor safety. The NRC's Reactor Oversight Process (ROP) encompasses the approach for monitoring, inspecting, and assessing commercial nuclear power plant reactor safety, radiation safety, and security-informed safeguards (NRC, 2024C; NRC, 2018 – 2022). Reactor safety spans four "cornerstones" that affect the safety of plant operations, including initiating events (e.g., turbine trips producing reactor scrams, feedwater loss, power loss); mitigations; barrier integrity; and emergency preparedness. The radiation safety cornerstone includes both public and worker exposure.

### 5.2.1 Performance-based and risk-based oversight

As noted by the American Nuclear Society, the NRC's ROP is risk-informed and performance-based (American Nuclear Society, 2021). The NRC's goal for performance-based regulatory actions "…focus on identifying performance measures that ensure an adequate safety margin and offer incentives for licensees to improve safety without formal regulatory intervention by the agency (NRC, 2020)." Regulated entities (i.e., licensees) submit performance indicator data for each of the safety "cornerstones" on a quarterly basis. A performance indicator is defined as:

A quantitative measure of a particular attribute of licensee performance that shows how well a plant is performing when measured against established thresholds (NRC, 2024D).

The ROP provides "risk-informed" indicator performance thresholds that call for increased vs. required regulatory responses and determination of unacceptable performance. Most importantly, the NRC independently verifies performance indicator data by conducting inspections and using a combination of its own inspection findings and the licensee performance indicator data to assess plant-specific performance (NRC, 2024D).

Risk-based and performance-based oversight applications are demonstrated in NRC's use of systems to gauges safety indicator performance for specific safety management cornerstones and to associate oversight response types with performance thresholds. A four-level color-coded system is used to characterize indicator safety performance (NRC, 2024F). "Green" denotes expected an performance level where cornerstone objectives are met. "Red", "white", and "yellow" denote significant reduction in safety margin, out-of-range indicator performance, and minimal reduction in safety margin, respectively. In the latter two cases, related cornerstone objectives are still met, and the overall system demonstrates NRC's use of progressive levels of performance measurement with opportunities to tailor oversight intervention while still within a margin of safety.

An example performance indicator and thresholds for oversight responses are outlined in the table below.

Table 8: NRC example performance indicator and response thresholds

| | | **Threshold** | | |
|---|---|---|---|---|
| **Cornerstone** | **Indicator** | **White** **Increased Regulatory Response Band** | **Yellow** **Required Regulatory Response Band** | **Red** **Unacceptable Performance Band** |
| Initiating Events | Unplanned Scrams Number of automatic and manual unplanned | > 3.0 | > 6.0 | > 25.0 |

| | | | | |
|---|---|---|---|---|
| | scrams during previous 4 quarters while critical per 7000 hours | | | |

In addition to evaluation of licensee performance indicator reports, the NRC also conducts inspections. Inspection findings are assessed for safety or security significance according to a different four-level color-coded system than that used for performance indicator results (NRC, 2024F). Here, "red" denotes high safety or security significance, and "yellow" denotes substantial safety or security significance. "White" means low to moderate safety or security significance, and "green" means very low safety or security significance.

Cases where a licensee has multiple, significant regulatory violations or poor configuration control of the facility operation and maintenance per its approved design basis are examples of "unacceptable performance." In such cases, the NRC "lacks reasonable assurance that the licensee can or will conduct its activities without undue risk to public health and safety." A limitation in determining unacceptable performance is outlined in NRC's Inspection Manual Chapter 0308 Attachment 4 Technical Basis For Assessment (NRC, 2023). Specifically, identification of adequate, objective, and reliable measures to indicate unacceptable performance proved difficult, and as a result, NRC's senior agency management must make a subjective decision to determine "unacceptable performance." Once such a determination is made, the subsequent regulatory response follows the NRC Enforcement Manual.

NRC's Risk-Informed Baseline Inspection Program (NRC, 2019), another example of risk-based oversight, is part of the ROP and is characterized as a minimum inspection of all power reactor licensees' performance per cornerstone safety objectives. The goals of the baseline inspection are not intended to diagnose root causes of identified performance issues but rather to:

- Determine a licensee's effectiveness in identifying and correcting problems and issues based on risk significance
- Verify the accuracy and completeness of licensee-reported performance indicators
- Enable the NRC to remain cognizant of plant status and conditions

The baseline inspection program focuses on inspectable areas that are not fully measured via licensee-reported performance indicators. Examples of inspectable areas are "as low as reasonably achievable" planning and controls; design bases assurance inspection, which verifies that plant components and associated modifications are consistent with and maintained according to their designs; emergency action level and emergency plan changes; and equipment performance, maintenance, and testing.

In addition to inspectable areas, event follow-ups are also conducted as part of safety cornerstone-based inspections. Inspectors screen events to gather and report details such as equipment faults and failures and operator errors to risk analysts to assess risk significance.

Plant status reviews use information about facility problems, emergent issues, and ongoing activities or changes that could impact safety as gathered by resident inspectors prior to baseline inspections. During baseline inspections, plant status review information is used to cross-check whether the licensee is effectively capturing related deficiencies and corrective actions.

The baseline inspection program also verifies licensee-reported performance indicators by reviewing raw data sources, such as maintenance records, corrective action records, and operating logs, and conducting certain real-time verifications during inspection. Any problems identified in performance indicator accuracy or completeness are tracked through corrective action records and inspection to verify adequate resolution.

The effectiveness of licensee problem identification, risk assessment, and resolution process is also addressed as part of the baseline inspection program. Licensee self-assessments, quality assurance audits, root cause analysis records, corrective actions, and the effectiveness of corrective actions taken are inspected via a performance-based review. (Details of the performance-based review approach are not addressed in the manual). Any deficiencies in the problem identification and resolution process may trigger additional, supplemental inspections with follow-ups to validate effective implementation.

### 5.2.2 Evaluating NRC oversight effectiveness

Performance-based oversight is also employed as part of the NRC's ROP effectiveness evaluation which uses internal, periodic self-assessments conducted by ROP program area leads. ROP oversight effectiveness is also independently evaluated through external reviews conducted by independent agencies such as the Office of the Inspector General.

As part of ROP, self-assessments are intended to evaluate:

- whether oversight program goals and outcomes are achieved
- the effectiveness and uniformity of the program implementation across locations, including the effectiveness of significant changes to the oversight program
- the timeliness of program responses to licensee performance issues and significant events
- detailed reviews of the baseline inspection program plus select topics

Annual self-assessment results are reported by the NRC Executive Director for Operations with results posted for public review (NRC, 2018 - 2022). ROP goals and intended outcomes outlined in are provided in the table below (NRC, 2022).

Table 9: NRC Reactor Oversight Program goals and outcomes

| **Goals** | **Intended Outcomes** |
|---|---|
| • Objective - Decisions are based on factual information and uninfluenced by emotion, surmise, or personal prejudice.<br>• Risk-informed - Risk insights are considered along with other factors (such as engineering judgment, safety limits, redundancy, and diversity) to better focus licensee and regulatory attention on issues commensurate with their importance to health and safety.<br>• Understandable - The process and its results are clear and written in plain language.<br>• Predictable - More than one individual can follow the same defined process and arrive at the same conclusion in a consistent manner (i.e., repeatable). | • Monitor and assess licensee performance<br>• Identify performance issues through NRC inspection and licensee PIs<br>• Determine the significance of identified performance issues<br>• Adjust resources to focus on significant performance issues<br>• Evaluate the adequacy of corrective actions for performance issues<br>• Take necessary regulatory actions for significant performance issues<br>• Communicate inspection and assessment results to stakeholders<br>• Make program improvements based on evaluation of stakeholder feedback and lessons learned<br>• Ensure reliable and predictable program implementation |

Green-yellow-red criteria are defined for assessing each ROP oversight process metric. The criteria include a mix of compliant/non-compliant guidance and numeric ranges for indicator values regarding number of discrepancies, deviations, days to complete or days late, etc. An example performance metric and criteria are provided in the table below. It should be noted that the metric and criteria are associated with oversight program functional areas of responsibility and deliverables and not safety incident or incident precursor occurrence rates. Per the ROP Inspection Manual, further evaluation and possibly ROP staff action is warranted when metrics fall in the "red" or "yellow" areas, where "red" denotes unexpected performance and may prompt evaluation of causes, and "yellow" may prompt correction before the acceptance criterion is exceeded. "Green" means ROP metric performance is as expected and does not need further evaluation (NRC, 2022).

Table 10: Example NRC Reactor Oversight Program metrics and performance criteria

| **Metric** | **Metric Definition** | **Criteria** |
|---|---|---|
| 05.01 R-1 Predictability and Repeatability of Significance Determination Results | Potentially greater-than-green inspection findings and the associated degraded conditions contain adequate detail to enable an | Green: 0 discrepancies Yellow: 1 discrepancy Red: ≥ 2 discrepancies |

| | | |
|---|---|---|
| | independent auditor to trace through the available documentation and conclude that the significance characterization is reasonably justifiable from both programmatic and technical positions. | |

Independent evaluations of ROP effectiveness are conducted by the Government Accountability Office and the Office of Inspector General, which appears to conduct the most frequent reviews of ROP oversight performance, with annual reports from 2010 onward shared on the NRC's ROP site.

In addition, NRC bi-monthly meeting notes on ROP initiatives, lessons learned, performance indicator findings and issues, and other discussion items are also posted for public review (NRC, 2024E).

# 6 Oil & gas and environmental safety oversight approaches

The Bureau of Safety and Environmental (BSEE) was established in 2011 in response to the Deepwater Horizon oil spill and replaced the Minerals Management Service as the responsible regulatory authority for offshore oil and gas operations. This Bureau falls under the Department of Interior and is charged with overseeing compliance with nearly all Federal Regulations related to the oil and natural gas industry on the U.S. Outer Continental Shelf (OCS). Responsibilities include developing, implementing, and enforcing regulations concerning oil, gas, and sulfur exploration, development, and production operations. According to its website, "Central to BSEE's mission is the continuous improvement of its regulatory functions involving worker safety, emergency preparedness, environmental compliance, and conservation of resources" (BSEE, 2024). BSEE collaborates with several other agencies, including the National Oceanic and Atmospheric Administration to monitor endangered species, the Department of Defense on projects affecting the OCS and shorelines, the Department of Transportation for pipeline safety and spill prevention, and the Environmental Protection Agency to enforce pollutant discharge regulations, among others.

Within BSEE, the Offshore Safety Improvement Branch is generally responsible for oversight of safety-related operations, including aviation safety. This office also maintains programs to manage medical standards, electrical system standards, and security risk, and provides oversight of Safety & Environmental Management Systems (SEMS).

BSEE employs a hybrid approach to its oversight activities, applying both compliance-based and performance-based methods, though the majority of its oversight practices appear to be compliance-based, relying on audits to ensure compliance with regulations, lease terms, and approved plans. Data on the BSEE website indicates it audits 2,000 facilities in Gulf of Mexico, Pacific, and Alaskan waters on an annual basis to ensure compliance with prescriptive regulations. However, BSEE also requires all operators to submit performance measure data, and this performance data is used to influence decisions regarding the allocation of inspection resources to focus oversight on larger and more complex operators, a risk-based aspect of BSEE's oversight approach.

## 6.1 SEMS Oversight and Enforcement Program (OEP)

The Systems SEMS OEP, developed in 2019, establishes BSEE policy for oversight and enforcement of compliance by OCS operators with SEMS regulations (BSEE, 2019). The document describes a national policy whereby an operator is responsible for the effectiveness of its SEMS program. The policy also relies on independent auditors to provide compliance-based oversight to assess the design, implementation, and maintenance of an operator's SEMS program by comparing the operator's documentation to applicable regulations. BSEE's role is to inspect operator facilities and review audit reports, and to collect and monitor incident reports for "frequency and relative seriousness." Based on the operator's documented incident performance and judgment of OEP Specialists, additional audits may be directed to search for possible "systemic weaknesses in an operator's SEMS."

During BSEE inspections, OEP Specialists may issue an Incident of Noncompliance (INC) to document deficiencies with a SEMS program or administrative failures regarding audit plans or corrective action plans as applicable. However, the policy makes no provision for an INC to be issued in response to the operator's incident performance. The policy does not contain guidance, thresholds, or standards for acceptable incident performance in terms of either frequency or seriousness.

## 6.2 Performance measures

Each year, all OCS operators are required to submit Performance Measure Data by March 31 using a standardized form, BSEE-0131 (BSEE, 2022). The data is broken down quarterly and summarizes the number of injuries or illnesses sustained during production, drilling, or construction operations. However, the seriousness of personnel injuries and the extent of any damage incurred is not reported. The data does include the number of hours worked by company and contract employees to establish an exposure metric that could be used as the basis for an expression of risk, though no such usage was found within the material reviewed. Finally, the number of oil spills and total volume of spilled oil in barrels is reported.

## 6.3 Audit analysis reports

Four analysis reports on SEMS challenges and successes have been produced since BSEE's inception, and two of these reports for October 2020 and February 2024 are publicly available via the BSEE website.

The October 2020 BSEE report refers to a third round of SEMS audits, with each round roughly encompassing a three-year period based on the required frequency of audits for most operators. The report finds that compared to previous audits, "there appears to be a general movement on the SEMS maturity path away from the need to design and establish SEMS policies and procedures… (BSEE, 2020)." The report recommends that BSEE improve its oversight by focusing more on "operator-specific risk management practices and less on SEMS design." The report itself includes numerous details regarding percentages of operators who have successfully implemented various elements of a SEMS program versus those with deficiencies. There is no data in the report regarding incident rates or trends, and the report finds no evidence of SEMS being effective in terms of achieving objectives for reduced injury and environmental incidents. However, the report states that "The benefits of a SEMS investment (e.g. better safety and environmental performance) will become clearer as companies increase efforts on implementation …" due to expected changes in organizational behavior.

The February 2024 BSEE report covers the fourth cycle of SEMS audits. This report echoes its predecessor, citing "stalled progress towards SEMS maturity and effectiveness" (BSEE, 2024). The report does find some improvement in some of the specific SEMS elements, but these are mostly administrative elements. The report states that elements that are fundamental to achieving SEMS objectives were responsible for most of the identified deficiencies, including hazard analysis, change management, safe work practices and contractor management, operating procedures, and mechanical integrity, among the most deficient areas. Additionally, the report finds that "many corrective actions proposed by operators were remedial or superficial in nature" and noted the "recurrence of deficiencies from prior SEMS audits" suggests a need for new or modified processes to ensure corrective action effectiveness is maintained over time and across all operator assets. In terms of proposed actions, the report suggests there may be a need for updating SEMS regulatory requirements and a corresponding need for BSEE to focus its oversight and monitoring actions on the most important, and most deficient, elements of SEMS. Like the 2020 audit report, the 2024 report summarizes administrative data such as deficiencies in documentation and SEMS maturity levels with categorical breakdowns but does not present data regarding injuries, damage, or environmental impact or whether SEMS implementation or BSEE oversight affected related data trends.

Of note, the 2024 BSEE report points out that "SEMS audits have been focused on assessing conformance with a 19-year-old management system standard and a 13-year-old regulation. Accredited auditors often use checklists (e.g., COS 1-01) to verify conformance with the 17 SEMS elements defined by these documents." It goes on to recommend "using updated performance-based management" and to focus on "system performance rather than the prescriptive requirements for documents found in the SEMS regulation." The report also recommends that BSEE take a new approach to SEMS oversight and "adopt more comprehensive approaches to operational risk management, which go beyond basic conformance and compliance" with regulations.

## 6.4 External analysis report

A Transportation Research Board special report was initiated in 2009 at the request of the Department of the Interior's Minerals Management Service (MMS), the predecessor of BSEE, on "Evaluating the Effectiveness of Offshore Safety and Environmental Management Systems." At the time the report was initiated, the goal was to develop alternative oversight activities that would be more effective in protecting human safety and the environment than the inspection procedures in place at the time, procedures that had been in use for approximately 30 years. MMS had proposed a rule that would have required offshore operators to adopt industry best practices published by the American Petroleum Institute (API) in 2004.

While the Transportation Research Board was conducting research and preparing its report, the Deepwater Horizon-Macondo accident occurred in April of 2010. In its wake, MMS officials requested the research be paused while the accident was investigated, and subsequently, the Department of the Interior undertook a major reorganization that led to BSEE being established in 2011 as part of the MMS restructuring. Simultaneously, new regulations were introduced that required offshore operators to develop and maintain SEMS practices that were largely based on the API standards. This led to a change in the scope and title of the report to cover the topic cited above. However, since none of the SEMS programs had been implemented by the time the report was published, it was not possible to evaluate the effectiveness of SEMS through observation. Instead, the report draws from its previous research to describe methods by which BSEE may evaluate SEMS effectiveness and provides recommendations for oversight methods the Transportation Board believes would reduce operational and environmental risks.

Within the report itself, the committee emphasizes the importance of safety culture, and the report stresses that "the agency will need to adopt and evolve an evaluation system for SEMS that emphasizes the assessment of attitudes and actions rather than documentation and paperwork" (Transportation Research Board, 2012). Ultimately, the report makes recommendation for BSEE to "take a holistic approach to evaluating the effectiveness of SEMS programs" implementing the following techniques at a minimum:

- Inspections
- Audits (operator-conducted and BSEE-conducted)
- Key performance indicators
- A whistleblower program

The report provides detailed explanations of each element, highlighting the dependent nature of these four areas and interaction between them as explanation and justification for the term "holistic." The key performance indicators must be tied to the objectives of safety and environmental protection, such as the number of injuries, degree of damage, and amount of oil or gas spilled. These indicators are essential to enabling performance-based oversight, and the report also mentions the value of benchmarking US performance against international operators. It emphasizes the need for highly trained and experienced inspectors to look at more than just facility policies and paperwork and to interact with on-site personnel, observe operations, and examine hardware to gauge the understanding of a SEMS approach and its influence on the organizational culture, and ultimately on well-defined performance metrics.

# 7 Food safety oversight approaches

The US Food and Drug Administration (FDA) addresses a range of public health areas including human and veterinary drugs, biological products, medical devices, food supply chain, and tobacco products. While its scope is broad, a focus of the FDA's regulatory responsibilities includes foods (e.g., food additives, water, and supplements); drugs, including both prescription and over-the-counter medications; biologics (e.g., vaccines, blood products, gene therapy products); medical devices (e.g., pacemakers, surgical implants); and tobacco. Full details of regulatory responsibility are detailed in CFR Title 21.

CFR Title 21 defines federal laws and regulations for the FDA. Specific to food products, regulations establish general provisions (e.g., labeling requirements), registration of food facilities, and establishment and management of records (e.g., when food products were received; name/address of supplier; lot or batch number; etc.). The regulations are prescriptive in nature, defining specific requirements and FDA offices that perform certification and inspections/audit. The regulations include requirements establishing accreditation bodies and third-parties that perform certification and audit of food facilities.

The Food Safety and Modernization Act (FSMA), originally signed in 2011, is a series of rules for proactive food supply safety improvement. Rules include Product Safety, Accredited Third-Party Certification, Food Traceability, Foreign Supplier Verification Programs for Importers for Food for Human and Animals, Laboratory Accreditation for Analysis of Foods, Mitigation Strategies to Protect Food Against Intentional Adulteration, and Preventive Controls for Human Foods. As part of the program, reports that include performance metrics are reported to Congress, addressing both activity performance and impact of the FSMA.

Specific to drug and medication oversight, the FDA organization includes a Center for Drug Evaluation and Research (CDER) organization focused on protection and promotion of public health with respect to prescription and over-the counter medications, which includes oversight responsibility. CDER actions to address safety a include "rigorous premarket review, post-market surveillance, and risk evaluation programs (FDA, 2024)."

Surveillance and oversight activities are performed both for specific drug products that CDER oversees and for general drug related topics, including supply chains and shortages. For individual drug product oversight, CDER manages compliance-based oversight programs, for example, Risk Evaluation and Mitigation Strategy. This program applies actions to specific drug products where there are known safety risks and work is required to ensure the medication benefits outweigh identified risks. Generally, this program includes defining requirements and safeguards to be applied when a medication is prescribed, which can include information for medical providers and patients, with the intent of reducing frequency and/or severity of negative events. In some cases, CDER may require more extensive testing prior to medication approval. In review of an example action (for a medication called Zyprexa Relprevv), the data collection and action appear to be more outcome-based, requiring providers, pharmacies, and patients to record effects of taking the medication vs. prescriptive action and monitoring of the medication development process. Besides oversight for individual drug products, the FDA conducts other, broader compliance-based programs. For example, compliance assessments are made for manufacturing facilities' adherence to 21 CFR Part 211 regulations, which specify requirements for buildings and facilities (e.g., lighting, ventilation); equipment (e.g., design, size, location); product containers and storage; and production and process controls; among others.

The FDA also developed and released guidance for oversight including Guidance for Industry Oversight of Clinical Investigations – A Risk Based to Monitoring (Food and Drug Administration (FDA), 2013). However, this document indicates that the recommendations are nonbinding. The guidance offers examples of opportunities for monitoring, and action focuses on review of data and outcomes, including missing, inconsistent, and outlier data and understanding how data trends are identified and addressed. It noted that oversight could include analysis of “site characteristics, performance metrics (e.g., high screen failure or withdrawal rates, high frequency of eligibility violations, delays in reporting data), and clinical data to identify trial sites with characteristics correlated with poor performance or noncompliance” (Food and Drug Administration (FDA), 2013). This focus on data outcomes is an element of performance-based oversight, although this terminology is not specifically used.

Based on review of FDA public policy and related organizational information, the approach to defining, assessing, and reporting performance measures appears to be specific to FDA organizations and programs. As noted above, the FSMA is an FDA program that assesses and reports safety and performance metrics and, in this program, the defined metrics align with the FSMA rules. The approach applied by the program is to define and assess a set of metrics for a set of desired outcomes. For example, FSMA’s defined outcome for “Increased Compliance by Industry with Preventative Controls Regulation Requirements” entails the following measures:

- Adoption of food safety plans by firms subject to the preventive controls for *Current Good Manufacturing Practice* and regulations for human and animal foods
- Preventive controls for human food supply-chain program requirements
- Number and percent of domestic preventive controls inspections classified for actions indicated as none, voluntary, or mandatory (i.e., official)
- Number and percent of animal food *Current Good Manufacturing Practice* inspections under 21 CFR part 507 classifications for actions indicated as none, voluntary, or mandatory (i.e., official)

Many identified FDA safety performance measures (aside from general trends such as the number of inspections and safety controls in place) are binary measures that reflect percent compliance vs. non-compliance with FDA rules and regulations. In this sense, the performance measures reviewed tended to focus on compliance achievement rather than safety performance achievement.

# 8 Other U.S. safety oversight agencies

In addition to the detailed survey of oversight approaches for aviation safety organizations and other select U.S. industry oversight organizations, targeted information on safety oversight for other U.S. safety organizations has also been reviewed as outlined below.

### 8.1.1 Federal Transit

The U.S. Federal Transit Administration (FTA) provides regulatory oversight and technical and financial support to transit including city / metropolitan transit agencies such as the Washington Metropolitan Area Transit Authority (WMATA) in D.C., regional transportation systems/authorities, state departments of transportation, public transportation agencies, and commuter rail agencies such as Virginia Railway Express (VRE).

In 2018, a final rule was introduced via 49 CFR Part 673 requiring implementation of an SMS for public transportation agencies. This regulation requires that each transit agency establish a safety plan to be reviewed and approved by the FTA and to address regulatory compliance. Additionally, this regulation indicates that each transit agency must certify its compliance on a yearly basis. To support this regulation, the FTA provides guidance to transit agencies on implementing an SMS and training about SMS and its component elements (e.g., a course on safety culture).

The FTA performs enforcement and oversight through compliance monitoring programs that include on-site inspections and assessing SMS programs; management and tracking of non-compliance and corrective action plans; and fines and other enforcement actions when required due to severity or on-going non-compliance.

In 2021, Congress passed legislation requiring the FTA to integrate a risk-based approach as part of its overall oversight (FTA, 2022). The legislation applies to risk-based inspections by the FTA Office of Transit Safety and Oversight and reflects elements of performance-based oversight in that the inspection program is designed to use quantitative data reflecting safety, reliability, efficiency, and customer satisfaction to guide risk assessment and inspection activities.

### 8.1.2 Department of Defense

U.S. Department of Defense (DOD) SMS policies and associated guidance were reviewed as part of this research. While many safety management policies are specific to military branches and agencies, DOD safety programs share common themes including:

- Development of safety standards and regulations that promote safety across systems, people, and operations
- Integration of proactive risk management to identify and mitigate system safety risks
- Promotion of a safety culture throughout the organization, with key elements of responsibility, commitment, and continuous improvement
- Continued training and education to enhance safety skills and knowledge

DOD agencies, such as the Marine Corps, have published specific policy and guidance documents addressing SMS. For example, Marine Corp Safety Management System (USMC, 2022) provides policy and guidance addressing safety management roles and responsibilities and processes for how hazards are identified, evaluated, and controlled. This Marine Corp implementation includes a "tracker [that] consists of 30 unique categories that measure different components of a command's safety readiness" (Naval Safety Command, 2023).

The Marine Corp Safety Management System defines requirements and guidance for each pillar of SMS. For instance, the pillar of policy and leadership provides guidance on how senior leadership reinforces commitment to safety standards. This standard also includes guidance on oversight activities. For example, there are requirements that Command Safety Assessments be conducted at least every 36 months to evaluate SMS compliance and oversight of subordinate organizations' SMS.

Other DOD organizations continue to refine, strengthen, and evolve their oversight approaches. In 2022, the Naval Safety Command release instructions regarding new functions and methods to strengthen oversight of Navy and Marine Corp SMS (Chief of Naval Operations, 2022). This document provides authority to safety oversight organizations (e.g. NAVSAFECOM) to take more actions in support of SMS oversight, including ensuring corrective actions are completed with authority to suspend activities pending risk mitigation (Naval Safety Command, 2022). This guidance also includes application of no-notice safety inspections, assessment of effectiveness of SMS practices, and collection and analysis of data which is noted as a critical part of oversight activities.

# 9 Key findings

Key findings derived from research interviews and surveys of industry safety management systems and oversight methods (sections 2.2 and 3 – 8) are presented below. Each finding is grouped topically and labeled according to the surveyed oversight authority or industry organization. AVS interview findings are labeled as "FAA" with a reference to the numbered finding theme in section 2.2.

| **Comprehensive Oversight** | |
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| ICAO-1 | Performance-based and risk-based oversight methods are not intended to be replacements for compliance-based oversight; rather, these methods are additions to a comprehensive oversight regime that allows regulatory authorities |

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| | to not only verify compliance through audits and inspections, but also assess performance and evaluate the suitability of risk management processes in place. |
| EASA-2 | The implementation of performance-based oversight does not mean less oversight, but a similar or even increased level of oversight will be better targeted to affect safety performance. |
| FAA-1(a) | Oversight resources, methods, and tools need to accommodate oversight of both prescriptive and performance-based regulations, as regulatory changes expand to incorporate more performance-based elements such as a Safety Management System (SMS) while retaining prescriptive regulations for safety critical operations and systems (multiple AVS organizations). |
| FAA-1(b) | Risk-based oversight strategies should include both compliance-based and performance-based elements, where compliance issues and safety performance, including SMS effectiveness issues, inform risk-based priorities for oversight focus areas, frequencies, and regulated entities (AFS). |
| AAM-1 | There is a recognized need for both prescriptive and performance-based oversight of pilot fitness and performance. |
| **Oversight Methods and Frequency** | |
| Transport Canada-1 | A holistic evaluation of an entire regulated entity across applicable elements such as manufacturing, operations, and maintenance is needed to understand associated risks and safety performance data, especially for large-scale, complex enterprises. |
| NRC-4 | A minimum baseline inspection scope and recurring frequency should be established for assessing regulated entity safety performance, including effectiveness in identifying and correcting problems and issues based on risk significance. The results of this minimum inspection should be factored into forward oversight planning tailored to that entity. |
| DOE-1 | Baseline oversight needs a consistent cadence, scope, and level of rigor to facilitate proactive safety oversight. |
| UK-1 | To assess management process effectiveness, inspectors should evaluate the safety awareness of the regulated entity’s staff, staff turnover, competency level, planning and implementation of continuous performance improvements, and change management. |

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| Transport Canada-2 | Surveillance frequency should be informed by occurrences and incidents, non-compliance history and number of safety observations from inspections, insufficient production of information by the regulated entity, and lack of regulated entity cooperation, among other factors. |
| AIR-3 | Oversight criteria for assigning risk levels to production approval holders according to their manufacturing processes' complexity, scale, and product/article criticality should be adapted to incorporate SMS effectiveness where oversight scope and frequency is adjusted according to risk. |
| **Safety Management System Oversight** | |
| FAA-3(c) | Some regulated entities lack knowledge and understanding of SMS, certification, and FAA continued operational safety policy and processes; the FAA will need to improve and expand resources for industry education and collaboration, as this area currently consumes many oversight resources (multiple AVS organizations). |
| ICAO-4 | Where there is limited history to assess maturity and effectiveness of an SMS (e.g., during initial implementation) a baseline of surveillance activities should be defined. This can be adjusted as more oversight data becomes available and processed. |
| AFS-2 | Provisions for SMS evaluation should verify that SMS / SRM is applied to evaluate proposed risk controls for unintended hazards and consequences. |
| AFS-3 | Provisions for SMS evaluation should specify thresholds for individual and aggregate indicators performance that prompt oversight responses with margins to intervene before undesired safety consequences occur. |
| AIR-1 | Research is needed to develop and validate methods and tools for performance-based oversight of SMS implementation effectiveness for Part 21 type certificate and production approval holders. Initial and recurring validation should incorporate scenarios to determine whether oversight methods reliably and consistently identify SMS (or any certificate holder system) process gaps or lapses that allow product and production quality issues to "escape" – a known challenge. Guidance for evaluating the processes that determine the safety-significance of quality issues should be established and also validated. |
| FAA-1(e) | Oversight of SMS effectiveness will require a "look-back" approach similar to root cause analyses, where the approach to issue identification and corrective |

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|  | action are supplemented by an approach to determine which SMS or other management system gaps and process lapses allowed the failure to occur (AIR). |
| **Safety Performance** |  |
| ICAO-2 | Comprehensive measurement of safety performance includes indicators that address both outcomes (e.g., what are the results and effects) and processes (what and how work is performed). |
| NRC-3 | Safety performance indicators should build in threshold progressions with margins of safety that allow time for both regulated entity and regulatory oversight intervention and escalation as needed (i.e., indicator performance that exceeds first and second thresholds, for example, should not correspond to hazardous outcomes). |
| NRC-1 | Oversight should include evaluation of performance indicators for safety risk precursors or initiating events and mitigating factors with defined thresholds for escalating levels of oversight response. |
| FAA-1(c) | Specific approaches to defining safety objectives, measuring safety performance, and evaluating safety management effectiveness must be defined and validated along with strategies to assure industry self-correction is occurring and effective (AIR). |
| AIR-4 | Follow-up research should confirm whether the results of the hazard and risk analyses required for Type Certification and subsequent major changes are carried forward into safety performance indicators or measures for oversight during production approval and later on for Continued Operational Safety with adjustments as needed for approved changes to certification bases. |
| AAM-3 | Safety performance goals and measures can be specific to hazards and outcomes, but there is an opportunity to apply measures at additional points in a risk model (e.g., barrier performance), including the influence of oversight actions throughout the model, which supports proactive safety action. |
| EASA-3 | Safety performance measures or indicators can help to identify risks, including earlier risk insights via leading measures, and can inform prioritization of oversight focus based on greater areas of risk. |
| **Oversight of Changes** |  |
| FAA-2(a) | Aviation industry and technologies are changing quickly, and as new and modified technologies and operations are introduced in the National Airspace |

System (NAS), the FAA needs to develop a comprehensive and independent understanding of those new technologies and operations, and especially safety-significant changes, to provide effective oversight (multiple AVS organizations).

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| AOV-1 | Oversight planning benefits from proactively gathering intelligence on regulated entity-proposed and ongoing changes to management systems, technology, procedures, and operations. |
| AOV-2 | Tools to formalize gathering and tracking of change intelligence can help cross-check that all anticipated regulated entity changes are evaluated for safety significance and to provide traceability to future oversight planning. |
| AOV-3 | The regulator's oversight process can serve as a risk barrier by being included in review or approval gates for regulated entity proposed changes to safety-related management systems and safety-significant technology, procedures, and operations. Such a review/approval gate also improves the regulator's awareness of regulated entity changes, providing an opportunity for the regulator to obtain details on the scope of the change and whether it is safety critical so that appropriate oversight methods can be applied. |
| AIR-2 | Oversight mechanisms designed to gather information on ongoing and planned certificate holder and Production Approval Holder changes to systems, processes, tools, and technologies are needed for forward oversight planning and as data points to verify and validate that SRM and safety assurance are being applied appropriately and consistently for such changes. |
| AFS-1 | AIR oversight provisions for SMS evaluation should verify that SMS / SRM is applied to production certificate holder changes that include application of existing systems for new missions or functions (i.e., even when that existing system is not modified). |
| AOV-4 | The regulator may benefit from inspections or monitoring safety indicators that address unauthorized changes implemented by the regulated entity when regulatory approval or review is required before implementation. This could involve reviewing the regulated entity's system and documentation change control data to check for corresponding SRM decision analyses. |
| **Incremental Oversight Evolution** | |
| EASA-4 | Adoption of a performance/risk-based oversight model should be incremental, with knowledge and experience gained in one domain before expansion to |

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| | others, with an integration of data and expert judgment from initial implementations. |
| NRC-2 | Oversight process changes should be piloted in a limited area and assessed for issues, effectiveness, and lessons learned as well as scalability and resource needs for broader implementation. Follow-up evaluation of pilot oversight process changes and broader implementation should be incorporated in recurring oversight effectiveness evaluations. |
| AAM-2 | Determining measurable performance goals for performance-based oversight is a challenge; processes that define goals will benefit from flexibility to adjust goals and to leverage lessons learned. |
| FAA-4(b) | Expectations for the required workforce development timeframe to adopt performance-based oversight need to be realistic in planning for expected outcomes and benefits (AIR). |
| FAA-1(d) | Oversight methods and approaches need to mature over time – for example, initially focusing on assessing the implementation and application of specific processes such as SMS and later focusing on measures that reflect effectiveness of safety risk management processes (AIR). |
| **Oversight Workforce Development** | |
| FAA-4(a) | An evolution of the oversight workforce is needed, focusing on expanding knowledge, experience, and confidence in applying performance-based oversight (multiple AVS organizations). |
| ICAO-5 | A shift in mindset and competency training for the oversight authority is required to enable assessment of the system as a whole for SMS oversight. |
| NZCAA-1 | Behaviors for success in risk-based oversight include systems thinking which recognizes interactions across system components and implications for safety; problem solving; critical thinking which applies analysis and evaluation techniques to produce balanced and evidence-based judgements; effective communication and engagement among stakeholders on objectives; and influencing participants to behave in a safe manner. |
| Transport Canada-3 | A multidisciplinary team of inspectors with experience across the technical and organizational aspects of the regulated entity is recommended to gather and analyze safety risk information about all facets of the entity's processes and operations, especially for complex enterprises. |

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| FAA-4(c) | Workforce training needs to address changes in approach and mindsets between compliance-focused and performance-based oversight, including the use of systems-level thinking to evaluate the effectiveness of the regulated entity management systems and to interpret and respond to collected oversight data (multiple AVS organizations). |
| **Safety Culture** | |
| ICAO-3 | Strong partnerships and a positive safety culture are important elements in achieving the performance and oversight objectives of SMS. |
| AVP-3 | A positive safety culture and a workforce that is trained and confident in their work functions and their safety impacts are important elements for a positive and effective adoption of performance-based oversight. |
| FAA-4(e) | When the aviation system appears to be safe, it can be difficult to motivate industry to invest in continued safety improvements and to fully promote SMS and safety culture principles within its operations and processes (multiple AVS organizations). |
| FAA-4(d) | Actions focused on achieving desired transparency and information sharing are needed both within the FAA and between FAA and regulated entities; this could include inputs to specific oversight methods as well as other activities to drive a positive safety culture (AVP, AIR). Success cases and lessons-learned can also be documented and shared as part of this activity (AFS). |
| **Oversight Harmonization and Data Sharing** | |
| FAA-3(b) | Oversight should take a holistic approach that accounts for how activities of different AVS organizations impact one another and the same regulated entities engaged in multiple oversight activities (AIR). |
| AVP-1 | Consistency in oversight policy and methods across the FAA safety organization can be beneficial for effective interactions with certification applicants and regulated entities. |
| FAA-3(a) | Oversight methods and tools that can be tailored for specific oversight needs within AVS organizations can also adapt to address provisions for performance-based oversight as related oversight processes are expanded and matured. As oversight tools become more integrated to meet needs across AVS, there is a greater need for data sharing among oversight organizations to realize the |

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| | benefits of those integrated tools in risk-based oversight planning and prioritization (AIR). |
| **Oversight Effectiveness** | |
| AVP-2 | The collection of performance data that reflects the safety impact of oversight actions within and among AVS organizations can be used to help validate safety policy, methods, and oversight effectiveness. |
| DOE-2 | To have effective oversight, an "unbroken chain of responsibility" must be clearly defined from oversight roles involved in managing and directing work through roles involved in executing oversight, including contractors. |
| NRC-5 | Annual self-assessments of oversight effectiveness should be conducted and published to gauge how well oversight program goals and objectives are being achieved. Such assessments examine the consistency of oversight program implementation across locations and organizations, the timeliness of oversight responses to regulated entity safety performance issues and significant occurrences, and the effectiveness of oversight program changes. |
| NRC-6 | Oversight program changes should be reviewed for effectiveness according to the reasons that motivated the change, verification that the objectives for the change are met, and no negative, unintended consequences resulted for individual and collective sets of changes. |

# 10 Conclusions and research recommendations

To facilitate the adoption of performance-based oversight, the FAA launched the Future of Oversight research initiative. As an initial step for this research initiative, the William J Hughes Technical Center Aviation Research Division conducted a literature survey to catalog and benchmark current oversight mechanisms used in aviation and other industries, focusing on performance-based and risk-based oversight strategies. The literature review encompassed over 200 documents and other media addressing safety regulations, safety management systems, and oversight approaches. Interviews were also conducted with FAA aviation safety leads and stakeholders with deep experience across the spectrum of oversight roles and responsibilities in the FAA AVS community. Based on findings from the literature review and stakeholder interviews, certain topics are proposed for further research as part of the Future of Oversight.

It is anticipated that proposed research topics will be refined and expanded, with traceability to research findings in a future version of this report. An update to this report planned for

September 2024 is intended to incorporate the results from a follow-up, targeted literature review to address findings from oversight stakeholder interviews, additional considerations for benchmarking performance-based oversight methods and features, and a survey of oversight systems and tools currently used in aviation.

Proposed Future of Oversight research topics are as follows:

**(1)** **Safety Objectives.** Define clear, measurable safety objectives for performance-based oversight by aviation sector and for communication within FAA oversight organizations and with industry.

**(2)** **SMS Effectiveness Objectives and Indicators**. Explore whether a minimum set of safety objectives and safety performance indicators can be standardized across regulated entities for SMS effectiveness evaluation to reduce regulatory burden in tailoring oversight guidance for each regulated entity's SMS implementation.

**(3)** **Applying Performance Thresholds**. Determine how to incorporate safety objectives into recurring baseline inspections that are risk-based with thresholds for performance that inform forward planning for future oversight activities.

**(4)** **Safety Benefit Validation**. To validate the safety benefits of effective SMS implementation for Part 121 and other federal aviation regulation parts with sufficient implementation history, compare safety performance results by regulated entity before and after SMS implementation phases, including voluntary implementation (where applicable) and mandatory. Results may help promote aviation industry investment in continued safety improvements and safety culture or point out SMS components that need improvement.

**(5)** **Applying Performance-Based Regulation Lessons**. Identify historical (non-FAA) oversight effectiveness problems with safety-related, performance-based regulations and what the regulator did afterward to improve regulations and oversight methods and procedures. Determine how these lessons learned can be incorporated into FAA performance-based oversight implementation approaches and guidance for developing performance-based regulations.

**(6)** **Safety Culture Evaluation**. Develop actionable safety culture evaluation criteria and guidance with thresholds for additional evaluation or oversight responses.

**(7)** **Stress Testing Oversight Processes**. Explore opportunities for safety improvements in FAA oversight processes for assessing quality and safety management effectiveness, leveraging data collected from observing inspections/audits in the field and table-top experiments to assess the inspection/audit process effectiveness in detecting and characterizing quality and safety management process lapses.

(8) **Risk Barrier Modeling and Evaluation**. Research the use of risk barrier models to understand how oversight methods can be applied as risk mitigations and determine if such models can provide a framework for recurring evaluation of oversight effectiveness in reducing risk.

(9) **Risk Interdependencies**. Research methods and means to identify and manage risk interdependencies across regulated entities and topics such as safety and security and align reporting approaches to foster government/industry cooperation and collaboration.

(10) **SMS Implementation Knowledge Sharing**. Research joint industry/government forums to establish and guide information exchanges on SMS implementation, including issues and best practices developed in a collaborative manner.

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# Appendix: Rationale for U.S. air carrier SMS

According to the Notice of Proposed Rulemaking for 14 CFR Part 5 SMS, the FAA was congressionally mandated as part of a 2010 FAA extension act to conduct rulemaking to require Part 121 operators to implement an SMS. Prior to this, ICAO introduced SMS requirements in Annex 6 for international commercial air transport in 2006 which the FAA deferred until rulemaking could be undertaken.

To provides insights into FAA rationale for introducing the Part 5 SMS rule, the NPRM explains:

> "the benefits of this proposed rule consist of the value of averted casualties, aircraft damage, and accident investigation costs by identifying safety issues and spotting trends before they result in a near-miss, incident, or accident. Although an SMS would help carriers detect problems early, the FAA also recognizes that both the severity of the problem and possible mitigation impacts the rate at which future accidents would be prevented. Over the 20-year period of analysis, the FAA estimates potential benefits of $1,143.1 million ($500.8 million in present value terms)."

The NPRM notes that potential gaps in managing air carrier operations' safety risk given increasing air traffic and changing systems, routes, and business models are best addressed by the operators. The rationale is that the operators have the best understanding of their specific operating environments and therefore are better positioned (than regulators) to identify safety gaps and implement risk controls. A regulation to implement SMS would promote proactive hazard identification and risk control before safety issues occur and make "the application of regulations more meaningful to achieve greater safety benefit."

The NPRM outlines air carrier accidents in which SMS processes (if such processes were in place pre-accident) could have prevented the hazards that led to the accidents. An Air MidWest fatal accident in 2003 was attributed to improperly rigged elevator controls during outsourced maintenance at an uncertificated maintenance facility. The SRM processes for hazard identification, safety assurance monitoring of risk control performance, employee confidential reporting of safety concerns, and safety promotion activities to disseminate safety critical maintenance issues to relevant staff are postulated as mechanisms that could have detected or prevented the safety lapses that led to the accident. A second case regarding a 2006 Comair fatal runway excursion was also highlighted in which the pilots began takeoff roll on the wrong runway.

Contributing factors noted flight crew noncompliance with standard operating procedures (e.g., an abbreviated taxi briefing) and pilots' distracting conversations; no ATC factors or technical mitigations were noted in the NPRM.  The NPRM indicated that SMS safety assurance, real-time line operations safety audits (i.e., conducted during taxi / flight), and potentially confidential safety reporting could have detected problems with flight crew performance and provided an opportunity to improve risk controls in flight manuals, checklists, and training.