

FED. SUPPLY CLASS

SAFETY MANAGEMENT SYSTEM PRACTICES FOR DESIGN AND MANUFACTURING

STANDARD PRACTICE



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PREFACE

This National Aerospace Standard (NAS) is arranged in two main sections. Section I constitutes the standard for voluntary implementation of a safety management system (SMS) by design and manufacturing (D&M) organizations. It sets forth introductory information, a discussion of the role of the system description in an SMS, a listing of 14 CFR part 5 SMS requirements along with comments about the context of D&M related to each requirement, and a hypothetical example of a possible SMS process scenario. Section I presents an acceptable, but not the only acceptable, means for a D&M organization to voluntarily implement SMS policies, processes, and procedures consistent with part 5.

Section II provides supplemental information that may be useful as explanatory material to provide additional insight about SMS to a D&M organization while planning, implementing, and maintaining its SMS in accordance with Section I. The information in Section II does not constitute or impose additional SMS requirements. It does not add any requirement for compliance beyond the Section I standard. Reference to Sections I and II will enable a D&M organization, at its discretion, to use its existing processes, procedures, and systems to the maximum extent for voluntary implementation of SMS consistent with part 5.

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SECTION I: SMS STANDARD

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1. SECTION I: SMS STANDARD

1.1 INTRODUCTION

This NAS is intended to enable United States (US) aviation D&M organizations to voluntarily implement a Safety Management System (SMS) that is consistent with 14 CFR part 5, Safety Management Systems. In order for a voluntary SMS to be accepted by the US Federal Aviation Administration (FAA) as consistent with part 5, the respective organization must demonstrate that the SMS satisfies the intent of part 5 in all important respects. When implemented in accordance with this standard, the resulting SMS may be eligible for acceptance by the FAA. At the time of writing of this NAS, D&M organizations are not required to comply with part 5.

International Civil Aviation Organization (ICAO) Annex 19, Safety Management, establishes standards and recommended practices (SARP) applicable to safety management functions related to, or in direct support of, the safe operation of aircraft. Annex 19 prescribes that each State shall require organizations under its authority responsible for the type design or manufacture of aircraft, engines, and propellers in accordance with Annex 8 to implement an SMS. Annex 19 further prescribes that the SMS of an organization responsible for the type design of aircraft, engines, and propellers shall be made acceptable to the State of Design, and the SMS of an organization responsible for the manufacture of aircraft, engines, and propellers shall be made acceptable to the State of Manufacture. The FAA has determined that the US meets the intent of the ICAO State Safety Program requirements (see AVP300-15-U.S. State Safety Program (v1.0) – 2015, p. 2). Therefore, pursuant to ICAO Document 7300/9 Convention on International Civil Aviation, Article 37 Adoption of international standards and procedures, and Annex 19, Amendment 1, Chapter 4, paragraphs 4.1.6 and 4.1.7, an FAA-accepted voluntary SMS implemented by a US D&M organization is acceptable to other ICAO States.

The FAA has determined that 14 CFR part 5 is consistent with Annex 19. Therefore, while this NAS is directed to US D&M organizations, international D&M organizations may find this NAS useful for implementation of an SMS acceptable to international regulators as being consistent with Annex 19.

The use of the term “design and manufacturing” in this NAS is intended to be consistent with its usage in Annex 19 and in the preamble of 14 CFR part 5. Use of the word “manufacturing” is not intended to exclude any aspect of a production system, such as quality assurance. The term “certificate holder” as used in this NAS refers to a holder of, or applicant for, a type certificate (TC) or production certificate (PC) for aircraft, engines, or propellers. It does not, for the purpose of an FAA-acceptable SMS, refer to a holder of a supplemental type certificate, parts manufacturer approval, or technical standard order authorization, although such holders may voluntarily implement an SMS using this NAS.

Throughout this NAS, the term “aviation safety” is used to refer to the context of SMS being “the safe operation of aircraft.” When the word “requirement” is used herein with reference to part 5, it is intended to refer to the need for consistency between an organization’s SMS and part 5. It is not intended to indicate any regulatory requirement of part 5 as being applicable to D&M organizations.

The term “product” is used herein to refer to an organization’s output; that is, the thing(s) the organization produces, such as aircraft, engines, or propellers. This NAS does not specifically address parts, components, appliances, articles, etc., but for the purpose of SMS implementation, these items may be considered “products.” In addition, “product” includes documentation necessary for its operation and maintenance. Examples of such documentation include Instructions for Continued Airworthiness, maintenance manuals, airplane flight manuals, service bulletins or instructions, and revisions to such documentation.

This NAS is intended to facilitate implementation of a tailored, appropriate SMS by individual D&M organizations. Because each D&M organization is unique, there is no “one size fits all” method for SMS implementation. The FAA expects that each organization will implement an SMS that works for its unique situation. The FAA has established via part 5 the fundamental requirements of an SMS, i.e., what it is the SMS must accomplish. Each D&M organization must define for itself how it intends to go about fulfilling the fundamental requirements. To accomplish this, it is important that each organization seeking acceptance of its SMS prepare a system description

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that identifies its organizational structures, processes, and business arrangements that it considers important to management of aviation safety. Based on the system description, the organization should identify or develop policy, processes, and procedures that establish its own safety management requirements consistent with part 5. Implementation of those policies, processes, and procedures with concurrence of the FAA will constitute an acceptable SMS. An organization will normally need to have processes and/or procedures that are present, suitable, and operating to address all applicable sections of part 5 in order to obtain an FAA acceptance. However, because each organization has unique circumstances, reasonableness is required when evaluating processes and procedures. For example, an organization may elect to develop a new process to address an SMS requirement. Prior to implementation of the SMS, there may not have been an occasion to exercise the new process. For the purpose of FAA acceptance of the SMS, such a new process may be evaluated as "operating" if it is in place and ready to be exercised.

1.2 The Role of the System Description

When considering a system description, it is important to understand what a "system" is in the context of SMS. A system is any of an organization's products, people, processes, procedures, facilities, services, and other aspects (including external factors) which are related to, and can affect, the organization's aviation safety activities. These systems should be considered for SMS purposes both as discrete sub-systems and in the aggregate for system-level safety management. These systems and sub-systems constitute the "operational procedures" referred to in 14 CFR 5.51(c) and the "operating environment" referred to in §5.53(b)(2). For D&M, the important systems include both those which could directly impact the aviation safety of a product and those which affect the ability or capacity of an organization to perform effective safety management. For many D&M organizations, such systems include the processes used to accomplish:

- Design and Certification
- Production
- Continued Airworthiness

In practice for a TC or PC holder, this understanding of a system results in emphasis on compliance with airworthiness regulations ("compliance assurance"), compliance with quality regulations ("conformity assurance"), and continued operational safety (COS) ("safety assurance") across the product life cycle phases of design and certification, production, and continued airworthiness. A D&M organization should remain mindful that hazards associated with the organization and its processes may be identified across those life cycle phases as well.

Through the system description, the D&M organization controls the extent of the organization that is subject to regulator oversight. The extent of the organization encompassed by the system description should be related to the safe operation of aircraft. For most D&M organizations, that would include:

- Processes used to design and certify a safe and compliant product (compliance assurance)
- Processes used for production of a safe and compliant product (conformity assurance), including supplier production
- Processes used to assure product continued operational safety (safety assurance)

Figure 1 illustrates an example of how existing processes used by a TC or PC holder (in this case an engine manufacturer) might be identified and linked in a system description to show their relationship to the system's operating environment as discussed above.

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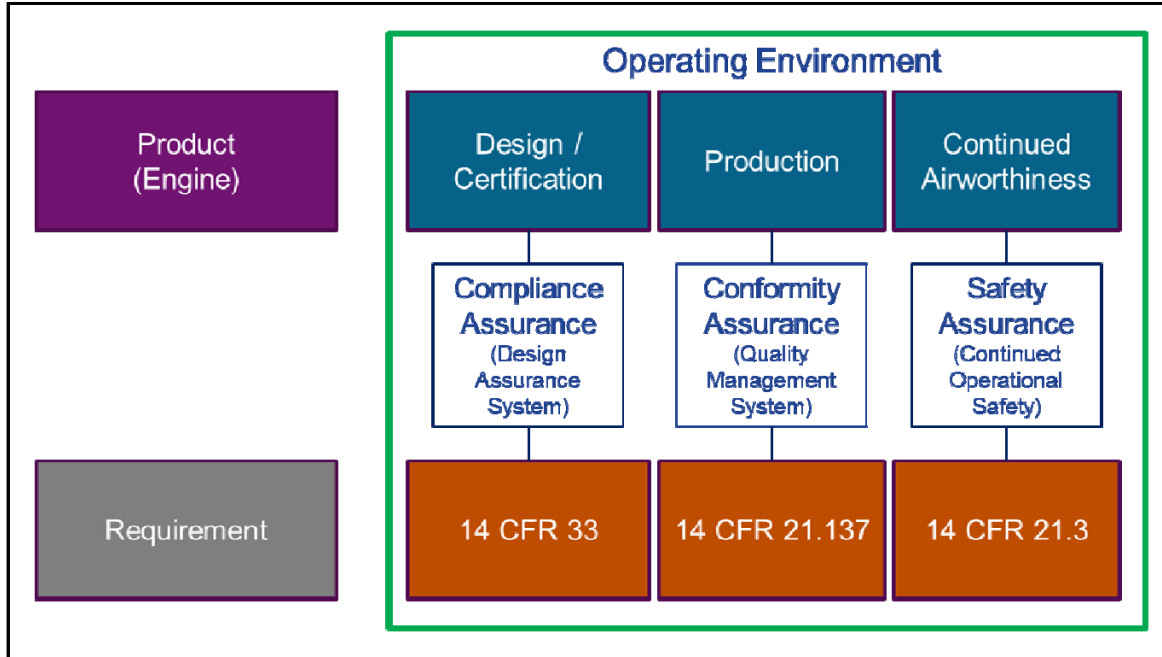


FIGURE 1 – EXAMPLE OF OPERATING ENVIRONMENT IDENTIFICATION

The defining characteristic of an SMS is that it accomplishes aviation safety decision making. It is therefore necessary for an organization to define and understand the extent of its system(s) that can affect aviation safety. A system description serves to identify the features of the product, the organization, and the D&M processes that might be sources of aviation safety hazards and associated safety risk, and therefore be appropriate for application of safety risk management (SRM) and safety assurance (SA). Importantly, it enables the organization to identify features of the organization that are not appropriate to require application of SRM and SA. This allows the organization to allocate safety management resources to sources of potentially significant safety risk, and avoid devoting resources to low or insignificant risk. Business processes that do not affect aviation safety are not within the intent of part 5 and would not be included in the system description. The FAA emphasis is on system-level safety management, i.e., that an organization is able to encompass relevant but disparate organization processes to manage aviation safety.

The use of a system description enables considerable flexibility for the D&M organization to deal with the great variety of business arrangements and interfaces that may be involved in the operating environment. The organization should assess its own arrangements and identify those that are related to, and can affect, the organization's aviation safety activities and therefore are appropriate for inclusion in the system description. An example of such flexibility is how an organization might choose to address the qualifications of people having duties or responsibilities identified in the system description. An organization might choose to specify that a person must meet certain qualifications prior to assignment to such a position. Alternatively, an organization might choose to identify unique qualifications for the position and how a person would acquire those qualifications after being assigned to such a position. An organization might identify any of a number of other approaches to individual qualifications. The individuals considered part of the safety accountability and authority defined in § 5.23 should be clearly described in the organization's system description. Another example is how an organization elects to manage supplier interfaces and supplier oversight. An aircraft manufacturer might rely on an engine manufacturer's own SMS for safety management related to an engine, or it might negotiate safety management terms and conditions as part of supplier contractual arrangements, or use another method. The emphasis of SMS requirements is on what must be accomplished, not on how it must be done.

Implementation of SMS does not fundamentally require an organization to change its existing processes. SMS is not intended to be a set of processes used to ensure compliance with airworthiness and quality regulations; however, it is intended to assure continuing effectiveness of those processes. These existing processes represent

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a set of baseline safety risk controls. In other words, these processes already contribute to managing aviation safety risk. These processes might include, for example, product design and certification, selection of location for production facilities, management of multiple TCs, 14 CFR 21.3 reporting, supplier surveillance, etc. There is no requirement to evaluate safety performance of existing processes prior to including them in the system description. When an organization elects to make a substantive change to those processes, the changes should be viewed as potentially affecting its baseline risk assessment, and the decision making process(es) used to arrive at those changes should include SRM applied to the changes. During development of operational procedures or a new system, or when any new hazard or ineffective risk control is identified, SRM would also be applied. SMS serves as a means to ensure that decision making processes are and remain effective to maintain compliance, conformance, and safety assurance. Therefore, it is important that decision making processes associated with compliance, conformity and continued operational safety assurance be included in the system description. Another example of existing organizational processes is the holding of a European Aviation Safety Agency (EASA) Design Organization approval. Such an approval also constitutes a set of baseline safety risk controls.

It is neither possible nor desirable to subject all changes of any process to SRM. Only changes that potentially have a substantive impact on aviation safety management should be included. Generally, those will be changes to the policy, processes, and procedures identified in the system description as being important to aviation safety. Even though each organization is unique in its business arrangements and processes, a number of features of the operational environment are common or similar among D&M organizations. Thus, there are typical events or situations, i.e., triggers, which should be considered potentially to have substantive impact on aviation safety management. In most cases, an organization's system description should include those common features and triggers. It should be noted that despite being common or typical, there is no requirement of part 5 that any particular feature or trigger must be included in the system description, nor be in place at the organization. However, if any are in place and the organization elects to include them in its system description, they would be encompassed by the SMS. Examples of common features and triggers include:

- Changes to the organization
 - o Change in ownership
 - o Relocation
 - o Opening a new production facility
 - o Change in the production organization, unless shown that independent checking function of demonstration of conformity is not affected
 - o Change in the parts of the org that contribute directly to the airworthiness or conformity
 - o Change to the independent monitoring (internal audit) principles
- Changes to responsibilities
 - o Change of head of the design or production organization
 - o Change of head of the airworthiness organization
 - o Change of head of the internal audit organization
 - o Change of responsibilities affecting airworthiness, quality, or continued operational safety
 - o Change in continued operational safety responsible organization or location
- Changes to procedures related to
 - o Type certification
 - o Classification of changes and repairs as Major or Minor
 - o The treatment of major changes and major repairs
 - o The approval of the design of minor changes and minor repairs
 - o The issue of information and instructions under a privilege of the organization, e.g., ODA
 - o The approval of documentary changes to the AFM

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- o The approval of the design of major repairs
- o Continued airworthiness
- o Configuration control
- o Quality system, including creation of a quality system
- o The acceptance of design tasks undertaken by partners or design suppliers
- o Substantive new manufacturing process
- o Manufacturing planning, including creation of new planning
- Changes to resources
 - o Substantial reduction in number, qualification and/or experience of staff
- Changes to organization privileges or limitations
 - o Scope of approval
 - o Categories of products
 - o Scope of privileges

As an organization gains experience with its SMS implementation, it may elect to apply safety management processes beyond the boundaries of the system description. Except when indicated by SRM or SA processes, there is no requirement that the system description be revised or expanded to encompass such "beyond compliance" activities. There is no requirement that such activities be included, for example, in safety performance monitoring and measurement. Although application of SMS processes beyond the system description is encouraged, it is not intended to necessarily expand requirements.

1.3 SMS Requirements in Part 5

Following are the part 5 requirements that form the basis for a D&M organization to devise the policies, processes, and procedures that constitute its own safety management requirements consistent with part 5. Each requirement is presented as a direct quote from part 5. Following each quote from part 5 are comments about the requirement in the context of D&M. Where appropriate, examples are offered for additional clarification.

1.3.1 Subpart A – General

§ 5.1 Applicability.

(a) A certificate holder under part 119 of this chapter authorized to conduct operations in accordance with the requirements of part 121 of this chapter must have a Safety Management System that meets the requirements of this part and is acceptable to the Administrator by March 9, 2018.

(b) A certificate holder must submit an implementation plan to the FAA Administrator for review no later than September 9, 2015. The implementation plan must be approved no later than March 9, 2016.

(c) The implementation plan may include any of the certificate holder's existing programs, policies, or procedures that it intends to use to meet the requirements of this part, including components of an existing SMS.

Section 5.1(a) does not apply for voluntary implementation of SMS at a D&M organization.

The implementation plan submission and approval deadlines in section 5.1(b) also do not apply for voluntary implementation of SMS at a D&M organization. Nevertheless, it is important to prepare an implementation plan. It should incorporate or be based on a gap analysis of the organization's existing policy, processes, and procedures compared to the SMS requirements. The gap analysis combined with the implementation plan will facilitate mutual understanding between the FAA and the organization about details related to acceptance of the SMS, and facilitate

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allocation of resources by both the FAA and the organization. Examples of such details might include concurrence about whether existing organization processes satisfy SMS requirements, and plans to address any needed revision of processes or development of new processes. Thus, the implementation plan serves to establish a path to an acceptable SMS for that organization. This NAS does not prescribe any time period or deadline for initiating an implementation plan or achieving acceptance. An appropriate implementation schedule leading to acceptance should be coordinated between the FAA and the organization.

§ 5.3 General requirements.

(a) Any certificate holder required to have a Safety Management System under this part must submit the Safety Management System to the Administrator for acceptance. The SMS must be appropriate to the size, scope, and complexity of the certificate holder's operation and include at least the following components:

- (1) Safety policy in accordance with the requirements of subpart B of this part;
- (2) Safety risk management in accordance with the requirements of subpart C of this part;
- (3) Safety assurance in accordance with the requirements of subpart D of this part; and
- (4) Safety promotion in accordance with the requirements of subpart E of this part.

(b) The Safety Management System must be maintained in accordance with the recordkeeping requirements in subpart F of this part.

(c) The Safety Management System must ensure compliance with the relevant regulatory standards in chapter I of Title 14 of the Code of Federal Regulations.

The requirement that, "The SMS must be appropriate to the size, scope, and complexity of the certificate holder's operation" need not be itself complex. The four required SMS components (safety policy, SRM, SA, and safety promotion) are the same for all organizations, but discrete processes are likely to vary. For example, a safety reporting process at an organization having 10,000 employees likely would need greater capability to receive and respond to reports than an organization with 100 employees. At the same time, both organizations might have existing reporting processes that could also accomplish safety reporting. An organization that designs and produces an extensive line of products may need to consider how to implement its SMS across those products, while an organization with a single product might not. Whatever the situation, the system description would identify the applicable products, processes, and procedures. The SMS functions do not need to be extensive or complex to be effective, and existing processes and resources may be used to meet SMS requirements.

Section 5.3(c) refers to the fact that SMS requirements do not replace, and may not be substituted for, compliance with existing technical or performance standards, such as the airworthiness requirements of part 23 or part 25. An organization may not use any output of its SMS to allow or justify noncompliance with airworthiness or other requirements. SMS outputs may nevertheless form one part of a showing of equivalent level of safety or may be part of substantiation for other risk-based assessments. SMS processes may be used as an acceptable means of compliance with certain requirements, such as reporting pursuant to 14 CFR 21.3. At the same time, SMS requirements are not intended to duplicate any existing obligation of an approval or certificate holder. For example, part 5 does not require reporting of safety information to the FAA. Therefore, it does not duplicate reporting required pursuant to § 21.3, but neither does it relieve an organization from any requirement for such reports. This does not preclude use of an SMS process to accomplish required reporting. An organization should ensure its SMS is not structured such that it conflicts with the organization's ability to comply with other requirements.

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1.3.2 Subpart B – Safety Policy

§ 5.21 Safety policy.

(a) The certificate holder must have a safety policy that includes at least the following:

- (1) The safety objectives of the certificate holder.
- (2) A commitment of the certificate holder to fulfill the organization's safety objectives.
- (3) A clear statement about the provision of the necessary resources for the implementation of the SMS.
- (4) A safety reporting policy that defines requirements for employee reporting of safety hazards or issues.
- (5) A policy that defines unacceptable behavior and conditions for disciplinary action.
- (6) An emergency response plan that provides for the safe transition from normal to emergency operations in accordance with the requirements of § 5.27.

(b) The safety policy must be signed by the accountable executive described in § 5.25.

(c) The safety policy must be documented and communicated throughout the certificate holder's organization.

(d) The safety policy must be regularly reviewed by the accountable executive to ensure it remains relevant and appropriate to the certificate holder.

The safety policy developed by an organization must be consistent with §5.21 except that emergency response planning pursuant to § 5.27 is not applicable for a D&M organization, and therefore organizations are not required to include such planning in their safety policy.

The safety policy may be described at a high level and does not need to be a long or detailed document. For example, safety objectives (5.21(a)(1)) may be described in broad terms, with details and linkage to safety performance indicators appearing elsewhere. The organization must establish, document, implement, and maintain its policy, and the processes and procedures that stem from the policy, in a way that works for itself. Some D&M organizations have developed a safety policy that fits on a single page. An example of safety policy is provided in Appendix D.

The requirement to sign the safety policy may be satisfied by an organization's document control system. Often, such systems do not involve a pen-and-ink signature on paper, but use electronic signatures or a defined approval process that represents the accountable executive's approval.

§ 5.23 Safety accountability and authority.

(a) The certificate holder must define accountability for safety within the organization's safety policy for the following individuals:

- (1) Accountable executive, as described in § 5.25.

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(2) All members of management in regard to developing, implementing, and maintaining SMS processes within their area of responsibility, including, but not limited to:

- (i) Hazard identification and safety risk assessment.
- (ii) Assuring the effectiveness of safety risk controls.
- (iii) Promoting safety as required in subpart E of this part.
- (iv) Advising the accountable executive on the performance of the SMS and on any need for improvement.
- (3) Employees relative to the certificate holder's safety performance.

(b) The certificate holder must identify the levels of management with the authority to make decisions regarding safety risk acceptance.

"Accountability" refers to active management and line employee involvement, and action in managing and maintaining safety performance. A D&M organization defines accountability by ensuring each of its management and line employees is aware of their specific role within SMS and actively participates in carrying out their SMS-related duties.

Organizations should exercise due diligence in considering which employees are included in safety accountability. Generally, all employees should be aware of the organization's safety policy and how the confidential employee reporting system works. The organizational functions for which employees have safety accountabilities should be identified in the system description.

§ 5.25 Designation and responsibilities of required safety management personnel.

(a) Designation of the accountable executive. The certificate holder must identify an accountable executive who, irrespective of other functions, satisfies the following:

- (1) Is the final authority over operations authorized to be conducted under the certificate holder's certificate(s).
- (2) Controls the financial resources required for the operations to be conducted under the certificate holder's certificate(s).
- (3) Controls the human resources required for the operations authorized to be conducted under the certificate holder's certificate(s).
- (4) Retains ultimate responsibility for the safety performance of the operations conducted under the certificate holder's certificate.

(b) Responsibilities of the accountable executive. The accountable executive must accomplish the following:

- (1) Ensure that the SMS is properly implemented and performing in all areas of the certificate holder's organization.
- (2) Develop and sign the safety policy of the certificate holder.
- (3) Communicate the safety policy throughout the certificate holder's organization.

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(4) Regularly review the certificate holder's safety policy to ensure it remains relevant and appropriate to the certificate holder.

(5) Regularly review the safety performance of the certificate holder's organization and direct actions necessary to address substandard safety performance in accordance with § 5.75.

(c) Designation of management personnel. The accountable executive must designate sufficient management personnel who, on behalf of the accountable executive, are responsible for the following:

(1) Coordinate implementation, maintenance, and integration of the SMS throughout the certificate holder's organization.

(2) Facilitate hazard identification and safety risk analysis.

(3) Monitor the effectiveness of safety risk controls.

(4) Ensure safety promotion throughout the certificate holder's organization as required in subpart E of this part.

(5) Regularly report to the accountable executive on the performance of the SMS and on any need for improvement.

The organization must identify an existing person in the organization who holds the ultimate decision making authority over the organization's operations to be designated as the accountable executive. This person is accountable for planning, organizing, directing, and controlling the personnel, organizational structure, financial, and other resources across the organization necessary to ensure proper functioning of the SMS. Although it is not expected or required that the accountable executive personally or directly carry out the listed responsibilities, the accountabilities may not be delegated to others. For example, the accountable executive may rely on others to assemble data, perform analyses, and prepare briefings or reports needed to "regularly review the safety performance of the organization" (§5.25(b)(5)). However, accountability for participating in the review and "direct[ing] actions necessary to address substandard safety performance" cannot be delegated and remains individually with the accountable executive. Another important function of the accountable executive is to facilitate development and maintenance of a positive safety culture. As an example, setting expectations is a key aspect of a positive culture, and expectations should be set for the organization by the accountable executive.

The actual title or position of the accountable executive may vary according to the business arrangements of the organization. For example, the chief executive officer of a large organization of which the D&M organization is one of multiple subsidiaries may not be an appropriate accountable executive for SMS.

The accountable executive must ensure the provision of the necessary financial and human resources for implementation and maintenance of the SMS. For example, the organization should ensure enough personnel are available to provide support for essential SMS functions such as analysis, assistance to operational managers in meeting their safety management responsibilities, and providing safety advice or guidance to the accountable executive. The administration of SMS functions is at the discretion of the organization. Some organizations may choose to use their existing management personnel to fulfill these responsibilities. Some may distribute the responsibilities among multiple management personnel. Other organizations may organize a safety department with a number of persons, or assign duties to existing personnel within each operational division. Regardless of the arrangement selected, the accountabilities and responsibilities must appear in SMS documentation, e.g., SMS policy, an SMS manual, or the system description.

Nothing in this section is intended to add any requirement beyond any other section of part 5. For example, the requirements of § 5.25(c)(2) and (3) apply to the safety performance assessment required by § 5.73, and do not create or imply any additional requirement for safety performance assessment.

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§ 5.27 Coordination of emergency response planning.

Where emergency response procedures are necessary, the certificate holder must develop and the accountable executive must approve as part of the safety policy, an emergency response plan that addresses at least the following:

- (a) Delegation of emergency authority throughout the certificate holder's organization;
- (b) Assignment of employee responsibilities during the emergency; and
- (c) Coordination of the certificate holder's emergency response plans with the emergency response plans of other organizations it must interface with during the provision of its services.

Section 5.27 does not apply for voluntary implementation of SMS at a D&M organization. However, coordination of emergency response planning should not be confused with the potential requirement in some cases for a D&M organization to immediately exercise SRM. For example, an accident investigation finding or detection of a quality system escape might indicate a need to immediately perform SRM to determine appropriate safety risk control(s). A D&M organization's SRM should include the capability for immediately exercising SRM when warranted.

1.3.3 Subpart C – Safety Risk Management

§ 5.51 Applicability.

A certificate holder must apply safety risk management to the following:

- (a) Implementation of new systems.
- (b) Revision of existing systems.
- (c) Development of operational procedures.
- (d) Identification of hazards or ineffective risk controls through the safety assurance processes in subpart D of this part.

To know when the SRM process may be required, it is important to know what a system is. Systems could be people, processes, procedures, facilities, services, and other support facets which are directly related to the organization's aviation safety activities. For D&M, the important systems are those which could impact the aviation safety of a product. Typically, these D&M systems include the following:

- Design and Certification
- Production
- Continued Airworthiness

Under 5.51, the SRM process is triggered when D&M organizations implement new systems, revise existing systems, developing operational procedures, or identifying hazards or ineffective risk controls through the SA processes in subpart D. See Section 2, paragraph 2.9.1, for examples.

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§ 5.53 System analysis and hazard identification.

(a) When applying safety risk management, the certificate holder must analyze the systems identified in § 5.51. Those system analyses must be used to identify hazards under paragraph (c) of this section, and in developing and implementing risk controls related to the system under § 5.55(c).

(b) In conducting the system analysis, the following information must be considered:

- (1) Function and purpose of the system.
- (2) The system's operating environment.
- (3) An outline of the system's processes and procedures.
- (4) The personnel, equipment, and facilities necessary for operation of the system.

(c) The certificate holder must develop and maintain processes to identify hazards within the context of the system analysis.

Systems analysis is the primary means of proactively identifying and addressing potential problems before the new or revised systems or procedures are put into place. The system analysis should explain the functions and interactions among the hardware (including the product), software, people, and environment that make up the system in sufficient detail to identify hazards and perform risk analyses. The process is started by describing the system (this can be as simple as flowcharting the system or writing a short narrative). For the purpose of system analysis and hazard identification, the "system" is the same as identified in the SMS system description. It may be necessary to analyze the system as various combinations of subsystems, depending upon the lifecycle phase(s) under consideration.

Section 5.53 requires D&M organizations to have a process to identify aviation safety hazards by describing and analyzing the systems identified in § 5.51. Section 5.53 does not replace or obviate any system safety assessments for product airworthiness compliance purposes. The system description and analysis provide a basis for understanding possible hazards related both to the product and the operating environment. Because statistical data for D&M systems in the operating environment (as opposed to a product) generally do not exist, qualitative analysis is acceptable. There is no requirement that a single analysis be used, nor that a single analysis be applied both to the product and the operating environment. There is no prescribed level of complexity or comprehensiveness required of the analysis. Any analysis methodology that supports identification of hazards and development and implementation of risk controls may be used.

With regard to design and certification, hazards are the conditions that could foreseeably lead to a noncompliant product that, if not addressed, would rise to the level of unacceptable risk. If an organization elects to use new or unestablished methods and processes, or to substantively revise existing methods and processes, it should develop and use hazard identification processes to identify conditions that could foreseeably lead to a noncompliant product with unacceptable risk.

For a manufacturing organization, hazards are the conditions that could foreseeably lead to a nonconforming product that, if not addressed, would rise to the level of unacceptable risk. If an organization elects to use new, unestablished, or substantively revised methods and processes, it should develop and use hazard identification processes to identify conditions that could foreseeably lead to a nonconforming product with unacceptable risk.

For continued airworthiness, hazards are the conditions that could foreseeably lead to unacceptable safety risk in a product. D&M organizations should have established and documented methodologies and processes (such as a COS program) for monitoring reported in service events; in-service failures, malfunctions, or defects; quality escapes; flight test events; supplier notices of escapement; and noncompliances related to the product certificates or approvals they hold. Each of these events should be analyzed per 5.53 to identify aviation safety hazards.

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§ 5.55 Safety risk assessment and control.

- (a) The certificate holder must develop and maintain processes to analyze safety risk associated with the hazards identified in § 5.53(c).
- (b) The certificate holder must define a process for conducting risk assessment that allows for the determination of acceptable safety risk.
- (c) The certificate holder must develop and maintain processes to develop safety risk controls that are necessary as a result of the safety risk assessment process under paragraph (b) of this section.
- (d) The certificate holder must evaluate whether the risk will be acceptable with the proposed safety risk control applied, before the safety risk control is implemented.

SRM requires the analysis of risk to determine the severity and likelihood associated with identified hazards. Various guidance is available for analyzing risk. An appropriate quantitative or qualitative method must be used.

Safety risk must be assessed to determine its acceptability. During design and certification, compliance with existing certification procedural and airworthiness regulations defines an acceptable safety risk.

During production, safety risk acceptability is defined by the part 21 requirements for a product to conform to its approved design and be in a condition for safe operation. In some situations, conditions such as assembly variations or a need to repair damaged parts or assemblies may arise during production. There may also be instances where a "disclosure" has been identified. A manufacturing organization, in coordination with the design organization, may use approved processes that address these situations to ensure the product conforms to its approved design and is in a condition for safe operation. These approved processes are an acceptable way to achieve acceptable safety risk.

During the continued airworthiness phase, safety risk acceptability is defined by the continued airworthiness of products in service. Safety risk acceptability during the continued airworthiness phase should be based on consideration of the applicable airworthiness standards and ensuring that no unsafe condition exists. The existence of an unsafe condition related to a product constitutes unacceptable safety risk. The opportunity for a D&M organization to determine that safety risk related to a product is acceptable applies only to situations where no unsafe condition exists. For those situations, there is no specific level of safety risk that is required in order to be considered acceptable, but determination of product safety risk acceptability by a D&M organization may be more conservative than 14 CFR part 39.

1.3.4 Subpart D – Safety Assurance

§ 5.71 Safety performance monitoring and measurement.

- (a) The certificate holder must develop and maintain processes and systems to acquire data with respect to its operations, products, and services to monitor the safety performance of the organization. These processes and systems must include, at a minimum, the following:
 - (1) Monitoring of operational processes.
 - (2) Monitoring of the operational environment to detect changes.
 - (3) Auditing of operational processes and systems.
 - (4) Evaluations of the SMS and operational processes and systems.

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(5) Investigations of incidents and accidents.

(6) Investigations of reports regarding potential non-compliance with regulatory standards or other safety risk controls established by the certificate holder through the safety risk management process established in subpart B of this part.

(7) A confidential employee reporting system in which employees can report hazards, issues, concerns, occurrences, incidents, as well as propose solutions and safety improvements.

(b) The certificate holder must develop and maintain processes that analyze the data acquired through the processes and systems identified under paragraph (a) of this section and any other relevant data with respect to its operations, products, and services.

The organization should conduct on-going monitoring of its system as defined in the system description to acquire data needed to assess safety performance in accordance with §5.73. Audits should be conducted periodically to determine whether processes are operating, and to assess whether they are effective.

Because of the manufacturer's expertise in the build of the product, it may also be requested to support investigations of incidents and accidents. Organizations should have a process or system in place to support an incident or accident investigation, if requested by the NTSB or other national agency. Any information from these investigations (within the limits of the investigation protocol) linked to the design or manufacture of the product should be evaluated per the SRM process to determine any applicable risk controls.

The intent of confidential employee reporting is to ensure employees have a nonpunitive means to communicate aviation safety information to the SMS. The organization should ensure employees are aware of the confidential reporting system and are using it as appropriate. Safety risk management should be applied to appropriate aviation safety concerns submitted via the confidential employee reporting system.

§ 5.73 Safety performance assessment.

(a) The certificate holder must conduct assessments of its safety performance against its safety objectives, which include reviews by the accountable executive, to:

(1) Ensure compliance with the safety risk controls established by the certificate holder.

(2) Evaluate the performance of the SMS.

(3) Evaluate the effectiveness of the safety risk controls established under § 5.55(c) and identify any ineffective controls.

(4) Identify changes in the operational environment that may introduce new hazards.

(5) Identify new hazards.

(b) Upon completion of the assessment, if ineffective controls or new hazards are identified under paragraphs (a)(2) through (5) of this section, the certificate holder must use the safety risk management process described in subpart C of this part.

Safety performance measurement is an assessment of the organization's capability to manage risk. It is a determination of the processes' success in managing risk and the resulting effectiveness of the implemented risk controls, from both a product and organizational perspective.

The organization should assess the data collected under §5.71 against its safety objectives to evaluate its safety performance.

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The organization should consider safety lessons learned. Particular interest should be focused on the processes and procedures related to implementing safety lessons learned from subparts C and D into the design. For D&M organizations, safety performance assessment and identification of ineffective controls or new hazards is primarily performed as part of continued airworthiness.

Section 5.73 requires an evaluation of how the product is performing in-service against the organization's safety objectives. The organization is expected to develop and maintain appropriate safety-related performance indicators. These indicators may be precursor indicators of incidents or accidents (such as high-speed rejected takeoffs or engine inflight shutdowns). It is not expected that there would be a safety performance indicator for every safety risk control, given that compliance with each airworthiness regulation is considered a risk control.

The organization must evaluate substantive changes to its SA or COS processes to ensure the processes still perform their intended purpose (that is, assessing its products in-service data and performing SRM as appropriate when an ineffective control, new hazard, or potential hazard has been identified).

§ 5.75 Continuous improvement.

The certificate holder must establish and implement processes to correct safety performance deficiencies identified in the assessments conducted under § 5.73.

The intent is to use the performance assessments from § 5.73 to identify where safety objectives are not being met and identify corrective action. "Deficiencies" refers to failure to achieve a safety objective, as indicated by measurement of safety performance. Processes to correct such deficiencies must be established and implemented.

1.3.5 Subpart E – Safety Promotion

§ 5.91 Competencies and training.

The certificate holder must provide training to each individual identified in § 5.23 to ensure the individuals attain and maintain the competencies necessary to perform their duties relevant to the operation and performance of the SMS.

Training may be tailored to employees' respective positions in the organization. An organization might elect not to provide SMS training to employees having no SMS-related accountabilities. It is important, however, that employees having responsibilities relevant to aviation safety, even if limited in scope, know how to report safety concerns and understand that it is their responsibility to do so.

The organization should develop the content, methods of delivery, and frequency of training that best meet its needs. Organizations may choose internal or external training. Regardless of the approach taken, the training must be specific to the organization's SMS and operations.

§ 5.93 Safety communication.

The certificate holder must develop and maintain means for communicating safety information that, at a minimum:

- (a) Ensures that employees are aware of the SMS policies, processes, and tools that are relevant to their responsibilities.
- (b) Conveys hazard information relevant to the employee's responsibilities.
- (c) Explains why safety actions have been taken.
- (d) Explains why safety procedures are introduced or changed.

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Safety policy and information could be provided as text, visual media such as posters or short videos, oral crew or team briefings, intranet websites, or other means as appropriate depending on the size and complexity of the organization. Messages should be delivered using whichever media the organization wishes to use.

1.3.6 Subpart F – SMS Documentation and Recordkeeping

§ 5.95 SMS documentation.

The certificate holder must develop and maintain SMS documentation that describes the certificate holder's:

- (a) Safety policy.
- (b) SMS processes and procedures.

Documentation of an organization's SMS policy, processes and procedures includes the steps involved, methods to be used, and associated criteria, objectives, expected outputs, and outcomes necessary to meet the requirements. The manner and format of documentation is at the discretion of the organization. The organization should have a means to maintain the documents dealing with these policies, processes, and procedures.

§ 5.97 SMS records.

- (a) The certificate holder must maintain records of outputs of safety risk management processes as described in subpart C of this part. Such records must be retained for as long as the control remains relevant to the operation.
- (b) The certificate holder must maintain records of outputs of safety assurance processes as described in subpart D of this part. Such records must be retained for a minimum of 5 years.
- (c) The certificate holder must maintain a record of all training provided under § 5.91 for each individual. Such records must be retained for as long as the individual is employed by the certificate holder.
- (d) The certificate holder must retain records of all communications provided under § 5.93 for a minimum of 24 consecutive calendar months.

The requirement to maintain records of outputs, training, and communications does not in itself create any requirement to submit those records to the FAA. However, these records should be made available to the FAA for oversight activities. The requirements of this section are not intended to require an organization to retroactively maintain or recreate records of activity before its SMS implementation. The requirements related to SMS records apply beginning with SMS implementation.

1.4 A Hypothetical Example of SMS Processes In Action: Management Decision to Outsource Software Development

ACME Aircraft Corporation has always developed critical flight control software internally using rigorous processes compliant with FAA regulations. ACME recently won a new contract and wants to outsource the software development since their engineering department is fully utilized on other projects. ACME's SMS evaluated this change to their design system (which is part of ACME's SMS system description and identified as important to management of aviation safety) and determined that SRM is required per 5.51(b) since flight control software is safety critical and outsourcing software development is a change to ACME's design processes.

This change triggered the requirement per 5.53 to analyze their design system and identify safety hazards. ACME had developed a system description which included their software design process and supplier selection procedures. Improperly functioning flight control software was identified as an aviation safety hazard that could lead to an accident. After analyzing the system, ACME identified the following hazards for outsourced software development:

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- 1) Supplier selection procedures lack sufficient detail to ensure the supplier is capable of developing flight critical software
- 2) Software requirements flowdown procedures are not sufficiently detailed to ensure proper understanding of design requirements
- 3) ACME does not have processes in place to provide oversight of software developed outside of the company

ACME gathered a group of SMS and software development experts to analyze the risk posed by each hazard. Results from this assessment were plotted on the risk matrix in Figure 2. The matrix shown in Figure 2 is a hypothetical example of a matrix that might be used by a hypothetical organization. The terminology and risk levels are not intended to be considered mandatory or required by this NAS. Organizations should develop terminology and risk level characterizations appropriate for themselves.

RISK ASSESSMENT MATRIX				
SEVERITY PROBABILITY	Catastrophic (1)	Critical (2)	Marginal (3)	Negligible (4)
Frequent (A)	High	High	Serious	Medium
Probable (B)	High	High	Serious	Medium
Occasional (C)	High	Serious	Medium	Low
Remote (D)	Serious	Medium	Medium	Low
Improbable (E)	Medium	Medium	Medium	Low
Eliminated (F)	Eliminated			

FIGURE 2 – ACME AIRCRAFT COMPANY SMS RISK MATRIX

- Hazard No. 1: Supplier selection procedures lack sufficient detail to ensure the supplier is capable of developing flight critical software. Risk Rating: Serious (Probability: Occasional, Severity: Critical)
- Hazard No. 2: Software requirements flowdown procedures are not sufficiently detailed to ensure proper understanding of design requirements. Risk Rating: Serious (Probability: Remote, Severity: Catastrophic)
- Hazard No. 3: ACME does not have processes in place to provide oversight of software developed outside of the company. Risk Rating: Low (Probability: Improbable, Severity: Negligible)

ACME's SMS requires risk control implementation for risk levels of Serious and High. The SMS team developed the following risk controls:

- Risk Control No. 1: Update supplier selection procedures to include a capability assessment prior to issuing any external contracts for software development. Updated Risk Rating: Medium (Probability: Occasional, Severity: Critical)

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- Risk Control No. 2: Review and update software requirements flowdown processes to ensure they function properly when working with external suppliers. Updated Risk Rating: Eliminated (Probability: Eliminated, Severity: Catastrophic)

The updated risk ratings meet ACME's SMS requirements for effective risk controls. With these risk controls in place, the SRM process was completed and ACME went ahead with the outsourced software development project.

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SECTION II: SMS IMPLEMENTATION CONSIDERATIONS

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2. SECTION II: SMS IMPLEMENTATION CONSIDERATIONS

2.1 The need for an NAS for Voluntary Implementation of an FAA-Accepted SMS

International Civil Aviation Organization (ICAO) Annex 19, Safety Management, establishes standards and recommended practices (SARP) applicable to safety management functions related to, or in direct support of, the safe operation of aircraft. Annex 19 prescribes that each State shall require organizations under its authority responsible for the type design or manufacture of aircraft in accordance with Annex 8 to implement an SMS. Annex 19 further prescribes that the SMS of an organization responsible for the type design of aircraft shall be made acceptable to the State of Design, and the SMS of an organization responsible for the manufacture of aircraft shall be made acceptable to the State of Manufacture.

In the absence of a FAA requirement for US D&M compliance with part 5, there is potential for any international regulator seeking adherence to Annex 19 SARPs to demand, as a condition of aircraft operation, registration, or importation, that a US D&M organization provide evidence of an SMS that complies with the SARPs. This NAS provides practices which may be used by D&M organizations to develop a voluntary SMS that is consistent with part 5, and is therefore eligible for acceptance by the FAA. Acceptance by the FAA, documented in the form of a letter or other written substantiation, is intended to facilitate acceptance of the D&M organization's SMS by international regulators pursuant to Annex 19.

2.2 Safety Culture and Safety Management

One key aspect that is essential to safety performance is the culture of the organization. "Safety culture" is the term that we apply to those aspects of the organization's culture that relate to safety performance. The concept of safety culture underlies safety management and is the basis for the SMS requirements of part 5. However, part 5 does not include any requirement to have, measure, or assess safety culture. It is not intended that any D&M organization be required to demonstrate a "positive" safety culture.

Because the culture of an organization includes the deeply ingrained and automatic psychological and behavioral aspect of human performance, there is a strong correlation between safety culture and accident prevention. Therefore, safety culture and SMS are interdependent. Management's constant attention, commitment, and visible leadership are essential to guiding an organization toward a positive safety performance.

Cultures are the product of the values and actions of the organization's leadership as well as the results of organizational learning. Cultures are not really "created" or "implemented;" they emerge over time and as a result of experience. Organizations cannot simply purchase a software program, produce a set of posters filled with buzzwords, require their people to attend an hour of slide presentations, and instantly install an effective SMS. As with the development of any skill, it takes time, practice and repetition, the appropriate attitude, a cohesive approach, and constant coaching from involved mentors. The learning and practicing of safety management skills, coaching by mentors, day-to-day exercise of SMS processes, and other discrete behaviors constitute "safety behaviors" that contribute to the development of the safety culture.

It is for this reason that a management framework that facilitates decision making and shapes the environment in which employees work is crucial to organizational performance in all aspects of the organization's business, including safety. A safety culture matures as safety management skills are learned and practiced, and the safety behaviors become second nature across the entire organization. The following have been found to be characteristics of organizations that consistently achieve safe results:

- Open Reporting. Policies and processes that foster open reporting while, at the same time, stressing the need for continuous diligence and professionalism. The organization should encourage disclosure of error without fear of reprisal, yet it should also demand accountability on the part of employees and management alike.

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- Just Culture. The organization should engage in identification of systemic errors, implement preventative corrective action, and exhibit intolerance of undesirable behaviors such as recklessness or willful disregard for established procedures. This is often referred to as a “just culture.”
- Personnel Involvement. Involvement of line personnel and all levels of management in functions dealing with aviation safety, including the accountable executive, is critical to effective safety management throughout an organization.
- Use of Information. Effective use of all safety information assures informed management decision making.
- Commitment to Risk Reduction. The organization expects direct management involvement in identifying hazards and managing risk.
- Vigilance. Processes that provide vigilance of ongoing operations and the environment to ensure effectiveness of risk controls and awareness of emerging hazards.
- Flexibility. Using information effectively to adjust and change to reduce risk, and a willingness to commit resources to making changes necessary to reduce risk.
- Learning. The organization learns from its own failures and from those of allied and similar businesses. The organization actually uses acquired data to feed analysis processes, the results of which yield information that can be acted upon to improve safety.

Management leadership should demonstrate their visible commitment to and involvement in safe operation performing their daily work. SMS processes do not have to be expensive or sophisticated; however, active personal involvement of operational leaders is essential. Safety management must be accomplished by those managers who “own” the processes in which risk resides. Safety cultures also cannot be “created” or “implemented” by management decree, no matter how sincere their intentions. Every organization has a safety culture. It is embodied in the way the organization and its members approach safety in their jobs. If positive aspects of culture are to emerge, the organization’s management must set up the policies and processes that create a working environment that fosters routine safety behaviors. That is the purpose of the SMS processes.

2.3 SMS Fundamentals

SMS can be a complex topic with many aspects to consider, but the defining characteristic of an SMS is that it is a decision making system. An SMS does not have to be an extensive, expensive, or sophisticated array of techniques to do what it is supposed to do. Rather, an SMS is built by structuring your safety management around four components: safety policy, safety risk management (SRM), safety assurance (SA), and safety promotion. A brief description of these components is provided below.

- Safety Policy
 - o Safety policy is where you set objectives, assign responsibilities, and set standards. It is also where management conveys its commitment to the safety performance of the organization to its employees. As SRM and SA processes are developed, you will come back to the safety policy to ensure that the commitments in the policy are being realized and the standards are being upheld.
- Safety Risk Management
 - o The SRM component provides a decision making process for identifying hazards and mitigating risk based on a thorough understanding of the organization’s system. For D&M, “a system” includes the product as well as the organization’s operating environment. Refer to Section 1.2 and Appendix A for more discussion of a D&M organization’s operating environment and system description. SRM includes decision making regarding management acceptance of aviation safety

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risk. The SRM component is the organization's way of fulfilling its commitment to consider aviation safety risk and to reduce or maintain it to an acceptable level. In that sense, SRM is a design process, a way to incorporate risk controls into processes, products, and services or to redesign controls where existing ones are not meeting the organization's needs.

- Safety Assurance
 - o SA provides the necessary processes to give you confidence that your system is meeting your organization's safety objectives and that your mitigations, or risk controls, developed under SRM are working. In SA, the goal is to watch what is going on and review what has happened to ensure the organization's objectives are being met. Thus, SA requires monitoring and measuring safety performance of operational processes related to the product and continuously improving the level of safety performance. Strong SA processes will yield information used to maintain the integrity of risk controls. SA processes are thus a means of assuring the aviation safety performance of the organization by assuring the safety performance of its product in the operating environment, keeping it on track, correcting it where necessary, and identifying needs for rethinking existing processes.
- Safety Promotion
 - o The last component, safety promotion, is designed to ensure that employees have a solid foundation regarding their safety responsibilities, the organization's safety policies and expectations, reporting procedures, and a familiarity with risk controls. Thus, training and communication are the two key areas of safety promotion.

An SMS does not have to be large, complex, or expensive in order to add value. If there is active involvement by the organization's leaders, open lines of communication are maintained up and down the organization and among peers, there is vigilance in looking for new hazards, and employees know that aviation safety is an essential part of their job performance, the organization will have an effective SMS that helps make better aviation safety management decisions.

Figure 3, Safety Management Decisionmaking Processes, provides an expanded view of the principal two sets of processes of the SMS: SRM and SA. The discussion that follows introduces some key terms and concepts related to SMS processes. A more detailed discussion of the SRM and SA processes is set out in sections 2.9 and 2.10 of this NAS. Because safety management is a decisionmaking process, the SRM and SA processes follow a set of processes outlined in Figure 3. These processes work as follows. The Description and Context step requires the user of the process to gain an overall understanding and context of the operation that either is being or will be performed. The Specific Information step requires the user of the process to obtain information about aspects of the systems and environments involved that may present risk. Under the Analysis step, the user analyzes or makes sense of that information. The Assessment step requires the user to make decisions regarding the acceptability or risk of system performance. Finally, under the Resolution step, the user takes necessary action.

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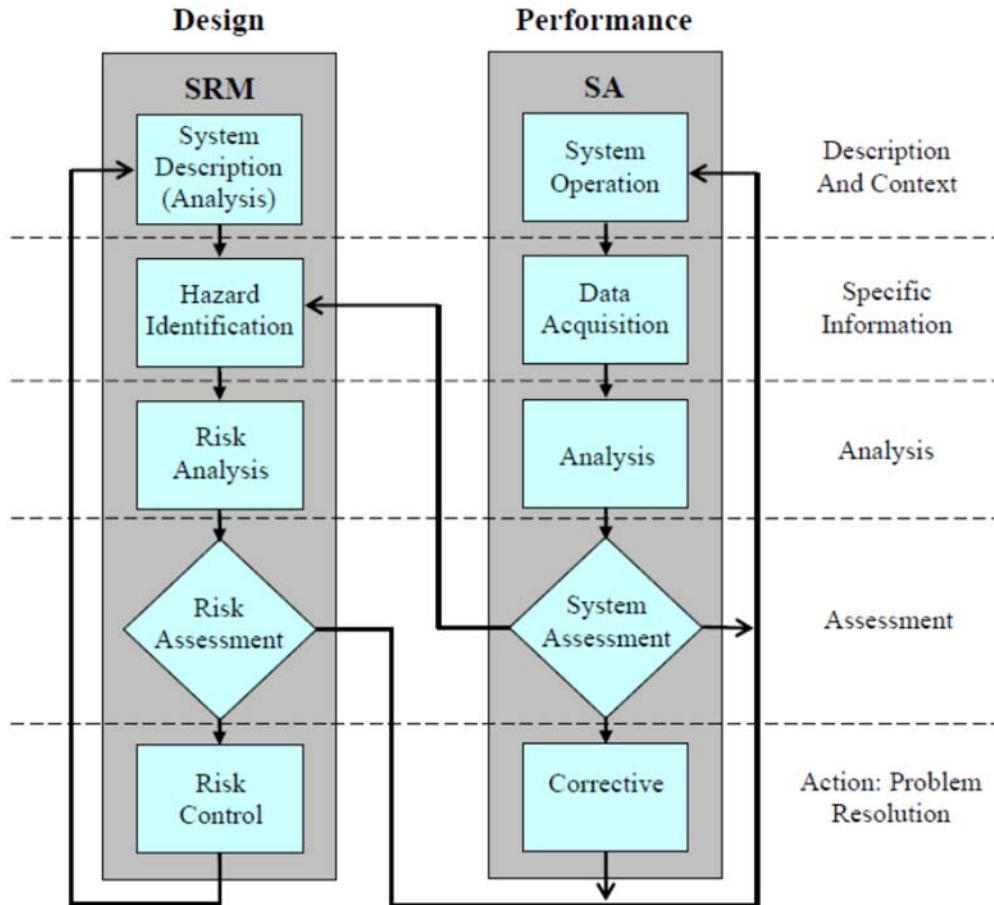


FIGURE 3 – SAFETY MANAGEMENT DECISIONMAKING PROCESSES

2.4 SMS for Design and Manufacturing

An SMS includes organizational considerations intended to enhance aviation safety. The objective of SMS for D&M is to manage safety risk associated with in-service operation of a product. To enhance aviation safety and meet the continued airworthiness objective, SMS should be applied through all phases of the product's life cycle. An SMS does not relieve a certificate holder from compliance with the applicable certification procedures (such as 14 CFR 21.17 and 21.101), airworthiness regulations (such as 14 CFR 25.1309), or manufacturing quality system (QS) regulations (such as 14 CFR 21.137). Nor does compliance to part 5 SMS circumvent the acceptable compliance to those or any other existing regulations. Although D&M organizations need to apply safety risk management (SRM) and safety assurance (SA) to compliance assurance processes, they are not required to develop new processes if the existing processes meet the intent of part 5.

The process of setting safety objectives, and monitoring, measuring, and assessing safety performance against the safety objectives, can be simplified and appropriately focused when the organization is able to correctly and completely understand its system. This is because the system description enables the organization to identify operational processes and aspects of the operational environment that are appropriate to be monitored.

With regard to performing SRM considering a system's operating environment, there are no industry-accepted methods to conduct quantitative safety risk assessments of organizations. Therefore, qualitative assessments are acceptable. As an organization's SMS matures and continually improves, the organization should be able to gain insight into the organizational factors in its own system, enhancing its SRM.

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2.5 SMS and Product Life Cycle

For D&M organizations, the management of aviation safety necessarily results in emphasis on the product produced by the organization. To facilitate clear understanding, the relationship between design and production aspects of SMS may be considered according to product life cycle.

SMS for D&M addresses the three phases in a product's life cycle: design and showing of compliance (i.e., design and certification), production and airworthiness certification, and continued airworthiness.

The existing certification procedural and airworthiness regulations required during the design and showing of compliance phase are intended to ensure the product is safe. Therefore, a design organization inherently fulfills much of the product-related intent of SMS for the design and showing of compliance phase when it designs and certifies a product pursuant to the existing procedural (14 CFR part 21) and airworthiness (14 CFR parts 23, 25, 26, 27, 29, 31, 33, and 35) regulations.

The existing production regulations required to get a production approval are intended to ensure each product conforms to its approved design and is in a condition for safe operation. These regulations require 1) a system in place for identifying, analyzing, and initiating appropriate corrective action for products that have been released from the QS and that do not conform to the applicable design data or quality system requirements; 2) procedures for receiving and processing feedback on in-service failures, malfunctions, and defects; and 3) a process for assisting the design approval holder to address any in-service problem involving design changes and determine if any changes to the ICA are necessary. Therefore, an organization inherently fulfills much of the product-related intent of SMS for the production and airworthiness certification life cycle phase when its QS is in accordance with the part 21 QS regulations.

An effectively functioning continued operational safety (COS) program inherently fulfills much of the product-related intent of SMS for the continued airworthiness life cycle phase. Additionally, manufacturing organizations perform the important function of supporting COS programs by coordinating information regarding quality escapes, in-service failures, malfunctions, and defects with the design approval holder. However, although many organizations have COS programs with working agreements between the organization and the FAA, these programs are only required by regulation for Organization Designation Authorization (ODA) holders approved under 14 CFR part 183, subpart D, specifically § 183.63.

Thus, many of the processes established for compliance with existing regulations could be used to meet SMS requirements. Likewise, there may be processes developed by D&M organizations, but not directly linked to compliance with existing regulations, that could satisfy the intent of SMS. Whatever the case, it will still be the D&M organization's responsibility to show how existing processes fulfill SMS requirements.

The following sections of this NAS contain more specific descriptions of acceptable means of compliance and how aspects of a D&M organization's design, certification, production, and continued airworthiness processes and procedures may be acceptable means of compliance with part 5.

The following descriptions of the three life cycle phases apply throughout this NAS. These descriptions are used to facilitate conceptual understanding of the application of SMS in design and manufacturing. It is important to note that when considering existing processes in any organization, there may be considerable overlap and merging of the phases. As an example, in many cases of certifying a product, there necessarily must be production during the design and showing of compliance phase of test articles that conform to the current design. Thus, the organization's SMS might need to encompass the application of production configuration management process(es) and production conformity assurance process(es) during the design and showing of compliance phase.

- Design and Showing of Compliance (Certification) Phase. This phase starts at the application for a design approval or a change to a certified design. If the D&M organization desires FAA involvement before application, it is the organization's prerogative to request that involvement.
- Production and Airworthiness Certification Phase. This phase starts with the manufacture of conformed parts.

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- Continued Airworthiness Phase. This phase starts when a TC is issued and continues until the TC is surrendered, suspended, or revoked. It includes each product produced while the organization holds the respective design or production approval.

2.6 Relationship between SMS and QS

A production approval holder that manufactures a product is required to have a QS that meets the requirements of § 21.137. Those requirements are the minimum elements necessary to ensure each product and article conforms to its approved design and is in a condition for safe operation. Many organizations have elected to implement a quality management system (QMS) that not only satisfies the requirements of § 21.137, but accomplishes organizational objectives beyond the regulations. Although QMS processes might also satisfy some part 5 requirements, this NAS is necessarily limited to discussion of the extent to which an organization's existing processes used to satisfy the minimum QS requirements might also satisfy some part 5 requirements. An organization with a QMS that includes processes exceeding the minimum QS requirements may wish to evaluate in a gap analysis whether those processes also satisfy part 5 requirements. If they do, and if the organization wishes to use those processes for its SMS, they should be included in the SMS implementation plan and documentation.

SMS and QS share many similarities and commonalities. For example, both systems:

- Must be planned and managed
- Depend on measurement and monitoring of performance indicators
- Involve organizational functions related to the design and manufacture of products
- Emphasize the identification of ineffective processes and procedures that must be modified to achieve performance objectives
- Use similar tools, such as root cause analysis and statistical trending analysis

Establishing a close relationship between SMS and QS is possible and even desirable. Processes used in a QS to accomplish auditing, inspection, investigation, root cause analysis, statistical analysis, change management, and other functions are also beneficial for an SMS. Also, quality principles, policies, and practices are closely linked to safety management objectives. Because of the similarities between the two systems, an organization that uses a QMS to satisfy its part 21 QS requirements may satisfy much of its SMS requirements. However, differences exist between a QS and a part 5 SMS, which has an objective of effectively managing aviation safety risk.

A QS focuses on the products and services of the organization, with a primary aim of ensuring identified requirements are met. Regarding compliance with part 21, this is accomplished by ensuring the product conforms to its approved design and is in a condition for safe operation. A part 21 QS also requires procedures for receiving and processing feedback on in-service failures, malfunctions, and defects as well as addressing quality escapes. When the QS links its procedures for assessing in-service failures, malfunctions, defects, and quality escapes with the design organization's COS process, it has in part satisfied part 5 SRM and SA requirements.

SMS and QS are complementary, not adversarial. An SMS builds on QS principles, and should include both safety management and quality management policies and procedures. Therefore, some features of a QS may serve as complementary features of an SMS.

When manufacturing and quality processes result in a product that conforms to its approved design and is in a condition for safe operation, an acceptable level of safety has been achieved from a manufacturing standpoint. However, production or quality issues may arise that represent hazards requiring application of SRM. The production organization must have the capability to identify product and organizational hazards, assess aviation safety risks arising from those hazards, and develop safety risk controls, or have the capability for its SMS to interact with the design organization to accomplish product related SRM. This is the key distinction for a

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