Federal Aviation Administration

2012 Manufacturers Safety Management System Pilot Project Report Design and Manufacturing Organizations

Table of Contents

Table of Figures

Executive Summary

The purpose of the pilot project was to work collaboratively with a group of design and manufacturing (D&M) organizations to develop a common understanding of Safety Management Systems (SMS) and their application within a D&M environment. The pilot project would provide experience and information to guide future FAA rulemaking decisions regarding application of SMS to D&M organizations.

In October 2009, the Aircraft Certification Service (AIR) chartered a team to conduct an SMS pilot project and to develop appropriate SMS materials in support of the project. The team consisted of representatives from AIR engineering and manufacturing inspection offices and included contractors experienced in aviation, engineering, manufacturing, and SMS. This team was called the Manufacturers Safety Management System (MSMS) team and was chartered to research various SMS documents/papers/literature from academia, industry, and international regulatory agencies, such as International Civil Aviation Organization (ICAO). The team also received input from members of the 2009 AVS-supported SMS Aviation Rulemaking Committee (ARC).

The MSMS team created an SMS framework along with guidance and tools to align with ICAO SMS recommendations. Subsequent revisions were made to the D&M SMS framework to improve alignment with the part 5 Notice for Proposed Rulemaking (NPRM). Tracking tools were developed to gather pilot project information and data. Many aspects of the SMS framework, guidance material, and assessment tools were validated by the MSMS team through feedback from participating companies.

Eleven companies representing the breadth of organizations that AIR oversees participated in the pilot project. These organizations varied in terms of size, the products they created, and the type of approvals they held. The companies were at various levels of SMS maturity at the end of 2012.

Two primary recommendations are: (1) Any FAA rulemaking decisions involving application of SMS to D&M organizations should align with ICAO requirements, (2) Future oversight models should be predicated on performance of the D&M organization instead of conducting specific SMS and certificate management oversight.

Some key areas of learning from the project are:

- Industry organizations vary widely in their understanding of SMS objectives and how to implement SMS with existing processes and procedures. The pilot project provided the FAA and industry with a unique opportunity to develop a stronger common understanding of SMS knowledge.
- The pilot project was an important activity to undertake. Consideration should be given to how pilot projects could be used in the future in other areas to help advance a more common understanding across industry and in advance of key industry and agency decisions.

- Industry has developed processes that effectively address much of the product-related risks, but additional work and process development will be required to provide a broader approach to organization wide hazards that can affect aviation safety. This represents the very essence of how SMS is different than existing practices. Much of the future work to implement SMS will involve process revisions, although some new process development will be required.
- Many companies see benefits associated with developing and implementing SMS, while others acknowledge the principles of SMS, but question if further work to develop and implement SMS would be cost beneficial (at a company or industry level) in light of improving safety trends in various segments of the industry
- Gap analysis and assessment tools were important to implement an SMS.
- Reducing the complexity of the SMS processes accommodated companies with multiple business units and multiple locations.

Having senior company executive commitment and direction was critical to the level of progression and learning within individual companies. Overall, participants benefited from involvement in the pilot project. Communication and understanding of SMS processes was enhanced, however SMS learning is still occurring as we move ahead into 2013 with the participants still developing their SMS.

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1-0 Overview of the MSMS Pilot Project

A Manufacturers Safety Management System (MSMS) pilot project was conducted to learn about applying Safety Management Systems (SMS) to design and manufacturing (D&M) organizations. Eleven D&M companies voluntarily implemented an SMS during the pilot project. The first company was kicked off in 2010 and the team concluded in 2012. Lessons learned from this project will guide future industry and FAA decisions regarding SMS, including rulemaking. The pilot project provided the FAA's Aircraft Certification Service (AIR) and the D&M industry with an opportunity to learn, gain experience, and share information about the challenges and benefits of implementing an SMS.

The participating D&M organizations varied in terms of size, production approvals, and products to provide a broad view of how SMS can be implemented in all facets of the aviation industry. They were not required to meet any deadlines in the pilot project, and variations in progress among the pilot project participants does not, in any way, indicate a lack of commitment to aviation safety. Participating in the project demonstrates the organizations' leadership positions in implementing progressive safety measures in the aviation industry. Most of the organizations already had some SMS elements in their quality and design processes. We would like to commend the participating organizations for their continuing efforts to assist the FAA with this important initiative.

Many aviation design and manufacturing organizations have existing, mature, and effective safety systems, such as a quality management system (QMS), internal audit quality assurance programs, continued operational safety (COS) programs, and certification processes that comply with existing regulations. SMS complements and enhances those systems and strengthens how companies fulfill their existing safety responsibilities through a more complete and process-based method for managing safety.

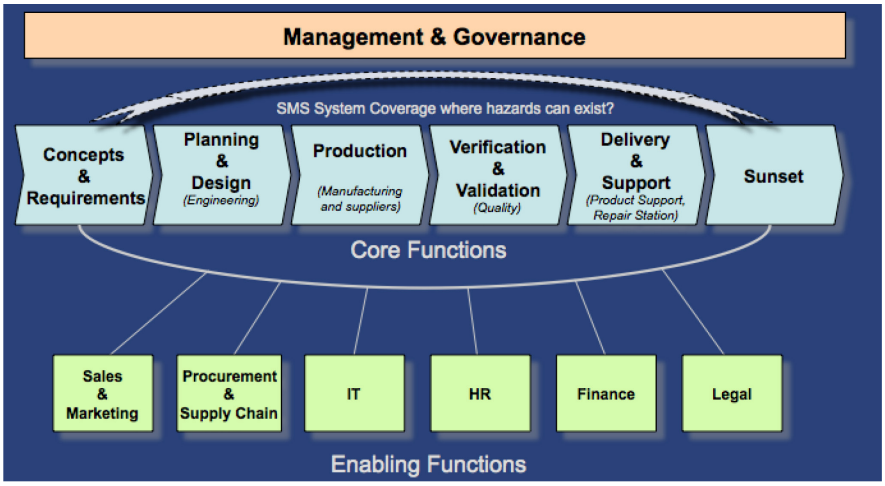
The scope of SMS should be limited to hazards associated with the design and manufacturing of an aircraft or that could affect the safety of aircraft operations.[1] It is not simply any hazard that can lead to injury, illness, or death to people; damage to or loss of a system, equipment, or property; or damage to the environment.

Almost every organizational system contains inherent potential safety vulnerabilities or hazards. Therefore, the boundaries of the system must encompass possible hazards that the system could encounter or generate. Figure 1-1 illustrates areas where the hazard identification process could be employed to identify new or existing hazards. Most organizations have fairly robust processes for addressing hazards related to product design and production. However, recognition of how

[1] Such a hazard is defined as a condition that could foreseeably cause or contribute to an aircraft accident. An aircraft accident is defined as an occurrence associated with the operation of an aircraft that takes place between the time any person boards the aircraft with the intention of flight and all such persons have disembarked, and in which any person suffers death or serious injury, or in which the aircraft receives substantial damage. Refer to Title 49, Code of Federal Regulations part 830.2, Definitions, for the National Transportation Safety Board (NTSB); and FAA Order 8020.11, *Aircraft Accident and Incident Notification, Investigation, and Reporting*, dated February 2, 2010, and FAA Order VS8000.367, *Aviation Safety (AVS) Safety Management System Requirements*, dated May 14, 2008).

hazards might be introduced in other areas of company operation or other phases of the product life cycle has been limited.

Figure 1-1: Typical Points Where Hazards Could Exist in Design and Manufacturing Organizations



This report has been written with the assumption that the reader has some knowledge of SMS and the four components associated with it. Additionally, this report has been written to provide an overview of the MSMS Pilot Project. The documents identified in Appendix B can be referenced for additional information.

2-0 Objectives of the MSMS Pilot Project

The MSMS team identified five high-level objectives for the MSMS pilot project. The objectives were defined to fulfill the pilot project expectations and learning, as well as produce deliverables beneficial to future rulemaking activities. The five objectives included the following:

1. Provide feedback for AIR rulemaking activities regarding SMS.
2. Develop and validate the draft D&M SMS framework.
3. Develop and validate the draft guidance material.
4. Collect information that will assist in the determination of applicability and scalability of a SMS rule for D&M industry.
5. Develop draft D&M SMS assessment and oversight processes and tools.

To assist the MSMS team in accomplishing the five objectives, the team developed various tools used for data collection and analysis. These tools included the following:

- Preliminary Gap Analysis (PGA)
- Detailed Gap Analysis (DGA)
- Implementation plan

- Pilot project tracking matrix

These tools enabled the MSMS team and D&M organizations to identify areas in each company that already contain components of SMS and areas where the company can further develop SMS.

3-0 Strategy for Implementing SMS During the Pilot Project

The strategy behind implementing a voluntary SMS pilot project was to examine the proposed SMS components and how they function in the D&M environment. The pilot project included as many different types of organizations in terms of size, products, and types of approvals held. By including different types of organizations, the MSMS team tried to learn as much as possible about the impact that SMS will have on them in order to guide future rulemaking considerations.

In 2006, the Flight Standards Service (AFS) began leading a pilot project in which various air carriers, regional operators, and repair facilities implemented SMS. Based on lessons learned from the AFS project, the MSMS team adjusted the initial plans for the pilot project. In addition, the MSMS team developed pilot project's associated documentation, defined the processes for selecting the participating companies, defined what data to gather from each company, assigned field support teams (referred to as Participant Management Teams [PMTs]) and outlined the expected outcomes of the project.

Instead of having all of the organizations simultaneously start immediately implementing an SMS, the MSMS team took a phased approach. As a result of the staggered start times between companies, each organization had the benefit of learning from each other. Another purpose of taking a phased approach was to ensure that the MSMS team and the pilot project participants had sufficient time and materials to succeed in the pilot project.

The MSMS team outlined a schedule, timeline, specific tasks, major milestones, and expected deliverables. This technique enabled each company to meet milestones along the way, identify accomplishments and deficiencies, and show progress. It was also a way for the MSMS team to gather data and track progress while understanding how the company was addressing SMS initiatives in relation to other priorities.

Before launching each SMS pilot project, the MSMS team provided an SMS information package to each participating organization to prepare them for the "Challenge Session" orientation. Before the orientation, the MSMS team hosted a telecon with each participant explaining the pilot project process, expectations, and outcomes. Additionally, the MSMS team requested each participant to read the SMS framework before the Challenge Session and PGA meeting.

3-1 Process for Selecting the Pilot Project Participants

The MSMS team selected a variety of organizations to represent the breadth and diversity of the D&M industry in terms of types of design and production forms of approval, size, and products.

Furthermore, to ensure additional area for comparison, the team wanted to have multiple organizations comparable in characteristics such as size, criticality, design, and production approval, etc. The team believed that this would provide the most data and help determine the applicability and scalability of an SMS rule to the D&M industry. The purpose of this goal was to identify similarities within the companies and to have an opportunity to see different situations and approaches between comparable organizations. Most of the organizations shared at least one characteristic with another (e.g., they produced the same product or had the same type of production approval).

The key categories included:

- Representation across design and production forms of approval
    - Production Certificate (PC)
    - Part Manufacturer Approval (PMA)
    - Technical Standard Order Authorization (TSOA)
    - Type Certificate (TC)
    - Supplemental Type Certificate (STC)
- Representation from D&M industry
    - Large transport category aircraft manufacturer
    - Small aircraft manufacturer
    - Rotorcraft manufacturer
    - Large engine manufacturer
    - Small engine manufacturer
    - Large PMA/TSOA manufacturer
    - Small PMA/TSOA manufacturer
- Company size
- Company criticality (e.g., product or unit criticality)
- FAA resource availability (e.g., appropriate division, directorate, and field office personnel to support the pilot project)

The team created a pilot project tracking matrix that the FAA MSMS team used for internal purposes.. It identified the D&M organizations and broke them down by location, scope of the implemented pilot project, pilot project selection criteria, certificates/approvals held, points of contact, company location, etc. Additionally, the matrix captured key differences between comparable companies that the team believed was important to understand how the companies would address these unique attributes.

A few of the areas of comparison included attributes for:

- Assessing a company that is geographically dispersed and has many projects with many FAA offices;
- Understanding how SMS would affect suppliers;

- Understanding how SMS could be applied to a very small company with less than 150 employees, including IT tools, training, etc.;
- Understanding how small and large companies differ;
- Understanding how SMS can be applied and developed within the general aviation environment;
- Understanding how less complex compares to more complex products; and
- Understanding the considerations of a manufacturer trying to simultaneously satisfy multiple airworthiness authorities' SMS requirements.

After assessing the company attributes, the team recommended a group of organizations to participate in the pilot project. The Aircraft Certification Management Team reviewed approved the selections and committed AIR resources to support the pilot projects.

3-2 Overview of the "Challenge Session" Orientation

The MSMS team was faced with a short timeline for getting the most information possible from the pilot project. The team wanted to make sure that the materials, tools, and processes were as close to fully operational as possible prior to beginning implementation. The MSMS team determined that the use of a Challenge Session to evaluate our pilot project processes would be beneficial in creating the best possible start.

A Challenge Session was held on November 3–4, 2010 to kick off the pilot project.

All 30 members of the MSMS team participated. They presented material to the participating D&M organizations covering the goals and objectives of the pilot project. In addition, FAA employees from the manufacturing and engineering offices from each directorate, an FAA Academy Instructor, and an AFS representative who was involved with the AFS SMS pilot project (AFS-900) attended the Challenge Session.

The Challenge Session covered the following topics:

- Overview of the pilot project to implement an SMS into D&M organizations
    - Purpose of implementing SMS
    - List of participants
    - Timeline for the pilot project
    - Pilot project objectives
    - Pilot project process
    - Roles and responsibilities of D&M organizations, MSMS team, FAA directorates, and FAA engineering and manufacturing offices
    - Communication approaches
    - Data collection and analysis approaches
- Lessons learned collection and sharing approaches

- Orientation materials
- D&M SMS framework document
- Guidance documents and materials
    - The Design and Manufacturing (D&M) Safety Management System (SMS) Pilot Project Guide, referenced in Appendix B
    - The Design &Manufacturing (D&M) Safety Management System (SMS) Developmental Guidance, referenced in Appendix B
    - Integrated Pilot Project Plan (IP3), referenced in Appendix B
    - Definitions
- Gap Analysis Tools including the preliminary, detailed and implementation plan
- Processes to assess the implementation of SMS at D&M organizations
    - Continuous assessments during the project
    - Cumulative assessments at the end of the pilot project
- Feedback session

The objectives of the Challenge Session were to:

- Collect feedback on pilot project plan
    - Clarify major tasks, roles, and responsibilities
    - Get feedback on approaches to communications
    - Get feedback and recommendations on data collection and lessons learned collection approaches
    - Ensure that the pilot project levels and processes make sense to participants
- Collect feedback on presentations in the Challenge Session
    - Ensure that the outline and key areas of content make sense
- Collect feedback on documentation and tools
    - Ensure that the documents appear are comprehensive and clear
    - Ensure that the documents cover all SMS applications
    - Ensure that the tools are clear and easy to use
    - Ensure that nothing was missing
- Verify that nothing is missing from the pilot project plan and approach
- Collect input on how implementing SMS in D&M organizations will affect AIR responsibilities and roles (to be used in the future change management efforts)

The MSMS team received over 200 comments from participants at the Challenge Session. The MSMS team incorporated most of the comments and feedback into the processes and procedures of the pilot project. Comments received varied across all topics. The team immediately learned that the feedback and discussions between industry and the FAA proved to be invaluable when learning and developing SMS guidance and tools.

3-3 Guidance Documents Developed for the Pilot Project

The MSMS team developed five documents to provide supplemental material for the MSMS team as well as the pilot project participants. The documents include the following:

- The D&M SMS Pilot Project Guide
- D&M SMS Gap Analysis and Implementation Plan Tool (GAIPT)
- Developmental Guidance for Design & Manufacturing (D&M) Safety Management System (SMS) Framework
- The Design &Manufacturing (D&M) Safety Management System (SMS) Developmental Guidance
- Integrated Pilot Project Plan (IP3)

All five documents are referenced in Appendix B.

The D&M SMS Pilot Project Guide

The D&M SMS Pilot Project Guide was referred to as simply "The Guide." The Guide served as the primary source of information for pilot project participants and FAA entities involved in the pilot project. The overall purpose of the guide was to:

- Provide D&M organizations with general information on how to begin developing and implementing an SMS; and

- Assist FAA Participant Management Team (PMT) members in evaluating an organization's SMS program and participating in further development of implementation and oversight strategies.

Specifically, the guide contained information to help ensure that an organization's SMS will be capable of:

1. Receiving safety input from internal and external sources and integrating that information into their operational processes;
2. Establishing and improving organizational safety policy to the highest level;
3. Identifying, analyzing, assessing, controlling, and mitigating safety hazards;
4. Measuring, assuring, and improving safety management at the highest level;
5. Promoting an improved safety culture throughout the entire organization; and
6. Improving efficiency and reducing operational risk.

D&M SMS Gap Analysis and Implementation Plan Tool (GAIPT)

The primary function of the D&M SMS GAIPT was to assist the D&M organizations in aligning their current business and safety processes to the proposed SMS framework. This was intended to identify areas that do not coincide with the SMS framework, or "gaps."

Having gaps should not be viewed as negative, but as an opportunity to understand the differences between what the companies currently have in place and areas requiring further development to support SMS. The GAIPT is a tool that can be used for closing the recognized gaps and outlining a schedule with associated tasks for doing so.

Developmental Guidance for Design and Manufacturing (D&M) Safety Management System (SMS) Framework

This document contained the functional expectations of the MSMS pilot project. This document contains listed requisites identifying the FAA's representation of what should be included when developing an SMS.

The Design &Manufacturing (D&M) Safety Management System (SMS) Developmental Guidance

The Design &Manufacturing (D&M) Safety Management System (SMS) Developmental Guidance was referred to as "the DG." It assisted the D&M organizations in developing their SMS using the D&M SMS framework. This document presented each framework building block or standard (STND). Each STND is followed by a developmental guidance section labeled "DG" containing further explanation and, where appropriate, one or more examples.

The "DG" document replicates the structure of the D&M SMS framework's functional expectations using a hierarchical structure of components. The components are composed of elements and sub-elements. The D&M SMS framework structure employs the four basic components of a safety management system:

1. Safety Policy and Objectives
2. Safety Risk Management
3. Safety Assurance
4. Safety Promotion

The Integrated Pilot Project Plan (IP3)

The Integrated Pilot Project Plan (IP3) was developed for the FAA MSMS team's internal use. It defined the work required to implement and execute a series of pilot projects to introduce a SMS with pilot project participants. This document outlined the timelines, actions, and activities necessary to launch the D&M SMS pilot project.

This plan was a living document.

3-4 An Incremental Approach to SMS Implementation

As mentioned in the overview section, the MSMS pilot project was modeled after the AFS pilot project. The AFS organization had been working on SMS with their major carriers for approximately three years when the AIR MSMS team was created. Flight Standards had already established a working process for maturing a company in the development of a SMS. The MSMS team looked closely at the AFS processes and numerous briefings were received on how and why the processes were developed.

The MSMS team decided to use AFS's processes to the greatest extent possible. The two main reasons for this decision were:

- To align with proposed part 5 SMS requirements affecting air carriers and create a common approach across AVS regarding SMS rulemaking for organizations that the FAA oversees; and

- To avoid conflicting requirements and processes for the D&M organizations that also hold an FAA repair station certificate, assuming future rulemaking will affect repair stations.

However, it was necessary to make some changes from the AFS program to tailor it to the needs of the D&M organizations. Some additional sub-elements were necessary to implement an SMS in D&M organizations. The other significant change was encouraging the organizations to define the scope (e.g., whether to implement SMS in one program or companywide, and in which functional areas) for the pilot project.

The following is a brief description of the four levels of SMS maturity used in these pilot projects, which are commonly recognized in international efforts. Appendix B contains a link to the *Design and Manufacturing (D&M) Safety Management System (SMS) Pilot Project Guide.* The guide contains a detailed description of each level's objectives, activities, inputs, outputs, and output documents.

Level One – Planning and Organization

The objectives for the D&M organizations in this level were to complete their PGAs and DGAs to identify gaps and to complete a comprehensive implementation plan that to close those gaps. In addition, a training plan should be created and top management should endorse the established safety policy.

Level Two – Reactive Process, Basic Risk Management

The primary objective in level two was to strengthen existing processes related to identifying potential hazards. These conditions may be identified through a variety of sources including past inspection and audit reports, accident and incident investigations, and employee reports.

In this level, the organization develops and implements basic safety risk management and safety assurance processes. Information acquisition, processing, and analysis functions are implemented and a tracking system for risk control and corrective actions is developed. This allows the organization to systematically address known problems and react to newly identified problems as they occur and to develop appropriate remedial action.

At the end of this level, most of the essential SMS structure and basic identification, analysis, and assessment functions will be in place. However because the forward-looking systems and task analyses have not yet been conducted, the system still functions at a reactive level. For this reason, this level is termed "reactive." While this is not the final objective of an SMS, it is an important step in the evolution of safety management capabilities.

In this level the PMTs begin assessing processes and procedures provided by the participant against the framework expectations.

Level Three - Proactive Processes, Looking Ahead

The specific objective of stage three is to develop processes to understand the critical characteristics of its systems and operational environment and apply this knowledge to the identification of future hazards, decision-making considerations, and the design of controls to mitigate risks.

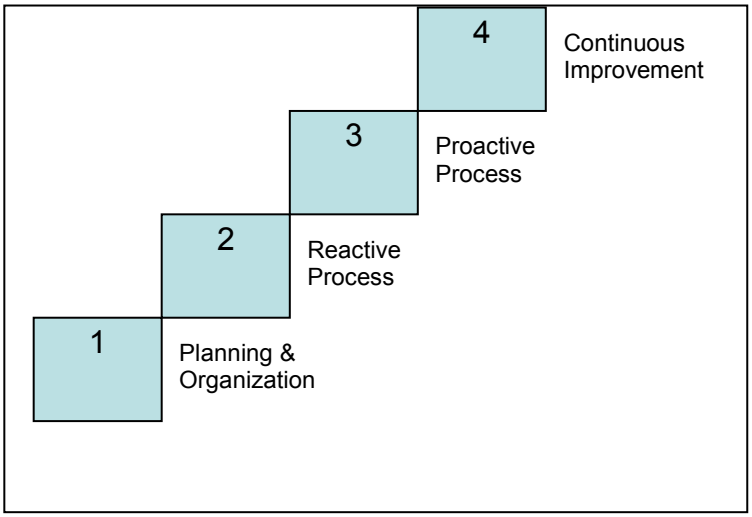
At the end of this level, the company has a fully functioning SMS.

Level Four – Continuous Improvement

The final level is the continuous improvement level. At this level, mature processes are in place and their performance and effectiveness have been verified. The complete safety assurance process, including continuous monitoring and the remaining features of the other SRM and SA processes are functioning. A major objective of a successful SMS is to attain and maintain this continuous improvement status for the life of the organization. The specific objective is for the organization to verify the performance and effectiveness of their SMS management practices and operational processes.

Figure 3-1 illustrates the four levels of SMS.

Figure 3-1: Levels of Implementing SMS



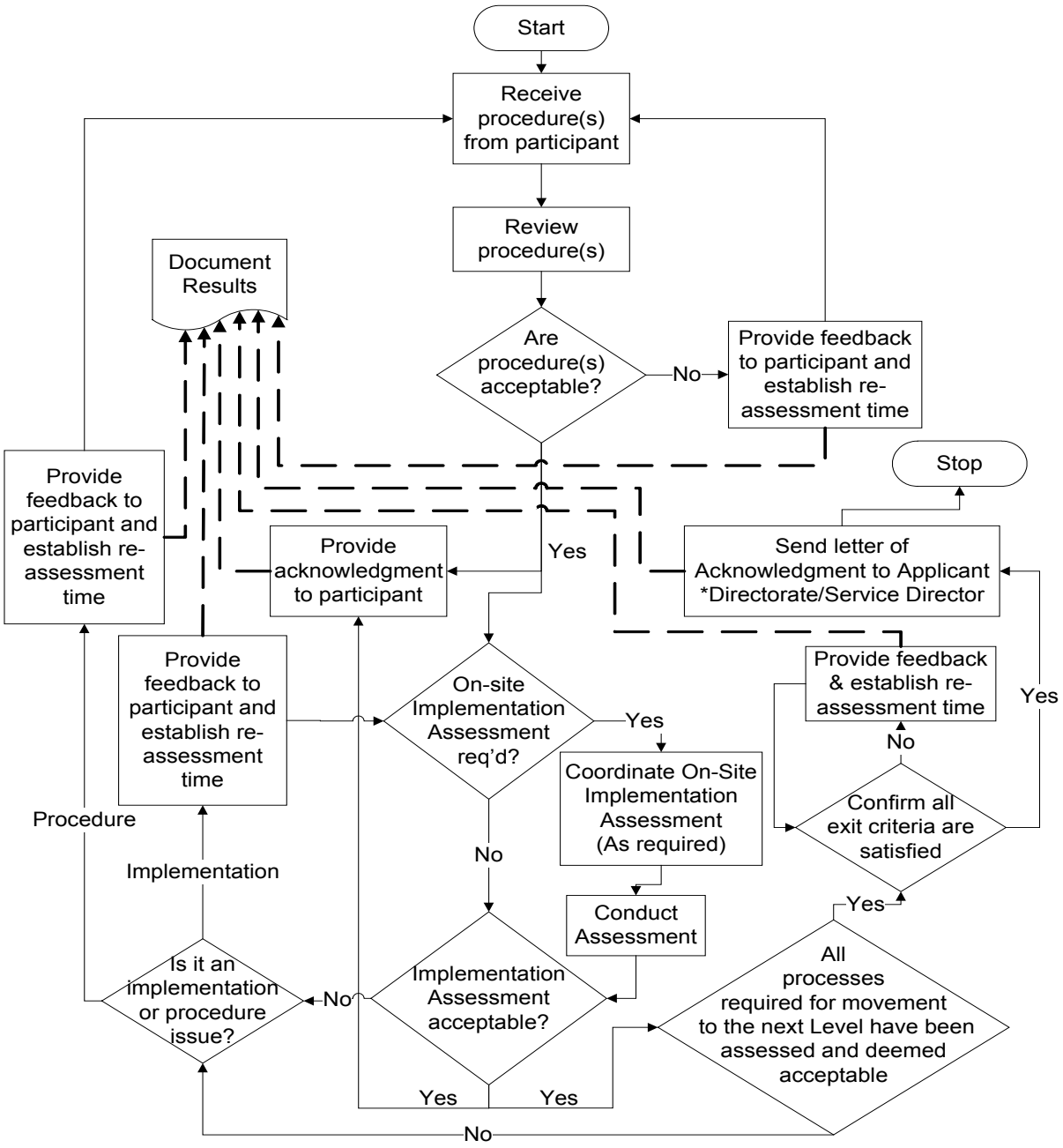
3-5 Pilot Project Assessment and Oversight

The MSMS team established a process for performing initial and incremental assessments of the organizations' development of their SMS procedures and processes. The assessments involved reviewing the required deliverables when they completed each level. The MSMS team reviewed the deliverables and assessments with the organizations and made suggestions based on their knowledge of SMS.

While performing these initial assessments, the MSMS team found that the specific stages in the recommended SMS framework did not always fit the needs of each participant. As a result, some D&M organizations created alternative stages that were more efficient. This point emphasizes the importance of working with each company and understanding that if the intent of SMS framework has been satisfied, the deliverable should be acceptable.

The assessment process in Figure 3-2 depicts how the MSMS team received SMS deliverables. It also illustrates how each company progresses to the next phase of the pilot project.

Figure 3-2: Assessment Process Overview



The FAA has not yet defined the details of how to oversee the D&M organizations' SMS, and this is a critical future task for AIR-150 and the Part 21/SMS Aviation Rulemaking Committee (ARC). However, the MSMS team recommends that defining oversight of an SMS should not contain specific or detailed instructions, but incorporated into the oversight of an organization as a whole. SMS is not intended to be a stand-alone process, but part of a company's everyday business process. Additionally, SMS is performance-based; therefore, it will take time for the SMS results to be realized. Establishing oversight of SMS includes auditing for compliance. However, this method will be phased out as the FAA moves toward performance-based oversight.

3-6 Three Options for FAA Rules and Actions with Varying Levels of SMS Scalability and Applicability

The MSMS team discussed the following options regarding applicability of a future SMS regulation to D&M organizations. The team also discussed the possibility of scaling certain aspects of SMS standards to accommodate the different sizes and complexities of D&M organizations.

Scalability must allow for small organizations to tailor their SMS procedures and processes to the complexity and criticality of their products. The FAA already has experience in approving production approval holder's quality systems that are scaled to the size and complexity of the company and criticality of their products.

The MSMS team recommends the first of the three following considerations as the most desired option for applicability. Our main objective is to align FAA actions with the ICAO standard.

MSMS Team's Recommendation and Consideration 1: Aligning with ICAO Requirements for aircraft manufacturers (TC and PC Holders) Only

Applicability of any future SMS rule involving D&M organizations would directly align with ICAO requirements. For example, the SMS rule would apply to aircraft manufacturers only as ICAO currently recommends. ICAO is currently discussing the possibility of expanding the applicability to include engines, and possibly propellers. If ICAO includes those two areas in an updated requirement, then the FAA should align with those requirements to minimize disparity in how the individual authorities oversee the implementation of SMS standards.

If the FAA decides to apply SMS only to aircraft (and possibly engines and propeller) manufacturers as currently proposed by ICAO, then all aspects of the proposed part 5 would be applicable, with the exception of any requirement(s) specifically addressing part 121 operations. These could be listed as exclusions in part 21 requirements.

If the cost benefit analysis does not support a rule for all applicants, holders of design and production certificates, and approvals for those that fall within the hazard definition, then the FAA should only apply an SMS rule to those types of companies identified by ICAO. Limiting

the applicability of SMS per ICAO standards would help maintain a level playing field for U.S. organizations.

Consideration 2: Scaling SMS Rules to Critical Products

An SMS rule would be scaled to those certificate and approval holders that design and/or produce critical products that meet the definition of a hazard, as currently defined in proposed part 5. This consideration includes scaling the SMS rule to the product.

The requirements of the proposed part 5 are scalable. The complexity of SMS is determined by the implementing organization. This may be determined by criteria such as the size of the organization, location(s) where the work is being performed, complexity and criticality of the design or production processes, etc. While this approach has flexibility, in that the applicability is not defined by the type of approval held, this approach could be very cumbersome as it depends on a definition of hazard that could conceivably go to a part level and require extensive coordination between multiple organizations (certificate/approval holder, suppliers, etc.) to fully implement.

So when discussing scalability, can certain aspects of the proposed part 5 rule be considered not applicable based on the size of the organization and/or the criticality of the product or article being designed and produced? Elements in the proposed part 5 rule can be seen as not applicable to certain D&M organizations such as emergency response. When discussing the applicability of SMS, if the FAA decides to apply SMS to some, but not all, TC, STC, PC, PMA, and TSOA holders, then there may be graduated requirements.

An implementation process could be based on an FAA determination of need. For example, if an article installed on an aircraft becomes critical based on hazards to that aircraft, then the FAA may require the organization to implement a partial or entire SMS. It will take additional study and research to determine which proposed part 5 requirements can be relieved and at what point.

However, if the FAA decides to apply SMS to certificate and approval holders that create critical parts or articles failure (meaning that if these parts or articles fail, it could foreseeably cause or contribute to an aircraft accident, therefore meeting the definition of a hazard), the MSMS team believes that all aspects of a proposed part 5 are applicable. However, this scope excludes any requirement(s) specifically addressing 121 operations, which would be listed as exclusions in part 21.

Consideration 3: Applying Rules to All Certificate Holders and Applicants

An SMS rule could apply to all certificate and approval holders and applicants. This consideration includes scaling the SMS to the size, complexity, and criticality of the company. (See Figure 3-4.)

If the FAA decides to apply the SMS rule to all TC, STC, PC, PMA, and TSOA holders, then some aspects of proposed part 5 may not be applicable. This will need to be explored in greater detail to identify which proposed part 5 requirements can be relieved. While this approach is all-

inclusive, the FAA will need to examine whether the benefits associated with this very broad approach would exceed the costs. Further research would be necessary to explore how FAA might increase broad support for implementing SMS outside of an overarching requirement realizing SMS is intended to more effectively fulfill our safety responsibilities versus fix an industry-wide problem.

Figure 3-3 shows how an SMS rule can be scaled to organizations based on product hazards and safety impact. Organizations at the bottom of the pyramid with no hazard and safety impact with their product would need no SMS. However organizations near the middle of the pyramid with increasing safety impact with their product would need to meet some of the SMS elements. And any organization at the top would need to meet the entire SMS requirement.

Figure 3-3: Applicability of SMS Requirements

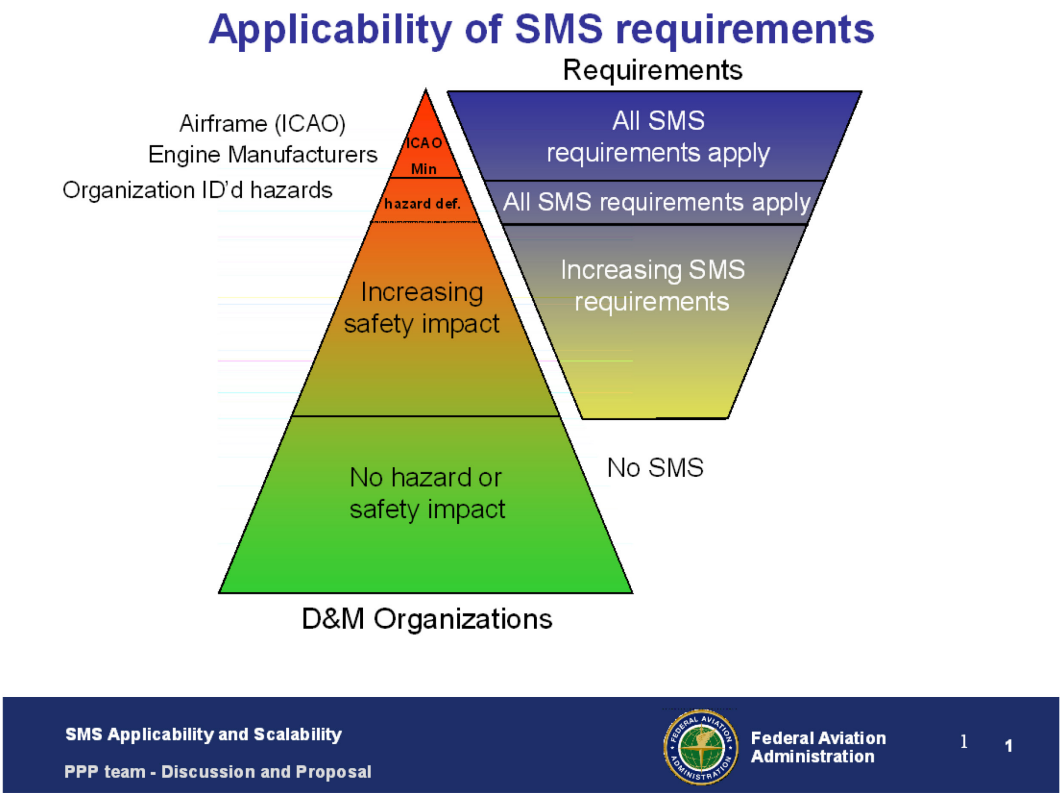


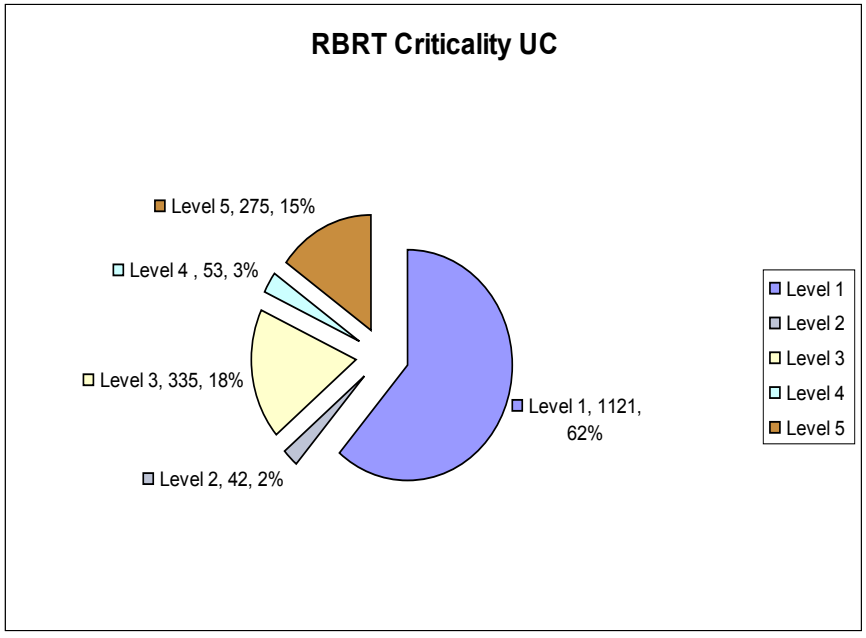
Figure 3-4 shows the levels of the criticality of products produced by PAHs and their effects on safety. If the FAA proceeds in a direction where scaling is necessary, these categories could be considered when deciding how to allocate resources.

Figure 3-4: Criticality of Products Produced by Production Approval Holders

Level 1	Level 2	Level 3	Level 4	Level 5
A product or part(s) thereof whose failure would have LITTLE TO NO effect on continued safe flight and landing of the aircraft.	A product or part(s) thereof whose failure would not prevent continued safe flight and landing; resulting consequences COULD reduce the capability of the aircraft or the ability of the crew to cope with adverse operating conditions or subsequent failures.	A product or part(s) thereof whose failure would not prevent continued safe flight and landing; resulting consequences WOULD reduce the capability of the aircraft or the ability of the crew to cope with adverse operating conditions or subsequent failures.	A product or part(s) thereof, whose failure COULD, IF OTHER CONDITIONS EXISTED, prevent continued safe flight and landing; resulting consequences could reduce safety margins, degrade performance, or cause loss of capability to conduct certain flight operations.	A product or part(s) thereof whose failure COULD DIRECTLY prevent continued safe flight and landing; resulting consequences could reduce safety margins, degrade performance, or cause loss of capability to conduct certain flight operations.
CPL CAT III		CPL CAT II		CPL CAT I

Figure 3-5 shows the number and percentage of PAHs in 2011 that were producing the various levels of products depicted in Figure 3-5. Only 15% of PAHs produce critical (level 5) products versus 62% producing non-critical (level 1) products. This data provides a quantitative perspective that needs to be further examined regarding the potential safety benefits should the FAA proceed with rulemaking using a very broad approach (consideration 3).

Figure 3-5: Number of PAHs by Production Approval Type 2011



3-7 MSMS Pilot Project Communication

During the pilot project, a strategic and layered communications effort was applied to engage the PMT members and the D&M organizations. Information flowed primarily from the MSMS team to the PMTs, and then to the members of their participating D&M organizations. Throughout each step in the communications path, two-way dialogue was encouraged. While the MSMS team often conveyed guidance to the PMTs (and onward to their participants), the MSMS team gained valuable insight from the data the PMTs provided.

Communication was maintained via regularly scheduled telecons between the PMTs and the team leads from the MSMS team. Webinars were held for all PMT personnel with representatives of the MSMS team.

The MSMS team directly engaged with participants on numerous occasions. Interaction included company-specific meetings and group meetings involving multiple pilot project companies and other companies interested in SMS development activities. Representatives of the MSMS team also interacted face-to-face during pilot project launches with each of the participants, as well as during progress and exit-level meetings.

It is difficult to say which communication method was most effective, because each provided a different insight and perspective. The regularly scheduled telecons allowed the entire team to interact, engage, and learn. However, in the broader industry meetings, the pilot project participants appeared to be more comfortable surrounded by their industry peers. This report captures lessons learned and best practices that are a direct product of communication with the internal MSMS team and the pilot project participants.

Moving forward, the MSMS team envisions that they will maintain SMS-focused communication with the organizations that are continuing to participate in the pilot project. The team plans to continue SMS outreach with the rest of the D&M organizations during industry group meetings and similar venues. In addition, the MSMS team will continue to encourage SMS discussions in their local offices and provide insight into the lessons learned from the pilot project.

4-0 Summary of Progress of D&M Organizations

In April 2010, FAA management approved the selection of twelve D&M organizations for the MSMS pilot project. As time progressed, one of the selected organizations decided to rescind participation due to other company priorities. This event occurred before the company was launched into the pilot.

Each of the eleven participating D&M organizations varied in its scope of implementing an SMS and varied in its progress of implementing it. In summary, at the end of the pilot project, the organizations had achieved the following milestones:

- Eleven have received at least one MSMS team visit from their respective PMT.

- Ten have completed the PGA tool and one did a PGA to the ICAO Annex 6 framework.
- Eight have completed a DGA and one completed the DGA in a modified manner.
- Nine have completed an SMS Implementation Plan and a Level One Exit Assessment.
- None have completed a Stage Two Exit Assessment as of December 2012.
- Three of the pilot project participants are in stage one of SMS implementation, while eight pilot project participants have achieved stage two.
- Eight entered level two by September 2012. Two organizations anticipate entering level three by the first quarter of 2013.
- The average time to complete level 1 was nine months.

All of the D&M organizations had significant difficulties with **Establishing the organizations' safety objectives per the SMS framework element 1.1(2)(e).** This added to the increased delay in progress by the companies. . Some participants commented that safety objectives need to be achievable and maintainable. Suggestions for safety objectives were quality, responsiveness to continued operational safety issues, customer satisfaction, schedule, compliance. Some felt they couldn't establish safety objectives until they had more SMS experience under their belts; some felt learning from implementing safety assurance and safety risk management would help enlighten them as to what they needed.

Measuring the safety objectives were also a concern when pilot project participants were deciding on them because of the various kinds of quantitative or qualitative measures. Several pilot project participants were concerned about putting safety objectives in their safety manual because they wanted to be able to easily modify them.

The MSMS team assured pilot project participants that it was not required to include their safety objectives in manuals. Companies can include their safety objectives in any media they choose. The MSMS team also explained that establishing safety objectives is a managed process that adapts to meet relevant and projected business objectives in the interest of safety. Changes or new safety objectives are introduced because specific processes are not under control and safety performance levels are not being met.

Also, some D&M organizations were concerned that vague safety objectives would be criticized.

General safety objectives identified during the pilot project included:

- Ensuring all appropriate personnel are trained for SMS,
- Timely reporting and resolution of safety issues,
- Identifying emerging safety related issues that affect the product,
- Ensuring first-time compliance with regulatory requirements, and
- Promoting safety reporting throughout the organization and our suppliers.

4-1 Summary of PMTs' Progress and Involvement in Implementing SMS in the D&M Organizations

The PMT members were selected by their management based on their experience and involvement with the D&M organizations participating in the pilot project. PMT members supported the D&M organizations as they developed and progressed through the levels of the SMS. The PMTs were responsible for participating in the orientation and assessment meetings as well as reviewing the participant's gap analysis, implementation plan, SMS procedures and processes, and assessing the participant's accomplishment at each level of the SMS implementation.

During the pilot project, the MSMS team had difficulties in keeping the PMTs engaged during level one. The MSMS team anticipated that the workload on the PMTs would increase significantly once the company reached level two. However, due to schedule delays and slower than expected starts, the PMT members did not have much participation in reviewing company procedures, policies, etc. Aside from attending meetings and telecons, the PMTs had few tasks.

As of June 2013, two of the pilot project participants have submitted procedures or processes to the PMTs for assessment and comments. One of the D&M organizations are in a mature stage of level 2 in the pilot project.

Overall the PMTs still need to learn how to effectively review and assess the companies' processes and procedures. It is unfortunate that this type of experience was unattainable during the official pilot project; however, as the companies progress, the PMTs and the D&M industry will continue to learn together.

5-0 Research Conducted During the SMS Pilot Program

At several points during the project, D&M organizations raised questions and concerns that required research to understand the potential impact of a SMS rule. The MSMS team employed universities and consulting companies to assist in research and analysis. The researchers were from Booz Allen Hamilton, Embry-Riddle Aeronautical University, IBM, St. Louis University, MITRE, and Volpe Center. The universities and consulting firms were chosen based on their level of expertise in aviation, business, research, analysis, training, and experience. Each university and company provided subject matter experts to assist the MSMS team in facilitating meetings, discussions, and training.

Seven main areas of research were conducted on the following subjects:

1. Comparison of SMS and AS9100 requirements
2. The process of defining a system description
3. The identification of sub-tier hazards within a company
4. SMS gap analysis of Reduced Vertical Separation Minima (RVSM) and Extended Operations (ETOPS)
5. How the Rotor Integrity Sub Committee (RISC)/Rotor Manufacturing Sub Committee (ROMAN) activity relates to SMS

6. SMS Airworthiness Directives study
7. Comparison of the proposed part 5 and MSMS framework

All seven of the studies provided guidance and additional information to the D&M organizations. They helped justify the reasons for implementing SMS into their business processes. A brief description of each of the seven studies is provided in the following sections.

5-1 Comparison of SMS and AS9100 C requirements

After multiple D&M organizations asked about the differences between SMS and AS9100 C requirements, the MSMS team tasked Embry-Riddle Aeronautical University's Center for General Aviation Research to contrast them.

The comparison used the *SMS FRAMEWORK: D&M Safety Management System (SMS) Pilot Project Participants and Voluntary Implementation of SMS Programs,* dated December 21, 2010, for the SMS standard. The AS9100C source was from the SAE Aerospace Standard AS9100, Revision C.

Alan J. Stolzer, Ph.D., analyzed the requirements and concluded that many of the SMS requirements can be found within the FAA/AS9100 approved systems; however, they are different in both their scope and in the ways they are applied.

Alan J. Stolzer, Ph.D. concluded, "AS9100C does not overtly manage safety; rather it manages quality. This is more than a semantical difference, and it is important that organizations adopting an SMS recognize that difference."

For more information, Appendix B contains a link to the study.

5-2 Process of Defining a System Description

The participating D&M organizations questioned how deep a company needs to go to define their system for SMS and asked whether there is a process for developing a system description. Alan J. Stolzer, Ph.D., at Embry-Riddle Aeronautical University supported this effort and wrote "System Description and Hazard Identification: A Process for Design and Manufacturing Organizations."

This document outlines a process for D&M organizations to create a system description for their specific type of organization. The document devised two examples of how the process could be applied: 1) to a small company that produces a critical part, and 2) to a large company that manufactures a complex airplane.

This document shows how the system description plays a key part in a company's SMS and supports other efforts such as safety policy, risk management, safety assurance, and safety promotion. It explains that while an organization may employ existing management systems

and/or other hazard and risk tools[2] the intent of a system description is, in part, to identify the existence and placement of these analysis methods within the organization or the absence thereof.

This research helped the D&M organizations by providing an example of how the system description could be defined.

For more information, Appendix B contains a link to the study.

5-3 Gap Analyses of RVSM and ETOPS

AIR tasked the Center for General Aviation Research to contrast the content of certain Reduced Vertical Separation Minima (RVSM) and Extended Operations (ETOPS) documents with the D&M SMS framework, Revision C. The purpose of conducting these two gap analyses was to identify the differences and similarities between the safety attributes of RVSM and ETOPS with the proposed SMS framework.

The study concluded that commonalities were more prevalent in the areas of safety assurance and some in safety risk management. The data showed that there were many differences; however, SMS principles are evident in RVSM and ETOPS.

For more information, Appendix B contains a link to the RVSM and ETOPS gap analyses.

5-4 SMS Airworthiness Directives (ADs) Study

The FAA and the Center for Aviation Safety Research at Saint Louis University conducted an analysis of FAA Airworthiness Directives (AD). This study looked at the overall scope and nature of safety controls implemented through ADs. This study was initiated to better understand how implementation and maturation of Safety Management Systems (SMS) at, design and manufacturing (D&M) organizations might change the scope and nature of future AD corrective actions.

The study examined trends and changes in ADs, researching whether they were implementing revisions to existing risk controls or implementing new risk controls. These two categories were important in evaluating the effectiveness of current industry practices/standards for safety management, and identifying opportunities for improvement with further development and maturation of SMS in D&M organizations. ADs targeting existing risk controls may indicate that hazard identification was sufficient but other aspects of SRM or SA were lacking. ADs implementing new risk controls may indicate opportunities for improving the effectiveness of hazard identification and developing appropriate mitigating actions.

Recommendations from the study includes considering how the FAA and industry can gain further insight into improving system safety through review of AD data. It may be appropriate to outline a pilot activity that could be conducted to see how *FAA and industry* could support, and

benefit from, regular review of these data at a system level. Consideration should be given to looking at AD follow-up actions to ensure that appropriate updates are made to various controls (processes, practices, standards) to capture system-level learning that could preclude future events.

5-5 Comparison of the Proposed Part 5 and SMS Framework

MITRE analyzed the differences and similarities between the proposed part 5, for part 121 certificate holders, and the proposed SMS framework. The MSMS team wanted to identify how closely aligned the proposed SMS framework was to the part 5 NPRM that was specifically written for part 121 certificate holders.

MITRE and the MSMS team concluded that although proposed part 5 is written for part 121 certificate holders, the two guidelines covered very comparable areas of proposed implementation.

For more information, Appendix B contains a link to the study.

6-0 Collection and Analysis of Data Gathered From D&M Organizations During the Pilot Project

The MSMS team collected specific non-proprietary data to meet the objectives of the MSMS pilot project. A database was created to input and organize data received during the pilot project. The data and analysis in this report were compiled from January 2011 until December 2012. Data collected after December 2012 will be collected by AIR-150, the Safety Management Design and Analysis Branch.

The FAA and the pilot project participants used a number of data collection methods. These methods include conducting a PGA and DGA over the two-year period and gathering data from surveys, interviews, and company feedback. Additionally, a SharePoint site was used to share information between the participants and FAA PMTs. Some D&M organizations used their own internal company web sites to share information with the PMTs.

The team determined the type of data to collect during the MSMS pilot project. The data collection processes evolved as the pilot progressed. The qualitative and quantitative data in this report are non-proprietary.

6-1 Collection and Analysis Methods

The data was collected sporadically throughout the 24 months of the project. The activity and progress of the organizations in the pilot project varied throughout the study. This was due to a number of factors including other company priorities, SMS learning curve, and slower progress than anticipated. Delays were not due to any lack of commitment to aviation safety.

The collected performance metrics and supporting data were reviewed periodically (monthly) to ensure objectives were being achieved. For example, the team looked for progress in areas of

processes becoming more robust that reflect how tasks are being performed and enabling safety to be improved. Some members of the MSMS team analyzed the data to support the pilot project objectives.

6-2 SMS Gap Analysis, Implementation Plan Process and Objectives

Overview of the Gap Analysis Processes

Two gap analyses are performed during the pilot project, a Preliminary Gap Analysis (PGA) and a Detailed Gap Analysis (DGA). The purpose of the gap analyses is to supplement the development of a comprehensive implementation plan. The Gap Analysis Tool (GAT) is provided as a separate Microsoft Excel spreadsheet. A link to the GAT is in Appendix B.

Figure 6-1 provides a list of the gap analysis assessment levels and their associated definitions.

Figure 6-1: Gap Analysis Status Scale

Assessment Level	Assessment Level Status Description	Assessment Scale Value
Not Performed	No action has been taken on this expectation of the D&M SMS framework.	**NP**
Planned	A plan exists with resources and a schedule identified to meet this expectation of the D&M SMS framework.	**P**
Documented	The organization incorporates expectations of this element/sub-element into documents such as manuals, training material, and work instructions, etc.	**DOC**
Implemented	Identifiable actions satisfy this Expectation of the D&M SMS framework. The organization allocates resources to accomplish the objectives of the SMS expectations. These actions have been observed in documentation (i.e. achieved "DOC" rating via policies, procedures, etc.) organizational actions, and employee actions.	**I**
Demonstrated	Participants have subjected this element/sub-element of the organization's SMS to at least one round of assessment to demonstrate performance. There is evidence that the organization has met performance expectations and reason to believe that performance expectations will be sustained going forward.	**DEM**

The Gap Analysis and Implementation Planning Tool (GAIPT)

The tool is a Microsoft Excel spreadsheet with instructions on the first worksheet (i.e., a tab in the spreadsheet file). The GAIPT is comprised of four sections, each on its own worksheet:

- A Preliminary Gap Analysis (PGA)
- A Detailed Gap Analysis (DGA)
- Implementation plan

- Assessment section for FAA use

The MSMS team and the D&M organizations used the GAIPT in conducting the analyses and creating the plans, as described in the following sections. A link to the GAIPT is in Appendix B.

Preliminary Gap Analysis (PGA)

The MSMS team intended that the two-day meeting to complete the PGA would involve a discussion between the PMT and the Subject Matter Experts (SMEs) from various departments within the D&M organizations. The MSMS team asked each organization to have their departmental/organizational SMEs at the meeting. They also were asked to determine the scope of where they planed to apply SMS before the PGA.

The PGA is a high-level subjective analysis of where the organization stands with respect to the D&M SMS framework. SMEs were needed to discuss which of the organizaton's systems met the expectations of the SMS framework. In this initial step, the organization analyzes and assesses its existing programs, systems, processes, and activities with respect to the SMS functional expectations in the framework. Any place that does not meet expectations is defined as a gap.

Using the GAT, the PMT explained each of the components and elements in the framework. The PMT asked the SMEs what existing documented procedures and processes met the SMS framework. An assessment value in the gap tool was selected to facilitate the gap analysis and plans to implement an SMS.

The objectives of the PGA are to:

1. Ensure the organization and FAA have a common understanding of the gap analysis process
2. Help the organization describe itself using a set of SMS system segments.
3. Develop a common understanding of the D&M SMS framework expectations in the context of the organization and its operations.
4. Obtain an initial understanding of the organization's processes across departments and/or organizations to determine if they meet the D&M SMS framework expectations.

MSMS Team Analysis of PGA

The MSMS team believed that most, if not all, of the pilot project organizations would have good representation of departments (e.g., engineering, quality, manufacturing, product support, flight operations, and supplier management) at the meeting. However, not all organizations were represented during the first MSMS team's SMS orientation meeting. The MSMS team believed this would have made the preliminary gap discussions more productive. For the subsequent meetings, the MSMS team emphasized that senior executives should attend the PGA meetings with SMEs, because without this level of expertise, the PGA is difficult to complete.

At most preliminary gap meetings, manufacturing and quality departments were not appropriately represented. The SMEs were predominately from engineering. Eighty percent of the preliminary gap discussions were lead by engineering SMEs and 20% by the quality department SMEs. The MSMS team noted that in most meetings where one department (e.g., engineering, quality, or manufacturing) dominated the discussions or where other departments were not adequately represented, the gap analysis was slow and arduous.

Several participants struggled to assess their company's procedures and processes against the SMS framework. We believed this was due to one department not being familiar with the other departments' procedures and processes. Several of the SMS Points of Contact (POCs) who led the gap discussion lacked knowledge and experience with manufacturing, flight testing, and type certification processes. This lack of knowledge slowed the momentum of the discussions, particularly in areas that one would not normally expect from an aerospace company.

One POC was extremely knowledgeable in SMS principles and had years of practical experience that he shared during the meetings. This participant provided the FAA with the most practical knowledge of SMS applications.

Another POC had lesser familiarity with SMS principles. Three organizations had a person from their maintenance department with prior SMS experience that was gained in repair stations. The gap discussions flowed more smoothly when someone from the maintenance department participated.

Detailed Gap Analysis (DGA)

The second type of gap analysis, the DGA, is a more in-depth analysis. It is performed by the organization with assistance of the PMT. It comprehensively assesses each program, process, and control of the organization and compares them to the D&M SMS framework.

Depending upon the size and complexity of the organization, the DGA was expected to take four to six months to complete. However, all of the eleven D&M organizations took the full 6 months, and longer in some cases. The DGA is a continuous process and is continually updated as SMS implementation progresses. Both the PGA and DGA processes cover all operations and elements of the D&M SMS framework. Using the DGA, the organization selected the appropriate status for each SMS expectation based on how well their organization's processes and information meet the status requirements. For SMS expectations that are planned or exist in some form, the organization documented the source of their corresponding data, process, or procedure.

The objectives of the DGA are to:

1. Obtain a thorough understanding of the organization's processes and information across system segments to determine the extent to which they meet the D&M SMS framework expectations.
2. Determine which processes and information could benefit from improvement.

3. Determine which D&M SMS framework expectations indicate a need for new approaches, processes, and information.
4. Provide the basis for establishing an implementation plan to close the gaps.

MSMS Team Observations During the DGA

During the DGA, many participants struggled to fit the assessment scale to the maturity of their existing systems. Several participants found their procedures and processes fit in some areas of the scale, and other procedures and processes were in between on the assessment scale. In this case, they had to choose between the higher or lower scale values. Most participants chose the lower value to be more conservative and to prevent skewing the results.

Several pilot participants expanded the scope of their initial SMS system description to apply to more areas after they saw the benefits.

Some D&M organizations have existing and mature safety systems and processes that meet or exceed part 21 regulatory requirements, such as certification processes, QMS, internal audits, and COS programs. Many organizations have a lot of of the SMS procedures and processes in place but were missing only certain aspects of the SMS elements that were necessary to close the gap.

SMS Implementation Plan

Based on the results of the DGA process, an implementation plan is prepared to fill the gaps between the organizations' existing processes and what the D&M SMS framework requires. The SMS implementation plan is a realistic approach on how to implement an SMS to meet safety objectives. It describes in detail how and when the organization will achieve its corporate safety objectives and how it will meet any new or revised safety requirements, regulatory or otherwise.

As the organizations progress through each level (1 through 4), the top management must approve the implementation plan and allocate necessary staffing and resources. The implementation plan also describes who is responsible for tracking and validating the implementation of each new or revised procedure and/or process. The implementation plan focuses on the SMS within the scope of the participant's system description.

The GAT includes a worksheet (pre-populated with the gaps identified from the DGA) to help create the implementation plan. The implementation plan need not be complex or excessively detailed, but it should provide a basic roadmap to meet the overall objective stated in the SMS framework. The implementation plan should also span the entire SMS development process through all levels of maturity and should be updated as necessary (along with the DGA) as the projects progress. The organization's SMS planning group should meet regularly with top management to assess progress of the implementation plan and receive commensurate resources.

In addition to the implementation plan, the organization should develop a written narrative in the DGA to describe the details of the implementation plan. Examples of what could go into the narrative are:

- Responsible personnel for executing the SMS plan
- Procedures and processes that need to be created or revised
- Procedures for the company to determine if the procedures and/or processes meet the performance expectations and, if not, the necessary actions
- Allocation of necessary resources
- Expected completion date
- A brief description of the manuals and procedures affected

Some companies have created a high-level SMS manual that incorporates the general SMS requirements that affects each organization. In the SMS manual, they have a matrix or index pointing to the procedures or processes that support the SMS.

MSMS Team Observations on the Implementation Plans

The implementation plan worksheet in the GAIPT was intended to be a simple way for the D&M organizations to document their plans and track their progress against the framework. Some participants used it, and others created a separate plan altogether.

Figure 6-2 is a summaryof the results from eight of the participating D&M organizations. Eight organizations submitted completed DGAs. It compiles all of the participants' gap analysis results with a percentage of where each company felt they were in compliance to the SMS framework requirements. This chart only remains accurate until the pilot project organizations begin executing their implementation plan. Once the gaps begin to close, the percentages below will change.

Figure 6-2: Detailed Gap Analysis

Detailed Gap Analysis Results	NP	P	DOC	I	DEM
Component 1.0 Safety Policy and Objectives					
The organization developed and implements an integrated, comprehensive SMS for its entire organization and will incorporate a procedure to identify and maintain compliance with current safety-related legal and regulatory requirements. The safety policy is	62%	38%			
Element 1.1 Safety Policy					
Top management defines the organization's safety policy and convey its expectations and objectives to its employees	25%	50%	12%		12%
Element 1.2 Management Commitment and Safety Accountabilities					
Management defines, documents, and communicates the safety roles, responsibilities, and authorities throughout its organization.	25%	50%		12%	12%
Element 1.3 Designation and Responsibilities of Required Safety Management Personnel.					

Designation and responsibilities of required safety management personnel.	38%	50%		12%	
Element 1.4 Emergency Preparedness and Response					
The organization developed and implements procedures, as necessary,that it will follow in the event of an accident or incident.	12%	12%	25%	25%	25%
Element 1.5 SMS Document and Records					
The organization develops and maintains documentation that describes the organization's safety policy and SMS processes and procedures.	38%	50%		12%	

Figure 6-2: Detailed Gap Analysis (continued)

Detailed Gap Analysis Results	NP	P	DOC	I	DEM
Component 2.0 Safety Risk Management (SRM)					
The organization has developed processes to determine the critical characteristics of its systems and operational environment and apply this knowledge to identify hazards, analyze and assess risk and design risk controls.	62%	38%			
Element 2.1 Hazard identification and analysis					
The SRM process is applied to initial designs of systems, organizations, and/or products; and the operation and maintenance of these systems, organizations and/or products.	38%	50%			12%
Sub-Element 2.1.1 System description and analysis					
The organization analyzes its systems, operations, and operational environment to gain an understanding of critical design and production performance factors, processes, and activities to identify hazards.	25%	38%	12%	12%	12%
Sub-Element 2.1.2 Identify Hazards					
The organization identifies and documents the hazards in its operations that are likely to cause death, serious physical harm, or damage to equipment or property in sufficient detail to determine associated level of risk and risk acceptability. The organi	38%	50%			12%
Element 2.2 Risk Assessment and Control					
Overall Element Assessment	62%	38%			
Sub-Element 2.2.1 Analyze Safety Risk					
The organization will determine and analyze the severity and likelihood of potential consequences associated with identified hazards, and will identify contributing factors	50%	50%			
Sub-Element 2.2.2 Assess Safety Risk					
The organization assesses risk associated with each identified hazard and defines risk acceptance procedures and levels of management that can make safety risk acceptance decision.	25%	38%		12%	25%
Sub-Element 2.2.3 Control/Mitigate Safety Risk					
The organization designs and implements a safety risk control for each identified hazard for which there is an unacceptable risk, to reduce risk to acceptable levels.	38%	38%			25%

Figure 6-2: Detailed Gap Analysis (continued)

Detailed Gap Analysis Results	NP	P	DOC	I	DEM
Component 3.0 Safety Assurance					
The organization monitors, measures, and evaluates the performance of risk controls.	62%	38%			
Element 3.1 Safety performance monitoring and measurement					
The organization monitors systems and operations to identify new hazards	50%	38%			12%
Sub-Element 3.1.1 Continuous Monitoring					
The organization monitor data throughout the lifecycle, including those associated with components and services received from suppliers and contractors, to identify hazards, measure the effectiveness of safety risk controls, and assess system performance.	38%	25%			38%
Sub-Element 3.1.2 Internal Audit					
The organization will conduct internal audits of the SMS at planned intervals, to determine if the SMS conforms to the organization's processes and procedures.	38%	38%		12%	12%
Sub-Element 3.1.3 Internal Evaluation					
The organization will perform regularly scheduled internal evaluations of its systems and operations to determine the performance and effectiveness of risk controls.	38%	38%	12%		12%
Sub-Element 3.1.4 Investigation					
The organization has procedures to collect data to investigate instances of potential regulatory non-compliance and to identify potential new hazards or risk control failures.	12%	25%	12%	12%	38%
Sub-Element 3.1.5 Employee Reporting and Feedback System					
The organization actively uses an employee safety reporting and feedback system	38%	50%			12%
Sub-Element 3.1.6 Analysis of Data					
The organization analyzes the data acquired in Sub-Elements 3.1.1 through 3.1.5 to assess the performance and effectiveness of risk controls in the organization's systems and operations	38%	38%			25%
Sub-Element 3.1.7 System Assessment					
The organization will assess the safety performance and effectiveness of risk controls, conformance to SMS expectations as stated herein, and the objectives of the safety policy.	38%	50%		12%	
Sub-Element 3.1.8 Management Review					
As part of their commitment to continual improvement, top management will conduct annual reviews of the SMS, at a minimum. Management reviews will include assessing the performance and effectiveness of the organization's systems and operations and the new	50%	25%		25%	
Element 3.2 Management of Change					
The organization will identify and assess safety risk for changes arising within or external to the organization that may affect established systems or operations. These changes may be to existing system designs, new system designs, or new/modified operations	38%	25%	12%	12%	12%

Figure 6-2: Detailed Gap Analysis (continued)

Detailed Gap Analysis Results	NP	P	DOC	I	DEM
Component 4.0 Safety Promotion					
Top Management promotes the growth of a positive safety culture and communicates it throughout the organization.	38%	62%			
Element 4.1 Competencies and Training					
Overall Element Assessment	38%	50%	12%		
Sub-Element 4.1.1 Personnel Expectation (Competence)					
The organization documents SMS competency requirements for those positions identified in Elements 1.2(3) and 1.3 and ensure those requirements are met.	38%	38%		12%	
Sub-Element 4.1.2 Training					
The organization will develop and maintain a safety training program that ensures personnel are trained and competent to perform their role within the SMS. The organization will also regularly evaluate training necessary to meet competency requirements of	25%	50%	12%	12%	
Element 4.2 Communication and Awareness					
Top management will communicate the outputs of its SMS to its employees, and will provide the oversight authority access to SMS outputs in accordance with established agreements and disclosure programs.	25%	50%	12%		12%

Figure 6-3 shows the changes in the assessment values of SMS elements between the times the PGA and DGA were conducted. The data represents the number of elements and the direction they went for all eight participating organizations. SMEs noted they were not as familiar or knowledgeable with other departmental procedures and processes as they thought. This explains the number of changes in direction in the status. Most participants found the DGA process to be beneficial because it helped them to discover disconnects and overlaps among their departments. The DGA also helped the participants recognize areas where SMS principles were effectively in place and areas that needed improvement.

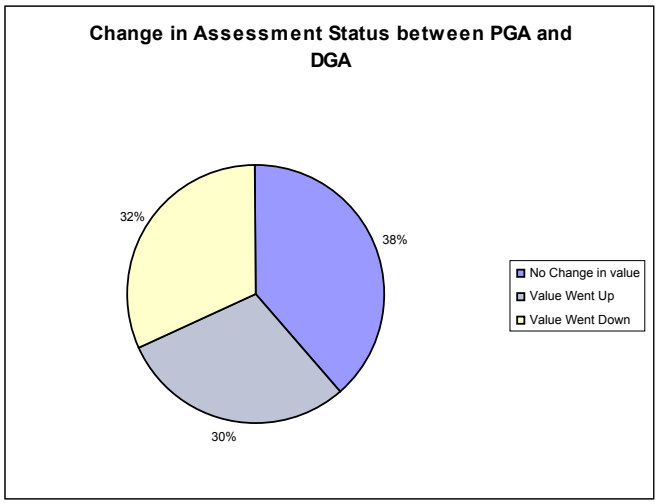
Figure 6-3: Aggregate Results From the Eight Participants' PGAs and DGAs

Preliminary to Detailed Analysis Changes	Same	Down	Up
Component 1.0 Safety Policy and Objectives			
	16 Elements	**14 Elements**	**18 Elements**
Component 2.0 Safety Risk Management (SRM)			
	30 Elements	**18 Elements**	**16 Elements**
Component 3.0 Safety Assurance			
	35 Elements	**25 Elements**	**24 Elements**
Component 4.0 Safety Promotion			
	19 Elements	**13 Elements**	**8 Elements**

Percentages of Change in the Assessment Status Between the Times When the PGAs and the DGAs Were Conducted

38% of the assessment scale values in the PGAs did not change after the DGAs.
30% of the assessment scale values in the PGAs went up one or more levels after the DGAs.
32% of the assessment scale values in the PGAs went down one or more levels after the DGAs.

Figure 6-4: Change in Assessment Status Between PGA and DGA



6-3 Pilot Project Data & Information

Based on the experiences of ten actively participating D&M organizations, the average time to complete level one was nine months. Three companies did not complete a DGA as of the date of this report. However, two pilot project participants intend to complete their DGA after December 2012.

Eleven D&M organizations started the pilot project. One D&M organization withdrew from the project and decided to develop its SMS on its own. Of the remaining ten pilot project participants, eight entered level two by September 2012. Two organizations anticipate entering level three by the first quarter of 2013.

Percentage of Procedures and/or Processes Fulfilling SMS Framework Elements

Results of eight DGAs show 21% of all of the eight organizations' procedures and or processes were rated as Documented (DOC), Implemented (I), or Demonstrated (DEM) to fulfill the SMS framework elements. 79% of the same eight organizations' procedures and/or processes were rated as Not Performed (NP) or Planned (P) to fulfill the SMS framework elements. Refer to Figure 6-5: DGA Percentages of Processes and Procedures below.

MSMS Team's Analysis of How the Organizations Fulfilled SMS Framework Elements

Completing the DGA required the organizations to fully assesses all parts of the SMS framework and compare them to their existing procedures and processes. When completing the DGA, most participants took a conservative approach. When they found that they were in between SMS levels, they marked a lower assessment value.

The MSMS team took the approach that if participants rated themselves as DOC or higher in level one, the MSMS team judged them to meet the framework item and moved them into level two. At level two, the participants and the MSMS team performed a deeper assessment of the SMS. At level three, the participants demonstrated the performance of the SMS. Any discrepancies would be identified and corrected in each level. The MSMS team believed that every organization's SMS would improve as everyone learned more about SMS.

Because the SMS pilot project was voluntary, it is important to note that if an SMS framework element is not met, this is not a deficiency in a company's existing system. Most of the time where gaps existed, the organization needed to make only minor modifications to the existing procedures and/or processes. Also, in many cases, it was only necessary for organizations to apply the SMS terminology to align the procedures and or processes with the intent of the framework.

In many cases, organizations had gaps that resulted from not implementing existing procedures or processes systematically across the organization. For example, in the area of SRM, organizations generally have mature processes for identifying product hazards, but not organizational hazards.

In most cases, selecting an assessment value during the PGA was purely a best guess. However, the value itself was not regarded as the most important aspect of the PGA because its intent was to open a dialogue among the PMTs and SMEs about how to interpretate the SMS framework.

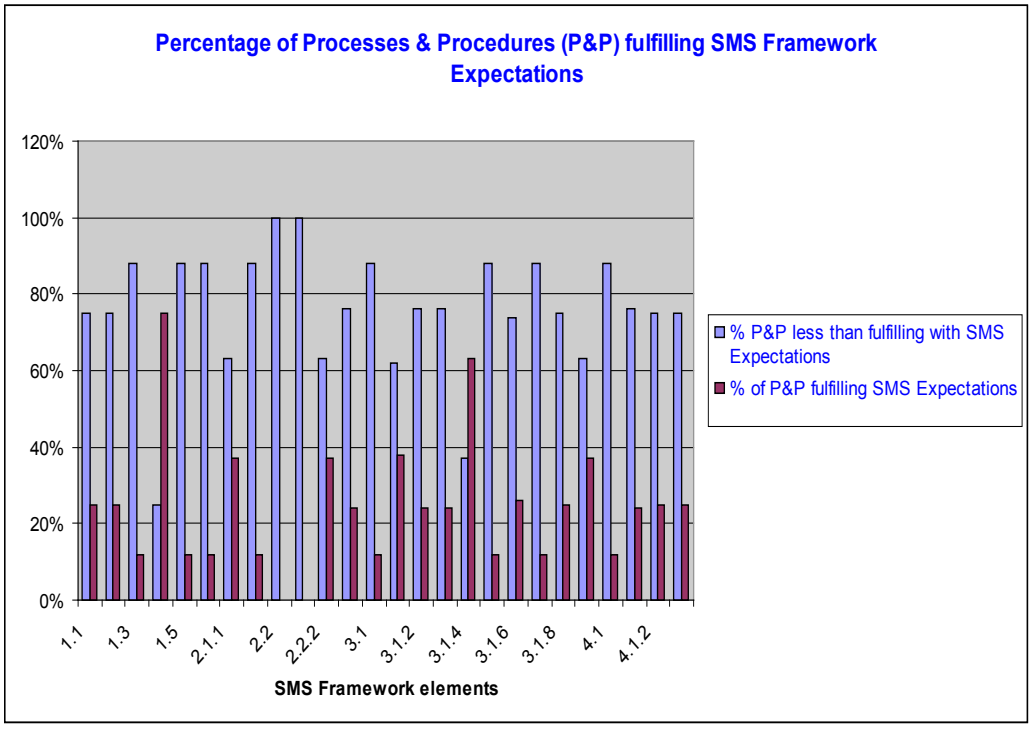
The DGA process was designed to resolve any misunderstandings or misinterpretations about the preliminary gap analysis. Furthermore, at the preliminary meeting, most of the SMEs were not adequately prepared to discuss the SMS framework because most of it was new to most of the SMEs. However, a few SMEs had knowledge and limited experience with the proposed part 5 NPRM and ICAO SMS requirements.

While Figure 6-5 shows plenty of gaps identified from the 8 organizations that completed the DGA, the efforts needed to close many of them are relatively minor. For example, element 1.0 of the SMS framework, establishing a safety policy, is something that the organizations already have. However, the participants conservatively assigned an assessment value of Not Performed (NP) or Planned (P) because the safety policy did not include certain SMS framework terminology. Some participants were not clear on how to establish safety objectives. Many deferred this action until they could learn more about what kind of tangible objectives they should establish.

However, some existing gaps are not as easy to close. The DGAs showed some areas where the efforts to close the gaps were sizeable (e.g., emergency response planning).

As the organizations' SMS continue to progress, the results are likely to change.

Figure 6-5: DGA Percentages of Processes and Procedures Fulfilling SMS Framework Expectations



6-4 Certification Outliers

The MSMS team conducted research on unique certification projects and circumstances called "certification outliers" that should be considered in future SMS rule and policy decisions. These outliers are not well-known to the general D&M industry and knowledge is limited to certain FAA field offices.

- Orphan Type Certificates (TC) and Supplemental Type Certificates (STC) - TC and STC where the legal person or company can no longer be found or ceased to exist.
- TC/STC holder has surrendered the TC/STC to the FAA.
- TC/ STC held by a company or person that is still a business but they no longer design and produce aviation products.
- TC/STC held by bank, or other non-aerospace business entity.
- TC/STC license agreements to foreign entities that are responsible to maintain the design.
- Restricted Category TC/STC that is for only one aircraft.
- Older non-complex TC aircraft where the design data (drawings/specifications) no longer exists.
- One only STC for one aircraft.

7-0 Lessons Learned

7-1 Sources of Lessons Learned

One of the goals of the MSMS team was to get feedback and document lessons learned during the pilot project. Feedback came from various methods throughout the pilot project. Feedback came from facilitated discussions after orientation meetings, calibration meetings, focus group meetings, questionnaires, emails and telecons.

7-2 Key Lessons and Best Practices

Key Lessons

The MSMS team did not receive as much "hard data" as originally expected, however, the team did receive enough information to compile key lessons as well as suggested best practices for the

MSMS team to promote for future projects and for the D&M industry to consider. As the pilot project progressed and more companies got involved in SMS development and implementation the MSMS team began to learn what worked best and what did not work as well. Key lessons learned identified in the pilot project include the following:

- Schedules and data expectations were more opptimistic than anticipated, therfore, data received was less than expected. This was primarily due to adjusting the MSMS team and pilot project participants to learning about SMS and how the system should be developed.

- In addition to the orientation sessions led by the FAA, it was very beneficial for the FAA team members and the D&M industry to take SMS training. This provided a foundation of knowledge that enabled all parties involved to be on a level playing field when discussing concepts of SMS.

- After providing the SMS framework to the pilot project participants the MSMS team received many comments that resulted in a shorter and more streamlined version of the framework. The framework went from 143 to 49 elements. This collaboration of resources by the FAA and the pilot project participants proved to be positive and valuable when developing cohesive documents.

- The MSMS team learned that maintaining a core group of presenters was the best option when presenting the pilot project. The presenters learned from previous sessions and maintained a consistent message.
- The pilot project orientations were three days long and included many presentations. The team found that providing frequently used definitions or terms saved the attendee's time and reduced confusion.

- Due to lack of FAA and company personnel unavailability the MSMS team was unable to launch each company into the pilot as quickly as originally intended. FAA management made the decision to launch a company every two or three months. The delayed launches resulted in less data received and did not allow the companies time to progress to the optimum level of maturity before the end of 24 month pilot project. Additionally scheduling a meeting was a difficult task because everyone had conflicting priorities and schedules.

Best practices

Based on information received during the pilot project the MSMS team has identified some best practices for future projects as well as for companies interested in engaging in SMS. Best practices have been summarized as either internal to the "FAA" or external to the "Industry":

FAA Best Practices

- Use of Sharepoint for data sharing and internal collaboration with the FAA Participant Management Team (PMT) and with the pilot project participants

- Developing and maintaining the Pilot Project Tracking Matrix

- Developing, maintaining, and using the Gap Analysis and Implementation Plan tools

- Use of outside consultants; e.g., IBM, Booz Allen Hamilton, MITRE, Volpe Center, Embry-Riddle Aeronautical University, and St. Louis University

- Cross-utilization of resources across the service and geographical locations

Industry Best Practices

- Using Transport Airplane Risk Assessment Methodology handbook (TARAM) as a reference for Safety Risk Management. It outlines a process for calculating risk associated with continued operational safety (COS) issues in the transport-airplane fleet. It explains how to use such risk-analysis calculations when making determinations of unsafe conditions, as well as selecting and implementing corrective actions.

- Utilizing Small Airplane Risk Analysis handbook (SARA). The handbook process provides Aviation Safety Engineers (ASEs) with guidance for estimating the risk associated with airworthiness concerns. SARA also provides guidance on how ASEs can use estimated risk as a consideration in making unsafe condition determinations and in evaluating corrective actions.

- Rotor Manufacturing Project Report (RoMan) DOT/FAA/AR-06/3. This report provides guidelines useful to ensure the manufacturing process minimizes the likelihood of manufacturing induced anomalies reaching service usage.
- When delivering SMS briefing/training materials and discussing the DGA internally, it was better to group employees by experience level and not by discipline. The less-experienced personnel were less likely to ask questions or speak out about potential hazards.

- Reducing the complexity of the SMS processes makes it more accommodating for companies with multiple business units and multiple locations.

- Having a senior executive oversee the implementation of the SMS ensures that the implementation process should not go through significant changes later due to management concerns.

8-0 Key Take-Aways from Pilot Project

8-1 Managing Change

- **Spirit vs letter of the law** - Industry is concerned that the FAA will not follow the spirit of an SMS rule but will execute the letter of the rule once an SMS rule is implemented. The MSMS team agrees that this has been an issue with other rule changes and the FAA should embrace a robust method to implement and manage changes in the future.

- Industry is also concerned about the unintended consequences where the local FAA offices do not move toward any newly envisioned oversight model.

8-2 SMS Progression

- **Safety Assurance process** – Voluntary safety reporting programs are a vital element of an SMS. However, obtaining safety information from repair stations is difficult and is a major concern of the pilot project participants. Most companies do not have any leverage (other than warranty return program) to entice repair stations to report field service data such as failures, malfunctions and defects. Their ability to proactively or predicatively address new or potential risks and hazards from aging fielded product is nearly impossible without new reporting rule(s) which means important data is lost.

- **Organizational hazard concept** – Identification of hazards associated with organizational factors, including human performance within an organization was a paradigm shift. Many pilot project participants had difficulty understanding that certain organizational decisions could impact the safety of a product. They also had a tendency to focus on product issues only and consideration of organizational factors that affect the product was not easy for them to embrace. Understanding that SMS could affect the whole organization was a cultural change that some participants pick up on more quickly than others. The MSMS team's research on hazards helped facilitate discussions about organizational, process and product hazards and we also displayed on the wall during the PGA meetings examples of organization, process and product hazards.

8-3 Project Management

- **Collaboration** - MSMS team collaborated with the D&M industry by considering their feedback, resulting in a more streamlined and useable SMS framework. The change to the framework was not only beneficial, but it also showed the D&M industry that the MSMS team was willing to work together and gained more of their trust. In addition to changes to the SMS framework the MSMS team also incorporated over 70 changes to the pilot project guidance and processes.

- **Core SMS Orientation Presenters** - The MSMS team learned that having only a few well versed and knowledgeable presenters to give the SMS orientation sessions was more effective. The few presenters learned from each orientation session and were able to better answer questions and give examples at the subsequent sessions. The presenters increased knowledge and proficiency was evident during subsequent orientation sessions.

- **Gap Analysis Facilitator_** - Having one "gap analysis expert" explain the GAT and walk the participant through the steps of a PGA was the most successful. Having an inexperienced person do it was slow and very ineffective.

- **Early SMS Pilot Project Engagement** – Launching the SMS pilot project for all participants early in pilot within 4 months vs 16 months would have yielded better data collection with little effect on field resources. The momentum was drastically slow from launching one participant every other month and there was incredibly little effect on office resources. The end result of this slow launch was that the team did not receive the expected SMS data. The FAA could have supported a much quicker launch sequence and the pilot project participants may have progressed into level 3 of maturity. The Participant Management Team would have had a greater learning experience and been utilized better with a more rapid launch. The MSMS team did not need field support early in the pilot project because there were no activity for them until the DGA meeting.

- **"ICAO SMS" Training** – Having pilot project participants take a course in ICAO SMS would have been beneficial as would have accelerated the gap analysis meeting discussions. There was a lot of coaching and mentoring by the MSMS team to get the pilot project participants up to speed. Most of the POCs were knowledgeable on SMS but the rest of the pilot project participants' internal SMS team was not.

9-0 MSMS Team Recommendations for Rules, Policies, and Guidance

The recommendations of the MSMS team are as follows:

1. An FAA-issued SMS rule should be applicable to design and manufacturers, defined as organizations responsible for type design and/or the manufacturing of aircraft. This proposed scope for the SMS rule is directly in line with current ICAO requirements.

2. Conduct oversight of an organization instead of conducting specific SMS oversight. To clarify, the FAA's oversight of an organization's SMS would be in conjunction with any other management system requirements (e.g., QMS). The oversight method should use performance-based processes for the SMS. Separate audits may be used for compliance of quality systems, repair stations, etc.

3. Use the *D&M SMS Pilot Project Guide* as the baseline for an FAA Order. This guide provides (1) general information to the D&M industry on how to begin developing and implementing an SMS with D&M industry and (2) guidance to FAA personnel for

evaluating an organization's SMS program and developing implementation and oversight strategies.

4. Use the D&M SMS DG as a baseline for an AC. The D&M SMS DG replicates the structure of the D&M SMS framework's functional expectations using a hierarchical structure of four basic components: Safety Policy and Objectives, Safety Risk Management, Safety Assurance, and Safety Promotion.

5. The FAA should continue to work with D&M organizations requesting FAA support to evaluate its SMS maturity before an SMS rule is published. This recommendation is resource-dependent, and the FAA should make decisions to support D&M organizations on a case-by-case basis.

6. Perform a cost benefit analysis based on the research of current FAA and industry practices and not a specific aircraft accident. Recommended areas for further research may include Airworthiness Directives (ADs), Special Airworthiness Information Bulletins (SAIBs), Alternative Method of Compliance (AMOCs), Mandatory Continued Airworthiness Information (MCAIs), etc.

7. Continue to have SMS focus group meetings with AIA, GAMA, FAA, and the D&M industry to share lessons learned as continue a conduit for information sharing.

8. The AIR SMS field focals should continue working with the existing SMS pilot project participants after a final rule has been published.

Appendix A: Acronyms and Definitions

Will add in definitions and acronyms list after final review

Acronym	Definition
AC	Advisory circular
AD	Airworthiness directive
AIA	Aerospace Industries Association
AIR	Aircraft Certification Service
AVS	Aviation Safety (organization)
ARC	Aviation Rulemaking Committee
CMIS	Certificate Management Information System
CPL	Category Part List
D&M	Design and manufacturing
DEM	Demonstrated
DG	Developmental guidance
DGA	Detailed gap analysis
DOC	Documented
EASA	European Aviation Safety Agency
ERAU	Embry-Riddle Aeronautical University
ERP	Emergency response planning
FAA	Federal Aviation Administration
FTE	Full-time employee
ETOPS	Extended-range twin-engine operational performance standards
GAMA	General Aviation Manufacturers Association
GAIPT	Gap Analysis and Implementation Plan Tool
HQ	Headquarters
I	Implemented
ICAO	International Civil Aviation Organization
IP3	Integrated pilot project plan
MSMS	Manufacturers Safety Management System
NP	Not performed
NPRM	Notice for Proposed Rulemaking
NTSB	National Transportation Safety Board
P	Planned

PC	Production Certificate
PGA	Preliminary Gap Analysis
PMA	Parts Manufacturer Approval
PMT	Participant Management Team
POC	Point of Contact
QA	Quality Assurance
QMS	Quality Management System
QSMS	Quality / Safety Management System
RBRT	Risk-Based Resource Targeting
RISC/RoMAN	Rotor Manufacturing Project Report
RVSM	Reduced Vertical Separation Minimum
SLU	St. Louis University
SME	Subject matter expert
STC	Supplemental Type Certificate
SMS	Safety Management Systems
STND	Standard (SMS framework)
TC	Type certificate
TSOA	Technical Standard Order Authorization

Definitions

Applicability - Scoping an SMS rule to certain design and production approval holders.

Elements - A subordinate level of the SMS framework functional expectations.

Framework Expectations - A uniform set of requirements that align with the structure and format of the International Civil Aviation Organization (ICAO) Framework**.**

Organizations – Company departments such as engineering, quality, manufacturing, supplier management, etc.

Organizational hazard - A condition that could foreseeably cause or contribute to an aircraft accident based on an organization's decisions, priorities, policies, processes, etc. These are activities over which any organization has a reasonable degree of control that could lead to an aircraft accident.

Pilot project participants - Design and manufacturing companies participating in the SMS pilot project

Scalability - Sizing SMS procedures and processes based on the complexity and criticality of the products design and produce.

Top management – An executive at a company that is accountable for SMS

Appendix B: Links to Documents Used in the Pilot Project

Note: All of these references are linked to an FAA intranet site. If the documents are unavailable, please contact Linda Navarro or Amy Garzaro in AIR-150.

B-1 The D&M SMS Pilot Project Guide, Revision C

B-2 The Developmental Guidance for D&M SMS Framework, Revision D

B-3 Integrated Pilot Project Plan for the MSMS Pilot Project, Revision 31

B-4 Gap Analysis and Implementation Plan Tool, Revision 7

B-5 Study Comparing AS9100C and SMS Framework

B-6 System Description and Hazard Identification: A Process for Design and Manufacturing Organizations

B-7 ETOPS and SMS Study

B-8 RVSM and SMS Study

B-9 Comparison between the MSMS Framework, Rev A and proposed Part 5