Safety Management System and Quality Management System Relationship

This paper was prepared by the Safety Management International Collaboration Group (SM ICG). The purpose of the SM ICG is to promote a common understanding of Safety Management System (SMS)/State Safety Program (SSP) principles and requirements, facilitating their application across the international aviation community. In this document, the term "organization" refers to a product or service provider, operator, business, and company, as well as aviation industry organizations; and the term "authority" refers to the regulator authority, Civil Aviation Authority (CAA), National Aviation Authority (NAA), and any other relevant government agency or entity with oversight responsibility.

The current core membership of the SM ICG includes the Aviation Safety and Security Agency (AESA) of Spain, the National Civil Aviation Agency (ANAC) of Brazil, the Civil Aviation Authority of the Netherlands (CAA NL), the Civil Aviation Authority of New Zealand (CAA NZ), the Civil Aviation Authority of Singapore (CAAS), Civil Aviation Department of Hong Kong (CAD HK), the Civil Aviation Safety Authority (CASA) of Australia, the Direction Générale de l'Aviation Civile (DGAC) in France, the Ente Nazionale per l'Aviazione Civile (ENAC) in Italy, the European Aviation Safety Agency (EASA), the Federal Office of Civil Aviation (FOCA) of Switzerland, the Finnish Transport Safety Agency (Trafi), the Irish Aviation Authority (IAA), Japan Civil Aviation Bureau (JCAB), the United States Federal Aviation Administration (FAA) Aviation Safety Organization, Transport Canada Civil Aviation (TCCA), United Arab Emirates General Civil Aviation Authority (UAE GCAA), and the Civil Aviation Authority of United Kingdom (UK CAA). Additionally, the International Civil Aviation Organization (ICAO) is an observer to this group.

Members of the SM ICG:

- Collaborate on common SMS/SSP topics of interest
- Share lessons learned
- Encourage the progression of a harmonized SMS/SSP
- Share products with the aviation community
- Collaborate with international organizations such as ICAO and civil aviation authorities that have implemented or are implementing SMS and SSP

For further information regarding the SM ICG please contact:

Claudio Trevisan
EASA
+49 221 89990 6019
claudio.trevisan@easa.europa.eu

Sean Borg
TCCA
(613) 990-5448
sean.borg@tc.gc.ca

Mark Liptak
FAA, Aviation Safety
(202) 510-8010
Mark.Liptak@faa.gov

Neverton Alves de Novais
ANAC
+55 61 3314 4606
Neverton.Novais@anac.gov.br

Ash McAlpine
CASA
+ 07 3144 7411
Ashley.Mcalpine@casa.gov.au

SM ICG products can be found on SKYbrary at: http://bit.ly/SMICG

To obtain an editable version of this document, contact smicg.share@gmail.com.

Contents

PURPOSE

It is vital for any aviation organization to establish a management system with clearly defined lines of accountability and responsibilities, as well as processes and procedures so that safety performance is maintained at an acceptable level (safety management) and specified outputs are achieved (quality management). Safety management and quality management are highly complementary and should work together to achieve the overall safety objectives of an organization. This paper clarifies the differences, commonalities, and relationship between quality management and safety management.

INTRODUCTION

Aviation organizations vary greatly in terms of overall size and complexity. Any organization has some type of management system that may be composed of multiple processes and subsystems "held together" through some form of governance structure and organizational goals. In a number of areas, aviation safety regulations have traditionally required some form of quality system, usually in the form of requirements for quality control, quality assurance, quality management, or a compliance monitoring function, as a means to ensure conformance to standards and monitor compliance with applicable requirements. For example, a Quality Management System (QMS),[1] which is sometimes limited to a quality assurance function, is an existing aviation regulatory requirement for many service providers including production approval (Annex 8), maintenance organizations (Annex 6, Part I), aerodromes (Annex 14, Chapter 2) and meteorological and aeronautical data service providers (Annexes 3 and 15, respectively). Quality principles, policies, and practices required by aviation regulations are clearly linked to the objectives of safety management, but a quality system on its own may not be sufficient to capture hazards and manage the related risks.

Where an ISO 9001:2015[2] or similar management system has been implemented within an aviation organization, its elements have typically focused on two areas: monitoring compliance with applicable regulatory requirements (including its own policies and procedures) and managing personnel competence. It also provides a structure to develop corrective actions, evaluate the effectiveness of corrective actions, and communicate results to an accountable manager. Other ISO 9001 QMS requirements, such as management review and monitoring stakeholder satisfaction, are not normally addressed in aviation safety regulations. Hence, an ISO 9001 type of QMS requires more than what is usually termed as a quality system or quality assurance system in the aviation safety regulations.

---

[1] When reference is made to QMS in this paper, this is intended to mean a "Quality Management System" based on ISO 9000 series industry standards.

[2] ISO 9001:2015 or similar management system standards, such as the AS/EN 9100 series, provide a quality management system framework. Depending on national aviation legislation and statutory and contractual requirements, aviation organizations may or may not be required to be certified against those standards.

The introduction of a Safety Management System (SMS) requires a need to identify, link, and clarify commonalities with a Quality Management System.

A QMS aims at providing consistency in the delivery of products and services that meet customer and applicable statutory and regulatory requirements to enhance customer satisfaction through the effective application of the system. Both QMS and SMS require the implementation of a governance structure and an independent assurance function. The quality assurance function utilizes a feedback loop to assure consistent delivery of products and services; it also identifies ineffective processes and procedures that should be redesigned for efficiency and effectiveness. By contrast, the objective of the SMS is to identify safety-related hazards the organization are faced with and to control the associated risks to an acceptable level. SMS is intended to manage safety risk and measure safety performance during delivery of products and services. Even though the objectives are different, QMS and SMS have a number of features in common.

CONVERGENCE OF MANAGEMENT SYSTEM STANDARDS

Over the last few decades, the focus of industry standards commonly used in aviation successively expanded beyond a focus on the physical product (quality control) to address also the processes (quality assurance) and then to bring management into the equation (quality management). The ISO 9001:2015 standard introduces risk-based thinking. This encourages organizations to decide how risks and opportunities are addressed in process improvements and in preventing undesirable results; to define the extent of process planning and controls needed; and to improve the overall effectiveness of the quality management system. The introduction of risk into the ISO 9001 standard may be indicative of an evolution of management system standards to consider risk management more explicitly as a standard management tool. In particular, the concept of risk that was implicit in previous ISO 9001 versions through the notion of preventive action is now explicitly addressed in the ISO 9001:2015 version that requires risks and opportunities to be identified and managed. This is a major step as it now obliges senior management to explain and justify their decisions with regard to risks and opportunities, encouraging them to continually reassess their processes and methodologies, operating environment, and even their values and organizational culture. This is very close to what is expected from senior management to ensure effective safety management.

In terms of aviation regulations, the introduction of safety management Standards and Recommended Practices (SARPs), originally presented within the various sector specific Annexes, led to the creation of a consolidated framework for safety management as part of ICAO Annex 19, "Safety Management." However, safety risks are not the only type of risks that aviation organizations are exposed to; in many cases they also need to implement risk management processes to deal with environmental, occupational health and safety, and security (including cyber security) risks. This is leading to organizations integrating the management of different risks under a unified management system framework[3].

---

[3] This may also require the future development of organizational management SARPs to integrate those areas under a unified management system framework.

COMPLEMENTARY NATURE OF QMS AND SMS

Both SMS and QMS rely on a management system for the organization to plan and perform its activities in order to achieve organizational goals.

ISO 9000 series standards focus on enhancing an organization's ability to consistently provide products and services that meet requirements and aim to enhance customer satisfaction through the effective application of the quality management system. The following quality management principles are promoted in ISO 9001:2015:

- Customer focus;
- Leadership;
- Engagement of people;
- Process approach;
- Improvement;
- Evidence based decision making; and
- Relationship management.

Adherence to those principles will also support the implementation of an effective SMS.

QMS requires organizations to implement a number of elements and processes that may be very useful for SMS implementation, such as:

- understanding the internal and external context;
- planning;
- process analysis;
- internal auditing and root-cause or causal analysis;
- clear assignment of organizational roles, responsibilities, and authorities;
- communication and training;
- fostering organizational knowledge;
- control of externally provided processes, products and services; and
- management reviews to ensure continued suitability, adequacy, effectiveness and alignment with strategic direction of the organization.

In addition, both the SMS and QMS:

- should be planned and continuously managed;
- require effective demonstration of senior management commitment;
- require organizations to document their main policies and processes to a certain standard;
- require the use of data and information for evidence-based decision making;
- call for measurable objectives;
- require performance to be monitored;
- require organizations to record outputs of their processes;
- involve all organizational functions related to the delivery of aviation products and services;

- require effective management of changes;
- should be auditable; and
- should strive for continuous improvement.

In practice, an aviation organization's safety and quality practitioners are essentially focused on the same goal of providing safe and reliable products and services to customers. Both are trained on the various analysis methods including root-cause analysis. Also, opportunities exist for data to be exchanged between QMS and SMS functions (e.g., data generated through the QMS may be helpful to identify possible safety risks and safety data may help quality auditors target safety critical processes). Quality assurance and quality control elements that prevailed in aviation regulations prior to the advent of SMS have proven useful in identifying opportunities for improvement, system deficiencies, and non-compliances to internal procedures or external regulatory requirements. SMS complements those elements with hazard identification, safety risk management, and safety assurance processes to improve overall organizational efficiency. Therefore, the aviation industry increasingly recognizes the benefit of harmonizing QMS and SMS to both deliver quality products and services and offer ever-improving levels of safety for the benefit of customers and stakeholders.

Moreover, QMS and SMS share the Plan, Do, Check, Act (PDCA) approach. The PDCA covers safety and quality components. The approach facilitates the integration of QMS and SMS into one single management system.

The synergistic relationship between both systems can be summarized as follows:

- An SMS is supported and informed by QMS processes such as auditing, inspection, investigation, root-cause/causal analysis, process design, statistical trending analysis, preventive measures, documentation, and training;

- SMS may anticipate safety issues that exist despite the organization's compliance with standards and specifications;

- With its focus on compliance with customer requirements and applicable statutory and regulatory requirements, a QMS may constitute a solid foundation upon which to build the SMS; and in return

- QMS activities may be leveraged through consideration of risks for all planning activities, in particular for the planning and performance of internal audits.

DIFFERENCES BETWEEN QMS AND SMS

QMS is traditionally aimed at fulfilling customer and stakeholder expectations in accordance with customer, regulatory, and statutory requirements. SMS requires consideration of more implicit expectations in terms of safety and safety risks entailed by the activities performed. SMS therefore builds on one fundamental customer, regulatory, and statutory expectation that is delivering a safe means of transportation.

As stated previously, the latest revision to the ISO 9001 standard (ISO 9001:2015) introduced the concept of risk-based thinking. This addition alone does not equate an ISO 9001:2015 certified

QMS to an SMS developed under the requirements of ICAO Annex 19 (or by aviation safety regulations based on Annex 19). This is due to the differences in terminology, objectives, and focus areas:

- ISO 9000:2015 defines risk as the "effect of uncertainty," which is much wider in scope than the ICAO Annex 19 definition of safety risk as "predicted probability and severity of the consequences or outcomes of a hazard." QMS focuses on customer satisfaction, meeting applicable requirements, minimizing business risks, and maximizing opportunities. Therefore, quality objectives are not specifically aimed at managing safety risks.

- For QMS, auditors tend to focus on process outputs for variance to specifications, whereas SMS requires a broad perspective, including not only process analysis, but also unwanted events and hazards, with investigations and safety risk analyses looking into causal and contributing factors from all influencing sources.

- QMS requires management to have a general overview of all performance metrics, usually summarized in a global dashboard representing the business, while SMS requires management to focus in addition on safety risks and the effectiveness of safety risk controls.

- QMS tends to be reactive and focuses on existing processes, whereas SMS is proactive and involves looking at not only events that have happened but also events that could happen.

CONCLUSION

Companies establishing an SMS need to take a pragmatic approach, building where possible on existing procedures and practices, particularly those established for quality management.

SMS assures that the design and implementation of organizational processes and procedures identify safety hazards, and control and/or mitigate safety risk in aviation operations. QMS provides a structured approach for assuring that these processes and procedures function as intended, correct any non-conformance when they do not, and continually improve their effectiveness. While SMS provides the mechanisms for the organization to carry out its operational functions within a framework of safety risk-based decision making, QMS ensures that this framework is operating in a structured, repeatable fashion and is able to meet its intended objectives and when not, provides the means to improve.

As SMS becomes more regulated, it will take on a dominant role in an organization's overall strategy. In an integrated management system with unified goals and decision-making, considering the wider impacts across all activities, SMS and QMS processes will be highly complementary and will support the achievement of the overall organizational goals without compromising on safety.

DEFINITIONS

Management System (ISO 9000): *A set of interrelated or interacting elements of an organization to establish policies and objectives and processes to achieve those objectives*

Quality Control (ISO 9000): *Part of quality management focused on fulfilling quality requirements*

Quality Assurance (ISO 9000): *Part of quality management focused on providing confidence that quality requirements will be fulfilled*

Compliance monitoring function (EASA): *Function to monitor compliance of the management system with the relevant requirements and adequacy of the procedures including a feedback system of findings to the accountable manager*

Quality Management System (QMS) (ISO 9000): *Part of a management system with regard to quality*

Safety Management System (SMS) (ICAO Annex 19): *A systematic approach to managing safety, including the necessary organizational structures, accountability, responsibilities, policies, and procedures*

SOURCES

SMICG paper: "Safety Management System (SMS) Integration: Points to Consider." Available at: https://www.skybrary.aero/index.php/SMS_Integration_%E2%80%93_Points_to_Consider

Helicopter Maintenance Magazine: "The Importance of an Integrated Quality Management System (QMS) and Safety Management System (SMS) in Aviation Operations." Available at: http://www.helicoptermaintenancemagazine.com/article/importance-integrated-quality-management-system-qms-and-safety-management-system-sms-aviatio

Appendix A: ISO 9001:2015 AND ICAO ANNEX 19 OVERVIEW

Theme	Ref. ISO 9001:2015	ICAO Annex 19 Appendix 2 (SARPs only)
Context of the organization	4.1 Understanding the organization and its context 4.2 Understanding the needs and expectations of interested parties 4.3 Determining the scope of the quality management system 4.4 Quality management system and its processes 7.1.4 Environment for the operation of processes	(cf. Note 2)
Leadership	5.1 Leadership and commitment	1.1 Management commitment and responsibility 1.5 SMS documentation
Organizational roles, responsibilities, and authorities	5.3 Organizational roles, responsibilities, and authorities *(no need to designate a management representative)*	1.2 Safety accountabilities 1.3 Appointment of key safety personnel *(need to appoint a safety manager)*
Policy	5.2.1 Establishing the quality policy 5.2.2 Communicating the quality policy	1.1 Management commitment and responsibility (1.1.1)
Objectives	6.2 Quality objectives and planning to achieve them (6.2.1)	1.1 Management commitment and responsibility (1.1.2)
Planning	6.1 Actions to address risks and opportunities 6.2 Quality objectives and planning to achieve them (6.2.2)	---
Documentation	7.5 Documented information	1.5 SMS documentation
Risk Management	6.1 Actions to address risks and opportunities *(not specifically addressing hazard identification, and not addressing safety risks)*	2. Safety risk management 2.1 Hazard identification 2.2 Risk assessment & mitigation *(not addressing opportunities)*
Management of changes	6.3 Planning of changes 8.5.6 Control of changes *(under 8.5: Production and service provision)*	3.2 Management of change *(limited to changes which may affect the level of safety risk)*
Customer focus	5.1.2 Customer focus 9.1.2 Customer satisfaction	---

Theme	Ref. ISO 9001:2015	ICAO Annex 19 Appendix 2 (SARPs only)
Performance monitoring	7.1.5 Monitoring and measuring resources (under 7.1 Resources) 9.1 Monitoring, measurement, analysis and evaluation 9.1.1 General 9.1.3 Analysis and evaluation	3.1 Safety performance monitoring and measurement
Internal audit	9.2 Internal audit	*(Note to STD. 3.1.1)*
Improvement	10.1 General 10.2 Nonconformity and corrective action 10.3 Continual improvement	3.3 Continuous improvement of the SMS
Training	7.2 Competence	4.1 Training and education
Communication	7.3 Awareness 7.4 Communication	4.2 Safety communication
Operation	8.1 Operational planning and control 8.2 Requirements for products and services 8.3 Design and development of products and services 8.4 Control of externally provided processes, products and services 8.5 Production and service provision 8.6 Release of products and services 8.7 Control of nonconforming outputs	*(addressed in the operational ICAO Annexes)*
Management review	9.3 Management review	---
Emergency response	---	1.4 Coordination of emergency response planning
Resources	7.1.1 General 7.1.2 People 7.1.3 Infrastructure	*(addressed in the operational ICAO Annexes)*
Knowledge management	7.1.6 Organizational knowledge	---