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SUMMARY PhD THESIS

DEVELOPMENTS AND CONTRIBUTIONS REGARDING THE IMPLEMENTATION OF THE INTEGRATED QUALITY-RISK MANAGEMENT SYSTEM IN THE ORGANIZATIONS FROM AEROSPACE INDUSTRY

PhD supervisor,
Prof.em.PhD.Eng.,PhD.Ec. Constantin MILITARU



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**DEZVOLTĂRI ȘI CONTRIBUȚII PRIVIND IMPLEMENTAREA
SISTEMULUI DE MANAGEMENT INTEGRAT CALITATE-RISC
ÎN ORGANIZAȚII DIN INDUSTRIA AEROSPAȚIALĂ**

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IMPLEMENTATION OF THE INTEGRATED QUALITY-RISK
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Foreword

The elaboration of the PhD thesis and the scientific reports were carried out under the careful supervision of **Prof.Em.PhD.Eng.,PhD.Ec. Constantin MILITARU**, who has constantly encouraged me to search for new approaches to the implementation of the integrated quality-risk management system in aerospace organizations, accepting to be my mentor and to guide me throughout the preparation of my PhD thesis.

An integrated quality-risk management system in the aerospace industry is a comprehensive approach to risk management and quality assurance. It is a set of processes, policies and procedures designed to identify, assess, mitigate and monitor risks while maintaining a high level of quality in the design, development, production and maintenance of aerospace products and services.

The quality and risk management system integrates risk management principles into the quality management system to create a holistic approach to risk management and quality assurance. The system is designed to provide a structured and systematic approach to identifying, analysing and managing risks throughout the aerospace supply chain.

Implementing an integrated quality-risk management system in aerospace can provide numerous benefits, including improving safety and reliability, increasing customer satisfaction, reducing costs associated with quality issues and ensuring compliance with regulatory requirements. It also helps minimise the potential impact of risks on industry, stakeholders and the environment.

In order to ensure the effectiveness of an integrated aerospace quality-risk management system, it is essential to establish a culture of quality and risk management within the organization. This requires training employees on quality and risk management principles, establishing clear procedures for reporting and addressing quality issues and risks, and monitoring and continuously improving the system.

* * * * *

First of all, I would like to thank the scientific supervisor of this PhD thesis, **Prof.Em.PhD.Eng.,PhD.Ec. Constantin MILITARU**, for giving me this excellent opportunity to work with him, he constantly guided me in the right direction whenever I needed or when I faced various problems during my research. I would especially like to thank him for his valuable advice and knowledge sharing in the field of quality and risk management.

At the same time, I would like to express my sincere thanks to the management of the Faculty of Industrial Engineering and Robotics of the National University for Science and Technology POLITEHNICA Bucharest, for their support during the whole period of my PhD thesis.

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I would also like to thank the management of the National Institute for Aerospace Research and Development "Elie Carafoli" - INCAS, as well as the colleagues who gave me their valuable time, knowledge and continuous support during the period I worked on my PhD thesis. I appreciate all the help I have received from you.

Last but not least, I would like to thank all my family members and friends for always believing in me and giving me support and moral support throughout the elaboration of the PhD thesis. Your support and encouragement has meant a great deal to me and I am grateful to have had you by my side in this challenging and rewarding endeavour.

Elena Ilinca Magdalena Soare (căs. Marin)

Introduction

In today's context, integrated quality-risk management in the aerospace industry is more important than ever. The aerospace industry is constantly evolving, with new technologies and materials being developed and new risks and challenges arising. In this complex environment, the need for robust quality and risk management processes is essential.

The solution presented in this thesis involves **the implementation of an integrated quality-risk management system in an organization in the aerospace industry** in accordance with the requirements of SR EN 9100:2018, specific to aviation, space and defense, and SR ISO 31000:2018.

The PhD thesis is organized in two main parts: the current state of research and contributions regarding the implementation of integrated quality-risk management system in aerospace organizations and it is structured in ten chapters, comprising 243 pages, 42 figures, 40 tables, 45 calculation relations, 108 bibliographic sources and an appendix, in total 251 pages, as follows:

Chapter 1 – **”Theoretical considerations regarding quality management”** addresses in six sub-chapters with the evolution of the concept of quality, current guidelines in the definition of quality, the evolution of the quality management system, quality standards used in the aerospace industry, the explanation of aerospace industry specific requirements in SR EN 9100:2018, the relationship between Total Quality Management, Lean Manufacturing, Six Sigma and SR EN 9100:2018, as well as some specific aspects of service quality in the aerospace industry.

Chapter 2 – **”Theoretical considerations regarding risk management”** presents in three sub-sections some aspects of risk classification concepts and criteria, considerations on the implementation of a risk management system according to SR ISO 31000:2018, and aspects of risk management in aerospace organizations.

Chapter 3 – **”General considerations regarding quality-risk correlation in the organizational framework”** covers the definition of quality-risk correlation, the role of quality and risk management systems, the concept of integrated quality-risk management and the ways in which they are related.

Chapter 4 – **”The opportunity of implementing an integrated quality-risk management system in an aerospace organization”** presents the benefits of implementing an integrated quality-risk management system, the main aspects on which the research in the field of the PhD thesis was focused, as well as the preliminary conclusions based on which the need to implement an integrated quality-risk management system in aerospace organizations is argued.

The last chapter of the first part of the PhD thesis includes a series of **”Conclusions on the current state of research on the implementation of integrated quality-risk management system in aerospace organizations”**, including an analysis of the current trends of research on integrated quality-risk management in aerospace organizations and a tabular representation of them.

The second part of the PhD thesis is dedicated to the presentation of contributions regarding the implementation of integrated quality-risk management system in aerospace organizations.

Chapter 6 contains **”Directions, main objective and research methodology”** used in this PhD thesis.

Chapter 7 – **”Developments and theoretical contributions regarding the integrated quality-risk management in aerospace organizations”** is structured in three sub-chapters as follows:

Subchapter 7.1. *Study regarding risk management implementation in aerospace industry organizations* includes the presentation of risk management concepts in the aerospace industry, various ways of dealing with risks and risk assessment techniques in the aerospace industry. Next, the FMEA method and risk matrix for risk identification and assessment are described.

Subchapter 7.2. *Designing the integrated quality-risk management system within an organization in the aerospace industry* covers the steps to design and implement the quality management system for organizations in the aerospace industry, the documentation required to implement the system and the steps to implement the risk management process within the quality management system.

Subchapter 7.3. *Relationship between quality management, risk management, and safety management in the aerospace industry* highlights how these three areas of management are interlinked and complement each other to ensure the efficient and safe operation of the industry.

Chapter 8 – **”Practical contributions regarding the implementation of integrated quality-risk management in aerospace industry organizations”** is structured as follows:

Subchapter 8.1. *Case study regarding the implementation of an integrated quality-risk management system in an aerospace industry organization* exemplifies the first steps involved in implementing an integrated quality-risk management system in an organization, called ABC Aerospace, and a set of key performance indicators used in the aerospace industry to assess and improve organizational performance. This sub-chapter is divided into four further sub-subchapters.

Chapter 9 – **”Considerations regarding the procurement management process within an aerospace industry organization”** is structured in three sub-chapters as follows:

Subchapter 9.1. *General considerations regarding the procurement management process within an aerospace industry organization* presents the activities carried out within an organization to ensure compliance with clause 8.4 ”control of externally provided, processes, products and services” of SR EN 9100:2018.

Subchapter 9.2. *Evaluation and selection criteria for suppliers in the aerospace industry* contains a set of evaluation criteria for monitoring supplier performance.

Subchapter 9.3. *Contributions regarding risk assessment associated with procurement management in the aerospace industry* contains some aspects of supply chain risks and the identification and assessment of risks in the FMEA procurement management process.

Chapter 10 – ”Final conclusions and main contributions regarding the implementation of integrated quality-risk management system in aerospace organizations” presents the final conclusions of the research findings, personal contributions to the field of study and development directions for future research.

Finally, the 108 bibliographical references resulting from the documentary study carried out during the preparation and completion of this work are presented, as well as a summary description of how the results were disseminated.

Keywords:

Quality management, risk management, safety management, quality-risk correlation, integrated quality-risk management system, SR EN 9100:2018 standard, AMDE (Failure Modes and Effects Analysis) method, risk matrix, analysis of context of the organization, identification of relevant stakeholders, process map, key performance indicators, procurement management process in the aerospace industry.

Abbreviations

No.	Abbrev.	Significance
01	AAQG	<i>Americas Aerospace Quality Group</i>
02	AC	<i>Certification Authority</i>
03	AMDE	<i>Failure Modes and Effects Analysis</i>
04	APAQG	<i>Asia-Pacific Aerospace Quality Group</i>
05	APQP	<i>Advanced Product Quality Planning</i>
06	AQAP	<i>Allied Quality Assurance Publications</i>
07	AQL	<i>Acceptable Quality Level</i>
08	BSI	<i>British Standard Institute</i>
09	CAQ	<i>Computer Aided Quality</i>
10	CNC	<i>Computer Numerical Control</i>
11	CTC	<i>Technical Quality Control</i>
12	DFSS	<i>Design for Six Sigma</i>
13	DMADV	<i>Define, Measure, Analyze, Design, Validate/Verify</i>
14	DMAIC	<i>Define, Measure, Analyze, Improve, and Control</i>
15	DOE	<i>Design of Experiment</i>
16	DPU	<i>Defect per unit</i>
17	EAQG	<i>European Aerospace Quality Group</i>
18	EASA	<i>European Aerospace Safety Agency</i>
19	EGR	<i>Risk Management Team</i>
20	EMM	<i>Monitoring and Measuring Equipment</i>
21	ENAC	<i>Ente Nazionale per l'Aviazione Civile (trans: Italian Civil Aviation Authority)</i>
22	ETA	<i>Event Tree Analysis</i>
23	FAA	<i>Federal Aviation Administration</i>
24	FAI	<i>First Article Inspection</i>
25	FOD	<i>Foreign Object Damage</i>
26	FTA	<i>Fault Tree Analysis</i>
27	HSL	<i>High Level Structure</i>
28	IAQG	<i>International Aerospace Quality Group</i>
29	ICAO	<i>International Civil Aviation Organization</i>
30	ICOP	<i>Industry Controlled Other Party</i>
31	IEC/CEI	<i>International Electrotechnical Commission</i>

No.	Abbrev.	Significance
32	ISO	<i>International Organization for Standardization</i>
33	IT	<i>Information Technology</i>
34	KPI	<i>Key Performance Indicator</i>
35	MR	<i>Risk Management</i>
36	MRO	<i>Maintenance, Repair, and Operations</i>
37	NOC	<i>Notification of Change</i>
38	OASIS	<i>Online Aerospace Supplier Information System</i>
39	OEM	<i>Original Equipment Manufacturer</i>
40	PAAP	<i>Production Part Approval Process</i>
41	PDCA	<i>Plan-do-check-act</i>
42	PEST	<i>Political, Economic, Social, Technological Factors</i>
43	PESTLE	<i>Political, Economic, Social, Technological, Legal, Ecological (environmental) Factors</i>
44	PPM	<i>Parts per million</i>
45	QFD	<i>Quality Function Deployment</i>
46	RPN	<i>Risk Priority Number</i>
47	SIMCR	<i>Integrated Quality-Risk Management System</i>
48	SIPOC	<i>Suppliers, Inputs, Process, Outputs, Customers</i>
49	SMART	<i>Specific, Measurable, Achievable, Relevant, and Time-Bound</i>
50	SMC	<i>Quality Management System</i>
51	SMR	<i>Risk Management System</i>
52	SMS	<i>Safety Management System</i>
53	SWOT	<i>Strengths, Weaknesses, Opportunities and Threats</i>
54	TC	<i>Technical Committee</i>
55	TQC	<i>Total Quality Control</i>
56	TQM	<i>Total Quality Management</i>
57	UAV	<i>Unmanned Aerial Vehicle</i>
58	VSM	<i>Value Stream Mapping</i>

Part I.

Current status of research regarding the implementation of integrated quality-risk management system in aerospace organizations

Chapter 1. Theoretical considerations regarding quality management

1.1. The evolution over time of the concept of quality. Current orientations in defining quality

The term "quality" originates from the latin language, deriving from the word "qualis", which translates to "way of being". Quality can be perceived as a philosophical concept. Under this interpretation, we encounter the term in antiquity, in Aristotle, then in German classical philosophy in Hegel, Dimitrie Cantemir probably used a personalized translation, "feldeință", and, of course, in the works of contemporary philosophers [12].

In 1947, the International Organization for Standardization (ISO) was established. Through standardization, major differences in product quality have been reduced or even eliminated in some cases.

In 1951, **A. Feigenbaum** formulated a definition of quality as an optimum in relation to conditions specified or determined by the customer, while J. Juran proposed another definition of quality, namely "quality implies product performance and lack of deficiencies" [12].

It also mentions two other definitions of quality that were very common at the time. In 1974, **J. Juran** proposed the famous definition, "fitness for use", and in 1979, **Crosby** considered quality as "conformity with the requirements". Since the 1980s, the concept of quality has placed the customer at the centre of its meaning, along with his needs. As proposed by the **American Society for Quality Control**, quality refers to the totality of features and attributes of a product or service that support its ability to meet specified needs [12].

According to **SR EN ISO 9000:2015**, quality is described as the degree to which a set of essential characteristics of an object meets established criteria [56]. "In the same standard, the object is defined as "entity, item, anything that is perceptible or imaginable" [56].

In conclusion, an analysis of the concept of quality shows its complexity, as it can be associated with many areas. With the evolution of product markets, as well as from the experience of interacting with customers, the notion of quality has evolved over time, thus developing different industrial practices that have proven necessary to implement in order to keep product quality under control. Today, quality is an area of concern not only for organizations but also for individuals. It is an integral part of an individual's education and culture, and this leads to a better understanding of the need to use and implement the concept of quality.

1.2. The evolution of the quality management system. From traditional quality to Total Quality Management

To improve work efficiency, **Frederick W. Taylor** (1856-1915) developed a series of methods of managing and organising production, in which workers were seen as part of the whole workplace, together with the machine-tool-technological equipment, and whose purpose was to carry out the instructions they received. According to this way of organising work, known as "taylorism", the staff of an enterprise are classified as follows: "the group of thinkers" and "the group of doers", and only a small proportion of employees are involved in the creative process. The results of the activities of the thinkers, the specialists in the field, have led to increased productivity through optimised technological flows and technical innovations.

In order to be able to assess the quality of the products produced, specialised **technical quality control** services - TQC - have been set up. The training and the level of demand of the inspectors, as well as the technical and methodological inspection possibilities available to them, directly influenced the quality of the products. Quality control was carried out "a posteriori", on parts and final products [11].

In the current edition of the SR EN ISO 9000:2015 standard, inspection is "determining conformity with specified requirements" [56]. Following an inspection, either conformity, non-conformity or a degree of conformity results. Inspection is usually carried out at the final stage of the manufacturing flow, with the aim of enabling the determination and sorting of compliant products.

Starting in 1924, **Walter Shewhart** initiated a research program at the American Bell Telephone Company. The result of the research was the inevitable variability in product manufacturing processes. To analyse this variability, Shewhart turned to the tools of mathematical statistics. This identified five random factors, which cannot be fully controlled, whose action determines variability, called the 5M rule: Machine-tool, Method, Raw materials and materials used, Workmanship, Working environment.

Since 1940, several special committees have developed quality standards for military products. At Columbia University, a task force was formed to improve quality and productivity in the American arms industry. During this period, the concept of "acceptable quality level" (AQL) was introduced, which is the minimum quality of a product or service that a recipient can expect from a supplier.

This concept has fostered the development of a new process: **quality control**.

In the SR EN ISO 9000:2015 standard, quality control is defined as follows: "*the part of quality management focused on the fulfilment of quality-related requirements*" [56].

In order to apply this procedure, it is necessary to establish a standard for the methods and means of comparison. Then, compliance with the standard must be established and, if necessary, corrective measures applied. Experience has shown the difficulty of keeping under control, verifying the quality characteristics of each component part of a more complex product, noting the inefficiency of statistical control and test methods.

Since the 1950s, based on the principles of quality control, a new approach, called **quality assurance**, has been emerging. According to it, control was required to be an integral part of the manufacturing process and the product had to be designed in accordance with the requirements of integrated control [12]. According to SR EN ISO 9000:2015, quality assurance is described as a component of quality management that focuses on providing confidence that quality requirements will be met [56]. Quality assurance has strengthened the bond between customer and supplier, based on the trust that the customer has in their supplier [12].

The SR EN ISO 9000:2015 standard defines **quality management** as the integrated activities to guide and control an organization with respect to quality [56].

In order to successfully implement quality management it is necessary to know and apply the principles of management. By applying these principles, decentralization of responsibilities is achieved and an enrichment of the content of service tasks takes place. Thus, relations between the organization's departments develop, customer-supplier relations become closer, and staff actively participate in achieving common goals. The role of management principles is to prevent the occurrence of negative effects that can be produced by quality assurance [28].

Total Quality Management (TQM), according to the former ISO 8402:1994 standard, is a quality-oriented way of managing an organization that focuses on the involvement of all staff and aims to achieve long-term success by meeting and exceeding customer expectations and provides benefits for all employees of the organization and society as a whole [12].

Total Quality Management emerged in the 1980s in industry. The name TQM comes from the concept of Total Quality Control (TQC) developed by Armand Feigenbaum in 1961 [12].

In summary, TQM is a holistic approach to organizational management that focuses on continuous quality improvement by involving all employees, changing the organizational culture and using specific strategies, tools and techniques.

1.3. Quality standards used in the aerospace industry

IAQG (International Aerospace Quality Group) sets quality standards that are used in the aviation, space and defense industry and provides input into quality improvement policies, standards and practices. Each standard establishes common/shared tools and methods for quality improvement used by leading companies in the industry, thus receiving mutual support in the implementation of global initiatives [83].

Standard SR EN 9100:2018 "Quality management systems. Requirements for aviation, space and defense organizations" includes all the requirements of SR EN ISO 9001:2015, and the specific requirements added for the aerospace sector are highlighted in bold italics. The requirements specified in this standard are complementary (not alternative) to applicable contractual, legal and regulatory requirements. In the event of a conflict between the requirements of this standard and the applicable legal and regulatory requirements, the latter shall take precedence. This standard is intended for use by organizations that design, develop, and/or manufacture aviation, space, and defense products, as well as organizations that provide post-delivery support, including the provision of maintenance services, spare parts, or materials for their products [39].

Standard SR EN 9110:2018 "Quality management systems. Requirements for maintenance organizations in the aviation industry" includes the SMC requirements under SR EN ISO 9001:2015 and specifies additional requirements, definitions and notes for the maintenance and continuing airworthiness industry in civil and military aviation. The standard specifies the requirements for an SMC when it is necessary for an organization to demonstrate its ability to consistently provide products and services that meet customer, applicable legal and regulatory requirements. SR EN 9110:2018 also aims to improve customer satisfaction through effective system implementation, continuous system improvement and compliance with customer requirements, applicable legal and regulatory requirements [42].

Standard SR EN 9120:2018 "Quality management systems. Requirements for distributors in the aviation, aerospace and defense industry" is used by organizations that purchase parts, materials or assemblies and resell these products, without modification, to a customer in the aviation, aerospace and defense industry, including organizations that purchase products that they divide into smaller quantities for resale, or by organizations that coordinate a customer or regulatory controlled process for the product [106].

All AS9100 series standards underwent significant changes at the end of 2016. While some of these changes were driven by a change to the base standard, SR EN ISO 9001:2015, many of the requirements of the aerospace, space and defense industry were also modified and improved.

The IAQG standards shown in Figure 1.9 can assist organizations when they are establishing or trying to improve their SMC, processes or activities. These additional standards do not require certification but provide guidance.

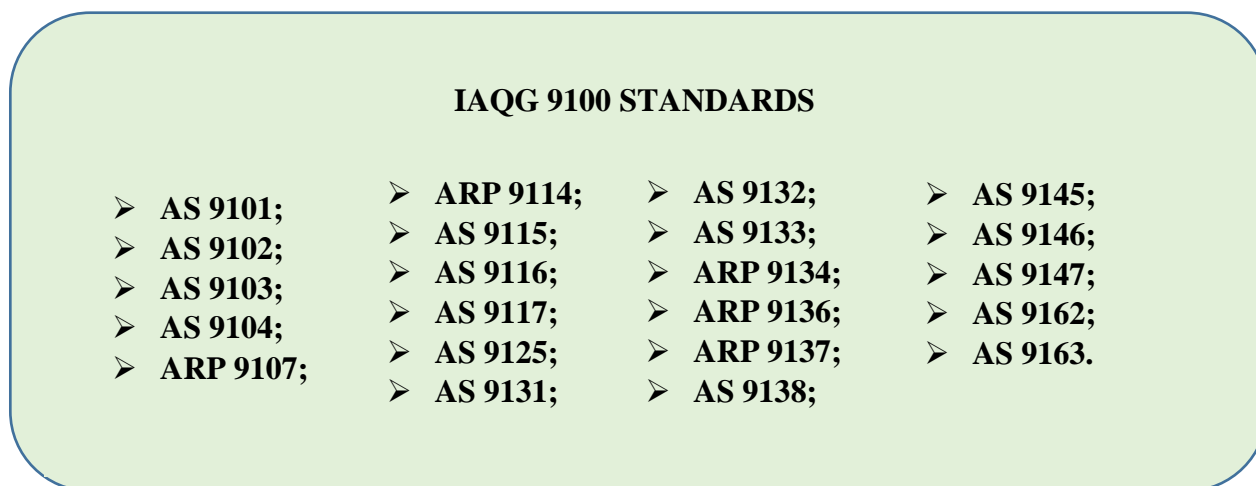


Fig. 1.9. AS9100 series standards developed by IAQG (author's adaptation after [82])

1.4. Explaining the aerospace industry specific requirements of SR EN 9100:2018 standard

Clause 8.1.1. Operational Risk Management

In the SR EN 9100:2018 standard, there is a note specifying that while clause 6.1 (actions to address risks and opportunities) addresses risks and opportunities for the SMC, clause 8.1.1

(operational risk management) is limited solely to risks associated with the operational processes necessary for the organization to deliver its products and services. Therefore, even though it may be possible to identify a risk within the SMC that the current product might soon face a competing product, this is not a risk that needs to be monitored as per clause 8.1.1, as it is not an operational risk.

It is necessary for the organization to ensure that the following five requirements are included when planning, implementing, and controlling the operational risk management process: assigning responsibilities, defining risk assessment criteria, identifying, evaluating, and communicating risks, identifying, implementing, and managing mitigation actions, and accepting remaining risks once mitigation is complete.

Clause 8.1.2. Configuration Management

Configuration management is achieved by tracking changes and versions of each part of the products and services. This allows for understanding the applicable requirements for each smaller component of the deliverable.

Within the SR EN 9100:2018 standard, four requirements related to configuration are found:

- 1) When conducting testing, it is necessary to ensure that the correct configuration of the item being tested is sent for testing.
- 2) Design and development results must include all data (e.g., drawings, parts lists, specifications, etc.) that help define the configuration.
- 3) Design changes are controlled using the configuration management process.
- 4) Identification and traceability processes must include identifying the configuration of products and services so that differences between requirements and what is actually delivered in products and services can be identified.

Clause 8.1.3. Product Safety

This is a short clause that requires maintaining product or service safety throughout its lifecycle and determining safety risks that need to be addressed. Following this assessment, it is at the organization's discretion to determine what actions are necessary to address any hazards and/or safety risks. There might be instances where the product or service has no safety risks, and in such cases, there will be no implementation processes required.

Clause 8.1.4. Prevention of counterfeit parts

Depending on the role and position within the supply chain, the risk of receiving counterfeit parts or assemblies with counterfeit parts varies for the organization.

The SR EN 9100:2018 standard includes some recommended options to consider when determining which processes to apply. These include training and awareness, using original or authorized manufacturers, verification and testing, monitoring the reporting of counterfeit parts from external sources, as well as quarantining and reporting counterfeit parts.

Clause 8.3. Design and development of products and services

Sub-clause 8.3.4.1. Necessary tests for verification and validation

Sub-clause 8.3.4.1. emphasizes the importance of planning, controlling, reviewing, and documenting tests carried out to verify and validate products or processes within the aerospace industry.

The reason this clause is included is the necessity to document testing plans for verifying and validating designs. Once the testing has been planned, there is a specific list of information included in the testing documentation according to the SR EN 9100:2018 standard: identification of the tested item, required resources, test objectives and conditions, parameters to be recorded, acceptance criteria, testing methods, test execution, and result recording methods.

Clause 8.3.5. Design and Development Outputs

Additionally, according to the SR EN 9100:2018 standard, the design and development outputs include:

- As appropriate, any critical elements, including any key characteristics and specific actions required for these elements.
- Approval by the authorized person(s) prior to release.

Also, the organization defines the data necessary to enable the identification, manufacture, verification, use, and maintenance of the product: This requirement underscores the necessity for organizations to define the data needed to identify, manufacture, verify, use, and maintain the product.

Clause 8.4. Control of externally provided processes, products, and services

In addition to the various controls, actions, and processes operating within the organization, there may be parts that are outsourced. The SR EN 9100:2018 standard requires that all outsourced operations be identified and appropriately controlled concerning quality management. Moreover, the SR EN 9100:2018 standard has requirements for maintaining all external suppliers. As a result, risks from external suppliers are identified and managed, necessary controls for each supplier are identified and implemented, and a register of external suppliers, including approval status and approval scope, is maintained. Additionally, actions are defined to address suppliers that do not meet the requirements, and periodic assessments of external suppliers are conducted.

The organization will need to establish and document criteria for selecting suppliers, which will include an assessment of how critical the outsourced product or service is to the quality of the product or service provided by the organization. Maintaining records of the evaluation, including a register of external suppliers, is necessary.

Also, controls are established to ensure that externally provided processes, products, and services do not adversely affect the products and services provided.

The organization retains responsibility for the compliance of all externally provided processes, products, and services, and it is necessary to manage identified risks for external suppliers.

Clause 8.5. Production and service provision

The additional requirements included in the SR EN 9100:2018 standard are as follows:

- 1) ***Foreign Object Prevention and Removal***: In the aerospace industry, detecting and removing foreign objects is extremely important. The organization establishes which processes are necessary to control this. This might include pre-counted parts to ensure no extra small pieces are left inside a unit, or inspections to check for these objects.
- 2) ***Equipment, Tools, and Software Programs***: When using any of these elements to automate, control, monitor, or measure production processes, it is essential that they are controlled so that when the final product or service is released, the data is accurate.

Clause 8.6. Release of products and services

When it is found that not all tasks have been fulfilled or the outcome of a task is deemed unacceptable, the organization needs to decide whether to fulfill the task to complete the testing or obtain permission to accept the situation as it is. The SR EN 9100:2018 standard specifies that this discrepancy can be approved by a relevant authority and, if necessary, by the customer. In cases where the customer performs an inspection or a necessary test that was missing, the customer will need to authorize this. They may be able to accept a non-conforming test result or may conduct a test at their facility, proving the requirement is acceptable. This is encompassed within the non-conforming outputs control process. On the other hand, if the inspection was done internally, then the internal management of the organization might be the relevant authority to approve the omission. It is important to include this information in contracts so that what is necessary to deliver to the customer is known.

Clause 8.7. Control of nonconforming outputs

A SMC reduces the risk of producing a product or service that does not meet requirements, but it does not eliminate that risk. That's why the SR EN 9100:2018 standard includes a process to

determine the necessary actions when this occurs. Organizations may have many different procedures and forms to address nonconforming products, but the basic process boils down to five main steps as follows: identification of nonconformity, problem isolation, decision-making on the disposition option, correction as per disposition, corrective action.

The disposition of the nonconforming product identifies what will happen to the product either to remedy it or dispose of it. The SR EN 9100:2018 standard identifies four ways to handle nonconformities: correction, acceptance authorization (often called "use-as-is"), informing the customer (often required for authorization for "use-as-is" or repair), segregation, isolation, return, suspension of delivery.

Clause 9. Performance evaluation

Clause 9.1.2. Customer satisfaction from the SR EN 9100:2018 standard specifies the information that needs to be monitored and used to evaluate customer satisfaction and highlights the organization's responsibility to develop improvement plans and evaluate their effectiveness. While the clause mentions specific elements such as product and service conformity, on-time delivery performance, customer complaints, and requests for corrective actions, it also emphasizes that this list is not exhaustive.

After collecting data regarding customer satisfaction, the organization is expected to develop and implement plans aimed at improving customer satisfaction. Ultimately, evaluating the effectiveness of the implemented improvement plans is necessary to determine whether the desired results have been achieved.

Clause 9.2. Internal audit

The SR EN 9100:2018 standard contains a note that emphasizes during internal audits, the organization's own requirements should include not only customer requirements but also the applicable statutory and regulatory requirements of the SMC.

Clause 9.3. Management review

In addition to the SR EN ISO 9001:2015 standard, it is necessary for the organization to plan and conduct management reviews, taking into account the on-time delivery performance. This performance measure provides valuable information regarding the organization's ability to meet customer requirements and expectations concerning delivery.

During the management review, top management evaluates the performance and effectiveness of the SMC, analyzes data and information related to various aspects of the organization's operations, and identifies risks and opportunities. The identified risks may include internal and external factors that could impact the achievement of quality objectives, customer satisfaction, or the organization's ability to comply with requirements.

Clause 10. Improvement

Clause 10.2. Nonconformity and corrective action

According to the SR EN 9100:2018 standard, it is mandatory to develop a procedure regarding the management process of nonconformities and corrective actions, or at least to document how the process operates. Additionally, SR EN 9100:2018 requires organizations to take the following actions when a nonconformity occurs:

- Control, correct nonconformities, and address their consequences.
- Decide whether to eliminate the cause of the nonconformity to prevent its recurrence.
- Determine who will implement the actions and then implement them.
- Analyze the effectiveness of the corrective action taken.
- Make changes to the SMC if necessary.
- Send the corrective action to an external supplier if necessary.
- Take measures when corrective actions are not implemented in a timely manner or are not effective.

Clause 10.3. Continual improvement

The SR EN 9100:2018 standard provides examples of continual improvement opportunities. These examples include lessons learned, problem-solving, and comparative analysis of best practices. To gain credibility with stakeholders, it is necessary for all aerospace and defense industry organizations to make efforts to obtain and maintain SMC certification in accordance with the SR EN 9100:2018 standard to demonstrate their commitment to quality, safety, and efficiency.

In conclusion, the SR EN 9100:2018 standard is a valuable tool for organizations in the aerospace industry looking to improve their SMC, enhance customer satisfaction, and gain a competitive advantage. By implementing a SMC that meets the requirements of this standard, organizations can demonstrate their commitment to quality and safety while simultaneously improving their operational performance.

1.5. Relationship between Total Quality Management, Lean Manufacturing, Six Sigma and SR EN 9100:2018 standard

Total Quality Management (TQM) has been around since the late 1970s and is a way of organising a company, continually improving its ability to provide customers with high quality products and services. The TQM approach varies greatly between organizations and there is no agreed approach to how it should take place. However, TQM relies on numerous quality management tools to implement this continuous improvement climate throughout the organization [102].

The general concepts of TQM are as follows:

- Customer requirements define quality.
- Quality can be increased by evaluating and improving work processes.
- Top management needs to be involved to drive improvement.
- If quality improvement is desired, it is a continuous effort throughout the organization [102].

There have long been a number of quality tools (*Pareto chart, cause and effect diagram, trend analysis*) that would be of great use in evaluating work processes to find improvements.

Although TQM is not required by SR EN 9100:2018, it is also not excluded by the standard. There are requirements for continual improvement within SMC, so it can be a process used to promote improvement throughout the organization.

Lean manufacturing is the concept that any activity that does not add value for the customer is a loss and that losses should be eliminated or at least reduced. In Lean, the Japanese words for waste, "Muda" and improvement, "Kaizen", are often used. Lean sees value as any action or process that gets done and the customer is willing to pay for it. By eliminating other wasted actions, value is preserved by spending fewer resources and doing less work [85].

Some of the more common tools used by Lean practitioners are: *5S method, Value Stream Mapping (VSM), Kanban, Key Performance Indicators (KPIs), Tool board, Poka-yoke* [85].

Six Sigma methodologies are a way of focusing improvement activities within the SMC. Although continual improvement is a key principle of SR EN 9100:2018, it does not explain how this improvement is implemented or maintained. The Six Sigma Method provides a way to implement this information on improvement. It is a collection of process improvement techniques and tools that can be applied to the processes set out in the SMC and can be used to improve them [86].

Both SR EN 9100:2018 and Six Sigma use a process-based approach in applying their methodologies.

Both systems have a basic methodology for using an improvement cycle. The SR EN 9100:2018 standard is based on a "plan-do-check-act" (PDCA) cycle that is used to focus efforts on system improvement [86].

The basic tool used in Six Sigma for process improvement projects is the DMAIC (short for Define, Measure, Analyze, Improve and Control) project methodology, which is a data-driven improvement cycle that is used to improve, optimize and stabilize business processes. In both

systems, all phases of the cycle are followed in order for it to work, and if steps are omitted, this can cause failure [86].

The main difference between SR EN 9100:2018 and Six Sigma is the scope. SMC can be certified according to the requirements of SR EN 9100:2018, while Six Sigma is just a set of tools and methods used to improve business processes. These tools are not meant as a means of developing a whole SMC [86].

Design for Six Sigma (DFSS), DMAIC (Define, Measure, Analyze, Improve, Control) and DMADV (Define, Measure, Analyze, Design, Verify) are three methodologies commonly associated with Six Sigma. Each of these methodologies represents a different approach to process improvement and quality management [73].

The SR EN 9100:2018 standard is based on the principles of quality management, which are described in the SR EN ISO 9000:2015 standard. The seven principles are shown in Figure 1.12.



Fig. 1.12. Quality management principles [56]

In conclusion, there are many different ways to apply these quality management principles. The specific nature and challenges faced by an organization will determine how they are implemented. Many organizations will find it beneficial to develop and implement a SMC based on these principles. Understanding the principles makes it easier to create a SMC that works in line with the individual needs of organizations.

1.6. Service quality in organizations from the aerospace industry

Service quality is the extent to which the level of service provided matches customer expectations. The delivery of a quality service is determined by whether it meets customer expectations on a consistent basis. Thus, service quality can be defined as the difference between customer expectations and customer perception. If expectations are met, service quality is perceived as satisfactory, and if not, service quality is less than satisfactory. If customer expectations are exceeded, the customer perceives the quality of service provided as more than satisfactory [27].

Service quality is a key aspect of the aerospace industry as it has a direct impact on customer satisfaction and safety. In the aerospace industry, service quality can be defined as the extent to which products and services meet or exceed customer expectations, including aspects such as safety, reliability, responsiveness, timeliness and overall customer experience.

In conclusion, the aerospace industry is aware of the importance of safety and recognises the role that product and service quality plays in aviation, space and defense performance. Both consumer and customer confidence are directly related to their perception of the quality of products and services that are manufactured and delivered in this specialised industry.

Chapter 2. Theoretical considerations regarding risk management

2.1. Concepts and criteria for classifying risk

Risk is often expressed as a combination of the consequences of an event, including changes in circumstances, and its likelihood. Uncertainty is the state, even partial, of information deficiency regarding the understanding or knowledge of an event, its consequences or its likelihood [38].

The Institute for Risk Management does not have a universally accepted definition of risk. Its documents include definitions such as "chance of negative consequences" or "exposure to the unexpected". The standard SR ISO 31000:2018, contains the following definition of risk: "effect of uncertainty on objectives" [58]. Figure 2.1 provides an explanation of the terms used in the definition of risk.

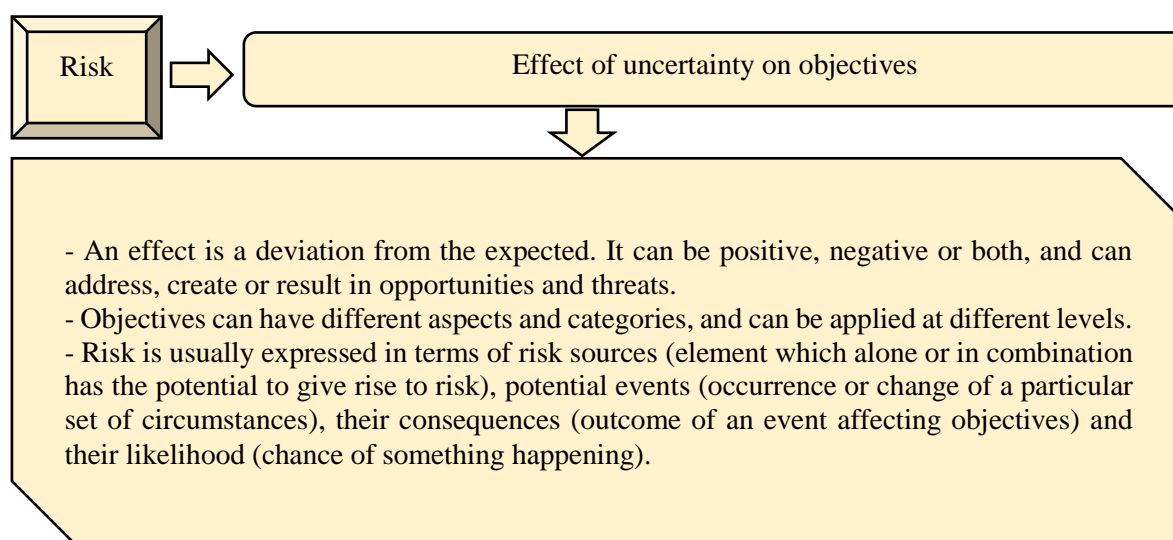


Fig. 2.1. Risk definition [58]

After 1999, the definition of risk includes the positive component. For example, in 2000, the British Standards Institute (BSI) defines risk as "uncertainty ... affecting the possibility of achieving objectives", and standards developed in Australia and New Zealand use a definition that incorporates both threats and opportunities [90].

In the Project Management Guide developed by the Project Management Institute in 2000, risk is seen as an opportunity to discover something new. According to it, risk is defined as an uncertain event or condition that may have an impact on the stated objective, either positive or negative [63].

In conclusion, risk is an unpredictable event which, when it occurs, can positively or negatively influence the objectives of an activity or set of activities. A risk can occur when something unplanned happens during an activity or when something planned does not happen as expected.

2.2. Risk management according to SR ISO 31000:2018 standard

The SR ISO 31000:2018 standard provides a framework of best practices and guidance for risk management in organizations. Its purpose is to support staff to create and protect value by managing risks, facilitating decision making, defining and achieving objectives and enhancing performance. The standard contains a set of principles, a comprehensive framework and a process for risk management [87].

The advantages of implementing risk management are numerous:

- provides a competitive advantage as ISO is an internationally recognised symbol for quality standards;

- it increases employees' awareness of organizational risks by including them in the management framework and giving them responsibility for the processes they routinely use;
- improves the success rate in all business operations by focusing on process, thinking preventatively instead of reactively and giving employees their job responsibilities.

The risk management process is illustrated in Figure 2.6.

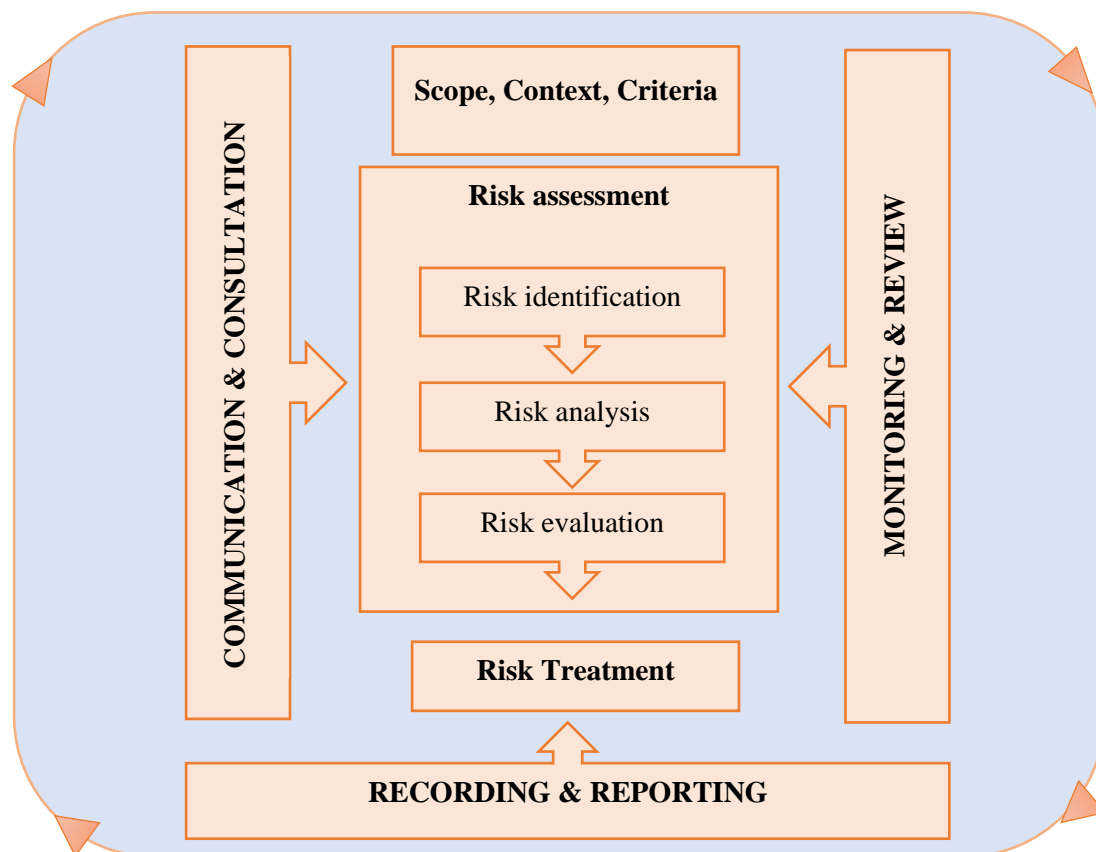


Fig. 2.6. The risk management process (author's adaptation after [58])

In conclusion, MR is essential for top-level management in making decisions, conducting business, protecting the organization and must be aligned with the organization's objectives and priorities. The organization's primary focus is on risk prevention measures, but also on reducing the consequences of an adverse event, and the SR ISO 31000:2018 standard certainly provides an opportunity for organizations to understand the causes and identify the necessary treatments to reduce the uncertainty of their future.

2.3. Risk management in aerospace organizations

To ensure sustainable growth and development in this challenging environment, it is necessary for organizations to have a thorough knowledge and understanding of the risks they face and to establish a strategy for managing these risks.

There are several sections in SR EN 9100:2018 where risk, or MR, is identified as follows:

1. **special requirements:** requirements identified by the customer or established by the organization, the realization of which presents high risks and requires inclusion in the RM process. Factors used in establishing special requirements include product or process complexity, previous experience or process maturity;
2. **critical elements:** elements (e.g. functions, parts, software, features, processes) that have a significant effect on the realisation and use of the product, including safety, performance, form, fit, function, manufacturability, service life, etc., that require specific actions to ensure appropriate management. Examples of critical items are safety critical items, breakage critical

items, mission critical items, key characteristics, etc. It is necessary to implement a risk management process to control these aspects;

3. **key characteristics** means an attribute or characteristic whose variation has a significant effect on product form, fit, function, performance, service life or manufacturability, requiring specific actions to control the variation. Risk associated with key characteristics is also managed through the risk management process;
4. **project management**: it is necessary for the organization to plan and manage the realisation of the product in a structured and controlled manner to meet the requirements with acceptable risk within resource and time constraints. It is necessary for any project management programme to include MR;
5. **risk management**: the organization is required to establish, implement and maintain a process for managing the risks to the fulfilment of applicable requirements, which includes, as appropriate, for the organization and products:
 - a) delegation of responsibilities for MR;
 - b) setting risk criteria (e.g. likelihood, consequences, risk acceptance);
 - c) detecting, assessing and communicating risks throughout the product development period;
 - d) identification, implementation and management of actions to reduce risks that exceed the defined risk acceptance criteria;
 - e) acceptance of residual risks after implementation of mitigation actions;
6. **product requirements analysis**: it is necessary for the organization to ensure that risks have been properly identified, such as new technologies, short lead times, resources or change of supply source;
7. **the procurement process**: the organization needs to determine and manage risks in the process of selecting and using suppliers;
8. **corrective actions**: the organization needs to establish corrective actions, including risk management, such as error checking, failure mode and effects analysis (FMEA) and information on product problems obtained from external sources [39].

The basic components of an MR process in aerospace are: risk identification, risk assessment, risk management process, culture for MR.

In conclusion, it is desirable for the organization to promote learning from the application of risk management by employees, promote experiential learning from issues that arise, incorporate RM in demonstrating management leadership, and support innovation in a structured risk management environment [89].

Chapter 3. General considerations regarding quality-risk correlation in the organizational framework

Quality-risk correlation describes the interrelationship that occurs between quality and risk. These two basic concepts are indispensable to each other in the process of production and service provision, and changes and variations in their magnitude are interdependent [5].

An effective management of the quality-risk correlation enables the determination of a quality strategy that takes into account the associated risks. This is achieved by establishing appropriate methods of quality information, measurement, analysis and control that are able to operate under conditions of risk and uncertainty [4].

In conclusion, the potentially high costs associated with both achieving and maintaining an adequate level of quality and with quality deterioration underline the importance of good quality risk management. This involves systematically detecting and addressing risks to minimise the negative impact on quality and associated costs [5].

Chapter 4. The opportunity of implementing an integrated quality-risk management system in an aerospace organization

In the current context, some key considerations for the implementation of an *Integrated Quality-Risk Management System in aerospace organizations* are presented:

- **Management Commitment:** Successful implementation of a SIMCR requires strong management commitment. It requires management at the highest level to support the initiative and ensure that it is adequately resourced and prioritised.

- **Establish quality and risk management policies and procedures:** To ensure that the integrated quality-risk management system is implemented effectively, it is necessary for the organization to establish policies and procedures related to quality and risk management. It is recommended that these policies and procedures define roles and responsibilities, outline the process for identifying and mitigating risks, and establish a process for monitoring and reviewing risk management activities.

- **Risk identification and assessment:** Aerospace organizations need to conduct a comprehensive risk assessment, taking into account internal, external and systemic risks. This assessment is intended to cover various aspects such as safety, operational, financial and compliance risks.

- **Development of risk management plans:** Based on the results of the risk assessment, it is necessary for the organization to develop risk management plans. It is recommended that these plans include strategies to mitigate the identified risks and be integrated into the organization's overall SMC.

- **Process integration:** It is desirable that a SIMCR is integrated into the organization's existing quality management system to ensure that risks are identified and managed in all processes of the organization. This will require a review of existing processes and the development of new procedures as appropriate.

- **Employee training and awareness:** It is recommended that employees are trained and made aware of the SIMCR and how it fits into the organization's SMC. This will help ensure that all employees understand their roles and responsibilities in managing risks and maintaining quality standards. Training programmes may include topics such as risk assessment, risk management planning and risk monitoring.

- **Performance monitoring:** It is recommended that the integrated quality-risk management system be monitored periodically to ensure that it is achieving its intended objectives. To do this, key performance indicators are established and data is collected and analysed to measure the effectiveness of the system.

- **Continual improvement:** It is recommended that organizations continually review and improve the SIMCR to ensure that it remains effective. This may involve updating risk assessments, improving risk controls or making changes to the SMC.

- **External collaboration:** Collaboration with industry partners, suppliers and regulators can provide valuable insights, share best practice and contribute to a holistic approach to the SIMCR.

In conclusion, the successful implementation of a SIMCR requires commitment and involvement from all levels of the organization, from top management to front-line employees. It is important to provide adequate training and resources to ensure that all employees understand the importance of risk management and are prepared to implement it effectively.

Chapter 5. Conclusions on the current state of research on the implementation of integrated quality-risk management system in aerospace organizations

Following bibliographic research in the field of quality management and risk applied in the aerospace industry, it can be noted that in the context of quality assurance development in globally accepted standards, this field of study has evolved into a specialized academic field. Most studies have indicated that management systems can be integrated in various ways, generally speaking, but there hasn't been significant interest shown towards approaching risk management as a component within an integrated management system in an aerospace industry organization.

The aerospace industry is known for its high standards of quality, safety and reliability, and **the current trend in quality management** in this industry is focused on a continuous improvement approach.

One of the main drivers of this trend is the increasing complexity of aerospace systems and the need to manage quality throughout the system lifecycle, from design and development to manufacturing and operation. To achieve this, industry is increasingly adopting digital technologies such as artificial intelligence, machine learning and data analytics to optimise processes and improve quality.

Another trend in aerospace quality management is the adoption of a risk-based approach. This involves identifying and assessing risks to quality and implementing measures to reduce these risks. It also involves a continuous process of monitoring and reassessment of risks to ensure that quality is maintained throughout the life cycle of the system.

Additionally, the aerospace industry places particular emphasis on risk management due to the critical nature of its products and services. **The current trend in risk management within the aerospace industry** involves a shift towards a more proactive approach to risk management, emphasizing the identification and mitigation of potential risks before they arise.

Specialists' opinions regarding the implementation of an SIMCR in the aerospace industry are generally positive. Some experts believe that an SIMCR can assist organizations in identifying and mitigating risks from the early stages of product development, ultimately leading to safer and higher-quality products. Others highlight that an SIMCR can help organizations streamline their quality and risk management processes, reducing duplicated efforts and improving efficiency.

Implementing a SIMCR can be challenging, but the benefits to aerospace organizations can be significant, particularly in terms of risk reduction and quality improvement. It is important for organizations to carefully consider the potential benefits and challenges before implementing a SIMCR.

Part II.

Contributions regarding the implementation of integrated quality-risk management system in aerospace organizations

Chapter 6. Directions, main objective and research methodology

6.1. Research directions

The topic addressed in this PhD thesis requires knowledge from multiple fields, including aerospace engineering, management, procurement, information technology, etc.. In setting the objectives and scope of the PhD thesis, the author took into account both previous research in the field and knowledge acquired over a period of approximately thirteen years working in an aerospace organization. This experience has enabled her to tackle a complex but challenging topic.

Following the analysis of the current state of play on the implementation of SIMCR in aerospace organizations, the following **research directions** have emerged:

- analysis of the context and the needs and expectations of relevant interested parties within an aerospace organization, and assessment of the associated risks and opportunities;
- identification of processes within an aerospace organization and their interaction using process mapping, and the development of turtle diagrams for the established processes;
- establishing the SIMCR policy and objectives within an aerospace organization, and assessing the risks and opportunities that may affect or help achieve the objectives;
- establishing criteria for evaluating and selecting aerospace suppliers to monitor their performance;
- conducting a risk analysis of the aerospace procurement management process to identify, assess and mitigate the various risks an organization may face.

6.2. Main research objective and specific objectives

The thesis aims to contribute to the understanding of how aerospace organizations can successfully integrate risk and SMC by providing information and practical examples for implementing a comprehensive and effective SIMCR. As the aerospace sector is characterised by stringent safety standards, complex processes and a dynamic environment, the integration of quality and risk management becomes crucial to ensure product reliability, compliance and organizational success.

The main objective of this paper is *to identify ways and best practice examples of implementing SIMCR in an aerospace organization.*

The specific objectives of the research are the following:

- identification of the documented information required by the SR EN 9100:2018 standard;
- researching the risk assessment methods used in the aerospace industry;
- analysis of the relationship between quality management, risk management and safety management in the aerospace industry;
- development of the implementation diagram of SR EN 9100:2018;
- development of the process map of an aerospace organization, called ABC Aerospace;
- analysis of the internal and external context in which an aerospace organization operates;
- identification of stakeholder needs and expectations, and the associated risks and opportunities;
- development of the policy and objectives of an aerospace organization's integrated quality-risk management system;
- identification and assessment of risks and opportunities that may affect, or promote, the achievement of the objectives set within an aerospace organization;
- conducting a study of key performance indicators used in the aerospace industry to assess and improve organizational performance;
- establishing criteria for the evaluation and selection of aerospace suppliers;

- development of an analysis of the risks associated with the procurement management process, as well as those related to the selection and use of aerospace suppliers, through the completion of an FMEA form.

6.3. Research methodology

The research methodology used in the thesis is structured as follows:

- analysis of the current state of play on the implementation of SIMCR in aerospace organizations and elaboration of conclusions on the basis of which the theoretical and practical objectives of the PhD thesis were established;
- analysis of the internal and external context in which an aerospace organization operates and the needs and expectations of relevant stakeholders, in order to develop the strategic direction of the organization, to manage risks effectively and to allocate resources efficiently;
- analysis of key performance indicators that can be used in the aerospace industry to assess and improve organizational performance;
- applying risk assessment methods that enable organizations to identify, assess, prioritise and mitigate risks, promoting a proactive risk management culture that supports evidence-based decision making;
- identification of criteria for evaluating and selecting aerospace suppliers that an organization can use to partner with suppliers capable of meeting demanding industry standards.

Chapter 7. Developments and theoretical contributions regarding the integrated quality-risk management in aerospace organizations

7.1. Study regarding risk management implementation in aerospace industry organizations

7.1.1. Concepts regarding risk management in the aerospace industry

The concept of risk management is described by the International Civil Aviation Organization (ICAO) as "the identification, analysis, and elimination (and/or mitigation to an acceptable or tolerable level) of those hazards, as well as subsequent risks, threatening the viability of an organization".

In general, aviation MR can be considered as the approach and actions applied in a structured and systematic manner to achieve effective and reasonable mitigation of identified and evaluated risks.

In the SR EN 9100:2018 standard, the operational MR process is supported by specific requirements within clause 8, aiming to drive increased focus on understanding the impact of risk on operational processes and making decisions regarding operational processes and actions to manage (e.g., prevention, mitigation, control) potential undesirable effects.

In aviation, space, and defense, risk is expressed as a combination of severity and the probability of potentially negatively impacting processes, products, services, customers, or end-users. In the SR EN 9100:2018 standard, operational risk management includes how the organization defines its risk assessment criteria (e.g., probability, consequences, risk acceptance) and ultimately accepting the remaining risks after implementing any mitigation actions.

While operational risk management is crucial for the organization's success, the SR EN 9100:2018 standard includes requirements to address three major risks faced by aerospace industry organizations: product safety, procurement of processes, products, and services, and prevention of counterfeit parts and customer satisfaction. These three risks concerning safety, purchased processes, products and services, and customer satisfaction are interconnected, each element affecting the other and requiring equal focus. By maintaining focus on how these risks are

handled and through efficient risk-based thinking, organizations will maximize the potential for positive risk outcomes and have a successful business [68].

7.1.2. Approaches to address risks in the aerospace industry

Risk in aviation or many other operations cannot be entirely eliminated, and many risk management activities may not be technically or financially feasible. There will always be some risk posing a danger to people, property, or the environment, but the aim of risk management is to maintain these risks within acceptable limits as determined by the industry and society.

Risk Identification

The first component of risk management is risk identification. Identifying risk is highly important because unidentified risk could ultimately cause significant issues within operations. It is recommended that each operation review its activities to identify any situation that has the potential to produce undesired and potential failures. Identified risks can stem from a wide variety of influences, such as financial, environmental, technical, and human factors. Additionally, the operation is encouraged to analyze existing policies and procedures to determine if daily processes or workflow inefficiencies could contribute to the emergence of any substantial risk.

Risk Assessment and prioritization

Identified risks are assessed based on the severity of their impact and the probability or frequency of their occurrence. It is recommended that the analysis includes probability, consequence, severity, and impact on customers. Risk criteria are established at this point, allowing the organization to determine which risks require mitigation and which risks are acceptable. Prioritizing risks enables organizations to focus their resources on addressing the most significant risks first, reducing the likelihood and impact of potential incidents [107].

Risk Mitigation

The purpose of addressing risks involves identifying and implementing necessary actions to respond to the identified risks. By addressing risks, previous risk analyses are translated into concrete measures for their reduction [16].

MR plays a vital role in addressing risk in practical terms. It requires a consistent and coherent process of objective analysis, especially for evaluating operational risks. Generally, Risk Management is a structured and systematic approach where actions are established to strike a balance between identified and assessed risks and the potential mitigation of those risks.

7.1.3. Risk assessment techniques used in the aerospace industry

The aerospace industry is highly regulated and involves high-risk activities, making risk management a critical aspect of aerospace operations. Some of the risk assessment techniques used in this industry include:

- *Fault Tree Analysis (FTA).*
- *Failure Modes and Effects Analysis (FMEA).*
- *Hazard and Operability Study (HAZOP).*
- *Event Tree Analysis (ETA).*
- *Bow Tie Analysis.*
- *Consequence/Probability Matrix* [59].

The use of risk assessment techniques in the aerospace industry is crucial to ensure the safety and reliability of its systems and operations. Selecting the appropriate technique depends on the specific analysis requirements, and these techniques can be used in combination with each other to provide a more comprehensive understanding of the risks associated with a particular system or activity.

7.1.4. Risk assessment with Failure Modes and Effects Analysis (FMEA) method

Figure 7.1. illustrates the steps to follow when conducting FMEA.

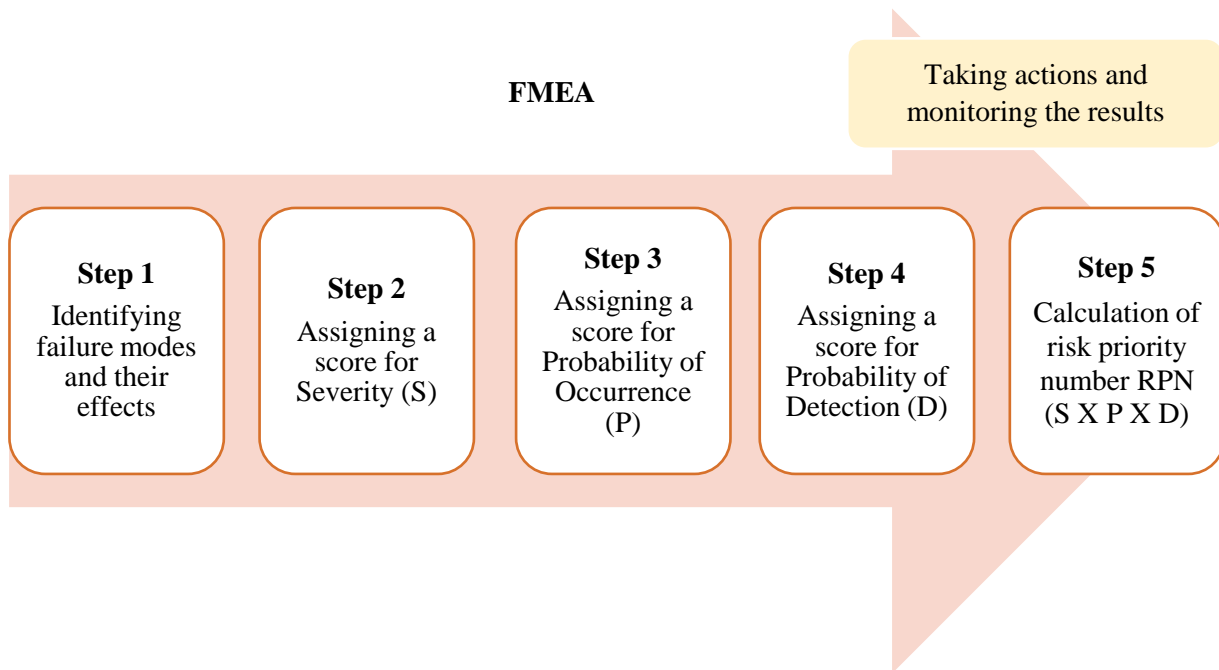


Fig. 7.1. FMEA steps (author's adaptation after [81])

Step 1. Identifying failure modes and their effects [81]

A potential failure mode refers to any situation in which a component or stage of the process cannot fulfill its intended function or functions.

For each failure mode identified, the potential effect on the system, process, product, service, customer or regulations will be determined. The effect is directly related to the ability of that specific component to perform its intended function.

Step 2. Assigning a score for Severity [81]

Generally, severity is rated on a scale from 1 to 10, where 1 is insignificant and 10 is catastrophic. Sometimes, a failure mode has more than one effect. In this case, only the score for the effect with the highest level of severity is recorded.

Step 3. Assigning a score for Probability of Occurrence [81]

The assigned score for the probability of occurrence for each risk is given by evaluating the frequency at which that particular risk occurs within the process. Because the FMEA analysis is conducted by individuals working within the process, they are well aware of what is most likely to occur within the process and what is least likely. Assessments are consequently given on a scale from 1 (almost never) to 10 (almost certain).

Step 4. Assigning a score for Probability of Detection [81]

For each cause, the current process controls are identified (such as tests, procedures, or mechanisms that the organization has in place to prevent failures from reaching the customer) that can prevent its occurrence, reduce the probability of occurrence, or detect the failure before it reaches the customer.

The probability of detection is assessed on a scale from 1 to 10, where 1 means it is almost certain that the issue will be detected, and 10 means the issue is almost impossible to detect, or there are no controls in place.

Step 5. Calculation of risk priority number [79]

The Risk Priority Number (RPN) is a numerical assessment of the risk assigned to a process or the stages of a process, as part of the FMEA analysis, where the team assigns numeric values to each failure mode that quantify the probability of occurrence, probability of detection, and severity of the

impact. RPN provides a relative ranking of risks. The potential risk increases as the RPN value increases.

The RPN is calculated using the formula for each failure mode and effect:

$$RPN = Severity \times Probability\ of\ Occurrence \times Probability\ of\ Detection \quad (7.1.)$$

Next, the risks are prioritized by sorting the RPN in descending order. This helps the team determine the most critical inputs and the causes of their failure.

In conclusion, FMEA is an important tool in risk management as it helps organizations proactively identify and analyze potential risks, prioritize these risks based on their probability and severity, and take action to reduce or eliminate these risks before they occur. By utilizing FMEA, organizations can enhance system or product reliability, reduce downtime, maintenance costs, and continuously improve their risk management practices.

7.1.5. Risk assessment using risk matrix

Figure 7.4. illustrates a combined risk and opportunity matrix. In the figure, it can be observed that the most significant risks and opportunities in the center of the matrix are located in the upper half, termed the "attention arrow" [74].

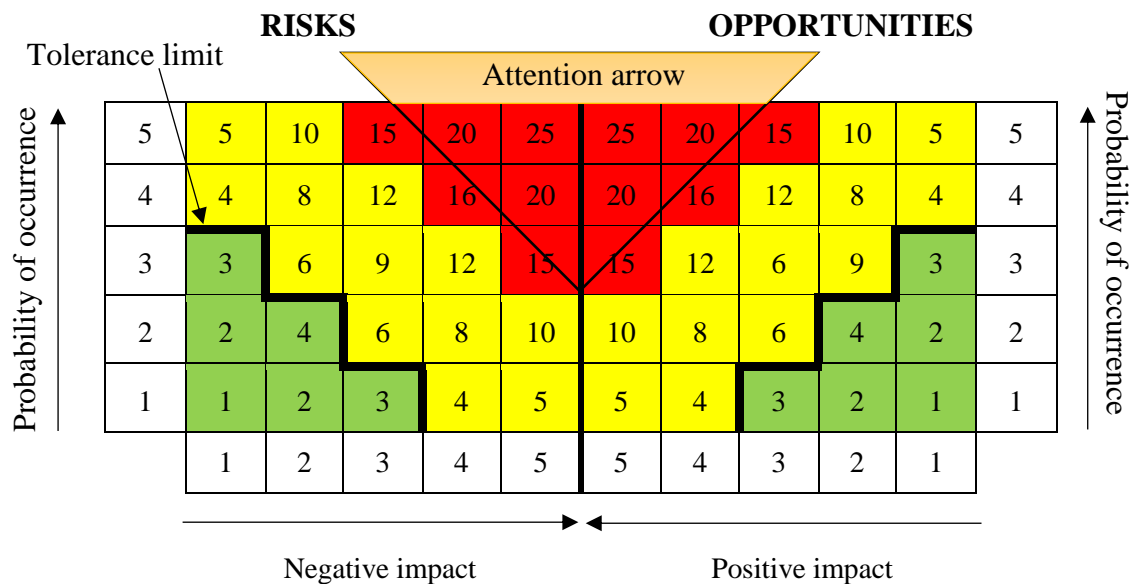


Fig. 7.4. Risks and opportunities matrix (author's adaptation after [74])

For an effective risk management, both those in the red and yellow zones require the implementation of mitigation measures. Risks in the green zone are considered as assumed risks, as they are below the risk tolerance limit.

Opportunities in the red zone will be prioritised as their implementation leads to improvements in organizational performance. Opportunities in the yellow zone, i.e. those in the green zone, require actions to be implemented to increase likelihood, impact, or both.

The risk exposure factor is a measure of the potential impact or severity of a negative risk event.

The risk exposure factor is calculated as follows:

$$Risk\ exposure\ factor = Probability\ of\ occurrence \times Negative\ impact \quad (7.2)$$

The opportunity factor is a measure of the potential benefit or positive impact of a risk event. It is calculated similarly to the risk exposure factor, but instead of estimating the financial impact of a negative event, it estimates the financial gain or benefit that could be realized when a positive event occurs.

The opportunity factor is calculated as follows:

$$\text{Opportunity factor} = \text{Probability of occurrence} \times \text{Positive impact} \quad (7.3)$$

In conclusion, the risk matrix is a widely used assessment tool that provides a visual representation of potential risks associated with a particular hazard or event. By evaluating the probability and consequences of each risk, stakeholders can prioritize and more effectively manage risks.

7.2. Designing the integrated quality-risk management system within an organization in the aerospace industry

7.2.1. Steps of designing and implementing quality management system for organizations in the aerospace industry

Establishing a SMC in the aerospace field, utilizing the requirements from the SR EN 9100:2018 standard, can be a complex task, raising several issues when the approach to implementation is not clear.

Step 1. Obtaining management support

This may not seem very significant, but the truth is that without management support for the IMS implementation, it will be very difficult to accomplish, or it might even result in complete failure. Top management plays multiple roles in the SMC, and if there is no full involvement, numerous difficulties will arise.

Step 2. Defining the organization's context and interested parties

A critical step added in the latest standard revision pertains to the requirements for determining the organization's context and the needs and expectations of stakeholders. The organization's context includes the circumstances shaping its framework and comprises both internal and external aspects that affect the organization. Regarding stakeholders, it is essential to identify those relevant to the SMC and how their needs and expectations apply to the organization.

Step 3. Defining the scope, management commitment, and responsibilities

Following the determination of the context and stakeholders, the scope of the SMC will be identified - the overall purpose intended to be achieved by the SMC. Then, quality objectives will be established along with other documented information to ensure that SMC objectives are communicated and understood.

Step 4. Defining processes and procedures

There are numerous processes and procedures outlined in the requirements of the SR EN 9100:2018 standard that are necessary for a functional SMC. It is crucial to identify these processes, their interactions, the documentation ensuring each process's intent is fulfilled, and the records required to demonstrate the correct execution of each process.

Step 5. Implementing processes, procedures, and controls

Once the processes, procedures, and controls have been defined, they can be implemented within the organization. This enables employees to start working in accordance with the new or updated documented information.

Step 6. Conducting training and awareness programs

It is not sufficient to describe processes in documented information. Additionally, it's essential for employees to receive training on these processes and be aware of how their activities impact the SMC. Training records will help demonstrate not only that this occurred but also that all employees were involved.

Step 7. Choosing a certification body

The certification body is the company that will come into the organization and audit the implemented SMC in compliance with the requirements of the SR EN 9100:2018 standard to subsequently issue a certification attesting to conformity. Finding the right certification body is crucial to benefit from audits that add value to the organization. It is necessary for external auditors

to have extensive knowledge in the industry in which the organization operates, as well as regarding the type of products and services provided.

Step 8. Operating the SMC

The certification body will compare the planned activities of the processes with what actually happens during process execution. To present the necessary records demonstrating the operation of the SMC, using the processes for a period is required. During this time, employees may identify some opportunities for improvement.

Step 9. Conducting internal audits

One of the primary ways to verify if the organization's processes are running as planned is through conducting internal audits. A schedule for internal audits covering all identified processes within the SMC will be established and then carried out. For all identified non-conformities, corrective actions will be determined to eliminate the root cause and ensure the issue does not reoccur.

Step 10. Management review

It's essential for the organization's management to be involved in reviewing the SMC to assess if it's properly implemented, effective, efficient, and improved. Top management's involvement is necessary to allocate the necessary resources for the SMC, meet customer needs, and enhance customer satisfaction.

Step 11. Conducting Stage 1 certification audit (documentation review)

During the Stage 1 certification audit, the certification body will send one or more auditors to evaluate the SMC documentation in relation to the requirements of the SR EN 9100:2018 standard to ensure nothing is missing and the documentation fulfills the intent of these requirements. They will issue a report, and for any identified non-conformities, corrective actions will be established, similar to internal audit procedures.

Step 12. Conducting Stage 2 certification audit (main audit)

The Stage 2 certification audit is considered the main certification audit. In this stage, the certification body will send auditors to evaluate each process and procedure within the SMC to determine if the evidence gathered during the operation of processes demonstrates that they meet the expected outcomes. Once again, a report will be issued, and corrective actions are necessary for any identified non-conformities.

In case the certification body's auditors determine that the SMC is in place and operational, they will recommend the organization to be certified as having a SMC that meets the requirements of the SR EN 9100:2018 standard. Subsequently, the certificate can be displayed on the organization's website and transmitted to customers. Additionally, work within the organization will continue to improve the SMC and customer satisfaction, as certification assists in promoting continual quality improvement and performance.

To maintain certification, it's necessary to conduct a surveillance audit annually and a recertification audit every three years. Surveillance audits are periodic audits that check if the organization continues to comply with the reference standard's requirements throughout the three-year certification cycle. During surveillance audits, the organization must demonstrate continual SMC improvements. The duration of a surveillance audit will depend on the organization's size and structure, the risk and complexity involved in activities, the number of standards included in the certification, and the number of locations covered by the certification scope.

7.2.2. Quality management system documentation in accordance with SR EN 9100:2018 standard

Within the SR EN 9100:2018 standard, it's quite clearly stated what must be documented. When the term "The organization **shall maintain** documented information" is used, it requires the development of a document. Conversely, when the term "The organization **shall retain** documented information" is used, it necessitates the creation of a record that demonstrates activities have been carried out as planned. An example of a process that is documented is the process of controlling nonconforming products and services.

When implementing an SMC, especially in the aerospace industry, there is a risk that a lot of documentation is unnecessarily developed in the belief that this will improve the system or that it is a requirement of SR EN 9100:2018. In fact, this edition has become even more lenient in terms of the number of documented procedures required by the standard. This leaves it up to each organization to determine what is important to document. The SR EN 9100:2018 standard uses the term "documented information", but it is useful to separate this into two categories: mandatory documents and mandatory records.

Following analysis of the requirements in SR EN 9100:2018, we have developed Table 7.6 in which we have listed each of this mandatory documented information, the clause where it is identified in the standard, and its type (D - document or Î - record).

Table 7.6. List of mandatory documented information required by SR EN 9100:2018
(author's contribution)

Mandatory documented information	The clause in the SR EN 9100:2018	Type of documented information
Scope of the SMC	4.3	D
List of relevant interested parties (can be included in the quality manual)	4.4.2	D
Scope of the SMC, including limitations and applicability (may be included in the quality manual)	4.4.2	D
Description of the processes required for the SMC and their application throughout the organization (can be included in the quality manual)	4.4.2	D
Sequence and interaction of processes within the SMC (may be included in the quality manual)	4.4.2	D
Responsibilities and authorities for the SMC processes (may be included in the quality manual)	4.4.2	D
Evidence that the SMC processes are carried out as planned	4.4.2	Î
Quality policy	5.2	D
Quality objectives and plans for achieving them	6.2	D
Calibration records of monitoring and measuring equipment	7.1.5.1	Î
Records of maintenance and calibration of monitoring and measuring equipment	7.1.5.2	Î
Competence records	7.2	Î
Information needed to provide confidence that processes have been executed as planned and are compliant with requirements	8.1	Î
Records describing: a) results of the review of requirements related to products and services; b) any new requirements for products and services.	8.2.3.2	Î

Table 7.6. List of mandatory documented information required by SR EN 9100:2018
(author's contribution) - continuation

Mandatory documented information	The clause in the SR EN 9100:2018	Type of documented information
Information needed to prove compliance with design and development requirements	8.3.2	Î
Records of design and development inputs	8.3.3	Î
Records of design and development controls	8.3.4	Î
Records of design and development outputs	8.3.5	Î
Records of design and development changes	8.3.6	Î
Procedures for controlling externally provided processes, products and services (outsourced processes)	8.4.1	D
Information on results of evaluation, selection, performance monitoring and re-evaluation of external suppliers	8.4.1	Î
Records on the characteristics of products to be produced, services to be provided or activities to be performed; and results to be achieved	8.5.1	Î
Records on the results of verification of the production process	8.5.1	Î
Records required to enable traceability (where necessary)	8.5.2	Î
Record of activities performed when customer property is lost, damaged or found to be unfit for use	8.5.3	Î
Record of changes in production and service provision	8.5.6	Î
Evidence of conformity and release of product and service	8.6	Î
Process for controlling non-compliant products and services	8.7.1	D
Record of nonconformity	8.7.2 & 10.2.2	Î
Results of monitoring and measurement activities	9.1.1	Î
Analysis and evaluation of monitoring and measuring data and information	9.1.3	Î
Evidence of the implementation of the audit programme and audit results	9.2.2	Î
Records of management review	9.3	Î
Process for managing nonconformity and corrective actions	10.2.1, 10.2.2	D
Records of non-conformities and corrective actions	10.2.2	Î

Implementing effective documentation practices in accordance with the SR EN 9100:2018 standard provides several benefits to organizations, such as:

- **Consistency and standardization:** Well-documented processes and work instructions promote consistency and standardization in all operational activities. This minimizes errors, reduces rework, and enhances efficiency.

- **Compliance and certification:** Comprehensive documentation enables organizations to achieve and maintain compliance with the requirements of the SR EN 9100:2018 standard. This simplifies the certification process and ensures a successful outcome during external audits.

- **Continual improvement:** Documentation serves as a basis for data analysis, identifying trends, and implementing improvement initiatives. It facilitates the identification of areas for improvement, leading to enhanced product quality and customer satisfaction.

- **Knowledge transfer and ensuring business continuity:** Documenting processes and procedures preserves organizational knowledge and facilitates smooth knowledge transfer during workforce turnover. This allows organizations to maintain operational continuity and mitigate risks associated with knowledge loss.

Documentation is a fundamental component of the SMC in compliance with the SR EN 9100:2018 standard. It provides the structure, clarity, and transparency necessary for aerospace industry organizations to ensure compliance, meet customer expectations, and drive continual improvement.

7.2.3. Risk management in the quality domain applied in aerospace industry organizations

MR in the quality domain is a systematic process involving the identification, evaluation, control, communication, and review of risks that could impact the quality of products, services, or processes within an organization. It's an integral part of quality management focused on identifying potential issues before they occur. The goal of quality risk management is to ensure that the products and services delivered meet customer expectations and comply with applicable regulations [80].

The steps involved in implementing the risk management process within the SMC are illustrated in figure 7.6.

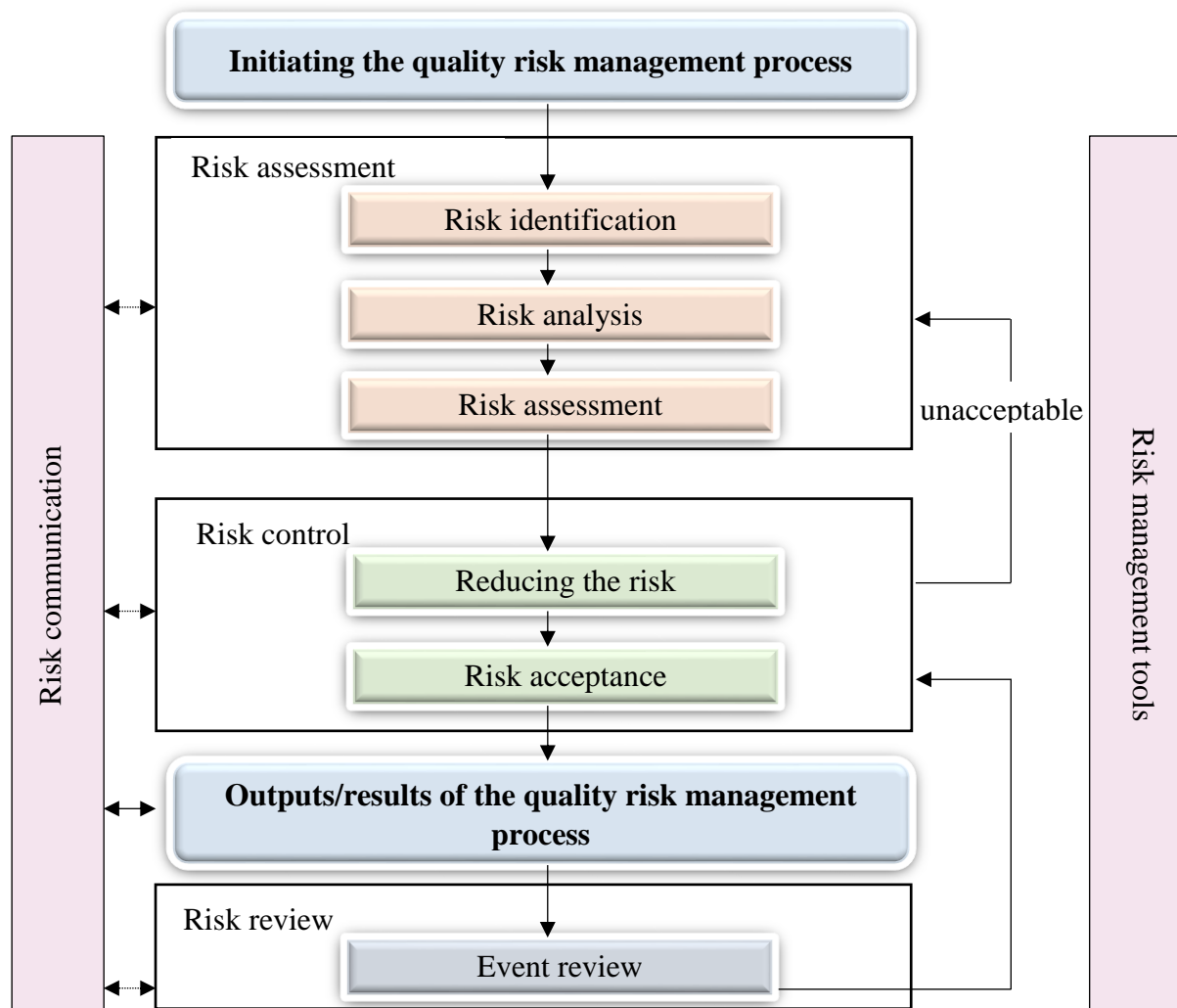


Fig. 7.6. Steps of implementation of the risk management process in the SMC [84]

Risk identification involves identifying hazards, followed by analyzing and estimating the risks associated with exposure to those hazards. Quality risk assessments begin with a well-defined description of the issue or a risk question. When the risk in question is well defined, an appropriate risk management tool and the types of information that will address the risk issue will be easier to identify.

Risk analysis is the process of estimating the probability and impact of identified hazards. This can be done through either a qualitative or quantitative approach by correlating the probability of occurrence with the severity of the risk. In some risk management tools, the ability to detect harm (detectability) also influences risk estimation.

Risk assessment compares the identified and analyzed risk with given risk criteria. Risk assessments take into account evidence for all three fundamental questions stated earlier. The robustness of the dataset is an important factor for the quality of the results of an effective risk assessment.

Risk control involves making decisions to mitigate and/or tolerate risks and bring them to an acceptable level. The effort expended on risk control is proportional to the level of risk. Decision-makers may employ various processes, including cost-benefit analysis, to determine the optimal level of risk management.

Risk reduction focuses on processes aimed at mitigating or preventing quality risk when it exceeds an established acceptable threshold. Risk reduction may involve actions taken to mitigate both severity and probability.

Risk acceptance represents the decision to tolerate risk. This acceptance can be a formal decision to tolerate residual risk or a passive choice in which residual risks are not explicitly addressed.

Risk communication involves the exchange of information regarding risk and quality risk management between decision-makers and other stakeholders. This communication can occur at any stage of the risk management process. The output data/results of the quality risk management process are appropriately communicated and documented.

For **risk review**, a mechanism for event review or monitoring is implemented. It is recommended that quality risk management be an integral and ongoing part of the quality management process. The results obtained from the risk management process are periodically reviewed to consider new information and accumulated experience.

Quality risk management supports a scientific and practical approach to the decision-making process. It provides documented, clear, and repeatable methods to follow the steps of the quality MR, relying on current information about assessing the probability, severity, and sometimes detectability of risk. Currently, quality-related risks have often been assessed and managed through various informal means (empirical and/or internal procedures). These methods were based on compilations of observations, trend analysis, and other relevant information.

In conclusion, risk management processes and quality management are inherently linked within an aerospace organization. It is essential for organizational success that both are implemented efficiently and that both processes are seamlessly connected to each other.

7.3. Relationship between quality management, risk management, and safety management in the aerospace industry

7.3.1. Relationship between quality management and safety management in the aerospace industry

The relationship between quality management and safety management in the aerospace industry is one of collaboration and integration. While quality management focuses on meeting customer requirements and maintaining quality standards, safety management emphasizes identifying and reducing safety risks. By integrating processes, aligning standards and regulations, and encouraging continuous improvement, aerospace organizations can enhance both the quality and safety of their operations, ensuring customer satisfaction as well as the well-being of personnel and the public.

7.3.2. Relationship between risk management and safety management in the aerospace industry

MR and safety management in the aerospace industry are closely related and complementary disciplines. They collaborate to identify, assess, and mitigate risks and hazards, establish safety measures, promote a safety culture, comply with regulations, and continuously improve safety standards. Through their integrated efforts, they aim to ensure the highest level of safety and security in the aerospace industry.

7.3.3. Relationship between the integrated quality-risk management system and the safety management system in the aerospace industry

The relationship between SIMCR and SMS in the aerospace industry is based on their common objective of maintaining safety, promoting quality, and managing risks within organizations. SIMCR integrates the principles of quality and risk management, while SMS specifically focuses on safety management practices. Together, they contribute to the overall safety culture and performance in the aerospace industry.

SIMCR combines quality and risk management into a unified system. It acknowledges that safety is a critical aspect of overall quality and integrates risk management principles to identify and mitigate potential safety risks. On the other hand, SMS focuses exclusively on safety management practices, aiming to prevent accidents, incidents, and injuries. SIMCR provides a framework to ensure that safety aspects are integrated into quality improvement initiatives.

Some of the advantages of integrating SIMCR and SMS include:

- **Enhanced Safety:** Integrating SIMCR and SMS allows organizations to comprehensively identify and manage risks, leading to improved safety outcomes. By incorporating safety considerations into quality management processes, potential safety risks can be proactively addressed, reducing the likelihood of accidents or incidents.
- **Streamlined Processes:** Integrating SIMCR and SMS allows for process streamlining, eliminating redundancies, and optimizing resource utilization. By leveraging common risk assessment methodologies and data, organizations can avoid duplicating efforts and achieve operational efficiency.
- **Holistic Decision-Making:** Integrating SIMCR and SMS provides decision-makers with a holistic view of risks, quality factors, and safety considerations. This comprehensive perspective facilitates informed decision-making, where the impact on both quality and safety can be evaluated simultaneously.
- **Improved Organizational Adaptability:** The integrated approach enhances organizational adaptability by fostering a risk-aware culture and continuous improvement. Organizations that efficiently integrate SIMCR and SMS are better prepared to handle unforeseen events, adapt to changes, and sustain long-term success.

In conclusion, SIMCR and SMS have a mutually reinforcing relationship within the aerospace industry. SIMCR integrates quality and risk management principles, including safety considerations, while SMS specifically focuses on safety management practices. Together, they contribute to maintaining a strong safety culture, promoting quality improvement, complying with standards and regulations, and driving continuous improvement efforts within organizations operating in the aerospace industry.

Chapter 8. Practical contributions regarding the implementation of integrated quality-risk management in aerospace industry organizations

8.1. Case study regarding the implementation of an integrated quality-risk management system in an aerospace industry organization

8.1.1. Integrated quality-risk management system implemented in an aerospace industry organization

To maintain data confidentiality, an organization in the aerospace industry, referred to as ABC Aerospace, was considered for this case study. The primary activity of this organization involves the design and development of aerospace vehicles.

Established in 2001, ABC Aerospace has served the engineering industry's needs through entrepreneurial concept development, aircraft modifications, conceptual projects of aerial vehicles, small-scale technological demonstrators, research in hybrid propulsion systems, and niche technical support. With these capabilities, ABC Aerospace will continue to provide cutting-edge system projects, development, testing, and demonstrative solutions to the engineering community.

To ensure it gets the best performance every time, ABC Aerospace decided to develop an integrated organizational framework that incorporates MR in all organizational processes, strategies, and management practices. This framework is also reflected in the organization's values and culture. As a result, top management has been actively involved in implementing a SIMCR in accordance with the SR EN 9100:2018 and SR ISO 31000:2018 standards.

To ensure compliance with clause 4.1. "Understanding the organization and its context" from the SR EN 9100:2018 standard, ABC Aerospace conducted a SWOT analysis and a PESTLE analysis. The SWOT analysis is presented in table 8.1.

Table 8.1. SWOT analysis of ABC Aerospace (author's contribution)

	Beneficial to the achievement of objectives	Jeopardizing the achievement of objectives
	Strengths	Weaknesses
Internal source (the organization)	<ul style="list-style-type: none"> Solid technological expertise in the field of aerospace engineering. Strong engineering capabilities for designing and developing complex aerospace systems. Highly skilled workforce. Solid financial position. Good relationships with suppliers and customers. High level of customer satisfaction. Good returns on capital expenditures. 	<ul style="list-style-type: none"> Dependency on government funding for a significant part of revenues. Long development cycles. Dependence on suppliers. High operational costs due to the complexity and safety requirements of the aerospace industry. Limited market diversification, with a focus on defense and space applications. High level of competition.

Table 8.1. SWOT analysis of ABC Aerospace - *continuation* (author contribution)

	Opportunities	Threats
External source (external environment)	<ul style="list-style-type: none"> • Growing demand for air transport. • Advances in technology. • The shift to green energy. • Military modernisation. • Expansion of the portfolio of products and services provided by ABC Aerospace. • Opportunities for partnerships and collaborations with other companies in the industry. 	<ul style="list-style-type: none"> • Increased competition in the aerospace industry. • Economic crises. • Environmental concerns. • Technological change. • Cyber security threats. • Supply chain disruptions. • Geopolitical risks.

PESTLE analysis is a tool used to evaluate external factors that may impact a business or organization. The acronym represents the political, economic, socio-cultural, technological, legal, and environmental factors.

The political factors that might influence operations within ABC Aerospace are as follows:

- *Government regulations* - The aerospace industry is heavily regulated, and changes in government regulations can impact industry operations and profitability. For instance, new safety regulations might increase production costs and reduce profit margins.
- *Government funding and contracts* - ABC Aerospace relies on government funding and contracts to sustain its design and development activities. Changes in government funding or public procurement policies could influence the organization's ability to initiate new design and development projects.

The economic factors that might influence operations within ABC Aerospace are as follows:

- *Funding* - The availability of funding for research and development projects is crucial for ABC Aerospace. Economic crises or recessions can lead to reduced funding, which may limit the scope and quality of design and development projects.
- *Market demand* - The demand for aerospace products and services can fluctuate based on economic conditions such as changes in consumer confidence, economic growth, and business cycles.

The socio-cultural factors that could influence operations within ABC Aerospace are as follows:

- *Consumer preferences and trends* - Consumer preferences and trends can impact the demand for aerospace products. For example, a trend toward sustainable travel might drive demand for aircraft with more fuel-efficient capabilities.
- *Workforce diversity and inclusion* - A diverse and inclusive workforce can lead to more creative and innovative design and development processes and can also help ABC Aerospace attract and retain highly skilled personnel.

The technological factors that can influence the activities carried out within ABC Aerospace are as follows:

- *Advances in materials and manufacturing technologies* - New materials and manufacturing technologies can enhance the design and development of aerospace products, such as reducing weight and increasing fuel efficiency.
- *Cybersecurity* - The aerospace industry heavily relies on digital technologies, and cybersecurity is crucial to protect against cyber threats that could impact the safety and reliability of aerospace products.

The legislative factors that can impact the activities carried out within ABC Aerospace are as follows:

- *Compliance with regulations* - The aerospace industry is heavily regulated. Aerospace companies adhere to various safety and environmental regulations, as non-compliance with these regulations may result in fines, legal actions, and damage to the company's reputation.
- *Contractual obligations* - ABC Aerospace works with suppliers, subcontractors, and partners and ensures that contractual obligations are met to ensure the timely and successful design and development of their products.

The environmental factors that can influence the activities carried out within ABC Aerospace are as follows:

- *Noise pollution* - Air traffic can generate noise pollution, and ABC Aerospace designs and develops products to minimize noise pollution by using advanced technologies or altering flight patterns.
- *Air quality* - Aircraft emissions can have a negative impact on air quality, and ABC Aerospace takes measures to reduce emissions to improve air quality.

Interested parties are individuals or groups that can affect or be affected by the SMC implemented within the organization and its ability to provide products or services that meet customer requirements. Identifying and understanding the needs and expectations of interested parties are essential for developing a customer-centric SMC. Table 8.2 identifies the relevant interested parties, their needs and expectations, and the associated risks and opportunities.

Table 8.2. List of the relevant interested parties from ABC Aerospace (**author's contribution**) - *extract*

Interested parties	Needs and expectatlons	Risk / opportunity	Likelihood of occurrence	Impact (positive/negative)	Risk exposure / Opportunity factor	Mitigation / valorization actions
Customers	Compliant products and services delivered on time; Compliance with legal and regulatory requirements; Rapid response to and resolution of complaints	R: Loss of revenue and trust due to low customer satisfaction	2	4	8	Plan and implement appropriate actions to ensure compliance of products and services with customer requirements
		O: Retaining existing customers and attracting new customers	3	4	12	Ensuring a high level of customer satisfaction by providing compliant and timely products and services
Top Management and Shareholders	Financial stability and return on investment; Operating legally and safely to prevent legal liability; Promote continuous improvement; Improving market reputation and exceeding customer expectations	R: Loss / reduction in investment levels due to loss of confidence from shareholders	2	4	8	Holding regular meetings with shareholders to present the organization's performance
		R: Risk of prosecution for breaching legislation	2	4	8	Implementation of all legal and regulatory requirements; Providing legal advice and counselling to employees for the smooth running of activities
		O: Creating an organizational culture that encourages creativity, innovation and analytical thinking	3	4	12	Establishing policies and procedures that promote innovation and productivity
Partners	Compliance with agreements between the parties; Honesty and integrity in business dealings; Effective communication; ...	R: Existence of disagreements or misunderstandings between partners	2	4	8	Clear definition of each partner's responsibilities; Maintaining an effective communication process

By identifying and considering the needs and expectations of the interested parties, ABC Aerospace can better align its SMC with customer requirements, manage risks, and enhance overall interested parties satisfaction.

In conclusion, considering the organization's context and the needs and expectations of stakeholders helps organizations design and implement a relevant and efficient SMC that responds to their specific circumstances. This allows for a holistic approach to quality management and supports the organization in achieving its strategic objectives, meeting customer needs, and complying with relevant regulations.

8.1.2. Development of process maps within an aerospace industry organization

The SR EN 9100:2018 standard requires an organization to follow a process-based approach when managing its business. Process maps are ideal for this purpose.

Process mapping is a visual representation of a sequence of steps or activities involved in a particular process. It helps to understand, analyse and improve processes within an organization. At the same time, process mapping is the basis for continuous improvement of the SMC, which enables an organization to analyse key business processes. Once the process map is established, the organization can work to ensure that its processes are effective (the right process is followed every time) and efficient (continuously improved to ensure that processes use as few resources as possible).

Process mapping is important for several reasons, including:

- Identifying inefficiencies - by mapping a process, one can identify areas where the process is inefficient, such as bottlenecks or unnecessary steps.
- Improving communication - a process map can help improve communication within an organization by providing a shared understanding of the process. This can reduce confusion and ensure that everyone is using the same common language.
- Improve customer satisfaction - a well designed process map can help ensure that the process meets the needs of the customer. By understanding the process from the customer's perspective, improvements can be made to increase customer satisfaction.
- Reduce errors and rework - by identifying areas where errors or rework are likely to occur, steps can be taken to reduce these problems. This can help save time and resources and improve the quality of the final product or service.
- Create a framework for continuous improvement - a process map can provide a baseline for measuring performance and identifying areas for improvement. By monitoring the process and making changes as needed, you can continuously improve the process over time.

Whether providing a service or making a product, successful organizations are constantly looking for better, faster and cheaper ways to satisfy their customers. Process mapping will give organizations an agreed and accurate understanding of their current processes and therefore provide new sources of stimulating ideas to solve problems, find improvements and map what the process looks like. Within each organization, processes are established and for its activities to be carried out effectively, it is necessary to understand the interrelationship between them, identifying any gaps in the internal structure.

The turtle diagram is a visual tool that displays all aspects of a process, including inputs, outputs, measurement criteria and other relevant information that helps to improve the efficiency of organizational processes [104].

The turtle diagram consists of four legs, (who, what, how, and units of effectiveness), a head (inputs) and a tail (outputs) [104].

Figure 8.1 contains the process map of the SIMCR and Figure 8.2 illustrates the turtle diagram for the overall management process.

Fig. 8.1. Process map of the integrated quality-risk management system - ABC Aerospace (author's contribution)

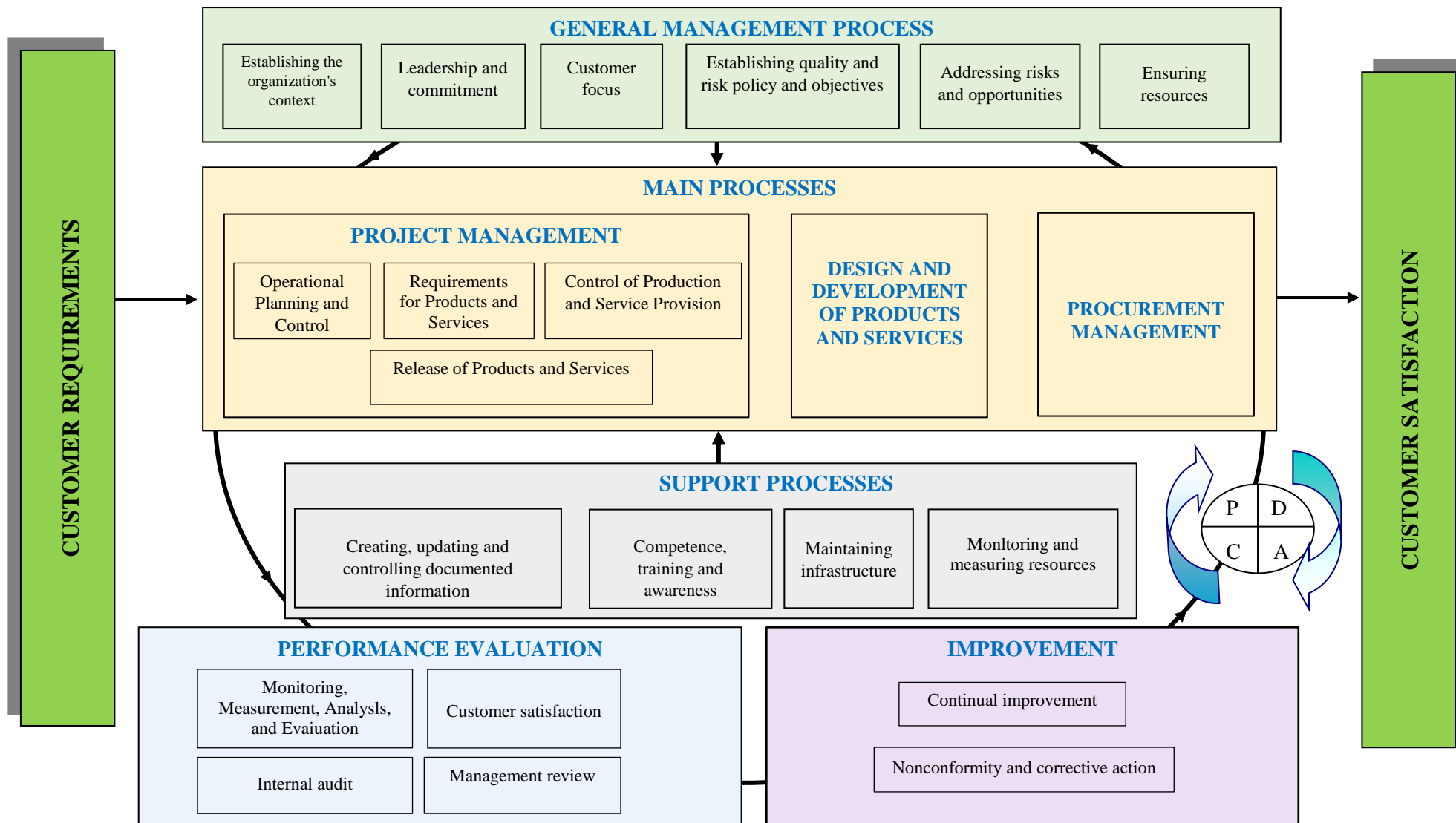
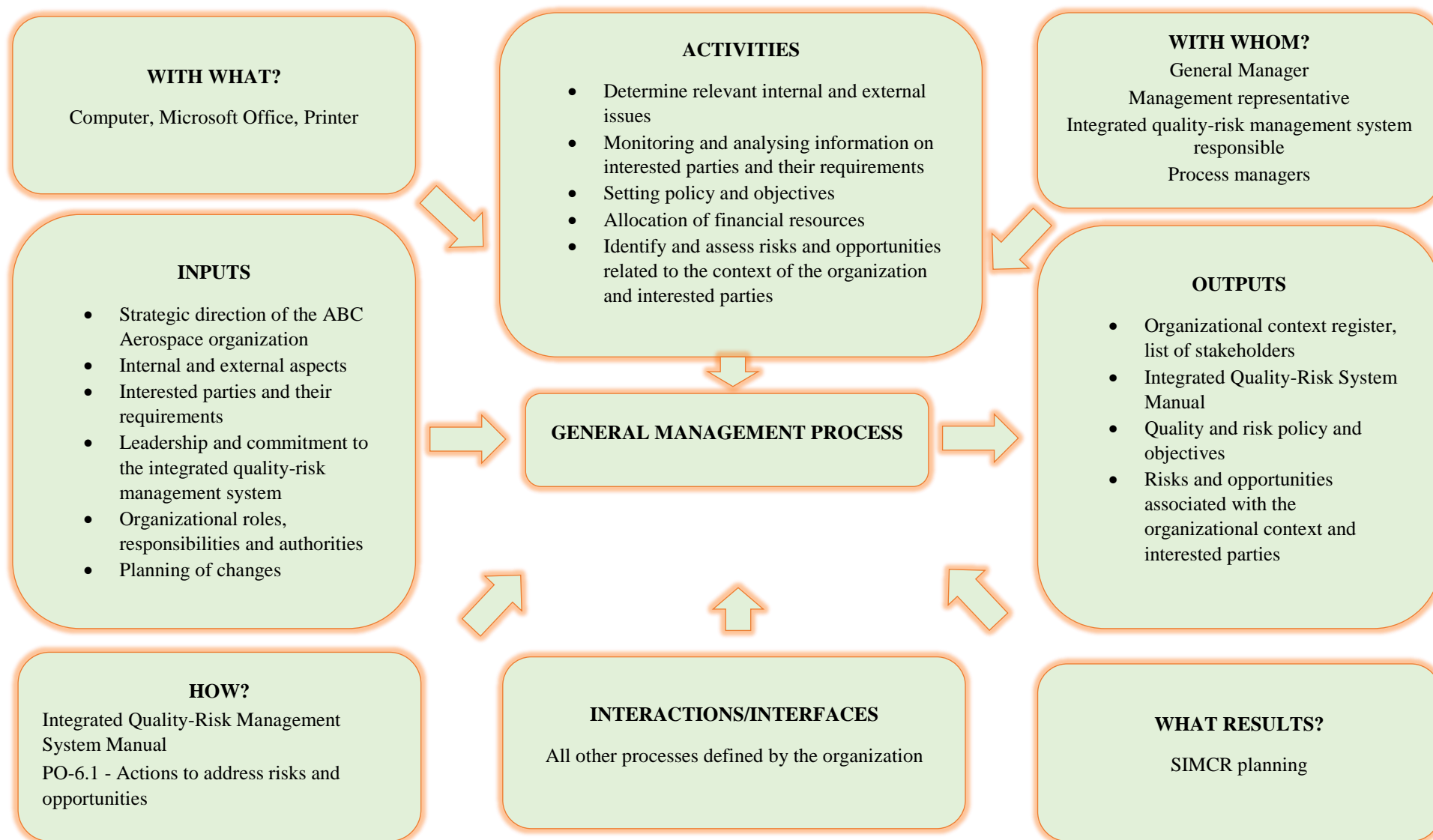


Fig. 8.2. Turtle diagram for the general management process (author's contribution)



Turtle diagrams can be simple one-page process maps that allow the intended process and knowledge of how it works to be quickly communicated so that its actual results can be evaluated and, if necessary, modified.

In conclusion, process mapping is a valuable tool for organizations that want to streamline operations, improve communication, reduce risk and drive continuous improvement. It helps foster a culture of efficiency, effectiveness and collaboration, leading to improved performance and better outcomes for the organization and its interested parties.

Whether the organization is made up of one person or thousands, for it to be successful, it needs to get to the point where all its employees understand what is needed, when it is needed and how to effectively implement it. The integrated quality-risk management system is designed to do just that.

8.1.3. Policy and objectives of the integrated quality-risk management system within an aerospace industry organization

The Quality and Risk Policy aims to achieve a balance between providing high quality, reliable products and managing the inherent risks associated with the industry. By effectively managing quality and risk, aerospace organizations can maintain their reputation, ensure customer satisfaction and support the safety of aerospace systems. Establishing a quality and risk policy involves creating a comprehensive document that outlines the organization's approach to managing both quality and risk.

The quality and risk policy is a documented statement outlining the organization's commitment to quality and its approach to managing the risks associated with its products, services and processes.

Quality and risk objectives provide a framework for improving performance, managing risk, meeting customer expectations, complying with regulations and driving overall organizational success. They create a structured approach to quality and risk management, aligning efforts across the organization and enabling continuous improvement and innovation.

In SR EN 9100:2018, requirements for planning the achievement of quality objectives have been included. As part of the plan for achieving quality objectives, it is necessary for the organization to determine what needs to be done, what resources it needs, who will do it, when it needs to be done and how the results will be evaluated. With the plan in place, progress towards achieving the quality objectives can be monitored.

According to clause 6.2 of SR EN 9100:2018, **”The organization shall establish objectives”**, not **”Top management”**, which means that several employees with different specialisations will be involved in developing objectives for the organization. The purpose of this approach to the requirement is to really turn them into organizational objectives, which means that it is recommended that all staff know the objectives and what each can do to support their achievement.

The quality and risk objectives achievement plan is a strategic plan that outlines the specific actions the organization will take to achieve its quality and risk management objectives.

In Table 8.3 I have developed the ABC Aerospace quality and risk objectives achievement plan. These objectives are specific, measurable, achievable, relevant and time-bound (SMART).

Table 8.3. ABC Aerospace quality and risk achievement plan (**author's contribution**) - *extract*

No.	Objective	Target	Performance indicator	Actions to achieve the objective	Responsible	Resources	Term
1.	Promote ABC Aerospace nationally and internationally to increase its visibility and support aerospace excellence	Min. 1 international conference/year Min. 1 national conference/year	Number of international and national conferences attended by ABC Aerospace	Dissemination of the results of the activities carried out within ABC Aerospace through the production of articles	Scientific Director Staff of the dep. Research and Development	Human resources: staff of the dep. Research and Development Material resources: computer, office equipment, consumables, financial resources for conference fees	31.12.2022
2.	Maintaining a low number of risks that have materialised into incidents	Max. 10 % risks materialised in incidents	(No. of materialised risks / No. of identified risks) x 100	Establish an appropriate risk management strategy; Implement effective risk mitigation measures	EGR	Human resources: EGR members Material resources: computer, office equipment, consumables	31.12.2022
3.	Maintain an effective process to manage all risks identified ...	100% identified risks monitored ...	(No. of risks monitored / No. of risks identified) x 100 ...	Conduct regular risk assessments and continuous monitoring for all risks; Determining increased threat levels ...	EGR ...	Human resources: EGR members Material resources: computer, office equipment, consumables ...	31.12.2022

Table 8.4 below contains the ABC Aerospace risk and opportunity register. Within this table I have identified and assessed the risks and opportunities that may affect, respectively favour the achievement of the objectives set by the organization.

The register of risks and opportunities within ABC Aerospace has been developed according to the methodology presented in sub-chapter 7.1.5 "Risk assessment using risk matrix".

Table 8.4. ABC Aerospace risk and opportunity register (**author's contribution**) - *extract*

Risk / Opportunity	Potential impact/benefit	Likelihood of occurrence	Impact (positive/negative)	Risk exposure / Opportunity factor	Mitigation / valorization actions
GENERAL MANAGEMENT PROCESSES					
R: Lack of strategic planning	Missed opportunities, low competitiveness, low profitability	3	4	12	Development and implementation of a comprehensive strategic plan, regular review and update of strategic objectives
R: Inefficient communication	Misunderstandings, decreased productivity, damaged relationships	4	3	12	Implement clear communication protocols, provide regular communication training for employees
R: Failure to meet compliance requirements	Fines, legal expenses, damage to the organization's reputation	3	5	15	Regular review of regulatory requirements, involve compliance experts in business processes, conduct regular compliance audits
R: Cybersecurity breaches	Loss of sensitive information, damage to organization's reputation, regulatory fines	3	5	15	Implement cybersecurity protocols, regularly train staff on cybersecurity best practices, conduct regular security audits
R: Economic crisis	Reduced sales revenue, reduced profitability, reduced project funding	2	5	10	Developing and implementing a business continuity plan, diversifying revenue streams, maintaining good relations with creditors

Table 8.4. ABC Aerospace risk and opportunity register (**author's contribution**) – continuation - extract

Risk / Opportunity	Potential impact/benefit	Likelihood of occurrence	Impact (positive/negative)	Risk exposure / Opportunity factor	Mitigation / valorization actions
O: Developing an innovation culture	Stimulating creativity, improving problem solving, increasing competitiveness	3	5	15	Encourage and reward innovation, participate in innovation training, implement innovation management processes
O: Expanding into new markets	Increasing income, reducing dependence on current markets, increasing competitiveness	3	5	15	Conduct market research, identify potential new markets, develop market entry strategies
PROJECT MANAGEMENT PROCESS					
R: Constraints related to financial, material or human resources	Project schedule delays, increased costs, reduced product quality	3	4	12	Planning and resource allocation in advance, regular monitoring of resource availability, prioritisation of critical tasks
R: Communication breakdowns with interested parties or between project implementation team members	Project schedule delays, increased costs, reduced product quality	3	3	9	Develop and maintain communication protocols, communicate regular project updates with stakeholders, encourage open communication between team members
R: Budget overruns	Reduced profitability, reduced funding for other projects, increased debt	4	4	16	Use project management tools to track expenditures and identify cost overruns, prioritize critical expenditure activities, adjust project scope as necessary

Table 8.4. ABC Aerospace risk and opportunity register (**author's contribution**) – continuation - extract

Risk / Opportunity	Potential impact/benefit	Likelihood of occurrence	Impact (positive/negative)	Risk exposure / Opportunity factor	Mitigation / valorization actions
R: Technical problems	Project schedule delays, increased project costs, reduced quality	3	3	9	Performing thorough technical evaluations, involving technical experts in project planning, implementing quality control processes.
R: Delays during project implementation	Project schedule delays, increased project costs, reduced quality	4	4	16	Develop and maintain a realistic project schedule, use project management tools to monitor progress, implement schedule recovery strategies if necessary
R: Issues related to supplier performance	Project schedule delays, reduced project quality, higher project costs	3	3	9	Identify and qualify alternative suppliers, maintain good relationships with suppliers, implement supplier performance management processes
O: Conduct periodic risk assessments	Effective risk management, improved project results	4	5	20	Establish a regular risk assessment process, involve project team members in the risk assessment process, implement risk mitigation strategies
O: Implementation of agile project management methodologies	Increased flexibility, improved project outcomes, increased stakeholder involvement	2	4	8	Conducting a thorough assessment of current project management processes, training staff on agile methodologies, establishing a dedicated team to implement it

In conclusion, it is recommended that the plan for achieving quality and risk objectives should be flexible and adaptable to changing circumstances. By continuously monitoring progress and making adjustments as necessary, the organization can ensure that its objectives are achieved and that risks are managed effectively.

8.1.4. Study on key performance indicators used in the aerospace industry to assess and improve organizational performance

SR EN 9100:2018, SR EN 9110:2018 and SR EN 9120:2018 standards require each organization to continuously improve its performance and determine actions to ensure that performance aligns with established goals. Relevant Key Performance Indicators (KPIs) are used to measure an ongoing activity with the aim of maximising the likelihood of achieving the target for that activity.

The main categories of KPIs used in the aerospace industry are as follows:

- A. Key performance indicators for procurement.
- B. Key performance indicators for customer relations.
- C. Key performance indicators for delivery.
- D. Key performance indicators for design and development of products and services.
- E. Key performance indicators for production.
- F. Key performance indicators for project/programme planning and management.

A. Key performance indicators for procurement (author's adaptation after [101])

A1. Purchase order performance

Purchase order performance contains the number of purchase orders that were submitted to suppliers in a timely manner in accordance with business needs and the supplier's contractual delivery time divided by the total number of purchase orders submitted in a time period, as follows:

$$I_1 = \frac{\text{Number of purchase orders sent on time in a period}}{\text{Total number of purchase orders in the period analysed}} \times 100, [\%] \quad (8.1)$$

The indicator measures the number of purchase orders sent on time against the total number of purchase orders. An example of the calculation of the indicator is given in Table 4.2.

Tabelul 4.2. Purchase order performance (author's adaptation after [99])

Purchase orders sent on time	455
Purchase orders sent late in relation to the needs of the organization	26
Purchase orders sent late in relation to the contractual delivery deadline	12
Total purchase orders released	493

$$I_1 = 455 / 493 \times 100\% = 92,29\%$$

A2. Confirmation rate for direct purchase orders

This indicator includes the percentage of purchase orders for direct materials confirmed by suppliers within the agreed timeframe.

The indicator is calculated as follows:

$$I_2 = \frac{\text{Number of direct purchase orders confirmed on time in a period}}{\text{Total number of direct purchase orders confirmed in the period analysed}} \times 100, [\%] \quad (8.2)$$

An example of the calculation of the indicator is given in Table 8.6.

Table 8.6. Confirmation rate for direct purchase orders (author's adaptation after [101])

Total purchase orders confirmed in December 2021 for all materials	344
Total purchase orders confirmed in December 2021 for direct materials	148
Purchase orders for direct materials confirmed on time (according to the due date mentioned in the contract/purchase order or organization standard)	122

$$I_2 = 122 / 148 \times 100\% = 82,43\%$$

B. Key performance indicators for customer relations (author's adaptation after [70])

B1. In-service failures/quality issues

In-Service Failures/Quality Issues include the number of the item non-conformities or quality issues (occurrences for a certain period of time or number of delivered products) that have not been detected before delivery to the final operator / final customer and have generated specific field actions after entry into service and within the warranty period, as follows:

$$I_5 = \frac{\text{Total number of items with non-conformities after entry into service}}{\text{Total number of items shipped}} \times 100, [\%] \quad (8.5)$$

The KPI measures the non-quality that has been exported to the operator or final customer and all quality filters have failed to detect and contain.

Example: Seven items have been claimed by the customer as being nonconforming after entry into service. The supplier has shipped 15000 items which are in service or within the warranty period.

$$I_5 = 7 / 15000 \times 100 = 0,046 \%$$

B2. Early in-service failures/non-quality issues

Early in-service failures/non-quality issues consist of the number of the item non-conformities or quality issues that have not been detected before delivery to the final operator / final customer and have been raised during the first weeks or months of service, as follows:

$$I_6 = \frac{\text{Non-conformities or quality Issues}}{\text{Items delivered}} \times 100, [\%] \quad (8.6)$$

This KPI measures the non-quality that the organization has not been capable to detect and correct before delivery and has immediate negative impact on the customer of operator at or very soon after the start of operations of the product.

The example in Table 8.8 shows the distribution of non-conformities/quality issues raised one month after delivery.

Table 8.8. Early in-service failures/non-quality issues (author's adaptation after [70])

Items delivered	Non-conformities	Customer / operator complaints	Warranty Claims
4620	4	3	2

$$I_6 = 9 / 4620 \times 100\% = 0,194 \%$$

C. Key performance indicators for delivery (author's adaptation after [71])

C1. Rate of non-conforming items identified by the customer

Rate of non-conforming items identified by the customer contains the number of non-conforming items under the organization's responsibility in relation to the number of items delivered by the organization in a given period and is calculated as follows:

$$I_7 = \frac{\text{Number of nonconforming items under the organisation's responsibility}}{\text{Number of items delivered during the period}} \times 100, [\% \text{ or PPM}] \quad (8.7)$$

The KPI measures the number of items delivered to the customer and subsequently identified by this customer as not compliant to the applicable definition or specification. It excludes non-conformities that are not under liability of the organization (e.g. parts damaged by the customer during installation).

Example: In one calendar month 4320 items were delivered, of which 15 were non-compliant due to the responsibility of the organization.

$$I_7 = (15 / 4320) \times 100\% = 0,34 \%$$

C2. Concession Rate (or Concession Number)

The indicator describes the number of conceded items delivered in relation to the number of items delivered by the organization during the period under review, as follows:

$$I_8 = \frac{\text{Number of conceded items delivered}}{\text{Number of items delivered by the organization during the period}}, [\%, PPM, \text{unit}] \quad (8.8)$$

The KPI measures the ratio of the number of items delivered by the organization to its customer covered by a concession accepted by the customer to the total number of items delivered by the organization to its customer during the period under review. It can also be the total number of items delivered by the organization to its customer covered by a concession accepted by the customer during the period under review.

Example: In one calendar month, 2268 items were delivered, of which 48 required concession.

$$I_8 = (48 / 2268) \times 100\% = 2,11 \%$$

C3. On Time Delivery

On-time delivery is the level of punctuality of item deliveries (to the customer) and is calculated as follows:

$$I_9 = \frac{\text{Number of purchase order lines /items due on time in the period}}{\text{Number of purchase order lines /items due in the period}} \times 100, [\%] \quad (8.9)$$

Those purchase order lines/items that have been delivered early or on time according to the dates agreed in the purchase order (date promised by the supplier) are considered **delivered on time**.

Transportation is to be taken into account according to the PO clauses. That means: "Departure date" + "transportation duration" ≤ "Supplier Promised Date".

Example: In one calendar month 1486 items were delivered, of which 1326 were delivered on time.

$$I_9 = (1326 / 1486) \times 100 = 89,23 \%$$

D. Key performance indicators for design and development of products and services (author's adaptation after [72])

D1. Design and engineering errors

Design and engineering errors are a measure of requirements not met or requirements non-compliant with the defined design or specifications and are calculated as follows:

$$I_{11} = \frac{\text{Number of revealed requirements missed or non-compliant with the defined design or specifications}}{\text{Total number of requirements defined in design or specification}} \times 100, [\%] \quad (8.12)$$

Example: Product includes 45 requirements in the design, from which 6 requirements are identified as non-compliant.

$$I_{11} = 6 / 45 \times 100\% = 13,33\%$$

D2. Cost of non-quality

The KPI describes the sum of the costs of engineering labor, development hardware and tests and is calculated as follows:

$$I_{12} = (\text{Rework engineering hours} \times \text{labor cost per engineering hour}) + \text{development hardware and test costs, [lei or currency]} \quad (8.13)$$

The KPI measures the non-recurring costs of fixing internal or external engineering errors.

Example: For a project, 30 hours are needed for engineering rework at 50 euro an hour and an additional 450 euro is needed for product re-testing.

$$I_{12} = 30 \times 50 + 450 = 1950 \text{ euro}$$

E. Key performance indicators for production (author's adaptation after [92])

E1. Labor force employment capacity

The indicator measures the ratio between the workload and the capacity of existing work forces (personnel) available for a work center (present and forecast) or for a project, as follows:

$$I_{18} = \frac{\text{Labor hours available}}{\text{Labor hours required}} \times 100, [\%] \quad (8.19)$$

The indicator measures the number of working hours required to complete work tasks against the total number of working hours available (number of persons multiplied by the number of working hours per person).

Example: Project needs for labor are 2800 hours, the actual available labor hours are 1800.

$$I_{18} = 1800 / 2800 \times 100\% = 64,28\%$$

E2. Manufacturing equipment utilization ratio (availability)

The indicator measures ratio between the productive time of the equipment (or machine) and the total available time for that equipment, as follows:

$$I_{19} = \frac{\text{Timpul productiv al echipamentului}}{\text{Timpul disponibil al echipamentului}} \times 100, [\%] \quad (8.20)$$

The KPI measures the ratio between the number of hours the manufacturing equipment (or machine) is running to produce or test product in a day (or in a period) versus the number of available hours (taking into account number of shifts per day and number of hours per shift).

Example: During the last month of production the effective manufacturing time for a CNC machine was 480 hours and the total availability was 520 hours.

$$I_{19} = 480 / 520 \times 100\% = 92,30\%$$

F. Key performance indicators for project/programme planning and management (author's adaptation after [94])

F1. Adherence to the project/program's control gates

The indicator measures the number of the project/program's control gates successfully passed on time as planned, as follows:

$$I_{39} = \frac{\text{Number of control gates passed on-time}}{\text{Number of control gates due to have been passed as planned}} \times 100, [\%] \quad (8.40)$$

The KPI measures the number of project/program milestones successfully passed on time.

Control gate is a decision point at the end of each milestone/phase of the Project/Programme Management Plan.

Example: To introduce a technical change, several milestones need to be met in order to launch a change.

Control gate 1. Technical version – Pass on time

Control gate 2. Industrialization – Pass on time

Control gate 3. Logistics for determining parts delivery terms – Late

Control gate 4. Programmes set by launch date based on milestones – Pass on time

$$I_{39} = 3 / 4 \times 100\% = 75\%$$

F2. Project/program non-recurring costs adherence

The KPI is a measure of adjustment of actual project/program non-recurring costs versus project/program target non-recurring costs. The indicator is calculated as follows:

$$\Delta I_{40} = \frac{\text{Actual project/ program non-recurring costs for the certain period of time}}{\text{Planned of target project/program non-recurring costs for the certain period of time}} \times 100, [\%] \quad (8.41)$$

The indicator measures non-recurring costs against the project/programme target. It is generally measured at specific stages of the project/programme.

Δ - difference between the current status and the previous status.

Some examples of calculations to determine the indicator are given in Tables 8.16 and 8.17.

Example 1: Program A/C XYZ, step 2.

Table 8.16. Project/program non-recurring costs adherence (example 1)
(author's adaptation after [94])

	Target	Actual
Non-recurring costs	800.000	980.000

$$\Delta I_{40} = 980000 / 800000 \times 100\% = 122,5 \% \text{ (sau } +22,5\%)$$

Example 2: Programul A/C XYZ, step 2.

Table 8.17. Project/program non-recurring costs adherence (example 2)
(author's adaptation after [94])

	Target	Actual
Non-recurring costs	900.000	750.000

$$\Delta I_{40} = 750000 / 900000 \times 100\% = 83,33 \% \text{ (sau } - 16,67\%)$$

In conclusion, key performance indicators represent a common area for improvement within organizational frameworks, as they are seldom rigorously developed. However, when appropriately utilized, KPIs can become a source of competitive advantage. Ineffective KPIs can be enhanced, and non-existent KPIs can be developed from scratch in a quick, easy, and efficient manner by tailoring the above-described KPIs to the organization's specificities.

Chapter 9. Considerations regarding the procurement management process within an aerospace industry organization

9.1. General considerations regarding the procurement management process within an aerospace industry organization

The requirements of the standard SR EN 9100:2018 regarding the procurement process (section 8.4) detail the fundamental processes that assist organizations and suppliers in using a common language. Firstly, it strengthens its own procurement processes to enhance the information that suppliers will base their actions on to meet the organization's requirements. Subsequently, controls are implemented to monitor supplier performance and take corrective actions if necessary.

Initially, the added requirements refer to using designated or approved suppliers by the client when designated. It emphasizes that the organization is accountable for the compliance of everything that comes from its suppliers, even if the client has imposed the supplier to be used. Additionally, the organization needs to identify and manage supplier risks (including those during supplier selection) and requires its suppliers to flow down necessary requirements to their suppliers so that all requirements are met.

Clause 8.4.1.1 is added to ensure the implementation of an approval and maintenance process for suppliers, including reviewing their performance and timely delivery, actions taken to address suppliers not meeting requirements, and how the organization controls documents provided by suppliers.

Clause 8.4.2 introduces control requirements, including periodic testing when there's a high risk of counterfeit parts, having a recall process if parts are released before all checks are completed, managing the delegation of checks to suppliers, and having an evaluation process for test reports received from suppliers if they are used.

Finally, there are several additions to clause 8.4.3 regarding information transmitted to suppliers. These include information about design control, special requirements (key characteristics and critical elements), testing and verification activities, the use of statistical techniques, and access rights for customers and regulatory agencies, where applicable.

Additionally, the organization requests that suppliers' employees understand how they contribute to product compliance and safety and the importance of ethical behavior.

The procurement process begins with identifying the need, in other words, what needs to be procured (for example: identifying the necessary spare part), how much to procure (identifying the quantity of spare parts needed), where to deliver it (identifying the delivery location), what quality standards are required (identifying any special quality requirements), etc. This need is communicated through a document called a "Purchase Requisition" to the procurement department.

Once the need has been communicated to the procurement department, actions will be initiated based on these requirements. The first and most crucial action is to convey the requirement to approved suppliers so that their bids can be received and processed to identify the most suitable ones.

Upon receiving the request for quotation, the supplier will respond with their offer in the form of a price quote. These price quote details will be analyzed by the procurement department. Each offer pertains to the details provided by each individual supplier. Details include the offer's validity period,

price discounts for larger quantities purchased, tax-related details/pricing/discounts, delivery terms, delivery details, etc.

The price quotes will then be analyzed for various factors such as quality, price, delivery date, etc., before being authorized. The authorized quote, which aligns with the organization's needs and expectations, will be referred to for creating a Purchase Order in the future within the quote's validity period. Once a quote is referenced in a purchase order, it can't be altered as the order is made with the available details.

Purchase orders can be generated either by referring to the purchase requisition or the price quote, and in this case, all purchase details are sourced from the referenced document. In the latter scenario, the purchase order can be created without referencing the purchase requisition or price quotes, with the employee manually inputting all information to be transmitted to the supplier (e.g., part name, required quantity of materials, etc.).

Finally, a check is conducted to ensure the received materials or services match those that were ordered and fully comply with the organization's requirements. This verification can be a simple confirmation upon product receipt or might involve formal inspections or testing. The organization assigns qualified and trained personnel to verify the product and confirm its compliance with the imposed standards.

If there's a desire for the product to be inspected before shipment, or if it's an explicit requirement of the customer to conduct the inspection themselves, a visit to the supplier's location can be arranged for product inspection. If necessary, the organization will need to specify this in the procurement documentation when placing the order or signing the contract. Ensuring the product fully complies with the standards will enable the organization to proactively meet requirements and smoothly transition to implementation.

In conclusion, maintaining an efficient procurement process can enhance financial performance, lead to increased customer satisfaction, reduce delivery times, and foster trust and commitment among suppliers. However, integrating supply chains to achieve expected benefits represents a key strategic challenge as managers operate in a complex, turbulent, and highly competitive environment where a rapid response to customer needs and flexibility are vital for the organization's survival and success.

9.2. Evaluation and selection criteria for suppliers in the aerospace industry

A specific feature of the procurement process in the aerospace industry is that the purchase of items takes place only from sources approved by the organization.

Supplier evaluation is a process that measures the performance of suppliers to ensure that they meet their obligations and customer expectations. It is important for an organization to implement a system whereby it can evaluate the performance of its suppliers as this will help to identify any problems or deficiencies in the relationship and implement appropriate corrective measures.

The criteria underlying the evaluation of suppliers are:

1. product or service conformity;
2. the price of the product or service;
3. reliability of the supplier (ability to consistently deliver an acceptable product when needed);
4. payment terms;
5. the quality management system.

Supplier approval to SR EN 9100:2018 is a process that aerospace and defense organizations use to ensure that their suppliers meet the high quality standards required by the industry.

The supplier approval process usually involves the following steps:

- **Identification of potential suppliers.** The organization will identify potential suppliers who can meet its product or service needs.
- **Evaluating suppliers.** The organization will assess the capability of potential suppliers to meet the requirements of SR EN 9100:2018. This can be done either by using criteria that form the

basis of the supplier assessment, reviewing the supplier's SMC documentation, conducting audits at the supplier's premises, or obtaining references from other customers.

- **Supplier selection.** Once the organization has evaluated potential suppliers, it will select suppliers that it believes can best meet its needs and meet the requirements of SR EN 9100:2018.
- **Supplier approval.** The organization will formally approve selected suppliers by adding the supplier to the list of approved suppliers.

Once a supplier has been approved, the organization will need to monitor their performance on a regular basis. Supplier approval is an important part of quality assurance of products and services in the aerospace and defense industry. By following a rigorous supplier approval process, organizations can help reduce the risk of quality issues and provide customers with the best products and services.

In conclusion, an organization's success in today's market depends not only on what it buys, but also on who it buys the products and services it needs to do business from. It is necessary to carefully evaluate suppliers and select those that bring not only cost savings but also sustainable value and growth potential, product innovation and a stronger competitive advantage.

9.3. Contributions regarding risk assessment associated with procurement management in the aerospace industry

Procurement management in the aerospace industry refers to the process of acquiring goods, services and resources needed for aerospace projects. It involves identifying suppliers, negotiating contracts, managing relationships and ensuring timely delivery of materials and equipment. However, this process is not without risks. A comprehensive assessment of these risks is therefore essential for the smooth functioning of procurement activities in the industry.

The procurement management process and the selection and use of aerospace suppliers present various risks that are important for organizations to be aware of and manage appropriately.

In Table 9.9 we have developed a practical example of analysing the risks associated with the procurement management process, as well as those related to the selection and use of aerospace suppliers, by completing an FMEA form, as described in sub-chapter 7.1.4. entitled "Risk assessment with Failure Modes and Effects Analysis (FMEA) method".

Table 9.9. FMEA (author's contribution) – extract

Process name: Procurement Management											Prepared by: Soare (Marin) Ilinca				
Process manager: P. I.							Date of initial preparation: 17.02.2020			Update date: 17.02.2023					
Process step	Potential failure mode	Effect of failure	Severity (S)	Cause	Probability of occurrence (P)	Method of detection	Probability of detection (D)	Criticality (RPN)	Recommended actions	Responsible and deadline	Actions implemented	Results of actions			
												Severity (S)	Likelihood of occurrence (P)	Probability of detection (D)	RPN
Identification of procurement needs	Underestimation or overestimation of procurement needs	Lack of availability of all products/services needed to produce the product/service; Blocking of financial resources	8	Incorrect assessment of supply needs	2	Product reception	8	128	Establish a clear and standardised process for identifying procurement needs and completing the purchase requisition; Train employees on how to correctly identify procurement needs; Implement a process for reviewing procurement needs	Comp. Purchasing Project Managers 31.05.2023	Develop a procurement management procedure including how to identify procurement needs; Employees participated in an internal training on the correct way to identify procurement needs	8	2	4	64
	The purchase requisition form has been completed incorrectly	Procurement period becomes longer	7	Lack of staff training	3	Approval of the request for supply	4	84				7	2	3	42
	Insufficient funding	Delay in making the purchase	8	Lack of funds	3	Preparation of the supply requirement	5	120	Obtaining appropriate approvals before starting the procurement process	General Manager Project Managers 31.05.2023	Verification of the existence of approvals of all procurement requests	8	3	3	72
	Unachievable deadline for completion of the procurement	Inadequate responses from bidders; Non-compliance with delivery schedule	9	Poor planning	3	Communication with the supplier	7	189				Improving forecasting, planning and consultation with users; Improving communication with potential bidders	Comp. Purchasing Project Managers 31.05.2023	Planning of project activities allocates sufficient time for the procurement process to take place; Maintain an effective communication process with bidders	9

Table 9.9. FMEA (author's contribution) – continuation - extract

Process step	Potential failure mode	Effect of failure	Severity (S)	Cause	Probability of occurrence (P)	Method of detection	Probability of detection (D)	Criticality (RPN)	Recommended actions	Responsible and deadline	Actions implemented	Results of actions			
												Severity (S)	Likelihood of occurrence (P)	Probability of detection (D)	RPN
Identification of procurement needs (continuation)	Failure to understand user needs	Delay in the delivery of the product/service; Increased costs; Product/service delivered is not compliant	8	Lack of skills	1	Product reception	8	64	Establishing an effective communication process with users	Project Managers 31.05.2023	Maintain an effective communication process with users to correctly and fully identify their needs	8	1	6	48
	Supply chain disruptions due to geopolitical factors	Delayed delivery of product/service	9	The outbreak of the war in Ukraine	8	Media	2	144	Evaluating and selecting multiple suppliers for the same type of product/service; Creating a stock of products	Comp. Purchasing 31.05.2023	Update the list of approved suppliers following their evaluation	9	5	2	90
Drawing up of specifications	Insufficient or restrictive specifications (e.g. manufacturer's name)	Exclusion from the procedure, delay of the product/service	9	Lack of skills	4	Supplier selection	2	72	Define all specifications to describe the product/service to be supplied; Use of functional and performance specifications	Comp. Purchasing Project Managers 31.05.2023	Development of specifications by trained employees with extensive aerospace knowledge	9	2	2	36
	Inadequate definition of the product/service	Delay of the product/service	10	Lack of skills	2	Elaboration of the request for proposal	4	80	Checking that the specifications are consistent with the needs analysis; Improving market knowledge; Use functional and performance specifications	Comp. Purchasing Project Managers 31.05.2023	Development of specifications by trained employees with extensive aerospace knowledge	10	2	2	40
	A biased attitude towards bidders	Complaints of unfair treatment	9	Lack of training and experience in tender	2	Review of specifications before publication	5	90	Compliance with the legislation in force to carry out transparent and non-discriminatory procedures	Comp. Purchasing 31.05.2023	Awareness of employees on compliance with the code of ethical and professional conduct in force	9	2	2	36

Table 9.9. FMEA (author's contribution) – continuation - extract

Process step	Potential failure mode	Effect of failure	Severity (S)	Cause	Probability of occurrence (P)	Method of detection	Probability of detection (D)	Criticality (RPN)	Recommended actions	Responsible and deadline	Actions implemented	Results of actions				
												Severity (S)	Likelihood of occurrence (P)	Probability of detection (D)	RPN	
Drawing up of specifications (continuation)				management												
Selection of purchase method	Incorrect selection of the tender procedure	The need to look for new offers; Extension of the procurement deadline	8	Incorrect calculation of the approximate cost or product characteristics are not known	2	Launching the procurement procedure	4	64	Compliance with the procedures and legislation in force in the field of procurement; Improve tender documentation and clearly identify evaluation criteria in requests for tenders; Use of appropriately trained and experienced staff	Comp. Purchasing 31.05.2023	Application of procedures; Training employees with the provisions of procurement procedures and practices, as well as with the legislation in force	8	2	2	32	
	Difficulties in identifying sources of supply	Delay in the realisation of the product/service	10	Failure to allocate sufficient time	2	Supplier selection	5	100	Improve procurement planning processes; Improving market knowledge	Comp. Purchasing 31.05.2023	Evaluation and selection of several suppliers for the same type of products/services; Conducting market research	10	2	3	60	
	Complication with the supplier	Non-conforming product; Additional costs	10	Lack of awareness	2	Supplier selection	8	160	Compliance with the procedures and legislation in force in the field of procurement; Participation of employees in refresher courses	Comp. Purchasing 31.05.2023	Applying the provisions of the procedures and legislation in force; Training employees with the provisions of the procurement procedures and practices as well as the legislation in force	10	2	5	100	

To manage these risks, organizations need to have a robust procurement management process and supplier selection process in place. This includes conducting supplier due diligence, monitoring supplier performance and having contingency plans in place for supply chain disruptions.

In conclusion, assessing the risks associated with the procurement management process provides organizations with valuable information and knowledge to improve decision-making, minimise uncertainty and optimise results in their procurement activities. Risk assessment helps to develop mitigation strategies. It enables the organization to anticipate potential problems and establish measures to minimise their impact on the procurement process.

Chapter 10. Final conclusions and main contributions regarding the implementation of integrated quality-risk management system in aerospace organizations

10.1. Final conclusions

The topic addressed in this PhD thesis is a highly topical one, namely **integrated quality-risk management in aerospace organizations**. In such an industry, a systematic approach to quality and risk is needed *to ensure the safety of passengers, crew and ground staff as well as to protect stakeholder investments*. Quality and risk management are critical components in the design, development, production and maintenance of aerospace systems and can have a significant impact on the overall success of an organization.

The significant findings of the PhD research towards the main objective, in relation to the methodological issues of reference (see Chapter 6.3), are as follows:

- By incorporating **risk-based thinking** throughout the product lifecycle, potential risks and hazards can be identified before they occur, the likelihood of safety incidents can be reduced, and ultimately the safety and reliability of aerospace products can be improved. In addition, risk-based thinking can also improve the efficiency and effectiveness of processes, and reduce costs associated with rework, repair and liability (see Chapter 7.2.3).
- **By monitoring key performance indicators**, aerospace organizations can identify areas for improvement, track progress towards quality objectives and make data-driven decisions to improve SMC performance. It is desirable that the setting of key performance indicators is based on the organization's objectives. These indicators are reviewed and updated regularly to ensure their relevance and effectiveness (see Chapter 8.1.4).
- **Any activity in the aerospace industry involves risks**. These activities may relate to: the design, manufacture, testing, operation and maintenance of aircraft and related systems. It is recommended that aerospace organizations identify, assess, prioritise risks and develop strategies to mitigate or manage these risks. By adopting a proactive approach to risk management, aerospace organizations can reduce the likelihood and impact of risks and ensure the safety and reliability of products and services provided (see Chapter 7.1.1).
- **By implementing an integrated quality-risk management system**, aerospace organizations can ensure the safety, reliability and efficiency of products and services provided and meet regulatory requirements. This can also contribute to improving their reputation, increasing customer satisfaction and reducing costs associated with safety incidents, accidents, rework and warranty claims (see Chapter 8.1.1).

10.2. Personal contributions

In fulfilling the main objective of the doctoral research activity, this PhD thesis makes a number of theoretical and applied contributions, the most significant of which are the following:

Theoretical contributions:

- **Identification of the documented information required by SR EN 9100:2018** with the aim of helping aerospace organizations to determine which documents and records are required to ensure

compliance with SR EN 9100:2018. Following the analysis of all the requirements of SR EN 9100:2018, the author has developed a list of all the required documented information, the clause where it is identified in the standard, and its type (document or record).

- **Research of risk assessment methods used in the aerospace industry** to highlight methods that enable aerospace organizations to proactively identify and manage risks, thereby contributing to the overall safety and efficiency of the aerospace sector. As a result of this research, the FMEA method for managing risks related to the procurement management process in an aerospace organization was selected.

- **Following the analysis of the relationship between quality management, risk management and safety management in the aerospace industry**, the author has highlighted that these three management aspects are interlinked and interdependent and contribute to maintaining a strong safety culture, promoting quality improvement, complying with standards and regulations, and driving continuous improvement efforts within aerospace organizations.

Applied contributions:

- **Development of the SR EN 9100:2018 implementation chart** and description of the steps required for the initial implementation of the standard.

- **Carrying out a case study on the implementation of SIMCR in an aerospace organization**, called ABC Aerospace, which contains:

- ❖ **the elaboration of the process map** in which the author presented the processes within the above-mentioned organization and their interaction;

- ❖ **analysis of the internal and external context in which an aerospace organization** operates provides essential information about an organization's positioning, capabilities and challenges. The author conducted a SWOT analysis that can help the management of ABC Aerospace to optimize performance, seek new opportunities, manage competition, maximize the return on resources used and minimize various business risks, and through the PESTLE analysis, external factors that may impact the organization were analyzed;

- ❖ **identifying the needs and expectations on interested parties**, and the associated risks and opportunities, is fundamental for aerospace organizations. Once these needs and expectations are understood, the organization can develop strategies and policies to meet their requirements, build stronger relationships with them and enhance its reputation;

- ❖ **developing the policy and objectives of an aerospace organization's integrated quality-risk management system** is critical to defining commitment, goals and strategic direction. The author proposes a template for a quality-risk policy statement and a plan for achieving the objectives set by the organization;

- ❖ **the identification and assessment of risks and opportunities that may affect or favour the achievement of the objectives** has been carried out according to the methodology presented in sub-chapter 7.1.5 "Risk assessment using risk matrix";

- **Conducting a study on key performance indicators used in the aerospace industry** is crucial for assessing, improving and ensuring organizational performance. The author has identified five categories of key performance indicators which have been customised with examples.

- **Establish criteria for evaluating and selecting aerospace suppliers** to ensure that suppliers meet strict quality and ethical standards, essential for producing reliable and safe aerospace products. The author proposes some criteria for the evaluation of suppliers, the ranking of suppliers according to their score, and a model for the supplier evaluation register and the list of approved suppliers.

- **Developing an analysis of the risks associated with the procurement management process, as well as those related to the selection and use of aerospace suppliers, by completing an FMEA form** allows a structured and systematic approach to identifying, assessing, prioritising and mitigating risks. For each stage of the procurement management process, the author identified

various potential failure modes, failure effect, cause, criticality (RPN), proposed certain actions, and reassessed the risks after implementation.

10.3. Future developments

The theoretical results and case studies presented in this PhD thesis show that there is a *need for some future developments in certain directions, such as:*

- the design, development, implementation and improvement of a **SIMCR in aerospace organizations**;
- **the use of methods to identify and assess risks and opportunities** that may affect or favour the achievement of the objectives set by the organization;
- developing a strategic direction for the development of the organization, using a **system of key performance indicators** to ensure quality, efficient and safe operations, identifying areas for improvement and taking actions leading to positive change;
- extending research on **the application of the FMEA method** to different stages of product development and manufacturing, including design, testing and production, to identify, assess and prioritise potential failure modes and their effects, and to take appropriate measures to prevent or reduce the risk of such failures;
- allocate sufficient funds **to train staff and promote a culture of quality and risk management** to improve the organization's performance, reduce costs and enhance its reputation for safety, reliability and quality.

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