Considerations on EN 9100: 2016 / AS 9100D standard new changes

Ilinca SOARE*,[1], Emil MILITARU[2]

*Corresponding author
*Universitatea POLITEHNICA din Bucureşti,
Splaiul Independenţei, nr. 313, Bucureşti 060042, Romania,
[1]INCAS – National Institute for Aerospace Research "Elie Carafoli",
B-dul Iuliu Maniu 220, Bucharest 061126, Romania,
soare.ilinca@incas.ro
[2]ICI Bucharest - National Institute of Research – Development in Informatics,
8-10, Mareşal Averescu, Bucharest 011455, Romania,
emil.militaru@ici.ro

Abstract: This article aims to highlight the main changes brought by the new edition of standard EN 9100: 2016 / AS 9100D. This standard is an effective tool for organizations working in the aerospace industry, providing the framework for achieving the ultimate goal of on-quality and on-time delivery of products and services. Using the SR EN ISO 9001: 2015 model for quality management system requirements and validation of compliance by third party assessment, EN 9100: 2016 / AS 9100D has been developed to include additional requirements that are of particular interest to the aerospace industry. Aspects of safety and performance of aerospace products are critical to stakeholders, appearing to be an uncompromising standard for guidance.

Key Words: EN 9100: 2016 / AS 9100D, quality management system, counterfeit parts/ components, on-quality and on-time delivery of products and services

1. INTRODUCTION

Within organizations operating in the aviation, space and defense industry, the ability to demonstrate quality and safety commitments plays an important role. The International Aerospace Quality Group (IAQG) has developed and implemented a set of global standards with common quality requirements in the aerospace and defense industry (9100 series, based on ISO 9001), as well as standards/ guidelines on best practices to increase product value and meet customer requirements [6]. IAQG is a non-profit international association, in accordance with Belgian law, based in Brussels, Belgium. This organization is made up of three sectors (America - AAQG, Asia Pacific - APAQG and Europe - EAQG) and aims to establish and maintain dynamic, trust-based cooperation between aerospace and defense companies, to bring about significant improvements of quality performances and cost reduction over the entire flow of value. The main point of interest is the continuous improvement of processes used in the supply chain to consistently deliver high-quality products, thus reducing costs and activities without added value [7].

2. MODIFICATIONS IN EN 9100: 2016 / AS 9100D STANDARD

The main changes in standard EN 9100: 2016 / AS 9100D are related to the changes brought to SR EN ISO 9001: 2015. In the new edition of the standard EN 9100: 2016 / AS 9100D specific requirements are reorganized to adopt the structure, concepts and terminology of the new SR EN ISO 9001: 2015.

The purpose of this review is also to take into consideration the needs of stakeholdes identified by the IAQG following the survey on the current version, as well as the clarification requests (several rewritten clauses, added notes) [4].

The main changes, determined by the new edition of SR EN ISO 9001: 2015, are the following:
- □ the structure according to the High Level Structure (HLS) and the terminology;
- □ risk-based thinking;
- □ the process-based approach strengthened by integrating the quality management system into the organization's business processes;
- □ the concept of preventive action addressed throughout the standard by identifying and reducing risks;
- □ introduction of knowledge management;
- □ clearer understanding of the organization's context;
- □ aligning the quality management system policy and objectives with the organization's strategy;
- □ explicit performance assessment requirements;
- □ greater flexibility of documentation;
- □ increased compatibility with services [5].

As a result of the new SR EN ISO 9001: 2015 structure, requirements are better organized and clarified, with notes and examples to enhance understanding, and the specific requirements according to EN 9100: 2016 / AS 9100D have been moved to the appropriate sections.

Changes to specific aviation, space and defense requirements are as follows:
- □ adding a separate clause to selected areas for product safety and preventing the use of counterfeit parts / components;
- □ combining current requirements with the new ISO requirements in terms of risk and putting emphasis on risks in operational processes;
- □ clarifying and improving the configuration management clause to meet the needs of stakeholders;
- □ increasing the requirements for awareness of the individual contribution to quality;
- □ inclusion of human factor as a consideration in the analysis of nonconformities and establishment of corrective actions [5].

Organizations in the aerospace industry that have well implemented and managed a quality management system according to EN 9100: 2016 / AS 9100D have many advantages:
- □ continuously produce and improve secure and reliable products that meet or exceed regulatory and customer requirements to ensure customer satisfaction;
- □ define and manage the processes necessary to carry out the activities;
- □ develop documentation that accurately reflects the work to be done and the actions to be undertaken;
- □ focus on the entire supply chain as well as on stakeholders;
- □ are recognized by regulatory authorities [5].

3. SUMMARY OF THE CHANGES; REQUIREMENTS DETAILED ONE BY ONE

The introduction does not bring any other novelties to those specified in SR EN ISO 9001: 2015. In the presentation of chapter 0.1 General, the following verbal forms are used:
"Shall" - indicates a requirement, "should" - indicate a recommendation, "may" - indicate permission, "can" - indicate a possibility or capability [1].

The principles of quality management can be used to improve the performance of an organization, implicitly of the processes identified and the quality of products or services, which also generates increased customer satisfaction. The seven principles of quality management are illustrated in Figure 1.
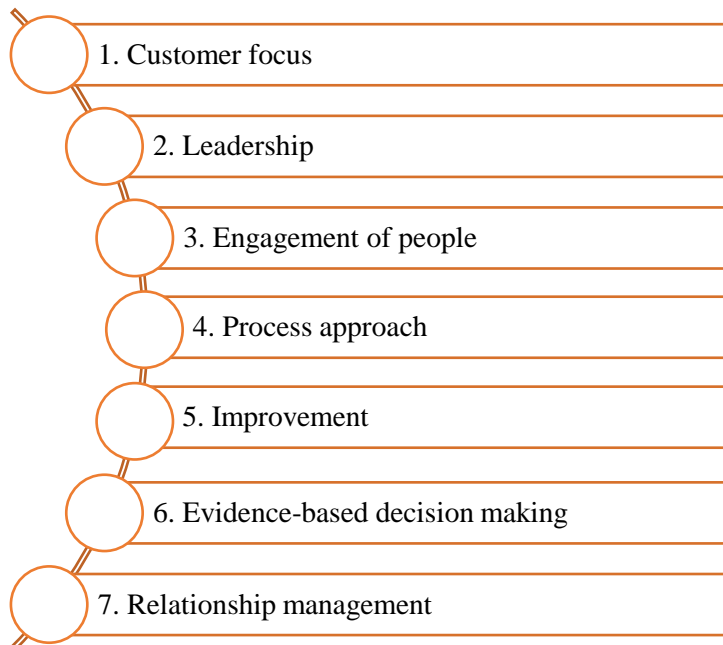

Figure 1 – Principles of quality management [1]

1. *Customer focus*. It implies understanding customers' needs, meeting requirements and even exceeding their expectations. This principle is closely related to a good customer communication process that provides accurate and complete information.
2. *Leadership*. Applying this principle contributes to increasing the effectiveness in achieving the organization's quality objectives, better aligning and coordinating the organization's processes, improving the communication system between different levels and functions of the organization, and improving the ability of the organization and staff to obtain and deliver results desired.
3. *Engagement of people*, having the following advantages:
   □ improving the understanding of the organization's quality goals determines an increase in motivation to achieve them;
   □ innovation, initiative and creativity in setting future goals;
   □ increased attention in terms of increasing staff satisfaction;
   □ staff availability to participate and contribute to continuous improvement.
4. *The process approach* has the main advantage of managing and controlling the interaction between processes and interfaces between functions within the

organization. At the same time, the ability to focus on key processes and opportunities for improvement increases, consistent and predictable results are obtained and the organization's ability to provide stakeholders with confidence in the efficiency and effectiveness of the organization improves.

5. *Improvement* is essential to maintain the organization's performance level and to create new opportunities. Applying the principle leads to improved process performances, increased customer satisfaction, a better focus on investigation and determination of the issues causes, followed by corrective actions, anticipation of risks and internal or external opportunities.

6. *Evidence-based decision making*, analyzing the data or information involves:
   □ collecting data and information relevant to the objective;
   □ ensuring that the data and information gathered are accurate, accessible and reliable;
   □ analyzing data and information using validated methods;
   □ understanding the importance of statistical techniques and their use;
   □ making decisions and implementing actions based on the balance between logical analysis, experience and intuition.

7. *Relationship management* improves the performance of the organization and stakeholders by addressing risks and opportunities, aims to create value for stakeholders through allocated resources, staffing competency and risk and opportunity actions, and also has in view to optimize the supply chain to ensure stable supply of products and services [1].

According to SR EN ISO 9001: 2015, Chapter 0.3 -The process approach includes a schematic representation of the elements of a process and the representation of the standard structure in the PDCA cycle. Subchapter 0.3.3 - Risk-based thinking emphasizes the need to plan and implement actions of risk and opportunities management in order to enhance the effectiveness of the quality management system. The risk concept has always been implicit in SR EN ISO 9001: 2015, but this new edition explicitly integrates it into the entire quality management system [5].

Successful companies intuitively adopt the risk-based approach because it has many benefits, such as:
   □ taking into consideration risks throughout the management system and processes;
   □ understanding the impact of risk on operational processes;
   □ improving customer confidence and satisfaction;
   □ creating a proactive culture of prevention and improvement;
   □ integrating preventive action into strategic and operational planning [5].

To implement the risk-based approach, the risks that arise in the organization are identified and prioritized. They depend on context, product or process complexity and organizational complexity. The next step is to determine the acceptable and unacceptable risks. Then, the action plan is drawn up, establishing measures to prevent, avoid, eliminate or mitigate risks. The plan is implemented, necessary steps are taken and then the effectiveness of the taken actions is checked and the results are analyzed. The last step highlights what can be improved throughout organizational processes, learning from experience [5].

Completions to EN 9100: 2016 / AS 9100D highlight the following:
   □ clause 6.1 is related to risks in the organization's quality management system and refers to the management of the risks considered at the organization level or at the processes level, such as: new customers or markets, partnerships, etc ;

□ clause 8.1.1 is related to risks in the operational processes defined in clause 8 and relates to the implementation of a formal risk management process as well as to the risk analysis in the exploitation activities, such as: contract analysis, introduction of new technologies, selection of external providers, etc [5].

The major differences in terminology are those in the new edition of SR EN ISO 9001: 2015 and refer to the following terms: product - replaced by products and services, documents, records, documented procedures - replaced by documented information (maintained = documents or procedures, retained = records), purchased product - replaced with externally provided products and services, supplier - replaced by external provider. The concept of allowing exclusions is maintained provided that the ability or the responsibility to ensure the conformity of products and services is not impaired. The definition for counterfeit parts / component and product safety [5] is added to the three specific definitions for special requirements, critical items and key characteristic.

One of the new aspects of the standard is the introduction of the organization's context. It is a combination of internal and external factors as well as of the conditions that can influence the organization's approach to products and services, investments and stakeholders. To define the context and identify changes in context, the organization evaluates both the internal conditions and the business environment in which it operates, and defines the influence of internal and external factors, how it reflects on the organization's ability to achieve the expected results for the implemented management system.

To understand the organization and the context in which it operates, both the relevant external issues (legal, technological, competitive, market, cultural, social, economic) and internal issues (values, culture, information systems, formal and informal decision-making processes, knowledge and organization performance) are determined. Understanding the needs and expectations of interested parties is about determining the requirements of customers, partners, authorities, shareholders, employees, suppliers, etc. which are relevant to the quality management system. This does not extend beyond the requirements of the quality management system and the scope of the standard.

As mentioned in the scope, EN 9100: 2016 / AS 9100D standard is applicable if an organization has to demonstrate its ability to constantly supply products and services that meet the customer's requirements, applicable legal and regulatory requirements, aiming to increase customer satisfaction. Determining the scope of the quality management system shall be documented and justified in any case where a requirement (exclusion) cannot be applied. Requirement 4.4 - Quality Management System and its processes contain an explicit requirement for documented information maintained with a defined content (can be called Quality Manual). Documented information to be maintained or retained, "to the extent necessary" are defined [5].

A series of significant changes can be found in chapter 5, Leadership. The term "management" has been replaced by "leadership", which involves an increase in the number of direct responsibilities and top management authority in the quality management system.

Top management demonstrates leadership and additional commitment by:
□ responsibility for the effectiveness of the quality management system; integration of management system requirements in business processes of the organization;
□ awareness, engagement, leadership and support for staff to contribute to: system effectiveness, promoting process approach, risk-based thinking, improvement and innovation, demonstrating leadership quality by those who hold management

positions, and implementing the system quality management in their areas of responsibility;
- □ ensuring that the quality management system achieves the expected results;
- □ communicating and understanding of responsibilities and authority assigned to the relevant functions of the organization.

Another additional requirement is that top management ensures that the risks and opportunities that may affect the compliance of products and services as well as the ability to enhance customer satisfaction are determined and addressed. With regard to communication of quality policy, it must be made available to relevant interested parties, as appropriate [3]. Unlike SR EN ISO 9001: 2015, a management representative is required to solve quality management problems [5].

The risk-based approach is highlighted in Chapter 6, Planning. The risks and opportunities identified in the quality management system processes are established, appropriate actions are planned to reduce unwanted effects and their effectiveness is assessed, communication on the achievement of the objectives is ensured and monitored and changes to the quality management system take place in a planned manner [5].

A number of new elements are found in Chapter 7, Support- Clause 7.1.2. People was separated from the clauses (7.2) - Competence and (7.3) - Awareness. Clause 7.1.4- Environment for the operation of processes includes human and physical factors. For Clause 7.1.6, Organizational Knowledge, the necessary knowledge gained from experience, lessons learned, success, failure, conferences, etc. are determined. EN 9100: 2016 / AS 9100D standard adds to clause 7.3- Awareness, the requirements for people to be aware of:
- □ their contribution to product or service compliance;
- □ their contribution to product safety;
- □ the importance of ethical behavior [5].

Documents and records have been replaced by documented information. The organization is required to maintain enough documented information (documented procedures) to support the operation of the processes and to keep the documented information (records) when necessary, to ensure that the processes are in line with the planning. The new edition of the standard EN 9100: 2016 / AS 9100D, adds the requirement to define data protection processes for electronically managed documented information to clause 7.5.3. Control of Documented Information.

For the purpose of suitability and for the service industry, Chapter 8 is referred to as Operation. Unlike SR EN ISO 9001: 2015, clause 8.1, Operational planning and control, from standard EN 9100: 2016 / AS 9100D has four other specific sub-clauses. Project management (clause 7.1.1 of EN 9100: 2009 / AS 9100C) and Work Transfer Control (clause 7.1.4 of EN 9100: 2009 / AS 9100C) are no longer separate clauses [2]. These are included in clause 8.1, where the concept of risk for the transfer of work is introduced and clarified. At the same time, planning and control activities are reinforced with provisions to ensure on-quality and on-time delivery of products and services. [5].

Sub-clause 8.1.1, Operational risk management, is related to the risks in the operational processes defined in point 8, while clause 6.1 is related to the risks in the organization's quality management system.

Sub-Clause 8.1.2, Configuration Management, has been revised to clarify stakeholder expectations.

Sub-Clause 8.1.3, Product safety, adds new requirements to address considerations on "product safety" throughout their life cycle.

Sub-Clause 8.1.4, Prevention of counterfeit parts / components, adds new requirements in order to plan, implement and control the process of prevention in using counterfeit parts or those susceptible to be counterfeit [5].

Analyzing the requirements for products and services should be in line with the organization's applicable functions, and if it is found that certain customer requirements are not met, actions must be taken.

Clause 8.3 - Design and development of products and services has been restructured to allow for a more process-oriented approach. The input elements of design and development must take account of handling obsolence, where applicable. Changes to design and development must be defined in a process as well as criteria for informing customers of changes affecting their requirements [5].

Clause 8.4, Control of externally provided processes, products and services, has been extended to cover products and services provided externally, which can be paid (supplied) or not (outsourced to other organizations in the same group). An explicit requirement has been introduced for external providers to apply appropriate controls to their direct and sub-tier external providers. The type and extent of the control includes the evaluation of the data on the test reports to demonstrate the compliance of the results with the requirements (e.g. the results of the test reports received from external providers are checked for tolerance requirements). It is necessary to validate the test reports for the precision of the raw materials identified as a significant operational risk (e.g., periodic programmed tests performed on samples for critical raw materials). Information for external providers contains more explicit topics to consider when communicating requirements to them [5].

Clause 8.5.1 Control of production and service provision, considers that monitoring and measurement activities will ensure the control of processes and outputs and acceptance criteria for products and services are met. The three sub-clauses are preserved: control of equipment, tools and software programs, validation and control of special processes, production process verification [5].

Post-delivery activities clarify that if problems are detected after delivery, the organization shall take appropriate action [3].

The release of products and services is intended to verify that all activities have been carried out prior to release and delivery by authorized persons [3]. Unlike SR EN ISO 9001: 2015, the control of nonconforming outputs should be maintained in a procedure that defines the responsibilities and control of the nonconforming product or service [3].

In addition to the provisions of the SR EN ISO 9001: 2015 standard, the management review has on-time delivery performance, as input data. Nonconformity and corrective action has been added to assess the need for action based on human factors to ensure that nonconformity is not repeated [5].

Annex A of the EN 9100: 2016 / AS 9100D standard provides the following:

□ structure of clauses and some of the terminology are modified to improve alignment with other management system standards;

□ subsequent changes in structure and terminology do not need to be reflected in the organization's quality management system documentation;

□ clauses structure aims to provide a coherent presentation of the requirements, not a model for documenting the policies, objectives and processes of an organization;

□ there is no requirement for the terms used by the organization to be replaced by the terms used in the international standard to describe the quality management system requirements [5].

This appendix is informative and includes clarification of the new structure, terminology and concepts, including clarifications for risk management, short presentation of international standards developed by ISO / TC 176, and standards developed by the IAQG, structured in a complete list.

4. CONCLUSIONS

This article proposes a brief overview on the main changes to standard EN 9100: 2016/ AS 9100D in order to increase the understanding of its requirements.

The new edition of the EN 9100: 2016 / AS 9100D standard focuses on:
- □ adding several references to product safety;
- □ clauses to prevent the use of counterfeit parts / components and the negative impact they may have on their use in final products;
- □ human factors and awareness are added as consideration for the quality and safety of products and services, along with ethical behavior issues approach;
- □ design and development requirements, supplier management and configuration management have been clarified and improved to meet the needs of stakeholders.

EN 9100: 2016 / AS 9100D is the only common quality management standard for the aerospace industry. It is used and supported by the world's leading aerospace companies and their supply chains. It can be used by aerospace organizations, including design, manufacturing, maintenance and distribution companies. By complying with this standard, suppliers can get a competitive edge and benefit from process improvement as well as continuous improvement.

If the current documentation system is structured on an earlier revision of the standard, consideration is given to rearranging the quality management system documentation around the organization's value flow. A value-based quality management system allows personalization of documentation according to the organization's unique business needs. Risk-based thinking is commonly used by organizations, as a greater emphasis is placed on planning and controlling processes that have a significant impact on the quality of the products and services they provide. It is continuous, increases the likelihood of reaching the proposed goals, reduces the likelihood of negative results, and makes prevention a habit.

REFERENCES

[1] * * * SR EN ISO 9001:2015, *Sisteme de mamangement al calității. Cerințe.*
[2] * * * EN 9100:2009/AS 9100C, *Sisteme de management al calității. Cerințe ale organizațiilor pentru aviație, spațiu și apărare.*
[3] * * * EN 9100:2016/AS 9100D, *Sisteme de management al calității. Cerințe ale organizațiilor pentru aviație, spațiu și apărare.*
[4] B. Clamens, *The EAQG Working Group is actively involved in the revision 2016 of the "9100" standard*, 2015, http://www.eaqg.org/upload/pdf/article_eaqg_web-site_9100cd_2015-07-28.pdf
[5] IAQG 9100 Team, *9100 revision 2016 Key changes presentation*, 2015. http://www.sae.org/iaqg/projects/9100-2016changes.pdf
[6] * * * http://www.eaqg.org/IAQG.html
[7] * * * http://www.sae.org/iaqg/