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EVOLUTION OF THE QUALITY MANAGEMENT SYSTEM

Abstract. The article presents the process of adapting the ISO 9001 standard to the changing environment. The course of changes in the Quality Management System implemented for use at OBRUM is described. The revised ISO 9001 standard has also been analyzed: 2008. The scope of introduced changes and differences between ISO 9001: 2008 and the revised ISO 9001:2015-10 are presented in detail.

Keywords: Quality Management System, ISO-9001:2008, ISO 9001:2015.

1. INTRODUCTION

OBRUM, striving to constantly improve the quality of manufactured products, even though it runs a double quality control system (internal control at the end of the technological process, which is additionally subjected to control by the 33rd Regional Military Representation), at the beginning of the 1990s started work aimed at implementing a Quality Management System based on the ISO 9000 series standards [1].

Quality management according to ISO 9000 standards has been used in organizations and institutions around the world for almost 30 years. These standards have gained particular popularity in Poland after joining the European Union. Today, possessing a quality management system (QMS) certificate in a company or an institution is a common requirement. Implementation of the QMS is not only the consequence of legislation, but it is above all part of the management culture.

Today, having an ISO 9001 certificate, is a generally required element for participation in tenders announced both at home and abroad.

1.1. The Quality Management System

The first efforts to implement a Quality Assurance System (QAS) were undertaken at OBRUM in September 1993. A specially appointed team coordinated the work related to the introduction of QAS in all organizational units. The necessary documentation for the system was developed by OBRUM employees. OBRUM was the first research and development institution in Poland to receive a certificate of the Quality Assurance System issued on March 20, 1997 by the German TUV CERT, certifying the existence and application of a quality assurance system in accordance with the international standard EN ISO-9001 [2]. Since then the Quality Assurance System at OBRUM is constantly improved. Appointed auditors carry out internal audits according to a schedule. System documentation is supervised on a continuous basis. Complete QAS documentation is accessible to OBRUM employees on an Intranet site [3].

Surveillance audits confirming the proper functioning of the system at OBRUM are carried out at least once a calendar year, except for the years in which renewal certification is

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to be carried out. The last recertification audit took place on 14.05.2018 and it was carried out by the Centre for Quality Certification of the Military University of Technology in Warsaw.

1.2. Government Quality Assurance (GQA)

The Government Quality Assurance (GQA) process for military purchases is based on the principle that the supplier has an implemented quality system. This system must ensure that the product quality determined in the concluded contract is maintained. The NATO quality assurance system requires the application of AQAP [4] type documents and standards of the ISO 9000 family. The purpose of the Quality Assurance System is to increase the confidence that the product ordered for the Polish Armed Forces meets the requirements specified in the contract. The rules for the implementation of Government Quality Assurance (GQA) and quality management are set out in the Standardization Agreement STANAG 4107 [5]. This document introduces contractual type AQAP standards, including elements necessary for quality control and for the identification of the area to be supervised by the Quality Assurance Representative (QAR). The application of the relevant AQAP requirements depends on the type and complexity of the ordered product [13]. Each subsequent edition of the ISO 9000 series standards, and in particular the ISO 9001 standard, results in the amendment of the AQAP standards, particularly those of the contractual type.

2. REVISION STAGES

The ISO 9001 standard has been revised several times since its creation to adapt to the new market requirements and to the changing trends in management. In 1994, the first revision of the standards was made, without introducing major changes to the requirements. In 2000 the standard was revised again [6], and fundamental changes were made in the structure of the standard. Also, for the first time, the process approach was applied, and the list of required documents was limited, reducing the number of procedures that had to be developed. Another revision of ISO 9001 [7] made in 2008 introduced minor additions. The next revision, ISO 9001:2015 [8], was published in September 2015. This was an update of ISO 9001:2008 [7], the aim of which was to adapt the requirements of the standard to current business needs and practices. The standard was adapted to a common framework. This means that ISO standards will have similar structure, which will facilitate the integration of management systems instituted in businesses. The new standard [8] comprises 10 sections developed by the International Organization for Standardization. On September 15, 2018 the PN-EN ISO 9001:2008 standard becomes void, and the previous QAS certificates will also be invalid and useless for business or marketing purposes.

3. SCOPE OF CHANGES IN ISO 9001:2015

In order to make appropriate changes to the existing QAS (including the existing system documents), the provisions of the new ISO 9001: 2015 standard [8] were compared with the previous version ISO 9001: 2008 [7], as shown in Table 1.

Table 1. Correlation between ISO 9001:2008 [7] and ISO 9001:2015 [8]

ISO 9001:2008	ISO 9001:2015
1. Scope	1. Scope
2. Normative references	2. Normative references
3. Terms and definitions	3. Terms and definitions
4. Quality Management System	4. Context of the organization
4.1 General requirements	4.4 Quality Management System and its processes
4.2 Documentation requirements	7.5 Documented Information
4.2.1 General	7.5.1 General
4.2.2 Quality Manual	4.3 Determining the scope of the quality management system
	4.4 Quality Management System and its processes
	7.5.1 General (concerns documented information)
4.2.3 Control of documents	7.5.2 Creating and updating 7.5.3 Control of documented information
4.2.4 Control of quality records	7.5.2 Creating and updating 7.5.3 Control of documented information
5.0 Management responsibility	5. Leadership
5.1 Management commitment	5.1 Leadership and commitment 5.1.1 General
5.2 Customer focus	5.1.2 Customer focus
	4.1 Understanding the organization and its context
	4.2 Understanding the needs and expectations of interested parties
5.3 Quality policy	5.2 Quality policy
5.4 Planning	6. Planning
5.4.1 Quality objectives	6.2 Quality objectives and planning to achieve them
5.4.2 Quality Management System planning	6. Planning

ISO 9001:2008	ISO 9001:2015
	6.1 Actions to address risks and opportunities
	6.3 Planning of changes
5.5 Responsibility, authority and communication	5.3 Organizational roles, responsibilities and authorities
5.5.1 Responsibility and authority	5.3 Organizational roles, responsibilities and authorities
5.5.2 Management representative	Title deleted 5.3 Organizational roles, responsibilities and authorities
	7.2 Competence
5.5.3 Internal communication	7.4 Communication
5.6 Management review	9.3 Management review
5.6.1 General	9.3.1 General
5.6.2 Review input	9.3.2 Management review input
5.6.3 Review output	9.3.3 Management review output
6. Resource management	7.1 Resources
6.1 Provision of resources	7.1.1 General 7.1.2 People
6.2 Human resources 6.2.1 General	7.2 Competence
6.2.2 Competence, training and awareness	7.2 Competence
	7.3 Awareness
6.3 Infrastructure	7.1.3 Infrastructure
6.4 Work environment	7.1.4 Environment for the operation of processes
7. Product realization	8. Operation
7.1 Planning of realization processes	8.1 Operational planning and control
7.2 Customer-related processes	8.2 Requirements for products and services
7.2.1 Determination of	8.2.2 Determining the requirements for products

ISO 9001:2008	ISO 9001:2015
requirements related to the product	and services 4.1 Understanding the organization and its context 4.2 Understanding the needs and expectations of interested parties
7.2.2 Review of requirements related to the product	8.2.3 Review of requirements for products and services
7.2.3 Customer communication	8.2.1 Customer communication
7.3 Design and development	8.3 Design and development of products and services
7.3.1 Design and development planning	8.3.1 General 8.3.2 Design and development planning
7.3.2 Design and development inputs	8.3.3 Design and development inputs
7.3.3 Design and development outputs	8.3.5 Design and development outputs
7.3.4 Design and development review	8.3.4 Design and development controls
7.3.5 Design and development verification	8.3.4 Design and development controls
7.3.6 Design and development validation	8.3.4 Design and development controls
7.3.7 Control of design and development changes	8.3.6 Design and development changes
7.4 Purchasing	8.4 Control of externally provided products and services
7.4.1 Purchasing process	8.4.1 General 8.4.2 Type and extent of control
7.4.2 Purchasing information	8.4.3 Information on external providers
7.4.3 Verification of purchased product	8.4.2 Type and extent of control 8.4.3 Information on external providers 8.6 Release of products and services
7.5 Production and service provision	8.5 Production and service provision
7.5.1 Control of production and service provision	8.5.1 Control of production and service provision 8.5.5 Post-delivery activities

ISO 9001:2008	ISO 9001:2015
7.5.2 Validation of processes for production and service provision	8.5.1 Control of production and service provision
7.5.3 Identification and traceability	8.5.2 Identification and traceability
7.5.4 Customer property	8.5.3 Property belonging to customers or external providers
7.5.5 Preservation of product	8.5.4 Preservation
7.6 Control of monitoring and measuring equipment	7.1.5 Monitoring and measuring resources
8. Measurement, analysis and improvement	9.1 Monitoring, measurement, analysis and evaluation
8.1 General	9.1.1 General
8.2 Monitoring and measurement	9.1 Monitoring, measurement, analysis and evaluation
8.2.1 Customer satisfaction	9.1.2 Customer satisfaction
8.2.2 Internal audit	9.2 Internal audit
8.2.3 Monitoring and measurement of processes	9.1 Monitoring, measurement, analysis and evaluation 9.1.1 General
8.2.4 Monitoring and measurement of product	8.6 Release of products and services
8.3 Control of non-conforming product	8.7 Control of nonconforming process outputs, products, and services
8.4 Analysis of data	9.1.3 Analysis and evaluation
8.5 Improvement	10. Improvement
8.5.1 Continual improvement	10.1 General 10.3 Continual improvement
8.5.2 Corrective action	10.2 Nonconformity and corrective action
8.5.3 Preventive action	Title deleted 6.1 Actions to address risks and opportunities (6.1.1, 6.1.2)

Among the fundamental differences between ISO 9001:2008 and ISO 9001:2015, the following most important aspects can be distinguished:

1. Thinking based on risk.

The organization should analyze the threats it may face and accordingly adapt to them its Quality Management System.

2. A broader view of risk management.

   Systematic definition and monitoring of the business context as well as the needs and expectations of stakeholders.

3. Emphasis on leadership, commitment of top management.
4. Targeting objectives meant as improvement factors and planning in respect of achieving the set objectives.
5. Paying more attention to external processes, products and services.
6. A greater emphasis was placed on planning and supervising the changes necessary in the processes and changes of management systems.

The sections of the standard were arranged in the cycle Plan-Do-Check-Act (PDCA) [9] – Fig. 1.

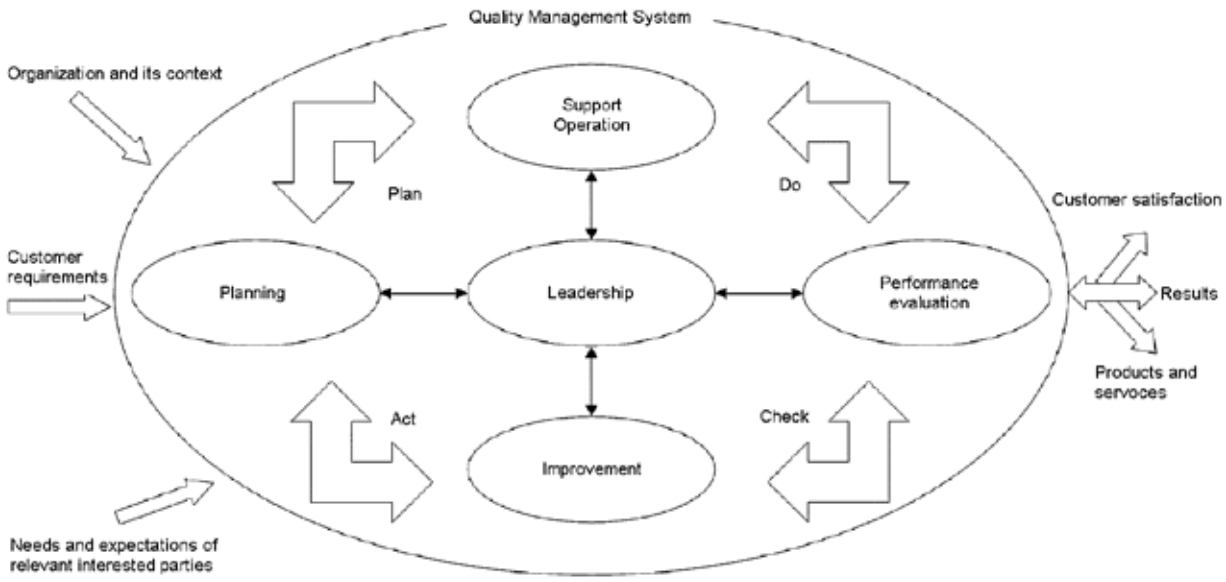

Fig. 1. The PDCA cycle (Plan-Do-Check-Act)

5. SUMMARY

At OBRUM there is in place an Integrated System which includes the Quality Management System ISO 9001 and a management system compliant with the AQAP standard selected.

OBRUM also meets the requirements of Article 11 para. 2 of the Act of November 29, 2000 [12] on foreign trade in goods, technologies and services of strategic importance for the security of the state, as well as for the maintenance of international peace and security.

Work on meeting the new standard requirements commenced in April 2017. A special team was established to implement the new requirements according to PN-EN ISO 9001:2015 [8], AQAP 2110:2016 [10] and the Internal Control System [11]. Documentation of the Quality Assurance System has been made available to the managers of organizational units in electronic form (in editable version) in order to adapt processes to the new requirements. It also allowed to evaluate the processes carried out in organizational units, not only by the direct process owners.

All of these efforts resulted in obtaining certification for compliance with the requirements of ISO 9001:2015 and AQAP 2110:2016.

The following certificates were granted by the Centre for Quality Certification of the Military University of Technology:

- ISO 9001:2015, valid from 30.05.2018 to 29.05.2021;
- ISO 2110:2016, valid from 30.05.2018 to 29.05.2021;
- ICS No. W-56/11/2018 valid from 06.02.2018 to 05.02.2021.

The entire modified current QAS documentation is posted in electronic form on OBRUM's Intranet [3] and is accessible to all interested employees.

6. REFERENCES

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