

# Quality management system-ISO 9001 in the context of industry 4.0

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**Abstract:** The article will examine the principles, approaches and documented information of the quality management system ISO 9001 in the context of Industry 4.0. will be analyzed the structure, implementation and maintenance of the quality management system in the conditions of Industry 4.0. Recommendations for future change of the version of the standard in the presence of digitization will be made.

**Keywords:** INDUSTRY 4.0,ISO 9001.

## 1. Introduction

Quality management systems{ISO 9001} are an integral part of industrial companies worldwide, as their goal is to ensure high quality, low cost of goods and services, more stable and greater market share. In practice, quality management system represents a competitive advantage of companies.Precisely for this reason, the question of how the quality management system will be implemented, maintained and managed in the context of Industry 4.0 and what will be the barriers to using their full potential as a strategic factor is relevant[1],[2].

To a large extent, the expected goals at implementation of Industry 4.0 overlap with those of the quality management system, but concerns that acquisition of one competitive advantage will limit another competitive advantage remain[3]. Developments in this direction are important for the discussion of a new version of the quality management system with focus not only on availability of electronic documents, but also their automatic maintenance, management, storage and improvement.

## 2.The principles of quality management system

The principles of quality management system are as follow[fig.1]



**Fig.1** The 7 principles of quality management system[4]

- Customer focus

Customer focus is important for both the quality management system and Industry 4.0, as the creation of the concept of Industry 4.0 is related to flexible and individual production, entirely designed as a pull process. The differences in this point are related to which determines the level of quality, because in the quality management system it is determined by the company, and in the philosophy of Industry 4.0 it is determined by the customer, similar to TQM, but in general the direction is the same

- Leadership

Leadership is related to strategic planning, the effectiveness and efficiency of key decisions in the business environment. When there is unity of leaders it leads to successful development of strategies. The implementation of Industry 4.0 is a typical example of leadership, so this principle will be respected.

- Engagement of people

The quality management system is based on the principle that everyone is engaged in the processes. The inclusion of people will increasingly give way to the implementation of vertical and horizontal integration in order to include machines in the smart factory.

- Process approach

. A process-oriented approach means comprehensive documentation of all key processes in the company, such as customer relations, resources, production management, quality control and management, risks, etc. To a large extent, the implementation of this principle will be related to possibilities for horizontal and vertical integration, equipment compatibility, software and hardware capabilities, availability of digital twins, degree of automation, etc.

- Improvement

Improvement is an integral part of the dynamic business environment and it must be present at all management levels. Flexible automatic production systems and modularity of Industry 4.0 enable technological improvement.

- Evidence-based decision making

The big concerns related to this principle are that autonomy of cyber-physical systems on one hand leads to timely and adequate decisions, but on another hand wrong data or defects in database can lead to system errors at the level of factory-degraded quality, wrong orders, damaged tools and equipment, etc.

- Relationship management

Relationship management will give way to communication management through the Internet of Things, the Internet of Services and ERP systems.

## 3.Documented information

Documented information is information for which there is a certain requirement to be controlled and stored by the company and the media on which it is stored. It is divided into documentation required by the standard and documentation determined to be necessary for the efficiency of the system. Documented information is divided into 4 levels{fig.2}.

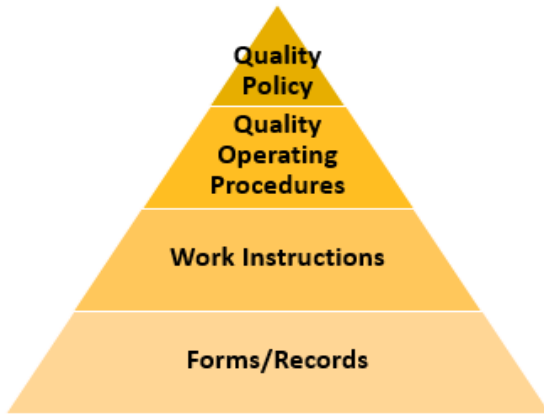


Fig.2 Levels of documented information [5]

Documented information{fig.3} should have a name, numbering, version and date in order to ensure identification and traceability, and there is no requirement for format (paper, electronic or combined),.

	Identical number	Version	
	ISO 9001:2015	Page	
	Name of the document	Signature	Date
Created by:			
Confirmed by:			

Fig.3 Headline of a documented information

In the context of Industry 4.0, documented information at all levels should be fully digitized, but the following obstacles exist:

- Templates and content of documented information will be different because they will depend on the existing software and hardware of the equipment. One control card will be presented differently on different machines.
- The identification of the documented information will be only by name, it will not be possible to use numbering, which is a significant inconformity.
- Archiving of documented information will be limited to storage capacity of the equipment.
- Electronic documents are more difficult to be protected

All these obstacles will lead to combined and duplicated information, which complicates management and storage.

#### 4. Clauses analyze of ISO 9001

The clauses of the entire ISO 9001 and the approach of the system is shown {fig.4}[6]. The context of the organization and determining the expectations of interested parties(fig.5) is also part of the orientation of the company as a whole, but the implementation of Industry 4.0 would lead to their revision and updating. The context of the organization cannot be done automatically, even with artificial intelligence, because it includes environmental, technological, economic, natural, resource, competitive context, as well as culture, corporate image and values of the company. In general, section 4 is too specific to be completed automatically.

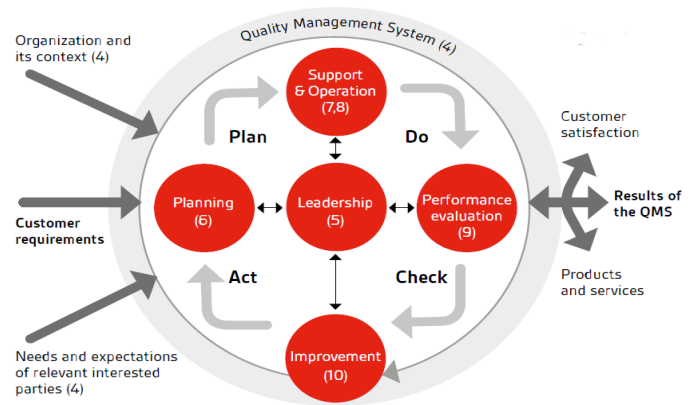


Fig.4 Structure of ISO 9001 and the PDCA approach[6]



Fig.5 Interested parties

Responsibility of management, are aimed at the successful functioning of the company, making a profit based on satisfying the requirements of customers and other interested parties. Management of the company demonstrates personal commitment through leadership and active participation in the management of all processes necessary for the system. Clause 5 includes the quality management policy, the organizational structure and roles and responsibilities in the company, also a risk management procedure{fig.6}, legal and regulatory requirements, quality objectives,

These are entirely management functions, which will not change in the conditions of Industry 4.0. Planned actions are carried out, in which circumstances and requirements of an external and internal nature are taken into account and the risks and opportunities that must be taken into account are determined in order to:

- create confidence that the system can achieve the intended results;
- increase the desired consequences;
- prevent or reduce unwanted consequences;
- achieve improvement.

		Impact on the Business					
		1 Negligible	2 Minor	3 Moderate	4 Critical	5 Catastro phic	
Probability	1 Near Impossible	1	2	3	4	5	Low Risk
	2 Unlikely	2	4	6	8	10	Medium Risk
	3 Notable Chance	3	6	9	12	15	
	4 Likely	4	8	12	16	20	High Risk
	5 Almost Certain	5	10	15	20	25	

Fig.6 Part of a risk procedure, FMEA example.

The quality goals should be consistent with quality policy and should be specific, measurable, realistic, achievable and timely. The quality objectives in the context of Industry 4.0 will be limited to the technical capabilities of the smart factory, they will be a function of the horizontal and the vertical integration, capabilities of the digital twins, modularity, level of the cyber-physical systems, etc. Higher quality goals will be associated only with a higher class of equipment. All activities in this clause may be supported by elements of Industry 4.0, but will hardly be fully automated

By determining and securing the resources necessary to achieve goals, management ensures that customer requirements are met. In the context of Industry 4.0, focus from human resource management will increasingly shift to a focus on infrastructure. One of the goals of Industry 4.0 is complete autonomy of infrastructure, as a large part of the information for planning and support will be electronic in the software of the machines themselves and it will be managed as Big data.

A barrier to the quality management system implementation to Industry 4.0 are the processes related to monitoring and measuring resources. The monitoring and measuring resources should be implemented in the control station equipment itself and control of the monitoring and measuring resources should be fully automated. This can lead to serious difficulties regarding compliance with relevant standards, as regards measurement accuracy, measurement frequency, number of measurements, dimensions, testing conditions, etc. Another big problem is about the calibration of resources for monitoring and measuring of such equipment, due to the lack of appropriate tools and standards in this direction.

Points knowledge and experience, competence and awareness should be completely focused on machine learning. Keeping these points in a future version should have a completely different interpretation.

Planning determines the resources needed to meet product and service requirements. The activities in clause 8 are customer-related processes, new product design, production planning and control, non-conforming product management, process management and products from external suppliers. Almost all activities in this section, except for design of a new product, may be carried out with full integration of the principles of Industry 4.0 automatically, though, Internet of things, Internet of services, machine-machine communication.

The design of a new product is usually a long main procedure that goes through following stages-design planning, determining the input data (normative, functional and operational requirements, information from previous developments), design results (compliance with the input data, characteristics related to safety), design review (evaluation of results, non-conformance analysis, verification of the entire design process, confirmation and validation. In any case, this procedure would be difficult to fully

automatically implementation, due to the great variety of potential new designs and the heuristic nature of the process.

Clause 9 contains the main procedure of internal audit and management review. In any case, the concept of Industry 4.0 presupposes conduct of a digital internal audit and all activities to be performed automatically without human intervention [7]. This will lead to independent verification by internal audit and higher results from its conduct. The management review will remain in its same format.

Clause 10 contains the points of corrective actions and continuous improvement. The corrective actions are expected to be performed primarily digitally by machine, as the prerequisites for this are the possibilities for processing Big data, timely decision-making.

Continuous improvement will continue to be based on the Deming-PDCA cycle because it is fundamental to the entire system.

### 5.Conclusion

The principles of the quality management system will remain for the most part even with the full implementation of Industry 4.0, as the inclusion of people will move more to the inclusion of machines in a smart factory, The management of relationships will move to management of digital communication. Changes in the principles of the quality management system will not change the integrity and objectives of the system.

Along complete digitization of the documented information of the quality management system, the question how the documents will be identified by numbers remains problematic. It would be good if the identification remains only by the name, but for this purpose a change in the standard is needed. The analysis of the structure of the standard shows, that some clauses will be very difficult to become digitized-Context, Leadership, Planning. The rest of the clauses-Support, Operation, Performance evaluation and Improvement may be digitized with appropriate technological development.

The combination of 9001 and Industry 4.0 should lead to a synergistic effect, and for this purpose the future version of the ISO 9001 standards should be related to Industry 4.0 and be normatively more flexible towards digital processes, in order to increase the competitiveness of industrial companies

### 6.Refferencies

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