Guide to ISO 9001:2015

Interpretation of the requirements of DIN EN ISO 9001:2015

Dear Reader,

Quality and customer satisfaction are vital factors when it comes to success on the competitive market. For many years now, the internationally recognised standard ISO 9001 has provided the basis for efficient quality management in a large number of organizations.

The environment in which companies and other organizations have to work has become much more complex in the past few years. This fact, which also has a decisive impact on all aspects of management, is taken into account by the new version of the Standard. This new version is to be adapted to present and future developments in such a way that it can retain its validity for a period of ten years. But one thing will not change — ISO 9001 will remain the only cross-sector certification standard for quality management systems.

We would like to keep you informed at all times about the latest developments, and so this Guide has been created to answer the most important questions regarding the new ISO 9001.

Some practical examples of interpretation of the Standard, along with suitable system documents and key indicators, will show how you can meet the changed requirements.

Dr. Klaus Oberste Lehn

In view of the transitional period of three years, you will have sufficient time to consider future planning for your quality management system and to discuss the transition to ISO 9001:2015 at leisure with our auditors.

We are looking forward to speaking to you!

Dr. Klaus Oberste Lehn
Head of Certification Body
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1. The Learning Organisation

1.1. How quality management helps organizations to progress

Quality management is a development concept for companies and other organizations. Development means the ability to adequately meet changing challenges. Many requirements, such as technological change or increasing competitive pressure, mean that organizations have to change continuously in order to adapt to their markets as effectively as possible. As important as it is to adapt, ongoing development of know-how is essential – for this is the prerequisite for growth and improvement in market position. However, this development is not simply a reaction to short-term crises, but is always a longer-term process. Therefore well-functioning quality management creates the necessary structure for continual development, in order to enhance customer satisfaction and therefore success on the market.

International Standard ISO 9001 is an internationally-recognised, reliable and tried and tested basis for such quality management. All over the world, it promotes further development of organizations and creates trust in the relationships between companies, their customers and their suppliers. The numbers speak for themselves: in 2013 there were a total of 1,129,446 certificates to ISO 9001 spread over 187 countries. This amounts to nearly three quarters of all ISO certificates – and the numbers are still rising.

Next to China and Italy, Germany is one of the countries in which most certificates have been issued. However, there is also increasing demand for ISO 9001 certifications in India and the USA.

1.2. History of ISO 9001

Just as companies develop as they base their quality management on ISO 9001, so does the Standard itself develop: around every five years, the Standard is subjected to thorough revision and updating in order to reflect changed conditions. Since its introduction in 1987, ISO 9001 has been through several stages on the way to its current form. This evolution is also connected with the development of TÜV NORD CERT: the certification unit for quality management at TÜV NORD was established in 1986.

The first version of ISO 9001 was based on one British and one US-American military standard. It provided for three different quality management systems, depending on the business activities of the organization to be certified.

The first revision took place in 1994: it placed particular emphasis on the theme of quality assurance and recommended preventive measures, instead of merely checking the end product. Organizations were still structured in terms of individual departments and organizational units.

The year 2000 brought a radical revision and adaptation of the standard to modern management methods. In place of quality assurance and control, concepts for quality management and process management at a deeper and more cross-departmental level were introduced; in addition, continual improvement of customer satisfaction came to the fore. Analysis of requirements, the process approach and the linking of different work processes became the focus of attention. Mere concentration on individual units within the organization gave way to a process-based way of seeing things, or in other words to an overall process landscape.

The new edition of 2008 did not bring about such far-reaching changes, but simply clarified some aspects of the standard. In the course of this, ISO 9001 was brought closer to Standard ISO 14001, which deals with environmental management. Even if an increasing trend towards sector-specific standards has been seen since the turn of the millennium, ISO 9001 remains the preeminent quality standard: no other standard is so widespread throughout the world, and no other standard is

so well able to combine generally applicable principles for establishing and maintaining quality throughout an organization under one umbrella. This means that ISO 9001 continues to be the main guide for organizations of all sectors and types, not only in order to determine the requirements of their customers, but also to fulfil them in the best possible way through provision of products and services.

1.3. The schedule for the changeover following publication of ISO 9001:2015

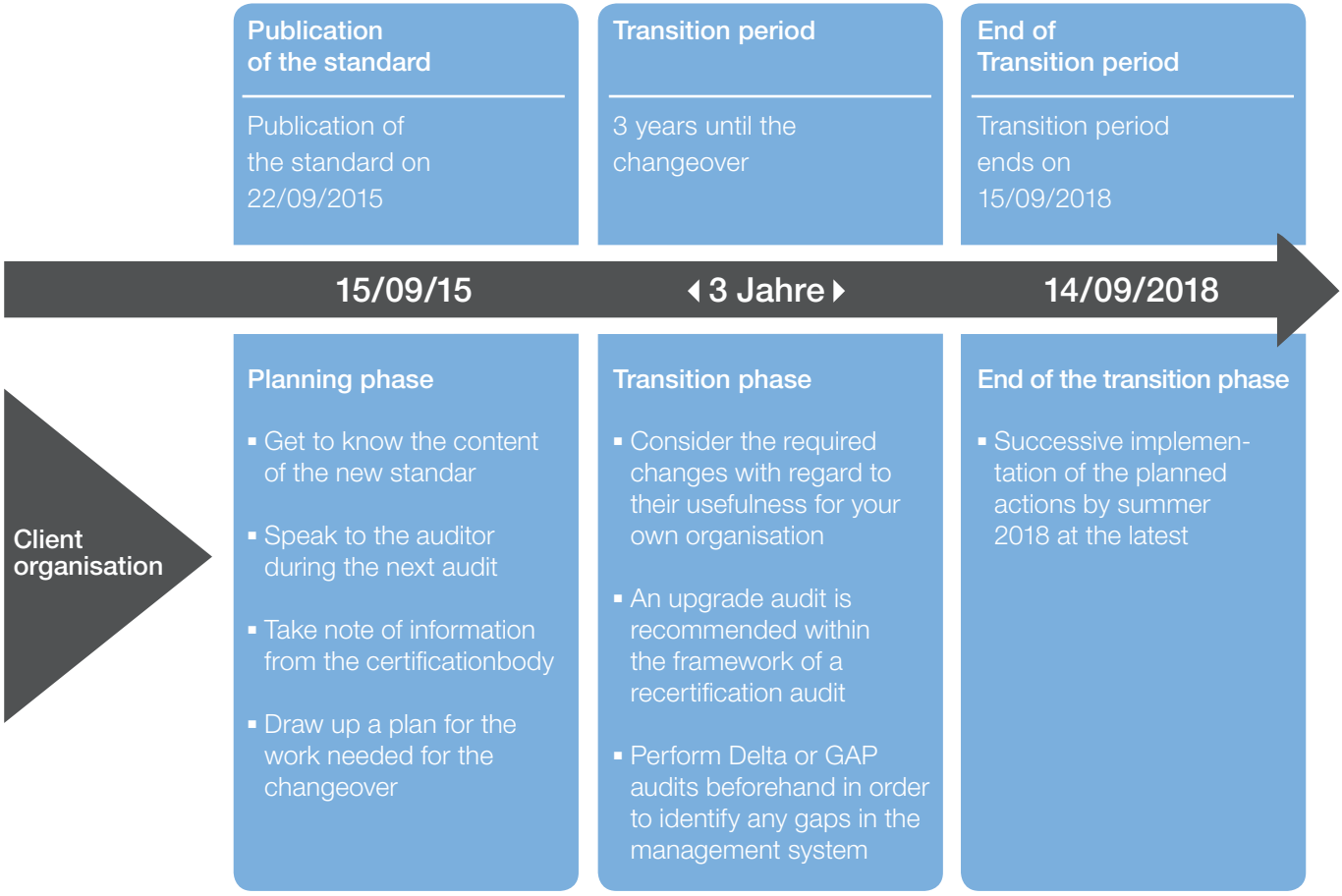

Figure 1 – ISO 9001 timeline

The three-year transition period for ISO 9001:2015 begins on 15/9/2015 and ends on 14/09/2018. Certificates according to ISO 9001:2008 that are still in circulation have a validity of three years provided that within the (aforementioned) transition period, the changeover is made to ISO 9001:2015 by means of an upgrade audit.

Following the changeover, new certificates will be issued based on ISO 9001:2015 for the remaining validity period of the old certificates (or based on the corresponding issue of the DIN EN ISO-standards). Since the publication of ISO 9001:2015, audits can also be performed according to ISO 9001:2015.

Audits according to the former DIS (Draft Standard) will not be recognised. Companies and other organisations that are already certified then have the possibility to change over by 14. September 2018. An upgrade audit within the framework of recertification is recommended. In order to achieve successful recertification according to the new standard, we recommend performance of Delta or GAP audits. GAP audits make it possible to identify the gaps in the management system in advance. The GAP audit can be added, for example, to the next surveillance or recertification audit. This means that there will be sufficient time for the transition phase. Simply contact us or send us a message if you require further information or an offer.

2. What's new? The main changes in ISO 9001:2015

2.1. Introduction of a "High Level Structure"

The most important new aspect of ISO 9001:2015 regards the establishment of the so-called High Level Structure. The background is that all management systems are based on certain basic elements – including ISO Standards such as ISO 9001, ISO 14001 for environmental management, BS OHSAS 18001 for occupational health and safety and ISO 27001 for information security. However, despite their close relationship with each other, these standards up to now did not share a common structure. In order to make harmonised structure and wording possible for all the relevant standards, a structure with identical chapter structures, texts, terms and definitions has now been established for all future management standards. This represents a very important step forward along the path to integrated management systems.

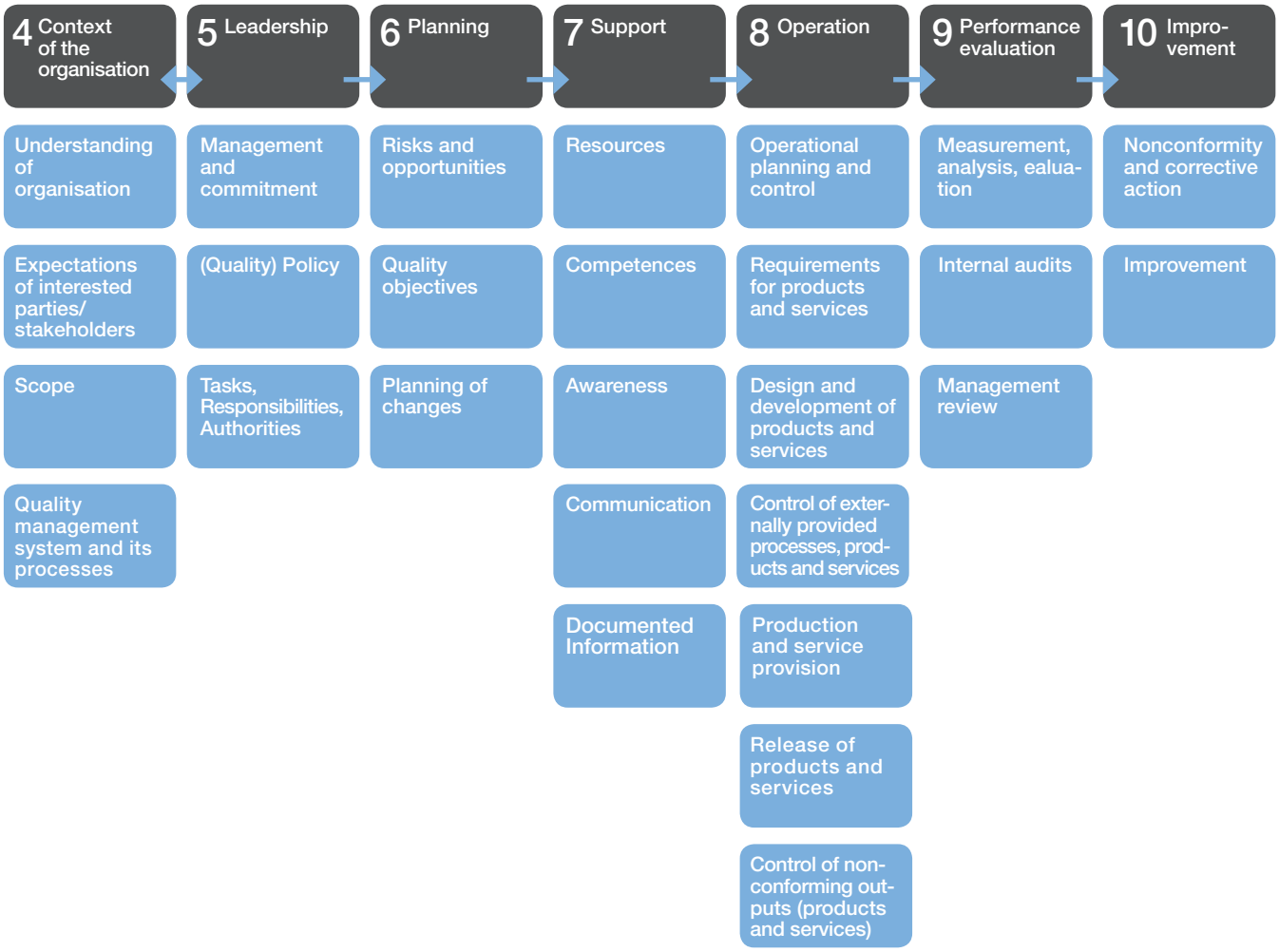

Figure 2 – Overview of the High Level Structure

Schedule for the changeover of all management systems to the new structure:

Standard	Already changed over to High Level Structure	Changeover 2016	Changeover 2017
ISO 27001	X		
ISO 9001	X		
ISO 14001	X		
BS OHSAS 18001		X	
ISO 22000			
ISO 22301			
ISO/TS 16949		X	
ISO 50001			X
ISO 13485			

2.2. Concept of risk-based thinking

ISO 9001:2015 assumes that a basic understanding of (product- or service-related) risk assessment is increasingly important for organizations of all kinds. For this reason, the concept of risk-based thinking is being introduced for the first time. Although no risk management as such is required, organizations should identify risks and be able to take them appropriately into consideration. In return, there is no specific requirement for preventive measures.

2.3. More freedom for documentation

The minimum six documented procedures are no longer required; instead of documents and proofs, the only mention is of documented information. This makes handling of documents more flexible. Based on its own specific competences and structures, the organization can decide for itself what it wishes to document and to what extent. This decision must be justified to the auditor within the framework of the certification.

2.4. Greater relevance of the standard for service provide

The fact that the service sector is growing is also reflected in ISO 9001:2015. Although it was possible to implement the standard across sectors in the past, the new version is more strongly focussed on the needs and interests of service providers. Among other things, the term "products" has now been expanded to become "products and services".

2.5. Concept of "interested parties"

At two points in the new version, reference is made to so-called "interested parties" (stakeholders), whose interests must be taken into consideration by the respective organization. Although this requirement also existed before, this aspect is now accorded greater emphasis. In concrete terms this means that the organization should not only consider statutory and regulatory requirements and the needs of their customers, but should also consistently think about their relationships with their employees, partners, suppliers and other parties who are relevant for their quality management system, such as banks, local authorities or even competitors.

2.6. Tasks of management, absence of qualitiy management representative

Assignment of roles and tasks has been overhauled; there is now a clearer requirement for acknowledgement of management responsibility and commitment. Instead of a separate quality management representative, in future a member of the company or organization management will fulfil this role. The management review is extended to include aspects of strategic focus, consideration of stakeholders and strategic risk assessment.

2.7. Improvement of customer satisfaction

The new version of the standard requires that necessary inputs and expected outputs must be specified and measured for each process. KPIs (Key Process Indicators) were not so clearly required before. This means that ISO 9001:2015 is driving forward consideration, monitoring and measurement of processes.

For more detailed information, an overview of the clauses in the Standard and a summary of the requirements and possible evidences that can be provided by your organization, please see the interpretation of the requirements given in Chapter 4 of this document.

3. Comparison of ISO 9001:2015 – ISO 9001:2008

The table below shows the difference between the structure of ISO 9001:2008 and the new version, ISO 9001:2015.

Clause 9001:2008	Basic ISO structure	Clause 9001:2015
1	Scope	1
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3	Terms and definitions	3
1	Context of the organization	4
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New	Understanding the needs and expectations of interested parties	4.2
1.2 / 4.2.2	Determining the scope of the quality management system	4.3
4 / 4.1	Quality management system and its processes	4.4
5	Leadership	5
5.1	Leadership and commitment	5.1
5.2	Customer focus	5.1.2
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4.2.1a / 5.3	Development of quality policy	5.2.1
5.3 d	Communication of quality policy	5.2.2
5.5.1 / 5.5.2	Roles, responsibilities and authorities in the organization	5.3
5.4.2	Planning	6
New	Actions to address risks and opportunities	6.1

Clause 9001:2008	Basic ISO structure	Clause 9001:2015
4.2.1a / 5.4.1	Quality objectives and planning to achieve them	6.2
New	Planning of changes	6.3
6	Support	7
6	Resources	7.1
6.1	General	7.1.2
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6.3	Infrastructure	7.1.3
6.4	Environment for the operation of processes	7.1.4
6.2 / 8.2	Monitoring and measuring resources	7.1.5
7.6 / 8.2	Traceability of measurements	7.1.5.2
New	Organizational knowledge	7.1.6
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6.2.2 d	Awareness	7.3
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4.2	Documented information	7.5
4.2.1	General	7.5.1
4.2.3 / 4.2.4	Creating and updating	7.5.2
4.2.3 / 4.2.4	Control of documented information (Documented information required) (Control of documented information)	7.5.3 7.5.3.1 7.5.3.2

Clause 9001:2008	Basic ISO structure	Clause 9001:2015
7	**Operation**	8
7.1 / 7.5.1	Operational planning and control	8.1
7.2	Requirements for products and services	8.2
7.2.3	Customer communication	8.2.1
7.2.1	Determination of requirements related to products and services	8.2.2
7.2.2	Review of requirements related to products and services	8.2.3
7.2.2	Changes of requirements related to products and services	8.2.4
7.3	Design and development of products and services	8.3
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7.3.1	Design and development controls	8.3.4
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7.3.7	Design and development changes	8.3.6
4.1 / 7.5.4	Control of externally provided products and services	8.4
4.1 / 7.5.4	General	8.4.1
4.1 / 7.5.4	Type and extent of control of external provision	8.4.2
7.4.2	Information for external providers	8.4.3
7.5	Production and service provision	8.5

Clause 9001:2008	Basic ISO structure	Clause 9001:2015
7.5.1	Control of production and service provision	8.5.1
7.6	Means of measurement	8.5.1
7.5.3	Identification and traceability	8.5.2
7.5.4	Property belonging to customers or external providers	8.5.3
7.5.5	Preservation	8.5.4
7.2.1 / 7.5.1	Post-delivery activities	8.5.5
7.2 / 7.3.7 / 8.2	Control of changes	8.5.6
7.4.3 / 8.2.4	Release of products and services	8.6
8.3	Control of nonconforming process outputs, products and services	8.7
8.1	**Performance evaluation**	9
8.1	Monitoring, measurement, analysis and evaluation	9.1
8.1	General	9.1.1
5.2 / 8.2.1	Customer satisfaction	9.1.2
8.4	Analysis and evaluation	9.1.3
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5.6	Management review	9.3
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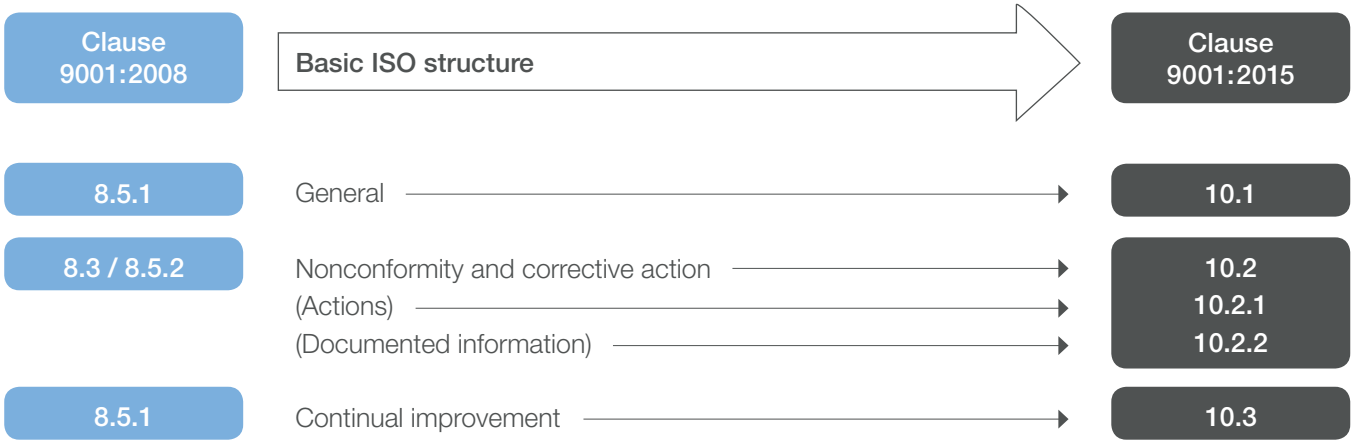
5.6.2	Outputs of the management review	9.3.2
5.6.3	Outputs of the management review	9.3.3
8.5	**Improvement**	10


Clause 9001:2008
Basic ISO structure
Clause 9001:2015
8.5.1
General
10.1
8.3 / 8.5.2
Nonconformity and corrective action
(Actions)
(Documented information)
10.2
10.2.1
10.2.2
8.5.1
Continual improvement
10.3

4. ISO 9001:2015 – Interpretation of the requirements

4.1. Notes for the user

In the following sections of this brochure we use a consistent presentation scheme. Each clause or sub-clause of the Standard will be shown in the following form.

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators

The column **Requirement of the Standard** contains the basic requirements of the respective clause or subclause of the Standard.

Under the heading **Interpretation / Activities,** examples are given of activities for practical implementation within a process-orientated framework in companies and organizations.

The column regarding **Examples of documentation / Evidences** shows some documents which can provide evidence of fulfilment of the requirements of the Standard.

The fourth column lists some practical **examples of Key Process Indicators.** However, the examples do not claim to be exhaustive, as in practice different KPIs or KPI systems are used in different organizations.

4.2. Interpretation of the requirements of ISO 9001:2015 clauses

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators

Clause 4 – Context of the organization

4.1 Understanding the organization and its context		
Understand the organization and its context	Determine external and internal issues that are important for the objectives and strategy of the organization, and continuously observe them. The aim is to define the themes and evaluate which ones influence the capability of the QM system and aretherefore relevant to the results to be achieved, e.g. fulfilment of customer requirements.	▪ analysis of the influencing factors **External themes:** ▪ List of the laws, changes and planned changes ▪ technical developments ▪ market analyses ▪ economic changes ▪ strategy papers **Internal themes:** ▪ mission statement ▪ performance, key indicators ▪ cultural themes (e.g. China)

4.2 Understanding the needs and expectations of interested parties		
Understand the needs and expectations of interested parties	Determination: ▪ of the interested parties who are relevant for the QM systems ▪ and the requirements and expectations of the interested parties that are relevant for the QM system The aim is to monitor and check the information supplied to the interested parties along with the requirements and expectations of the interested parties. This is in order to determine the effect on the capability to provide products and services which fulfil customer requirements and legal requirements.	List of interested parties and their requirements: ▪ customers ▪ owners ▪ suppliers ▪ banks ▪ partners ▪ official bodies / authorities ▪ universities ▪ associations, federations ▪ development centres

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
4.3 Determining the scope of the quality management system			
Determine the scope of the quality management system	▪ Determine the boundaries and scope of the QM system ▪ Determine the scope, taking the internal and external themes into consideration, and also the requirements of the interested parties ▪ Documented scope, stating the products and services which fall under the QM system products and services supplied by the organization.	▪ scope ▪ description of the processes within the scope, including outsourced processes ▪ geographical and technical scope ▪ justification of exclusion of requirements	
4.4 Quality management system and its processes			
Quality management system and its processes Requirements for the quality management system: ▪ structure, implementation, maintenance and continual improvement of the QM system ▪ determination and use of the necessary processes and their interactions Documented information that is needed in order to support the processes and carry them out as planned must be updated and kept.	The aim is to determine, use, monitor, assess and improve the processes of the QM system that are needed to achieve the intended results. The following must be taken into consideration: ▪ inputs and outputs ▪ sequence and interaction of processes ▪ criteria, methods, measurement of performance indicators for ensuring effective implementation and control of the processes ▪ resources needed and available ▪ responsibilities for processes ▪ risks and opportunities ▪ necessary changes ▪ opportunities for improvement	▪ description of the interactions of the processes, e.g. process model ▪ list of process owners ▪ tasks, function/job description of the process owners ▪ process indicators for measuring effectiveness of processes ▪ assignment of the process indicators to the processes ▪ measurement, monitoring and evaluation of the processes ▪ linking of the processes with further documents (documented procedures, work instructions) ▪ available resources ▪ analysis of processes with regard to risks and opportunities and associated planning, implementation and assessment of actions ▪ list of the documents needed for implementation of the processes, document control and storage	▪ customer satisfaction indicators ▪ process quality indicators ▪ process performance indicators ▪ process cost indicators ▪ resource indicators ▪ target achievement indicators ▪ business management indicators

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators

Clause 5 – Leadership

5.1 Leadership and commitment

5.1.1 Leadership and commitment for the quality management system	The top management shall demonstrate leadership and commitment by taking responsibility for the effectiveness of the QMS ▪ establish quality policy and objectives that are appropriate to the strategy and context of the organization ▪ communicate quality policy and ensure that it is understood and implemented in the organization ▪ ensure integration of the QMS into business processes ▪ promote awareness of the process approach and risk-based thinking and communicate importance of fulfilment of the requirements of the QM system ▪ ensure necessary availability of resources ▪ ensure that the desired QMS ▪ support employees and others, in order to ensure the effectiveness of the QMS ▪ promote the continual improvement process ▪ support others in their management activities	▪ written quality policy and objectives ▪ evidence of training on quality policy/informative events ▪ statements of top management ▪ evidence of attainment of targets (BSC) ▪ improvement projects ▪ results from top management meetings ▪ management review ▪ performance charts ▪ reaction plans if results/ targets not achieved ▪ training plans/evidences regarding process approach, processes, methods ▪ communication with employees (notices, agendas of information events) regarding effectiveness of the QM system ▪ personnel development plans ▪ employment of personnel ▪ protocols regarding targets ▪ project plans ▪ investment plans ▪ training budget ▪ factory agreements with employees ▪ continual improvement projects ▪ results from top management meetings ▪ corporate policies ▪ mission statement	▪ rate of target fulfilment ▪ rate of meeting deadlines ▪ customer satisfaction index ▪ complaint rate ▪ qualification index of personnel ▪ return on Investment (RoI) ▪ benchmark hit list (ranking) ▪ profit margin (genera) ▪ implementation rate of training budget ▪ investment implementation rate ▪ employee fluctuation rate ▪ employee satisfaction index

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
5.2 Customer focus			
5.2 Customer focus The top management shall demonstrate leadership and responsibility for customer satisfaction	Leadership and commitment for customer satisfaction through ▪ communication, understanding and fulfilment of customer requirements and the currently valid statutory and regulatory requirements ▪ determination of risks and opportunities concerning product and service compliance ▪ focus on improvement of customer satisfaction	▪ analysis of customer satisfaction ▪ SWOT analysis ▪ action plans ▪ list of customer requirements ▪ list of statutory and regulatory requirements ▪ assessment of fulfilment of customer requirements ▪ action plans ▪ analysis of customer surveys ▪ market analyses ▪ analysis of complaints documentation	▪ customer satisfaction index ▪ complaint rate ▪ new products/time unit ▪ break even point for new products ▪ life cycle of products ▪ number of product liability cases ▪ key indicators for production risk ▪ field failure rate
5.2 Policy			
5.2.1 Development of quality policy	The top management shall determine, implement, monitor and maintain a Q policy. The quality policy must ▪ be appropriate for the objective and the context of the organization ▪ create a framework for determination and review of Q objectives ▪ contain the obligation to fulfil appropriate requirements ▪ contain the obligation to undertake continual improvement	▪ written statement of Q policy ▪ review of Q policy for appropriateness	
5.2.2 Communicating the quality policy	The quality policy must: ▪ be available as documented information ▪ be communicated, understood and applied within the organization ▪ be available to relevant interested parties, as appropriate	▪ written version of Q policy ▪ documentation from informative events, Intranet entries etc. for employees, printed versions for stakeholders of the organization, possibly publish on the Internet	

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
5.3 Organizational roles, responsibilities and authorities			
5.3 Organisational roles, responsibilities and authorities	Assignment, communication and understanding of responsibilities and authorities for relevant roles within the organization, in order to ensure that ▪ the QM system fulfils the requirements of ISO 9001:2015 ▪ the processes provide the intended result ▪ the performance of the QMS and potentials for improvement are reported to the top management ▪ customer focus is promoted ▪ the integrity of the QMS is maintained, even if changes occur	▪ organisation charts ▪ job/function descriptions ▪ definition of members of management and top management ▪ letters of appointment ▪ control rights ▪ contracts with third parties ▪ budget ▪ requirement profiles ▪ process owners ▪ key accounts, customer support staff ▪ change management ▪ communication rules ▪ status reports/Q-analyses ▪ reports on internal audits ▪ reports regarding Q situation ▪ statistical evaluations ▪ management review ▪ innovation projects ▪ project planning for change	▪ key indicators regarding the effectiveness of the QM system ▪ rate of fulfilment of performance assessments ▪ rate of fulfilment of Q objectives ▪ rate of fulfilment of process results ▪ employee fluctuation rate

Clause 6 – Planning for the quality management system

6.1 Actions to address risks and opportunities			
6.1.1	The objective is to plan the QM system so that, taking into consideration the internal and external themes, the requirements of the interested parties and the risks and opportunities that have been determined, ▪ the QM System achieves the intended results, ▪ undesired effects are prevented or reduced ▪ desired effects are strengthened ▪ continual improvement is achieved and maintained, even if changes occur	▪ project plan for change projects with inputs ▪ list of external themes ▪ list of internal themes ▪ list of risks ▪ list of opportunities ▪ investment plans ▪ strategy plans ▪ QM plans ▪ production plans ▪ resource plans/evidences	

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
6.1 Actions to address risks and opportunities			
6.1.2	Measures for handling risks and opportunities shall be planned, integrated into the QM system, implemented and assessed for effectiveness. Determination of risks and opportunities is related to creation of products and services. Determination of the measures is orientated on the possible influence on conformity.	▪ list of risks ▪ list of opportunities ▪ FMEAs ▪ risk analyses ▪ action plans ▪ QM plans ▪ production plans ▪ resource plans/evidences ▪ process descriptions ▪ work and test plans	▪ risk priority number ▪ implementation rate of actions
6.2 Quality objectives and planning to achieve them			
6.2.1	Q objectives shall be specified and maintained in written form for relevant functions, levels and processes. Quality objectives shall ▪ be consistent with the Q policy ▪ be measurable ▪ take appropriate requirements into consideration ▪ be relevant for product and service and also relevant to increase of customer satisfaction ▪ be monitored ▪ be communicated ▪ be updated when necessary ▪ must be documented and the documentation must be kept	▪ Q objectives and their determination and communication ▪ internal/external target agreements (business plans, project plans, qualify agreements) ▪ organization-related, product-related, customer-related objectives ▪ employee information ▪ rules regarding updating ▪ rules regarding control ▪ harmonisation with Q policy ▪ level of achievement and trends	▪ implementation rate of Q objectives ▪ customer-related quality objectives: fulfilment of delivery dates, complaint rate, customer satisfaction index ▪ product-related quality objectives: tonnage, internal production times, OEE, machinery utilisation rate, rework rate, scrap rate, stocks, key indicators for process quality, cpk values, throughput times, processing times, ▪ external providers: complaint rate, adherence to delivery deadlines
6.2.2	When planning how to achieve its quality objectives, the organization shall define ▪ what will be done ▪ what resources will be required	▪ action plans ▪ results of evaluations	

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
6.2 Quality objectives and planning to achieve them			
6.2.2		▪ who will be responsible ▪ when it will be completed ▪ how the results will be evaluated	

Clause 7 – Support

7.1 Resources			
7.1.1 General	The organization shall determine and provide the necessary resources for the QMS. The following must be taken into consideration: ▪ capabilities and limitations of the existing internal resources ▪ what information has to be gathered from external providers	▪ requirement profile (employees, infrastructure) resource planning (internal and external) ▪ project management ▪ availability (personnel, infrastructure) ▪ job or function descriptions ▪ service/quality agreement (if using external resources)	▪ extent of resources ▪ capacity utilisation of persons involved ▪ risk assessment/planning of redundancies ▪ sickness rate
7.1.2 People	The organization shall provide the persons necessary for effective implementation of the QMS	▪ personnel, staff position planning ▪ definition of key qualifications ▪ status of available qualified staff and qualifications ▪ qualification plan ▪ staff deployment planning	▪ qualification index ▪ rate of further training undertaken (qualification index)
7.1.3 Infrastructure	The organization shall determine, provide and maintain the infrastructure necessary for operation of its processes to achieve conformity of products and services. Examples are buildings, tools, equipment, software, hardware, transport, IT	▪ investment plans ▪ resource planning ▪ material flow analyses ▪ warehouse capacity assessment ▪ process capability studies ▪ measuring instrument capability studies	▪ availability of plant and machinery

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
7.1 Resources			
7.1.4 Environment for the operation of processes	The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services, e.g. physical, social, psychological and environmental factors and other factors such as temperature, humidity, ergonomics and cleanliness)	▪ handling and storage conditions (temperature, air humidity, cleanliness, identification, traceability etc.) ▪ servicing and maintenance plans ▪ risk and hazard assessment ▪ factory tour reports/logs	▪ implemented training courses ▪ employee satisfaction index ▪ employee fluctuation rate ▪ accident statistics
7.1.5 Monitoring and measuring resources 7.1.5.1 General	Where monitoring and measurements are necessary for the conformity of the product or the service, the organisation shall determine the resources needed to ensure valid, reliable monitoring and reliable measurement. ▪ Measuring instruments shall be regularly maintained in order to ensure continuous availability for use in accordance with the intended purpose, and corresponding documented information must be available.	▪ test planning concept ▪ test planning ▪ qualification requirements for testers ▪ test instructions ▪ determination or resource requirements ▪ measuring equipment capability studies ▪ validation of test software ▪ register of measuring equipment and standards ▪ evidences of calibration ▪ reference to international standards ▪ corrective actions in case of defective measuring instruments	▪ rate of tests not OK (to assess process capability) ▪ proportion of measuring devices with calibration results not OK ▪ accumulated use times of a measuring instrument ▪ calibration times (available/ non-available periods) ▪ set/actual stock of instruments ▪ proportion of measuring instruments which could not be located at the planned time of calibration ▪ time/cost for re-testing and further actions (e.g. recall), if defective measuring instruments were used
7.1.5.2 Measurement traceability	Where measurement traceability is a statutory or regulatory requirement, a customer or relevant interested party expectation, or considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring instruments shall be verified or calibratedat specified intervals or prior to use against measurement standards traceable to international or national	▪ test planning concept ▪ test planning ▪ qualification requirements for testers ▪ test instructions ▪ dermination of resource requirements ▪ measuring equipment capability studies ▪ validation of test software ▪ register of measuring instruments and standards ▪ evidences of calibration ▪ reference to international standards	▪ rate of tests not OK (assessment of process capability) ▪ propertion of measuring instruments with calibration result not OK ▪ accumulated use times of a measuring instrument ▪ calibration times (available/ non-available periods)

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
7.1 Resources			
7.1.5.2 Measurement traceability	measurement standards. (If no standards exist the basis for calibration or verification must be retained in documented form) ▪ identified in order to determine their calibration status ▪ safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results. If a defective measuring instrument is identified, the organization shall review the validity of the previous measurement results. Corrective action must be taken.	▪ corrective actions in case of defective measuring instruments	▪ set/actual stock of instruments ▪ proportion of measureing instruments which could not be located at the planned time of calibration ▪ time/cost for re-testing and further actinos (e.g. recall), if defective measuring instruments were used
7.1.6 Organizational knowledge	The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and made available to the extent necessary. When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access the necessary additional knowledge.	▪ information entry and onwards transfer points ('knowledge hierarchy') ▪ list of relevant legislation ▪ knowledge database ▪ customer database ▪ analysis of product management reviews ▪ complaint database ▪ employee competence matrix ▪ training plans ▪ resource plans/project management ▪ FMEAs	▪ current nature of list of relevant legislation on a defined date ▪ proportion of obsolete standards in use at the time of the document review ▪ number of proposals for improvement ▪ number of implemented improvements

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
7.2 Competence	The organization shall: ▪ determine the necessary competence of employees/ person(s) doing work that affects its quality performance ▪ ensure that these employees/ persons are competent on the basis of appropriate education, training or experience ▪ where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken ▪ retain appropriate documented information as evidence of competence.	▪ qualification requirement profiles ▪ qualification matrix ▪ job/function descriptions ▪ employee meetings ▪ initial instruction plans ▪ mentoring programmes ▪ evidences of training ▪ assessment of effectiveness of training or mentoring programmes ▪ see previous section, 7.1.6	▪ implementation rate related to training requirement ▪ number of training units per year and employee (rate) ▪ analyses to evaluate the effectiveness of training or mentoring programmes ▪ training costs (rate) ▪ proportion of external/ internal training ▪ employee satisfaction index
7.3 Awareness	Persons doing work under the organization's control shall be aware of ▪ The Q policy ▪ The relevant Q objectives Their contribution to the effectiveness of the quality management system, including the benefits of improved quality performance	▪ minutes of meetings regarding performance and effectiveness of the system ▪ evidences of initial instruction and training ▪ participation in complaint meetings, Q circles ▪ evidences regarding knowledge of Q policy and objectives	▪ level of implementation
7.4 Communication	The organization shall determine the internal and external communications relevant to the quality management system, including ▪ On what it will communicate ▪ When to communicate ▪ With whom to communicate ▪ How to communicate	▪ communication plans (internal communication guidelines) ▪ job/function descriptions ▪ meeting hierarchy ▪ PR plans ▪ marketing concepts ▪ meeting reports	▪ analysis and evaluation of customer portfolio ▪ analysis of number of customer visits/surveys ▪ participation rate in continual improvement process or suggestion system ▪ participation rate in employee surveys

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
7.5 Documented information			
7.5.1 General	The QMS shall include: ▪ the documented information required by this Standard ▪ further information considered by the organization to be necessary for the effectiveness of the QMS.	At least: **4.3** Scope and exclusions **4.4** Process model and interactions, process responsibilities, performance indicators, risks, opportunities, resources, input, output, resources, necessary instructions like test instructions, work instructions, documented procedures **5.2.2** Q policy **6.2.1** Q objectives **7.1.5** calibration, verification **7.2** evidences of competence **7.5** rules regarding creation, updating and control of documented information **8.1** evidences of process control measures (e.g. cpk values, test logs, machine setting releases, product releases…) **8.2.3** assessment results of offer/contract review, including new and changed requirements **8.3.2** evidence of the fulfilment of requirements for development **8.3.5** development results **8.3.6** development changes **8.4.1** results of performance monitoring and new assessment **8.5.1** instructions for ensuring controlled conditions **8.5.2** storage of documented information for identification with regard to traceability **8.5.6** changes and results of the assessment and monitoring for unplanned changes to production/ service provision	

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
7.5 Documented information			
		8.6 evidences regarding conformity with requirements must be kept (release), with traceability to the person responsible for the release **8.7** the activities and decisions which were undertaken in relation to the nonconforming products/services shall be kept as documented information **9.1.1** suitable documented information shall be kept as evidence of results of monitoring and measurement **9.2.2** documented information as evidence of realisation of the audit programme shall be kept **9.3.2** the results of the management review shall be kept in the form of documented information	
7.5.2 Creation and updating	Documented information shall be ▪ identifiable and assignable (title, date, author, reference number etc.) ▪ have an appropriate format (language, software compatibility and graphics) and medium (paper or electronic) ▪ be subject to appropriate review and approval	▪ coding or number key ▪ rules on format ▪ establishment of responsibilities for review and approvals	
7.5.3 Control of documented information 7.5.3.1	The documented information shall be monitored and controlled to ensure that it ▪ is available where needed ▪ is adequately protected (confidentiality, integrity and use for intended purpose)	▪ list(s) of valid documents ▪ distribution keys/lists ▪ revision lists ▪ change procedures ▪ release procedures ▪ authority and access concept ▪ rules of behaviour ▪ security concept ▪ archiving rules	▪ review cycle ▪ information acquisition costs (laws, directives, standards and other regulations)

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
7.5 Documented information			
7.5.3.2	Document control shall include the following activities (in so far as applicable): ▪ idistribution, access, easy location and use ▪ filing/storage and preservation ▪ monitoring of changes (e.g. follow-up of versions) ▪ archiving period, disposalreview and approval	▪ list of necessary external documents ▪ control and identification of external documents, e.g. – laws, standards – customer specifications, drawings – requirements/contract specifications – datasets	

Clause 8 – Operation

8.1 Operational planning and control			
8.1 Operational planning and control	Control processes shall be planned, implemented and monitored. The following shall be considered: ▪ requirements for the product and services ▪ process criteria and acceptance criteria for the products and services ▪ resources needed to achieve conformity of products and services ▪ control of the processes in accordance with the defined criteria ▪ internal documentation that is necessary in order to have confidence in the control processes and to demonstrate conformity of products and services to requirements. The output of the planning shall be suitable for the organization's operations. Planned changes shall be controlled and consequences of unintended changes shall also be reviewed.	▪ Control process planning, controlling documents ▪ Evidence of product/ service acceptances from customers	▪ number of processes ▪ process cycle time ▪ process capability index ▪ customer satisfaction index ▪ complaint rate ▪ customer loyalty rate ▪ key indicators for process resources ▪ energy saving key indicators (e.g. reduction of consumption figures) ▪ further key indicators are given in the following paragraphs

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
8.1 Operational planning and control			
	Outsourced processes shall be controlled in accordance with 8.4.		
8.2 Determination of requirements for products and services			
8.2.1 Customer communication	Processes of customer communication shall be established in relation to: ▪ information relating to products and services ▪ enquiries, contracts, order handling, including requests for changes ▪ customer views, perceptions, complaints ▪ handling of customer property, if applicable ▪ contingency actions, where relevant	▪ product catalogues and lists, product descriptions ▪ complaint management ▪ contingency plans ▪ order documentation, contract documentation ▪ results of customer surveys	▪ number of enquiries to customers regarding clarification of product requirements ▪ reaction time regarding faults, nonconformities, complaints and claims ▪ customer satisfaction index
8.2.2 Determination of requirements related to products and services	A process shall be established, implemented and maintained to determine the requirements for the products and services to be offered to potential customers. It must be ensured that ▪ product and service requirements, including those considered necessary by the organization, and applicable statutory and regulatory requirements, are fulfilled ▪ the organization can fulfil these requirements and substantiate the claims for the products and services it offers	▪ project plans ▪ tender and performance specifications ▪ statutory and regulatory requirements	▪ product indicators (e.g. price, performance, lifetime, technical features, service supply capability) ▪ requirements regarding key indicators arising from statutory and regulatory requirements

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
8.2 Determination of requirements for products and services			
8.2.3 Review of requirements in relation to products and services	The following shall be reviewed as applicable: ▪ customer requirements, including for delivery and post-delivery activities • requirements not stated by the customer but necessary for the customer's specified or intended use • statutory and legal requirements • contract or order requirements differing from those previously expressed Requirements can also arise from the interested parties. The review shall be conducted prior to the commitment to supply products and services and must ensure that differences from the previously-defined requirements are resolved. Where the customer does not provide a documented statement of their requirements, the requirements shall be confirmed in writing by the organization prior to acceptance. This documented information shall be retained. Changes in the requirements shall also be included in the documented information and the relevant personnel shall be made aware.	▪ contracts ▪ order confirmations ▪ communication in case of changes ▪ see also 8.2.1	▪ key indicators regarding testing time and costs ▪ (e.g. duration of testing, frequency of testing, ▪ scope of testing) ▪ production costs ▪ production time ▪ time needed for feasibility study

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
8.3 Design and development of products and services			
8.3.1 General	A design and development process shall be established, implemented and maintained, which is suitable to make the subsequent production or service provision reliable and secure.	▪ project plans ▪ development plans/ flowcharts ▪ milestone plans ▪ measurement and test plans ▪ verification and validation rules ▪ rules for release/sign-off ▪ responsibility matrix ▪ risk assessment	▪ number of development plans per time period ▪ fulfilment rate of customer requirements ▪ fulfilment rate of customer expectations ▪ number of existing patents ▪ lifetime key indicators ▪ design and development times
8.3.2 Design and development planning	When specifying development stages and control, the following shall be taken into consideration: ▪ nature, duration and complexity of activities ▪ requirements that specify particular process stages, including reviews ▪ design and development verification and validation ▪ responsibilities and authorities ▪ need for internal and external resources ▪ interface control ▪ need to involve clients or users in the development process ▪ requirements for subsequent production or service provision ▪ the control level expected by customers and other relevant interested parties ▪ documentation that is required in order to evidence fulfilment of the requirements	▪ documented procedures for design and development ▪ process landscape for design and development ▪ project plans ▪ development plans/ flowcharts ▪ milestone plans ▪ measurement and test plans ▪ verification and validation rules ▪ release specifications ▪ responsibility matrix ▪ risk assessment	▪ number of development plans per time period ▪ fulfilment rate of customer requirements ▪ fulfilment rate of customer expectations ▪ number of existing patents ▪ lifetime key indicators ▪ design and development times
8.3.3 Design and development inputs	The organisation shall determine the requirements essential for the specific type of products and services being designed and developed.	▪ tender specifications/task set ▪ performance specifications (as written by supplier)	

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
8.3 Design and development of products and services			
	The following must be taken into consideration: ▪ functional and performance requirements ▪ information gained from previous comparable development activities ▪ statutory and regulatory requirements ▪ standards and procedural rules of the organization itself ▪ consequences of defective products and services Inputs must be appropriate for the development objectives, and must be complete and clear. Conflicts among inputs shall be resolved. Documentation of design and development inputs shall be retained.	▪ statutory and/or regulatory implementation guidelines ▪ reports of results from previous developments of the same kind ▪ evaluation of customer need evaluations ▪ patent searches ▪ release documents ▪ complaints analysis ▪ warranty analysis ▪ FMEAs	▪ rate of fulfilment of requirements and expectations in % ▪ number of projects to be processed ▪ number of statutory and/or regulatory requirements ▪ fulfilment rate of needs and expectations in % ▪ number of projects to be processed ▪ number of legal and/or statutory requirements ▪ index for ease of repair ▪ test cost index ▪ training and further training costs for the designers and developers ▪ design and development costs ▪ material cost index ▪ cost index for possible cooperation partners
8.3.4 Design and development controls	The controls shall ensure that ▪ the results to be achieved in the development are clearly defined ▪ the design and development reviews are conducted as planned ▪ verification is conducted to ensure that the results of the design and development have met the input requirements ▪ validation is conducted to ensure that the resulting products and services are suitable for the intended use	▪ performance specifications ▪ results of product quality controls ▪ verification logs ▪ validation records	▪ number of necessary tests ▪ fulfilment rate of development rules and specifications ▪ rate of fulfilment of process requirements ▪ number of follow-up actions ▪ disposal costs ▪ duration of development ▪ fulfilment rate of statutory and regulatory requirements: ▪ environment ▪ occupational health and safety ▪ health ▪ product liability etc. ▪ costs of testing time ▪ testing costs ▪ fulfilment rates for specified characteristics ▪ time and cost of follow-up actions

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
8.3 Design and development of products and services			
8.3.5 Design and development outputs	The design and development outputs shall ▪ meet the input requirements for design and development ▪ be adequate for the subsequent processes for the provision of products and services ▪ include or reference monitoring and measuring requirements and acceptance criteria as applicable ▪ ensure that products or services are fit for the intended purpose and their safe and proper use Documented information regarding the development outputs shall be retained.	▪ evidences from Clause 8.3	
8.3.6 Design and development changes	Changes that are made during development or subsequently to design inputs and outputs shall be determined, reviewed and controlled so that there is no negative impact on products on conformity to requirements. Documented information regarding changes to design inputs and outputs shall be retained, including results of reviews and the authority to make changes and instigate necessary actions.	▪ written change requests (e.g. of the customer, from production) ▪ new revision status of tender specification, drawings, process descriptions, test procedures, test equipment etc. ▪ comments/test reports regarding changes ▪ release documents regarding changes implemented ▪ communications sent to customers and departments regarding changes ▪ withdrawn documents ▪ change history	▪ number of development changes ▪ new verification and validation time/cost ▪ cost index for development changes ▪ savings rate

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
8.4 Control of externally-provided processes, products and services			
8.4.1 General	The organization shall ensure that external processes, products and services conform to the specified requirements. Control is necessary when external providers supply products and services which ▪ are incorporated into the organization's own products and services ▪ products and services are provided directly to the customer(s) by external providers on behalf of the organization ▪ are provided by an external provider as a result of decision by the organization Criteria for the evaluation, selection and monitoring of performance of external providers must exist and be applied. The most important aspect is conformity with the specified requirements. The organisation shall retain documented information regarding the resulting activities and actions.	▪ supplier assessment ▪ product specifications ▪ QM documentation of the supplier ▪ checklist ▪ evidences from supplier assessment ▪ list/database of approved suppliers ▪ assessment criteria ▪ complaints ▪ ppm statistics ▪ quality agreements ▪ performance specifications	▪ complaints regarding suppliers ▪ delivery reliability
8.4.2 Type and extent of control	Externally provided processes, products and services shall not have an adverse effect on the ability of the organization to consistently deliver conforming products and services to its customers. Externally provided processes shall remain under the control of the QMS of the organization. In order to define external provision, the following shall be taken into consideration:	▪ supplier management ▪ results of supplier audits ▪ own complaints issued to suppliers ▪ results from receiving inspection	

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
8.4 Control of externally-provided processes, products and services			
	▪ what influence do the externally-provided processes, products and services have on the conformity of the products/services supplied by the organization ▪ how effective are the control measures taken by the external provider him/herself Verifications and other activities must be correspondingly introduced and implemented in order to ensure conformity.		
8.4.3 Information for external providers	Applicable requirements for the following shall be communicated to external providers: ▪ the products, services or processes to be provided or performed ▪ approval and release of products and services, methods, processes or equipment ▪ competence and qualifications of personnel ▪ interactions with the QMS of the organization ▪ control and monitoring of the external provider's performance by the organization ▪ verfication activities that the organization or its customer intends to perform at the external provider's premises The adequacy of specified requirements shall be ensured prior to their communication to the external provider.	▪ evidences of communications with external suppliers ▪ overviews of requirements ▪ internal evaluations/reports regarding suitability of the requirements ▪ audit programme for supplier audits	

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
8.5 Production and service provision			
8.5.1 Control of production and service provision	Conditions for production and provision of services must be controlled. Controlled conditions shall include, as applicable: ▪ availability of documented information regarding the characteristics of products and services, activities to be carried out and results to be achieved ▪ availability and application of suitable resources for monitoring and measurement ▪ performance of monitoring and measurement activities ▪ suitable infrastructure and process environment ▪ competence and qualification requirements for persons ▪ validation and regular new validation of the processes when the resulting output cannot be verified by means of monitoring or measurement ▪ measures to prevent human error ▪ release of products, services, delivery activities, post-delivery activities	▪ written releases from customers ▪ results of internal quality controls ▪ test and measurement results ▪ results from internal audits	▪ process performance index ▪ process quality index ▪ processing times (e.g. for set-up, manufacturing, downtimes, control times, transportation times) ▪ machine flexibility rate ▪ reserve capacity rate ▪ equipment level of machinery ▪ tool utilisation rate ▪ proportion of optimum batch sizes ▪ order processing time to completion ▪ number of completed orders ▪ scrap rate ▪ machine downtimes ▪ process qualification rate ▪ proportion of special processes ▪ energy cost rate ▪ process control costs
8.5.2 Identification and traceability	Where necessary, identity and traceability shall be ensured. The status of process outputs (e.g. intermediate products, parts or services) shall be identified during the entire production process or service provision with respect to monitoring and measurement requirements. Where traceability is a requirement, it shall be maintained by means of suitable documented information.	▪ work instructions ▪ accompanying documents, e.g. process slip/routing card ▪ production plans ▪ EDP records ▪ marking on products ▪ evidences of testing ▪ blocking notes ▪ releases	▪ identification costs ▪ time and cost for preparation of recalls

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
8.5 Production and service provision			
8.5.3 Property belonging to customers or external providers	Property belonging to the customer or external providers shall be handled with care, identified, verified and protected. If the property is damaged, lost or incorrectly used, this shall be communicated to the customer or external provider.	▪ work instruction regarding handling of customer property ▪ list of customer property ▪ identification marking (labels, engraving, storage and warehouse lists etc.) ▪ correspondence with the customer ▪ records of verification and maintenance that have been performed ▪ receiving inspections	▪ costs due to reduction in quality of customer property ▪ proportion of storage costs for customer property ▪ costs for maintaining quality of customer property
8.5.4 Preservation	Process outputs shall be preserved during production and service provision to the extent necessary to ensure conformity with the requirements. Preservation can include identification, handling, packaging, storage, transmission or transportation and protection.	▪ packaging, storage, preservation and despatch rules ▪ parts lists ▪ storage lists ▪ stock location and removal plans ▪ rules regarding storage periods and any necessary segregation of items ▪ despatch labelling ▪ shelf life monitoring ▪ assembly/operating instructions	▪ Number of times MSL (minimum shelf life) is exceeded ▪ costs for packaging, storage and preservation ▪ transportation cost index ▪ process performance index ▪ process quality index ▪ processing times (e.g. for set-up, manufacturing, downtimes, control times, transportation times) ▪ machine flexibility rate ▪ reserve capacity rate ▪ equipment level of machinery ▪ tool utilisation rate ▪ proportion of optimum batch sizes ▪ order processing time to completion
8.5.5 Post-delivery activities	The requirements for post-delivery activities shall also be met as applicable. The following shall be taken into consideration in order to determine these: ▪ statutory and regulatory requirements ▪ possible undesired consequences in connection with products and services ▪ nature, use and lifetime of the products and services ▪ customer requirements ▪ customer feedback	▪ warranty rules ▪ obligations regarding disposal ▪ maintenance ▪ servicing	▪ product indicators (e.g.: price, performance, lifetime, technical characteristics, service capability) ▪ key indicator rules from statutory and regulatory requirements

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
8.5 Production and service provision			
8.5.6 Control of changes	Unplanned changes shall be reviewed and controlled with regard to product/service conformity. Documented information regarding the results of the review of changes, the personnel authorizing the change and any necessary actions related to change control shall be retained.	▪ evidences regarding changes in the monitoring activities ▪ job descriptions for veto persons ▪ documented procedure for release/change management	▪ number of development changes ▪ new verification and validation time and costs ▪ cost index for development changes ▪ savings index
8.6 Release of products and services			
8.6 Release of products and services	Release of products and services shall be implemented in stages. Evidence of conformity with the acceptance criteria shall be retained. Release of products and services to the customer shall not proceed until product conformity has been satisfactorily verified and also approved by the customer. Documented information shall provide traceability to the person(s) authorizing release.	▪ internal evidences regarding release and evidences from the customer	▪ number of articles that should be supplied with certificates ▪ number of deliveries conformant with specification ▪ testing time/costs in receiving inspection area ▪ fulfilment of delivery times by suppliers ▪ inspection time and costs ▪ nonconformity rate ▪ scrap rate ▪ costs for repair/rework ▪ testing time ▪ complaint rate

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
8.7 Control of nonconforming process outputs, products and services			
8.7 Control of non-conforming process outputs, products and services	Process outputs, products and services which do not fulfil the requirements shall be identified and controlled, so that they are not used or delivered unintentionally. Suitable corrective actions should be taken also for nonconforming products and services that are only detected after delivery of the product or during the provision of the service. The organization can deal with nonconforming products and services in one or more of the following ways: ▪ correction ▪ segregation, retention, return or suspension of provision of products and services ▪ informing the customer ▪ obtaining release for use as is or continuation, or reprovision ▪ acceptance under concession The conformity shall be verified again following the corrections. Documented information regarding these activities shall be retained.	▪ blocked goods store ▪ blocking notes, reminders ▪ evidences, see 8.6	▪ number of defects according to type ▪ number of defects in specific areas/departments/groups ▪ costs of defects ▪ status of corrective and preventive actions ▪ costs of corrective and preventive actions

Clause 9 – Performance evaluation

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
9.1 Monitoring, measurement, analysis and evaluation			
9.1.1 General	The organization shall determine ▪ what needs to be monitored and measured ▪ the methods for monitoring, measurement, analysis and evaluation (to ensure valid results) ▪ when the monitoring and measuring are to be performed ▪ the time when the analysis and evaluation should be performed Monitoring and measuring activities shall be performed Documented information shall be retained as evidence of the results. The quality performance and effectiveness of the QMS shall be evaluated.	▪ test planning concept ▪ test plans ▪ sampling plans ▪ test instructions ▪ analysis procedures ▪ analyses (failure/scrap rates, most frequent failures and defects, trends) ▪ reporting (quality reports, review reports)	▪ KPIs regarding quality status ▪ process capabilities ▪ key indicators for lifetime ▪ comparative figures with competitors (benchmark) ▪ scrap and rework costs and times
9.1.2 Customer satisfaction	The organization shall ▪ monitor customer perceptions of the degree to which requirements have been met ▪ obtain information regarding the impressions and opinions of customers ▪ determine the methods for obtaining and using this information	▪ customer satisfaction surveys (user surveys) ▪ reports of visits to customers ▪ analysis of traders' statements ▪ market surveillance and observation ▪ customer satisfaction analyses ▪ analysis of market shares ▪ complaint reports ▪ spontaneous expressions of satisfaction ▪ benchmarking	▪ customer satisfaction index ▪ complaint rate, penalties, goodwill and guarantee costs ▪ proportion of established to new customers ▪ customer loyalty rate ▪ customer structure (proportion of large-scale customers) ▪ rate of orders won

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
9.1 Monitoring, measurement, analysis and evaluation			
9.1.3 Analysis and evaluation	Data and information from monitoring, measurement and other sources shall be analysed and evaluated. The results of the analysis and evaluation shall be used to ▪ demonstrate conformity of products and services to requirements ▪ assess and enhance customer satisfaction ▪ assess conformity and effectiveness of the QMS ▪ demonstrate that planning has been successfully implemented ▪ assess the performance of external providers ▪ demonstrate the need and opportunities for improvement in the QMS ▪ supply inputs to the management review	▪ risk analyses (FMEA) ▪ quality records ▪ test logs ▪ statistical analyses ▪ results of internal and external audits ▪ Q reports ▪ customer satisfaction analyses ▪ supplier assessments ▪ action plan for improvement of customer satisfaction or other improvements ▪ management review	▪ quality-relevant key indicators (including failure rate, penalties, goodwill and guarantee costs) ▪ process capabilities ▪ customer satisfaction indices ▪ supplier assessment (reliability) ▪ benchmark comparison figures (quality-relevant and economic indicators)
9.2 Internal Audit			
9.2.1	Internal audits shall be performed at planned intervals in order to verify that the organization's own requirements for its quality management system and the requirements of 9001:2015 are effectively implemented and maintained.	▪ documented procedure for internal audits ▪ set values, target values with regard to the requirements	▪ cost/benefit index ▪ audit times in relation to operational performance
9.2.2	With regard to internal audits, the organization shall ▪ plan the audit programme (frequency of audits, methods, responsibilities,	▪ audit programme ▪ audit plans ▪ audit criteria ▪ audit records ▪ audit evaluations ▪ audit reports	▪ requirement fulfilment rate ▪ implementation rate of internal audits

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
9.2 Internal Audit			
	planning, reporting, quality objectives, importance of the processes concerned, customer feedback, changes with an impact on the organization and consideration of the results of previous audits) ▪ define the audit criteria and scope for each audit ▪ select auditors and conduct audits to ensure objectivity and impartiality of the audit process ▪ report results to relevant managers ▪ take necessary correction and corrective actions without delay ▪ retain documented information as evidence of the implementation of the audit programme and the audit results	▪ nonconformity reports ▪ action plans for introduction of corrective actions ▪ management reviews ▪ reports regarding the effectiveness of corrective and preventive actions ▪ proofs of qualification of internal auditors	
9.3 Management review			
9.3.1 General	The QMS shall be assessed by top management at planned intervals with the aim of ensuring its continuing suitability, adequacy and effectiveness. The following aspects shall be considered: ▪ status of actions from previous management reviews ▪ changes that affect the QMS, including strategic direction ▪ information regarding the quality performance, including developments and indicators in case of external documents, e.g. – nonconformities, corrective actions – monitoring and	▪ management review report ▪ reports of – internal audits – process audits – product audits ▪ quality analyses ▪ status of corrective and preventive actions ▪ resource requirement and use plans ▪ supplier quality status ▪ risk analyses (technical/economic/business)	▪ see above ▪ quality-relevant key indicators, including failure rate, complaint rate, penalties, goodwill and guarantee costs) ▪ capability of processes ▪ customer satisfaction indices ▪ supplier assessment (reliability) ▪ benchmark comparison figures (quality-relevant and economic/business indicators) ▪ see previous clause, 9.1 ff., for further examples

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
9.3 Management review			
	measurement results – audit results – customer satisfaction – issues concerning external providers and interested parties – adequacy of resources for the QMS – process performance and conformity ▪ effectiveness of actions taken to address risks and opportunities ▪ new opportunities for improvement	▪ documented procedure for internal audits ▪ set values, target values with regard to the requirements	
9.3.2 Management review inputs	The input must include ▪ Status of actions from previous management reviews ▪ Changes in external and internal issues that are relevant to the quality management system ▪ Information on the performance and effectiveness of the quality management system (fulfilment of quality objectives, process performance etc.) ▪ Adequacy of resources ▪ Effectiveness of actions taken to address risks and opportunities ▪ Opportunities for improvement	▪ Status, progress and incident reports ▪ Key process indicators (KPI) ▪ Risk assessments, complaints statistics ▪ Results of market observations ▪ Evaluations from internal suggestion system ▪ Evaluations of customer satisfaction analyses	
9.3.3 Management review outputs	The outputs of the management review shall include decisions and actions related to: ▪ opportunities for improvement: ▪ any need for changes and resources for changes The organisation shall retain documented information as evidence of the results of management reviews	▪ Management review ▪ Status and progress reports ▪ List of open points (LOP) ▪ Records regarding follow-up of corrective and preventive actions	▪ Level of agreement (Compliance) ▪ Status of resources for implementation of corrective and preventive actions ▪ Time needed up to complete implementation of corrective and preventive actions

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators

Clause 10 – Improvement

10.1 General

10.1 General	Opportunities for improvement shall be implemented and necessary actions shall be determined in order to ▪ improve products and services, taking future needs and expectations into consideration ▪ reduce or prevent undesired events ▪ improve the performance and effectiveness of the QM system	▪ improvement projects ▪ rules for implementation of improvement projects ▪ continual improvement potential database ▪ quality management plans ▪ project plans ▪ target lists and reports ▪ progress reports ▪ management reviews ▪ corrective action plans ▪ preventive action plans	▪ key indicators from the FMEA ▪ trend indicators ▪ lifetime indicators ▪ emission indicators ▪ disposal costs ▪ unit costs ▪ risk indicators ▪ comparative figures with competitors ▪ scrap and rework costs or times ▪ benchmarking results ▪ total costs ▪ failure and fault costs ▪ process cycle times ▪ planning times ▪ planning costs ▪ number of suggestions/ number of employees ▪ cost saving per suggestion ▪ implementation costs per suggestion ▪ fulfilment rate of targets in the continual improvement process ▪ number of higher-level improvement groups

10.2 Nonconformity and corrective action

10.2.1	When a nonconformity occurs, the organization shall react and if appropriate ▪ take action to control and correct it ▪ deal with the consequences ▪ determine the causes and take appropriate corrective actions ▪ determine if similar nonconformities exist or could occur ▪ review effectiveness of any corrective actions taken ▪ update risks and opportunities ▪ change the QMS if appropriate The aim is that nonconformities should not recur or recur somewhere else.	▪ records of fault identification ▪ statistical analyses ▪ test/result logs and reports ▪ instructions for corrective actions ▪ root cause analyses ▪ training plans ▪ training evidences ▪ complaint analyses ▪ any changed supply contracts, ▪ Q agreements ▪ review logs ▪ Ishikawa diagrams ▪ pareto analyses ▪ histograms ▪ 5 Why ▪ FMEA Review ▪ 8-d Report	▪ complaint rate ▪ scrap, rework and guarantee costs ▪ goodwill costs ▪ customer satisfaction index ▪ self-assessment index ▪ process performance index ▪ process stability index

Requirement of the Standard	Interpretation / Activities	Examples of documentation / Evidences	Examples of Key Indicators
10.2 Nonconformity and corrective action			
10.2.2	The organisation shall retain documented information with regard to: ▪ the nature of the nonconformities and any actions taken ▪ the result of any corrective actions		
10.3 Continual improvement			
10.3. Continual improvement	The suitability, adequacy and effectiveness of the QMS must be continually improved. The aim is to determine needs and opportunities that require action as part of the continual improvement process. Results, analyses and assessments and also the results of the management review must be considered in this connection.	▪ project plans ▪ logs and trends regarding set targets ▪ progress reports ▪ management reviews ▪ corrective action plans ▪ preventive action plans ▪ system of suggestions for improvement	▪ rate of target achievement ▪ number of implemented improvements ▪ benchmarking/ranking index ▪ saving from improvement group work ▪ cost/benefit ratio ▪ reaction and implementation time

5. Annexes

ISO 9001:2015 – Questions and important perspectives from the point of view of sales

1. When will ISO 9001:2015 and ISO 14001:2015 be published and when will DIN EN ISO 9001:2015 and DIN EN ISO 14001:2015 appear?
Following publication of the English-language version of ISO 9001:2015 on 15/09/2015 and of ISO 14001:2015 on 15/09/2015, the German DIN standards DIN EN ISO 9001:2015 and DIN EN ISO 14001:2015 have now also appeared. The Issue Status of both standards is November 2015.

2. From when can the certifications be performed according to the new standards?
Audits according to ISO 9001:2015 and ISO 14001:2015 can be carried out as from the date of their publication. Audits based on the previous DIS (DIN-ISO) standards will not be recognised.

3. How long is the transition period?
ISO 9001:2015: The transition period of three years begins on 23/09/2015 and ends on 22/09/2018 for the changeover to ISO 9001:2015.
ISO 14001:2015: The transition period of three years begins on 15/09/2015 and ends on 14/09/2018 for the changeover to ISO 14001:2015.

4. From when can certificates according to ISO 9001:2015 and ISO 14001:2015 be issued?
Due to the change in the accreditation procedure for all certification bodies by DAkkS, ISO 9001:2015 and ISO 14001:2015 certificates can only be issued without the addition of the letters “FDIS” starting from 28/10/2015. According to a decision of DAkkS, certificates according to DIN EN may also only be issued as from 28/10/2015 at the earliest.

5. What are the advantages of the new standards?
The new High Level Structure creates greater harmony between the ISO management system standards, making it easier to extend existing systems into an integrated whole. The themes of user friendliness and market orientation receive more emphasis. This means that the standard focuses more strongly on the characteristics and needs of service companies and that documentation requirements are more flexible. The direct responsibility of organizations is emphasised much more strongly than before. The same applies to the process approach and the responsibility of top management.

6. What is the structure of the new standards?
ISO 9001:2015 and ISO 14001:2015 will have a new structure, the so-called High Level Structure. This is intended to provide the same binding structure for all the management system standards, and results in two very important benefits. Firstly, terms, definitions and structures can be used for all the standards and secondly, standards are easier to understand and synergies are possible when different standards and certifications are combined.In detail, the current draft version indicates that the structure of the ten clauses will be as follows:

1. Scope
2. Normative references
3. Terms and definitions
4. Context of the organization
5. Leadership
6. Planning
7. Support
8. Operation
9. Performance evaluation
10. Improvement

7. What is particularly important for the new standards with regard to consideration of risks?
The treatment of risks plays a more central role than is currently the case – amongst others in the clauses on “Leadership” and “Planning”. Although a specific risk management system as such is not demanded, organizations should be capable of identifying risks that are

associated with the realisation and the utilisation/usage of the products/the service and of taking them into consideration in an appropriate way. However, there is no specific requirement for preventive measures. Companies profit from this new way of seeing things, as they have the chance to recognise risks early on and take corresponding action.

8. What is the relationship to stakeholders in the new standard?
In the new version of the standard, organizations not only have to fulfil legal requirements and the expectations of customers, but will also need to engage with other interested parties. This requirement means that the complexity of today's working and social environment is taken into account, and it also offers opportunities to achieve desired improvements and minimise risks.

9. Who specified the additional time needed for the upgrade to DIN EN ISO 9001:2015 or DIN EN ISO 14001:2015?
The German Accreditation Body (DAkkS) has specified the additional time as standard for all certification bodies in the document regarding "Instructions for the transition to ISO 9001:2015 and ISO 14001:2015" (Anleitung zum Übergang ISO 9001:2015 und ISO 14001:2015) issued on 20/04/2015.

10. How much extra time is needed to upgrade within the framework of the surveillance audit?
The additional time to upgrade to the requirements of ISO 9001:2015 or ISO 14001:2015 within the framework of a surveillance audit is at least 20 per cent of the audit time for the surveillance audit, but at least 0.5 audit days on site.

11. Are certificates issued if the upgrade takes place within the framework of the surveillance audit?
After the surveillance audit is complete, you receive the certificates according to ISO 9001:2015 or ISO 14001:2015. The term of validity of the certificate does not change, i.e. it corresponds to the term of validity of the original certificates.

12. How much extra time is needed to upgrade within the framework of the recertification audit?
The additional time to upgrade to the requirements of ISO 9001:2015 or ISO 14001:2015 within the framework of a recertification audit is at least 10 per cent of the audit time for the recertification audit, but at least 0.25 audit days on site.

13. What must be taken into consideration regarding the certificates for the upgrade during recertification?
After completion of the recertification procedure, you will receive the certificates according to ISO 9001:2015 or ISO 14001:2015 with a validity of three years. The term of validity follows on from the previous certificate. This means that the expiry date corresponds to the previous threeyear time interval (expiry date of the old certificate plus 3 years) if the recertification procedure is performed in good time or if the performance of the audit and the NC (nonconformity) management is completed in good time (by the due date).

14. Is a "gap audit" or preliminary audit necessary for the upgrade?
If you are not sure what is missing from your system in order to upgrade to the new standards, we will be happy to offer you a "gap audit" or preliminary audit. The gap audit can be added to the next surveillance or recertification audit, for example. Just let us know if you need further information or an offer for a gap audit.

15. Is an upgrade within the framework of the recertification audit more favourable?
For some sizes of organization, the additional time needed can be less for a recertification audit than for a surveillance audit.

An example for an organization with 80 employees and a certificate valid until 30/04/2017:

- Upgrade in the recertification audit with 4.0 audit days means additional time of 0.4 audit days.
- The new certificate is valid from 01/05/2017 – 30/04/2020.
- Upgrade in the 2nd surveillance audit in 2016 with 2.0 audit days means additional time of 0.5 audit days.
- The new certificate is valid from the date of the certification decision up to 30/04/2017.

16. Why is upgrade in the recertification audit recommended?
The new requirements of the standard affect almost all areas of the organization. This means that the extra time needed for the organization to prepare and the number of representatives that have to be present is just as great as in the case of recertification.

17. If the upgrade does not take place in the recertification or the surveillance audit, what are the other possibilities?
It is possible to carry out the upgrade in a special audit. This is an additional audit date between the regular audits. The additional time and cost is greater than for the surveillance or recertification audit. This is because of the extra time needed for preparation and follow-up and possible consideration of changes since the last audit. Travel costs are also charged.

18. What must organizations do so they can upgrade to the new standard in the next recertification audit?
The notice of the date for the recertification audit, which is sent to you in good time before the audit date, already contains a reminder for the upgrade to the new standard. If you wish the upgrade to take place during a surveillance audit, we ask you to let us know as soon as possible, but at the latest three months before the planned audit date, as we also have to plan for the additional time. Please note that we recommend that the upgrade takes place during the recertification audit.

19. How much more expensive is first (initial) certification if an organization upgrades directly to the new standard?
Basically the same man day table applies as before, i.e. it is not more expensive if you undertake certification to the new standard in a first (initial) certification.

20. Is it recommended only to consider the new standard in initial (first) certifications?
If the organization begins now with the implementation of the quality management system, it seems useful if the organisation concerns itself directly with the new ISO 9001:2015 und ISO 14001:2015 standards.
If certification is absolutely required within a short time, it can be helpful to undertake certification according to 9001:2008 or 14001:2009 and to make the upgrade in the transition period. The transition period is three years from the date when the new standard is published.

21. When will it no longer be possible to undertake first certifications according to the old version of the standard?
First certifications according to the old version are no longer possible after expiry of the transition period of three years.

22.What is the procedure in the case of transfer from another certification body?
It is possible to upgrade to the new standard during the transfer audit. The same rules for additional time apply as for upgrade during a recertification, surveillance or special audit.

23. Is it possible to carry out the transfer with the old version and then to upgrade in the surveillance audit?
Yes, it is possible. It is even a good way to make the upgrade, as the auditor, the audit procedure and many other details already change for the customer during the transfer. If the upgrade is made in the surveillance audit, the customer does not have to handle everything at the same time.

24. Are transfer costs covered with the upgrade if the company shifts within the transfer?
No, the times and costs have to be added together.

25. Which is easier to implement – the old or the new version?
The advantage of the 2015 version is that the structure of the standard follows the processes in the organization. This means that it is easier to implement the 2015 version. An important advantage of the 2015 version is the reduced requirement for documented procedures. This means that the organization can build up its own QM system with tailormade documentation.

The main emphasis of the 2015 version is the focus on results. It is no longer so important where (i.e. in which document) something is described. The most important question is whether the process is effective. This promotes acceptance of the standard.

26. What are the most important differences between the old and the new versions that the customer has to take into consideration in implementing the 2015 version?
The standard has a new structure. All clauses from 4 to 10 have to be covered, with the exception of justified exclusions (concessions). Some requirements are new. These include risk-based thinking, consistent implementation of the process approach, the documented information, the context of the organization, handling of outsourced processes, more emphasis on management commitment and responsibility, quality controlling and some other requirements.

27. Which are the greatest traps and problems to be expected in recertifications according to the 2015 version?
It is absolutely not recommended to “throw away” the existing quality management system too quickly. In future, documentation will still be required in order to provide evidence of processes and process evaluation. Even if there is no longer a requirement for a top management representative for quality, the responsibility for the quality management system still has to be laid down and the resources that are needed for maintenance of the management systems must be planned.

28. How far is the service sector now involved?
The new standard can also be used across all sectors. Service providers are not explicitly mentioned and therefore find implementation easier. Organizations which use a large number of outsourced processes in order to conduct their business will find that handling of outsourced processes is included in the standard. If outsourced processes are used, the interfaces and the monitoring have to be described and key indicators have to be established for them. The outsourced processes are taken into consideration in the calculation of the number of man-days required for the audits.

29. Does the new version of the standard particularly address organizations which have to consider the risks of the processes they use? Which organizations are they?
The standard requires risk-based thinking within the framework of the PDCA cycle. Here, it is a question of process-orientated risks. Those risks must be determined which are present (or could be present) in connection with the realisation of the product or the provision of the service and whose occurrence could have a negative impact on customer satisfaction.

30. What advantages do service providers have with the ISO 9001:2015 version compared with the current 2008 version?
When service providers implemented the ISO 9001:2008 version, they had to transfer the idea of “product” to mean “service”. This is no longer necessary, as services are explicitly mentioned in the standard.

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