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Martin Hinsch

ISO 9001:2015 for Everyday Operations

All Facts – Short, Concise and Understandable

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ISSN 2197-6708 ISSN 2197-6716 (electronic)
essentials
ISBN 978-3-658-25549-7 ISBN 978-3-658-25550-3 (eBook)
https://doi.org/10.1007/978-3-658-25550-3

Library of Congress Control Number: 2019933161

Springer Vieweg

This Springer Vieweg imprint is published by the registered company Springer Fachmedien Wiesbaden GmbH part of Springer Nature
The registered company address is: Abraham-Lincoln-Str. 46, 65189 Wiesbaden, Germany

What you can find in this *essential*

- Explanation of key features and focal points of ISO 9001:2015
- Presentation of the content structure, in particular the high-level structure
- Explanation of the most important terms and definitions
- Short, concise explanation of the requirements of ISO 9001:2015 relevant to everyday operations in the same chapter structure as the standard
- Useful tips for transferring the standard requirements into your QM system

Preface

Springer's "essentials" series is aimed at practical users who are looking for quickly applicable knowledge in a compact form and want to gain an overview of a complex topic. This also applies to this book.

This booklet is aimed at beginners or users with little knowledge of the ISO 9001 standard. It can be used as an introduction or refresher.

Each individual standards chapter is explained with the most important requirements of everyday operational routine. It is aimed primarily at those QM enthusiasts who would like to gain a basic understanding of the standard briefly, concisely and precisely about all the requirements relevant to everyday operations. The fact that the depth of detail sometimes suffers in a compact movement is self-explanatory.

Hamburg
January 2019

Prof. Dr. Martin Hinsch

Contents

Introduction

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This booklet is divided into two main parts. First, the structure and basic principles of ISO 9001:2015 are presented. Chapter 3 also explains the main features of the certification process.

The second part then focuses on the actual content of the standards at chapter level. All chapters of the standards, including the important requirements necessary for day-to-day operations, are explained briefly and comprehensibly. For the sake of simplicity, the text is structured analogously to the structure of ISO 9001 from Chap. 4. Wherever applicable, this procedure was applied up to the enumeration level.

For copyright reasons, it was not possible to print the original text of the standard. In this respect, this book is only a supplement, but not an alternative to the actual ISO 9001:2015 text.

In the course of the standard, "appropriate" conditions are often demanded, whereby this term is usually too nebulous and not very specific for the layman. Appropriate means

- according to customer requirements,
- according to industry standards (e.g. recognized by other standards and industry-typical procedures),
- according to Good Workmenship (generally usual work execution),
- the requirements for on-time and conform performance of work.

M. Hinsch, *ISO 9001:2015 for Everyday Operations*, essentials,
https://doi.org/10.1007/978-3-658-25550-3_1

2 Fundamentals, Structure and Key Characteristics

2.1 Basic Principles and Structure

All ISO management standards are based on the idea that a QM system that can be understood by third parties is the best prerequisite for an appropriate level of quality. The standard therefore specifies minimum requirements that are independent of the specific service provision (product or service) and the size of the organization in order to enable a uniform and comparable quality standard.

The conformity or certification according to the 9001 standard serves the goal,

- to create and maintain a sustainable competitiveness through an effective QM system with efficient processes and its constant evaluation.
- to constantly and systematically plan, implement and evaluate improvements to the QM system.
- that the organization is constantly dealing with its own non-conformities, weak points and waste in order to sustainably eliminate the root causes.

The content of ISO 9001 remains largely unspecific. Although the standard defines *what* has to be implemented in the end, it does not define *how* processes and work steps have to be designed in detail. No tools, instruments or implementation methods are specified, only the output requirements are defined. The standard therefore leaves the detailed process design, i.e. the choice of means, to the organization.

M. Hinsch, *ISO 9001:2015 for Everyday Operations*, essentials,
https://doi.org/10.1007/978-3-658-25550-3_2

High Level Structure

All management system standards have a uniform and so-called High-Level Structure. This means that the first and, in most chapters, the second level of structure is identical in all important system standards. Whether ISO 9001, EN 9100 (aviation), IATF 16949 (automotive), ISO 14001 (environment), OHSAS 18001 (occupational health and safety) or ISO/IEC 27001 (information technology), all these and other standards have the following uniform basic High Level Structure:

Overview
4 Context of the organization
4.1 Understanding the organization and its context
4.2 Understanding the needs and expectations of interested parties
4.3 Defining the scope of the quality management system
4.4 XXX [Requirements of the respective] management system
5 Leadership
5.1 Leadership and commitment
5.2 Policy
5.3 Organizational roles, responsibilities and authorities
6 Planning
6.1 Actions to address risks and opportunities
6.2 XXX [Requirements of the respective management system] Objectives and planning to achieve them
7 Resources
7.1 Resources
7.2 Competence
7.3 Awareness
7.4 Communication
7.5 Documented information
8 Operation
8.1 Operational planning and control XXX [Requirements of the respective management system]
9 Performance evaluation
9.1 Monitoring, measurement, analysis and evaluation
9.2 Internal audit
9.3 Management review
10 Improvement
10.1 General
10.2 Nonconformity and corrective action

The texts and terminology of the standards have also been adapted in certain areas in line with this. The High-Level Structure simplifies the work of organizations and auditors in the case of multiple certifications because it simplifies a consolidated presentation of their own quality management. Different standards can be better interlinked within the organization and do not have to run in isolation. However, organizations are not obliged to adapt the high-level structure for their own QM system as long as only the respective standard requirements are fulfilled.

2.2 Key Characteristics of the ISO 9001:2015

Process Orientation

Since its major revision in 2000, ISO 9001 has followed the approach of process-oriented quality management, which has not only been adopted by the revision in 2008, but has also been tightened up in its current version. For ISO certification, a fundamental understanding of the process-based organizational structure is therefore more necessary than ever.

Through this approach, the process orientation demands and promotes a stronger examination of operational processes and responsibilities. The organization is made more comprehensible and thus facilitates the clarity and comprehensibility of the process structures. The employees recognize their place within the processes relevant to them as well as within the entire value chain.

It is important for the success of the process-oriented approach and thus also for the passing of the certification audit that an internal control loop is established between the incoming customer requirements (input) and the determined customer satisfaction (indirect output). ISO 9001:2015 therefore requires the implementation of Deming's PDCA cycle (Plan-Do-Check-Act) (see Fig. 2.1).

The process orientation must also be reflected in the QM documentation. The starting point is a process map in order to obtain a complete overview of the organization and its core processes. On the second level, which serves to describe individual processes, flow charts, flow diagrams or turtle diagrams, for example, are used. Tasks and procedures, which are visually divided into process description are thus easier to identify. It is important that the employees are instructed in such a form of presentation. They must find their roles, activities and interfaces and understand how their tasks are integrated into the entire operational value chain.

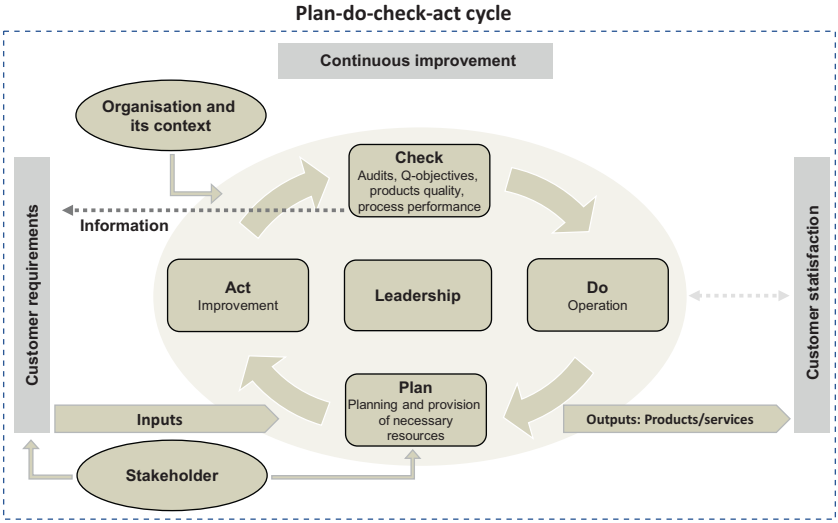

Fig. 2.1 The Plan-Do-Check-Act cycle (PDCA)

Risk-based Thinking

Section 6.1 of ISO 9001:2015 requires risk-based thinking and actions within the organization. The aim is to deal in a structured manner with operational risks, in particular those which have a direct or indirect influence on the organization's objectives. These include process risks, risks in customer and supplier relationships, dependencies on employees, machine failure risks, planning risks, etc.

As an important element of the QM system, risk-based action is a management task and must be anchored throughout the organisation. However, the standard provides only limited information on the type and scope of the expected risk orientation. In any case, the management must ensure that a risk process is established and that the risk concept is anchored in all processes, so that a structured identification, evaluation and control of hazards is ensured in operational practice. One of the essential tasks is to identify risks on time and to keep them under control or eliminate them wherever feasible by means of targeted measures.

Customer Orientation

Customer orientation is a core characteristic not only in numerous business management approaches, but also in ISO 9001. Some basic requirements are formulated in Sect. 5.1.2 for this purpose.

The aim is to place the customer at the centre of all business activities. An essential element for successful customer orientation is the consistent process orientation of one's own organization. Today's customers' basic needs such as flexibility, short reaction times and low prices can only be met if the organisations own operational processes are properly coordinated and smoothly connected.

A structured customer orientation is particularly required in the sales area (Sect. 8.2), where customer contact is naturally intensive. However, customer care also requires clearly defined procedures and behaviour after signing the contract, especially in the case of subsequent changes to the order.

In order to do justice to the "C" (check) of the PDCA cycle, Sect. 9.1.2 defines requirements on customer satisfaction.

The Certification Process

3

3.1 Preparation of the Certification Audit

The certification audit is the last, decisive stage on the way to the ISO 9001 certification. However, this is preceded by a longer decision-making process of the management in which the pros and cons of a certification are weighted. In this phase, the person responsible for QM, in particular, has to deal intensively with the requirements of the desired standard.

The decision in favor of a certification is followed by about three to twelve months for the operational implementation of the standard's requirements. Therefore, it is necessary to study the ISO 9001 and its requirements in detail in order to determine where action is required. A cross-reference list can be helpful here. In such an overview, those ISO requirements that have already been fulfilled are marked as "completed" by means of objective evidence (documents, records, etc.). In case of defincencies deadlines and responsibilities for implementation and, if necessary, further remarks are documented.

Experience has shown that the greatest need for action lies in quality-awareness and the appropriate implementation of a quality culture as well as in documentation and its use in organisational practice. Last but not least, quality policy, quality objectives and its monitoring should be improved in many organizations.

Documentation

An essential part of the ISO 9001 implementation is the preparation of the QM documentation. In addition to the definition of a quality policy and the quality objectives, it is necessary to ensure process stability. Process descriptions as well as procedures and work instructions must be kept available for this purpose.

M. Hinsch, *ISO 9001:2015 for Everyday Operations*, essentials,
https://doi.org/10.1007/978-3-658-25550-3_3

These descriptions help with process structuring because work/process steps, tasks and responsibilities are defined and assigned. In addition to solid training, only the written word or diagrams and documented visualizations can create process awareness for the employees concerned. In addition, tools such as forms, checklists and completion instructions must be created to ensure process stability.

External support
When preparing for certification, an external consultant can provide valuable support and at the same time speed up the implementation process. Thus, a consultant can contribute his knowledge to the interpretation and appropriate implementation of ISO requirements. Each organization must decide for itself whether external support is generally necessary, whether a consultant should accompany the entire preparation phase or whether support should only be used on a daily basis for larger operational knowledge gaps.

Selection of a certification body and an auditor
Parallel to the implementation of the requirements, a certification auditor and a certification body should be selected at an early stage (about 3–6 months before the planned audit date) (Fig. 3.1).

3.2 Executing of Stage 1 Audit

The main certification audit must be preceded by a stage 1 audit to assess whether the organization is basically prepared for the certification process.

The Stage I audit usually starts with an inspection of the organization's facility. The objective of a stage 1 audit is, however, the examination of documented informations. For this purpose, the auditor gets an overview of the documents and records of each audit chapter. For this purpose, at least the following documented informations must be kept available for the stage 1 audit:

- internal audit reports of the last 12 months,
- protocol of the last management review,
- customer satisfaction analyses, documentation of customer complaints and complaints,
- performance parameters/key figures for process measurement, product and service conformity
- process map, quality manual (if available), process descriptions, procedures

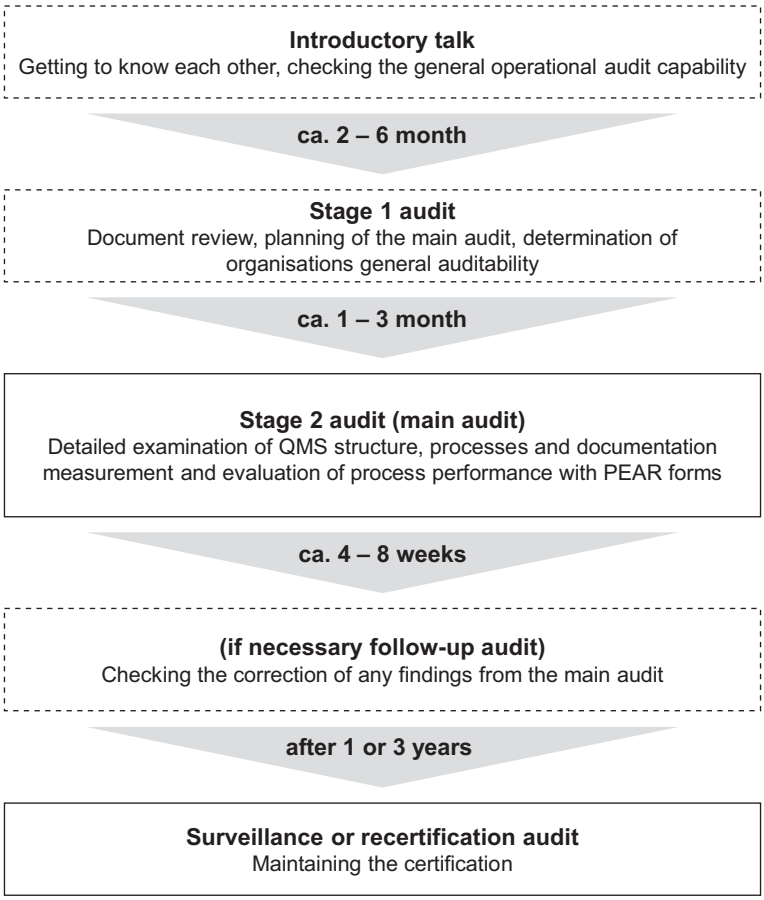

Fig. 3.1 A three-year audit cycle. (acc. to Hinsch 2012, S. 313)

The stage 1 audit also serves the purpose of planning the main audit and coordinating the audit program for the 3-year certification cycle.

This pre-audit should take place 2–8 weeks before the main audit, because the auditor might identify weak points, followed by a demand for rework, which must be finished until the stage 2 audit.

3.3 Executing of Stage 2 Audit

In the main audit, the conformity of the organizations QM system with the requirements of ISO 9001 is checked in detail. The concerned processes and departments have been made known to the organization via the audit plan prior to the audit. The key elements of every certification audit are the

- opening,
- conduct of the audit,
- audit evaluation and the preparation of audit records; and
- closing and final discussion.

Information is collected and evaluated by means of random sampling in order to check that organizational processes comply with the ISO 9001 requirements. This is done by interviews and observations as well as by reviewing records and documents.

In the final meeting, the auditor presents the audit results. If non-conformities against the ISO 9001 requirements (findings) have been identified, the auditor will explain the further procedure and deadlines. Following the notification of the audit results, the auditor informs about the certification recommendation. The auditor himself is not authorised to submit the final decision on the audit result - this is the responsibility of the certification body.

3.4 Audit Findings

Often the organization does not succeed in implementing all ISO 9001 requirements in daily operation. It is an essential task of a certification audit to identify such non-conformities. In this case, the auditor must make finding. According to ISO 19011 Sect. 6.8 there are the following classifications of nonconformities/findings:

- significant nonconformity
- minor nonconformity
- recommendation/improvement

A major finding exists when it must be assumed that the nonconformity

1. leads to a failure of important elements of the QM system,
2. if processes are not controlled, or
3. if it must be expected that the non-compliance will have noticeable consequences for the customer.

Minor nonconformities refer to errors occurring singularly or to nonconformities of individual requirements without substantial or lasting influence on the QM system, on the processes or on the product or service.

Findings are recorded in a nonconformity report (NCR). There, the auditor describes the deviation, names the associated objective evidence and the corresponding ISO 9001 chapter/requirement and determines whether the finding is a major or minor deviation.

For correction, the appropriately analyzed root cause and initiated (!) corrective action must be documented in the NCR and reported back to the auditor. This is also the organisations request for closing the audit finding.

Only after the release of the corrective measures, may the auditor recommend the issuance or extension of the certificate to his certification body.

3.5 Surveillance- and Re-Certification Audits

Surveillance audit

After an initial or re-certification audit, the surveillance audit takes place twice (one per year) in a three-year certification cycle. It is approximately half as long as the initial or re-certification audit. The scope of this audit is based on the audit program for the certification cycle, defined in stage I audit.

Re-certification audit

The re-certification audit takes place every three years and corresponds in scope to the initial audit. During this audit, in contrast to the surveillance audit, the fulfilment of all ISO 9001 requirements is checked. The focus is on auditing process effectiveness (PDCA) and process performance, evaluating the ability to supply compliant products and services and assessing customer satisfaction. Furthermore, the auditor(s) usually concentrate on the implementation of follow-up measures from the last surveillance audit as well as changes made to the QM system since then.

Audit for a special reason

In addition to planned surveillance and re-certification audits, there are also audits for special reasons. The reasons for this can be, for example, the change of the certification body or the extension of the scope outside the regular certification process.

Context of the Organization

4

4.1 Understanding the Organization and its Context

In addition to the operative business, organizational questions must be answered beyond day-to-day business. The standard therefore requires regular reflection on one's own internal situation and the external environment. This enables a strategic orientation in the market and thus the achievement of the quality objectives and long-term targets. However, this requires a systematic and structured approach, initiated by the management. Typical aspects for an evaluation of the external environment are:

- adaptation of the product portfolio, expansion of operations, innovations and technical developments
- effects of digitalization,
- the future staff requirements,
- market orientation of competitors, changes in customer demand,
- legislative initiatives, activities of chambers and associations.

The certification auditor must become clear from the discussion with the management that it knows their own operational strengths and weaknesses and is aware of market opportunities and risks.

The management must present important issues in the areas of organizational growth, market, competition, resources and legislation. For this, systematic and documented action must be shown during the certification audit and a processing of the relevant issues in the sense of the PDCA cycle must be recognizable. Appropriate evidences are for example:

M. Hinsch, *ISO 9001:2015 for Everyday Operations*, essentials,
https://doi.org/10.1007/978-3-658-25550-3_4

- corporate strategy, e.g. SWOT or PEST analysis,
- financial, investment and project planning,
- market and competition surveys,
- risk activities/management,
- product development reports.

4.2 Understanding the Needs and Expectations of Interested Parties

Organizations have to deal not only with the question of *what* affects the provision of products and services both internally and externally, but also with the question of *who* has influence on operational issues. Such influencers are referred as interested parties (stakeholders). These are institutions, groups or individuals, such as direct or indirect customers, suppliers, employees, owners, trade unions, associations, initiatives or chambers of commerce as well as competitors and partners, but also think tanks or the media.

Those stakeholders must be known and kept in mind within the scope of the own value creation. The organization must have an idea of who influences the provision of products and services and how it is done. The management must be aware of the views, requirements and needs of the market participants.

For example, a small company will have to show in the certification audit the needs and requirements of the following stakeholders, including the opportunities and risks resulting from them:

- main customers and their end customers
- private customers,
- employees, as a rule also their family requirements
- bank advisors,
- local competitors,
- main suppliers,
- Chairman of the Chamber of Crafts, Mayor and Pastor (for acquisition-related information), if applicable.

Large companies up to the size of groups of companies or corporations are confronted with additional interested parties, here at the example of an airport:

- customers and customer groups (airlines, retailers, cargo handlers),
- indirect customers (passengers—separated according to first, business and economy, forwarders, customers of the forwarding agents),
- other modes of transport (local taxi trade, public transport),
- suppliers (for customers and own value added),
- politics (municipality, state, federal government, EU),
- owner (usually federal government, state, municipality = politics)
- local, national and international authorities (building or health authorities),
- Police, Customs, Federal Aviation Authority,
- citizens' initiatives,
- associations, NGOs and societies (Greenpeace),
- trade unions.

4.3 Determining the Scope of the Quality Management System

Organizations must specify in writing where the ISO certification is to apply, incl. the boundaries. The scope to be defined includes the product portfolio and the affected sites or organizational units. Not every requirement is applicable to every organization. A company that provides cleaning services generally does not carry out any developments. Thus, non-applicable requirements may be excluded or declared as inapplicable.

Elements of standards concerning the QM system, customer satisfaction and product or service conformity may not be excluded. In everyday certification business, non-applications are typically limited to the area of product and service implementation (Chap. 8) or monitoring and measuring resources (Sect. 7.1.5). In the mentioned example of the commercial cleaner, Sect. 8.3 on development can therefore usually be declared inapplicable and excluded from auditing.

4.4 Quality Management System and its Processes

This Section primarily focusses on operational processes. With the corresponding standard requirements, it is intended that the provision of products and services be aligned with the ideal process flow and not determined solely by the functional organizational structure (hierarchy). This is intended to achieve a stronger orientation of value creation towards the needs of the customer.

A process map must be kept available. With the aid of process descriptions, procedures or work instructions, the processes must be defined, e.g. by means of flow charts. Interactions between the processes, in- and outputs as well as responsibilities must also be taken in account and described.

Once the processes have been defined for the first time, they are to be monitored and continuously improved in accordance with the PDCA cycle and managed in accordance with Sect. 6.2 via quality objectives. Further information on process orientation can be found in Sect. 2.2.1.

Leadership

5

5.1 Leadership and Commitment

General

The top management must implement, maintain and continuously develop an effective QM system that is in conformity to the ISO standard. It is thus responsible for carrying out the following activities:

- definition and communication of a quality policy and quality objectives,
- implementation of a strict quality, process, risk and customer orientation,
- establishment of repetitively observable processes,
- definition of roles, responsibilities and authorizations,
- provision of the necessary resources (personnel, equipment and machinery, material),
- systematic surveillance of the organization according to the PDCA approach,
- permanent improvement,
- leadership and responsibility towards employees and
- support of subordinate executives.

The success and acceptance of quality management throughout the entire organization depend on the QM awareness and QM acceptance of the top management. In order for employees to understand what their tasks are and where management wants to take them, leadership should be focused on appropriate competence, motivation and awareness. Leadership includes in particular the internal communication of the following points:

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https://doi.org/10.1007/978-3-658-25550-3_5

- processes and their interactions,
- importance and tasks of an efficient QM system,
- quality policy and quality objectives (see also Sect. 5.2 and 6.2),
- effects of non-compliant actions,
- risk-based thinking.

Customer focus

As already described in Sect. 2.2.3, customer orientation is one of the core characteristics of ISO 9001:2015. The most important element for successful customer orientation is the fulfilment of the requirements and needs of the customer. To this end, they must be recorded, systematized, evaluated and taken into account in the product or service. The basis for this can come, for example, from the customer specification, market knowledge or own trend analyses, experience with customers, interested parties or previous orders.

It should not only be talked about customer orientation, it should also be lived ("shown"), e.g. by pro-active customer communication, identification and implementation of not explicitly mentioned customer needs, by elimination of risks or by provision of product updates. In this context, risks should also be dealt with in a structured manner and opportunities seized.

Successful customer orientation can be proven in the certification audit, for example, by the following KPIs:

- on-time-delivery (OTD),
- product and service conformity (On-target-quality—OTQ),
- complaints, warranty claims,
- customer satisfaction through surveys.

5.2 Policy

The quality policy describes the organizational quality standards. It should make clear how the management sees or wants to see its own organization positioned in terms of quality. At the same time it must become clear that the management attaches great importance to the topic of quality.

It is necessary that the quality policy serves as an individual guideline for the strategic orientation in line with the organization.

Minimum elements of every quality policy is an obligation of the management to:

- compliance with applicable requirements (e.g. customer, legal and official requirements)
- ensuring continuous improvement of the QM system.

The quality policy is not only be communicated to the employees, it must also be understood and applied so that it has a practical benefit. The quality policy must therefore be available in a documented form.

If the policy is documented in the QM manual, it should be supplemented by an publication in the intrat or framed by a notice or on the black board. Documentation in the QM manual alone is usually not effective. The quality policy must be reviewed regularly, i.e. at least once a year, and adjusted if necessary.

5.3 Organizational Roles, Responsibilities and Authorities

Responsibilities and authorizations must be defined and communicated in the organization. The necessary determination must be documented in the organization chart, in job descriptions, in an authorization matrix, in process instructions and/or in the QM manual, if available.

Every employee must know his area of responsibility and scope of authorization, because every person involved in the product or provision who carries out work has a responsibility for quality. QM issues do not necessarily have to lie with a QM representative—such a function is not mandatory in ISO 9001:2015. However, it makes sense to bundle quality management competence.

The standard attaches importance to the fact that each employee has not only "heard" about his or her own responsibilities and authorizations, but knows and understands them precisely. For example, therefore a signed copy of the employee's current job description can be archived in the personnel file as proof. This is useful for ISO certification and as a waiver of liability in the event of accidents at work and gross misconduct.

Planning

6

6.1 Actions to Address Risks and Opportunities

Every organization is obliged to consciously deal with its own operational risks and opportunities. Organizations must anticipate their risks, assess their influence and be able to deal with them appropriately. However, the standard is based only on a risk-based approach and therefore a systematic, generally accepted risk management is not required.

However, risks must be consciously identified, evaluated, minimized and monitored. Risks in processes, products, services and resources must be monitored in the same way as risks in an external context (competition risks, supplier risks). The management of individual risks depends on the possible extent of damage and the probability of occurrence.

The range of services and the organizational culture play an important role in the design of risk management. A long-established auditing firm, for example, will choose a different risk management approach than a young dotcom company. In both cases, however, recognizable components of a risk orientation must be anchored in the planning processes. In any case, the focus must be on the structured identification, evaluation and the handling of countermeasures in accordance with the PDCA approach. The same applies to opportunities.

During the certification audit it must be shown that risks are actively addressed and that the following points have been implemented for the organizational risks an opportunities:

- identification,
- evaluations,

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https://doi.org/10.1007/978-3-658-25550-3_6

- measures,
- dates and responsibilities,
- previous risk management activities.

6.2 Quality Objectives and Planning to Achieve Them

Quality objectives support the implementation of the quality policy at the operational level. They must be understandable and accepted. To this end, they should be documented and the degree to which the objectives have been achieved should be communicated via CIP boards, the intranet or bulletin boards. Quality objectives must not only be defined for the core processes, but also for important management and support processes, departments or functions. Quality objectives must be actively managed and become an important operational controlling tool. Important Q-goals should be monitored monthly for this purpose.

Q-targets must be measurable in order to enable an objective determination of one's own quality position at any time. In addition, it is important that statements on product or service conformity or customer satisfaction can be made with the objectives. Therefore, suitable quality targets are delivery dates, complaints, supplier performance, reworking, customer complaints, etc. Incidentally, financial goals are not the main focus here.

As a rule, once defined, objectives should be kept as far as possible over time. Only the respective target value has to be continuously increased.

In the certification audit the auditor will ask about measures, ways and the planned resources for the achievement of objectives.

6.3 Planning of Changes

A QM system is not a static structure, which is set up once and not changed afterwards. QM systems are constantly changing, after all, their components are found throughout the entire organization. It is always affected when changes are made that have a direct or indirect influence on the conformity of the products or services.

Such changes must be planned in a structured way before they can be implemented, taking into account existing resources, and only then must they be implemented. Such changes must be planned in a structured way and under consideration of the existing resources. The process for implementation of changes to the QM system is as followed:

- changes to the QM system are assessed in type and scope,
- their influence on the organization and the conformity of products and services is determined,
- measures/activities derived,
- responsibilities and authorisations are defined,
- changes are tested for effectiveness after implementation.

Support

7

7.1 Resources

General

The management must ensure that the personnel, infrastructure and financial resources required to implement and maintain a QM system in accordance with ISO 9001 are made available on time. The organization must consider the internal resources as well as the resources to be procured. In Sect. 7.1.1, the requirements for resources are only formulated unspecifically, detailed specifications can be found in the further course of Chap. 7.

People

Section 7.1.2 of the standard requires sufficient personnel availability (quantity) and appropriate personnel competence (quality) as important prerequisites for ensuring high product and service quality.

The quantitative personnel capacity results from the operational planning and the actual workload, while the necessary personnel quality depends on the type of activities to be performed. Well-trained employees are not only necessary from the ISO point of view, they also minimize the risk of work errors and are themselves better protected by correct and safe work execution.

Infrastructure

The facilities and the equipment must be appropriate to the scope and extent for the processes of product and service provision. Therefore, the it must be checked regularly for adequacy and condition. The infrastructure includes:

M. Hinsch, *ISO 9001:2015 for Everyday Operations*, essentials,
https://doi.org/10.1007/978-3-658-25550-3_7

- offices, workshops, test stands, workshops, workplaces and storage areas, sanitary, kitchen and rest areas, heating and ventilation systems as well as energy and water supply.
- operating materials such as machines, equipment, instruments, tools and work equipment, storage systems, office equipment, safety and rescue equipment
- material transport systems and transport structures for inbound and outbound deliveries
- communication-systems such as telephones, email and fax
- IT structures including data backup systems and data connection

For equipment that requires regular maintenance, plans and instructions must be available and records must be kept of the measures taken.

With regard to IT infrastructure, special requirements apply because functional stability of organisational processes and data security must be taken into account. In the event of data loss or the non-availability (crash) of IT systems, at least medium-sized and large companies generally should have an emergency concept/planning available.

Environment for the Operation of Processes

The working environment must not trigger performance limitations with regards to processes, staff (e.g. excessive distraction) or resources. Ideal environmental conditions include:

- appropriate temperature, humidity, ventilation,
- as little dust and other air pollution as possible,
- adequate lighting,
- minimum, but at least acceptable, noise level,
- workplace-specific precautions with regard to product preservation,
- workplace-specific precautions with regard to health protection, occupational safety and environmental protection,
- order and cleanliness.

Also, care must be taken to ensure a working environment that takes into account the human factors. The standard specifies the following aspects:

- avoidance of a lack of attention through tiredness & exhaustion,
- working conditions in compliance with social norms,
- minimization of pressure and stress.

Monitoring and Measuring Resources

Monitoring and measurements are necessary to ensure that products and services meet the defined requirements. For these activities, organizations must determine the necessary resources. The focus is on monitoring and measuring equipment (also: test equipment), although documents and qualified personnel are, strictly speaking, also monitoring and measuring resources. However, the standard deals with staff and documented informations more detailed in other chapters.

The ISO 9001 requires an appropriate introduction of test equipment by marking and, if necessary, briefing the employees concerned. Subsequent, measuring and monitoring equipment must be monitored during its service life. This is done by tests and calibrations according to recognized standards and methods.

If a test device turns out to be defective, it must be checked whether there was any negative influence on the test results of previously tested products and services. The organization must define a procedure that shows how to deal with the non conforming test equipment and, above all, with the products and services concerned.

Organizational Knowledge

In organizations, knowledge is at least as important as the presence of machines, plants and equipment. This is all the more true in service industries. Knowledge of the existing organizational know-how (actual) and the required knowledge (target) is an indispensable factor for long-term business success. The necessary know-how must be identified, communicated, preserved and expanded. This requires systematic monitoring and control of knowledge. Every organization should ask itself the following questions:

- What knowledge is required for the provision of products and services or in the processes? What is the organizational edge in knowledge over competitors?
- Where does the knowledge come from and how can it be updated?
- What are the sources for updating knowledge, how is new knowledge rolled out in the organization and integrated into the products or services?
- How is knowledge lost and how can it be protected?

There is not one single tool for organizational knowledge management—it is a bunch of instruments, for example, lessons learnt meetings, wiki systems, training, idea management, incentive systems, project or product databases, quality circles.

7.2 Competence

Systematic staff competence is one of the key elements for guaranteeing high product quality and safety. Only appropriately trained employees can ensure that operational processes are stable over a long period of time and at the same time continuously improve. It must be possible to demonstrate in the certification audit that a constant personnel quality is secured.

In a first step, the qualification requirements or the necessary personnel competence must be defined as a target requirement. Qualification and inital familarization plans that contain information on necessary on-the-job training, subject-specific initial and recurrent training and instruction are most suitable for this purpose. If necessary, they shall specify the extent to which periodic refresher courses are necessary.

By determining the employee skills, these target-specifications are to be compared with the actual skills. If gaps appear, qualification measures must be taken. It should be noted that the standard requirements are not only applied to the organization's own permanent staff, but also to all employees who perform activities under its supervision (e.g. temporary workers).

The overall company training requirements must be summarized in a training plan in order to ensure, maintain and, if necessary, expand the personnel qualification capacity as well as to enable a timely provision of financial resources.

After qualification measures have been carried out, an assessment of the effectiveness must be carried out. Two approaches are therefore used in daily practice:

- assessment of the training by the participant and
- review if the trained content is applied by the trainee.

The second point is in the foreground. It is to be examined that the trainee can applies the training content in the operational everyday life. This control of effektiveness shall be documented by specifying the date of the inspection, inspector and inspection object (e.g. order number).

7.3 Awareness

The standard requires an awareness of the employees for their range of tasks and the importance of a QM system. Thereby, the personnel must become aware of their own actions and their effects. They must be able to judge when products or services meet the requirements. An important part of this is familiarity with the characteristics and elements of

- customer orientation,
- process orientation,
- of risk-oriented action.

For this purpose, the QM system with its characteristics and objectives as well as the specific processes, procedures, supporting documents and specifications must be understood.

As a further measure to create a comprehensive quality awareness, the standard requires adequate publicity of quality policy and quality objectives and their understanding irrespective of the type and duration of employment.

During the audit, employees may need to demonstrate that they understand the main aspects of the quality policy and the main objectives and where they can read them.

7.4 Communication

The management must ensure appropriate communication within its own organization and with external parties, e.g. by meetings, e-mails, exchange of information via the intranet, telephone, company newspapers, information sheets or notices.

Especially in larger organizations, communication is hardly more than sufficient, so that shortcomings arise in the communication of quality management issues across all hierarchical levels. As a result, employees then lack detailed knowledge about updates in processes or products as well as an awareness of operational quality requirements in general. To prevent this, clear communication structures and standards must be defined. A communication matrix can help for the certification audit.

7.5 Documented Information

General

An essential characteristic of QM systems is comprehensive documentation. The ISO-term "documented information" is used for all types of documentation regardless of the medium. This can be in detail:

- operational QM documentation (e.g. QM manual, process descriptions, work instructions, written procedures, templates, filling instructions and (unfilled) checklists, job descriptions, videos),

- (internal) technical documents (e.g. own production instructions, ingredients, part lists, job cards/work orders, drawings, schematics/wiring diagrams, test instructions, test plans, photos, samples, videos),
- external documentation (e.g. customer specifications, customers operating or maintenance instructions, production manuals, drawings, video recordings, standards, laws, directives).
- records (e.g. certificates, minutes, release documents, stamped job cards, audio- or video recordings, jpeg's, completed checklists).

Basically, the standard distinguishes between documents (specification documents) and records (verification documents). While specification documents define the way something has to be performed, records indicate how, when, by whom and under what conditions activities were carried out. Compliance documents in this respect are e.g. completed checklists or forms, certificates, protocols, documented measurement results or stamped work orders.

The type and scope of the documented information are based on the individual conditions of the organisation. The main factors influencing this are, in accordance with the note in Sect. 7.5 of the standard:

- the size of the organization, the nature of the activities and the products and services,
- process complexity,
- qualification of the personnel.

By the way: a typical QM manual is not (any longer) mandatory.

Creating and Updating

All documents must pass through a structured release procedure before they can be officially distributed within the organization. This is to prevent unqualified or unauthorized employees from introducing inappropriate guidelines. Besides to an adequate identification (title, date, creator, rev. status, etc.), the format must also be properly checked and finally the document has to be approved by an authorized person. ISO 9001 does not specify any requirements with regard to the publication medium. Therefore, paper, pdf, MS Word, Excel, PowerPoint, photos, video or audio files are permitted.

Control of Documented Information

The standard specifies numerous requirements for the handling of documented information after it has been released, above all:

- the documented information required for carrying out the work must be available near the respective workplace and not only in principle,
- newly approved documents shall be made known and distributed within the organization to ensure that the latest version of the document is always used at the workplace.
- Documents and records must be adequately protected and remain readable. Protection against technical IT data loss and IT data theft usually plays a greater role than physical document damage due to improper use.
- Documented information must be archived over a defined retention period.
- The storage of documented information must have a structure and order that makes it possible to retrieve data within a reasonable period of time.
- These requirements apply not only to the organization's own documented information but also to external documents from customers and suppliers.

Operation

8

8.1 Operational Planning and Control

Long-term, high-quality product and service provision is only possible in an environment of clearly defined and structurally controlled processes. Section 8.1 of the standard defines requirements that are intended to help establish a systematic framework for operational design, production and procurement activities as well as for customer interaction.

The provision of products and services must be planned systematically. The framework of the value chain is defined by the core processes. The necessary process support must also be defined, e.g. through job card and archiving systems, IT support or determination of outsourcing.

Testing & inspections: Quality must be sufficiently checked during and at the end of the product or service provision. At the same time, it is necessary to define when the service provided corresponds to the target specifications (definition of measured data and tolerances).

Resources: It must be ensured that the necessary resources such as staff capacity, technical equipment and facilities are available to carry out the product and service provision in accordance with the requirements. This includes own operational production factors (personnel, premises, operating resources, IT) as well as products and services to be procured externally (e.g. materials, ingredients, operating materials, equipment, temporary personnel, designs, etc.).

Control: The provision of products and services must not only be carried out according to the defined processes, but also controlled and monitored.

Documented information: Documents and records must be available or created to an appropriate extent so that the activities of the value chain can be carried out

M. Hinsch, *ISO 9001:2015 for Everyday Operations*, essentials,
https://doi.org/10.1007/978-3-658-25550-3_8

and proven in the intended manner. Detailed requirements are described in the subchapters.

In the case of outsourced processes, the organization must ensure that the customer requirements and other specifications of the standard are met by the supplier.

The requirements of Sect. 8.1 increase in detail for the most part in the further course of Chap. 8.

8.2 Requirements for Products and Services

Customer Communication
Sufficient communication structures with the customer must be established. It must be ensured that information on product and service characteristics is available to (potential) customers. An appropriate exchange with the customer must take place during order initiation and completion. During and after the provision of products an services, the organization must systematically record and process customer feedback—especially complaints.

Determining the Requirements for Products and Services
Knowing what the customer wants is a prerequisite for initiating a business relationship and meeting customer expectations. Identifying and implementing customer needs is an essential factor in achieving customer satisfaction. In this respect, it must also be made clear during a certification audit how the organization sees itself in a position to fulfil the requirements of the products an services it offers.

Review of the Requirements for Products and Services
In order to be able to submit a quotation, the organization receives an article number or a description of the requirements (specification) from the potential customer. The purpose of the customer specification is to obtain the most complete, coherent and unambiguous description possible of the product or service to be provided.

In large series or mass production, the relevant requirements are only to be checked generically. In the case of individual enquiries, the customer specification must first be broken down into sensible individual requirements. The customer must be consulted if there are doubts or ambiguities.

In addition to technical feasibility, the assessment of product and service requirements also includes an appropriate assessment of availability of resources,

an examination of capabilities for on-time delivery and, if necessary, at least rough project or order planning.

In a certification audit, the documentation for the technical and capacitive evaluation of a customer inquiry is usually checked. For larger sales activities, it is to be expected that the identification and assessment of order-specific risks will also be checked.

Changes to Requirements for Products and Services

Changes in the quotation must find their way immediately in the documentation for order initiation—the requirements of previous revisions must therefore be revised. They must also be made known internally to the parties involved in order to create awareness of the latest change status.

8.3 Design and Development of Products and Services

General

At the beginning of every product lifecycle is the design phase, which serves to transform an idea into a marketable product. After the market launch, design activities again play a role if modifications, extensions or extensive repairs are made to the original product. A controllable development may not only be necessary for products, but also for services such as medical research, IT programming or design offices.

Organizations that include design activities in their range of services must carry them out under controlled conditions and therefore establish and apply an internal design process.

Section 8.3.1 contains no specific requirements. The requirements of this Sect. 8.3.1 are met once all other design requirements have been implemented.

Design and Development Planning

Economic and timely design goals can only be achieved through systematic preparation. The development as a whole and the individual design phases must be formulated comprehensibly with regard to scope, task and objective. All in all, the expected results must clearly be defined. In operational practice, project management is used for this purpose. The starting point for this is usually a project or customer order, on the basis of which a project plan is created. The project plan must precede what is to be done, when and by whom. It provides information about resource requirements, deadlines and responsibilities, project phases as

well as tests and milestones. Such a plan must have a level of detail that makes it possible to later control and monitor the design project. Customers, suppliers, design partners and other users may also be involved in the development process.

In the certification audit, a current or recently completed project is usually inspected. It must be possible to demonstrate that development is taking place under controlled conditions.

Design and Development Inputs

The starting point of a development are documented specifications and oral information. Ideally, these describe the design goals comprehensively and unambiguously. In most cases, the information provided by the client only indicates what is to be achieved with the design activities and often no or only view detailed input characteristics. Inputs of the development form in their sum a description of the planned design. Possible inputs are among others:

- performance characteristics (e.g. dimensions, design, properties, weight/quantity, performance, comfort, price),
- qualification (e.g. reliability, reaction time, optics, tolerances, weight, cleanliness),
- requirements for quality, costs, data protection, delivery dates, maintenance, material or transport and storage,
- results from market analyses,
- environmental protection and hazardous substance specifications,
- standards or generally accepted test standards/process standards,
- legal and official requirements.

In operational practice, different requirement levels can be distinguished, for example such as *must*, *should*, *can* or *restrictive* criteria or *desirable*, *recommended* or *mandatory* criteria.

Design and Development Controls

It must be ensured that the development outputs are complete, comprehensible and understandable as well as correctly and consistently defined.

As soon as a design projects has started, it must be controlled not only in terms of design progress, but also in terms of capacity and scheduling, as well as continuously compared with the planned results. In addition to daily or weekly operational control of the work progress, design projects must also be monitored by the organizational management in reviews. In these meeting, the status and progress of the design project is systematically checked against the specifications of the planning from a strategic/management point of view. The processing for the identified problems and risks has to be arranged in such a way that the corresponding activities are clear and comprehensible for the next review.

Development Verification and Validation

When a design phase or development activities have been completed, the solution must be verified (tested). The process focuses is on a technical level, to verify compliance with the design inputs (requirements).

Methodically, verification can be carried out by means of document checks, calculations and analyses, as well as simulations, inspections or tests.

For the design verifications, documented information are to be prepared. These comprise test plans, test procedures, checklists and forms as well as compliance documents such as test reports or the above mentioned calculations, analyses or reviews.

While verification checks against the specification or inputs, during validation the check is against the original purpose of the customer as well as against official or legal requirements. The methods of validation may correspond to those of verification. Moreover, these can be pilot projects, field studies, user tests on prototypes and/or tests on system-integrated components. The validation methodology is usually already derived from the customer specification. In many cases, validation is not part of external design projects, as customers often insist on carrying it out themselves.

Design and Development Outputs

In the end, it must be ensured that the development results meet the original input-requirements. The outputs must have a level of detail that makes it possible to produce or execute the developed solution in constant quality without further inquiries. Sometimes auditors recommend the use of operational or industry-specific standards when preparing design documentation, e.g.:

- specifications on the format and structure of the design documents,
- reference to standard procedures instead of own specifications,
- use of forms or checklists
- use of text modules, use of simplified English.

An essential part of the design outputs usually are production and test specifications as well as operating and maintenance instructions. These documents include for example:

- specifications, drawings, calculations, samples, photographs, contracts, software, layouts, drafts, schematics, wiring diagrams, prescription, formulas and other system or component descriptions that define the configuration and design characteristics of the product or service,
- information on processes, procedures, instructions for action, manufacturing techniques as well as instructions for installations or product processing, specifications for procurement and storage,

- material parts lists and information on the properties of the materials to be used,
- test instructions including necessary test steps as well as permissible results and tolerances, if applicable, including associated test devices.

Design and Development Changes
Design changes must be prepared and executed in a structured and comprehensible way. Regardless of the type and scope of the change, the associated design change process is normally divided into the following components:

- initiation and assignment,
- evaluation (in particular impact assessment and risk analysis),
- approval or release of the planned change,
- implementation, monitoring and documentation.

In the course of the initiation, the advantages, risks and technical effects should be listed, as well as an initial estimate of time, resources and costs. As the design change is finally approved, the detailed design activities and its monitoring begins. Documented information (i.e. specifications or proofs) must be prepared at least for the changes themselves, the associated evaluations, the approval and measures to prevent adverse occurrences. In the basic structure, the requirements for design changes do not differ from initial developments and are therefore similar to the requirements of the Sect. 8.3.1 to 8.3.5.

8.4 Control of Externally Provided Processes, Products and Services

It is generally not sufficient for organizations to rely only on own resources to produce products or to provide services. Due to the constantly increasing specialization, purchased products and services as well as outsourced processes have become more and more important over the years.

For the procurement chapter in the standard, terms are to be considered, because ISO 9001 uses “provision” instead of “procurement”. Besides suppliers are called “external providers”. Among them are all kinds of subcontractors and/or service providers for outsourced processes, external firms, connected enterprises like e.g. subsidiaries, parent or sister companies (outside the own certification scope) subsumed.

General

At the beginning of a procurement process, requirements for the external supplier must be defined, checked and monitored during the following service provision. The most important procurement requirements are:

- product features and service
- price and delivery conditions
- flexibility and delivery times
- the general quality capability of the supplier

The standard requires a systematic procedure for the selection, evaluation and monitoring of suppliers. Before awarding a contract, the qualification must usually be checked by means of supplier questionnaires, offer quality, test deliveries or supplier audits. On this basis, a comprehensible release decision must be made.

External providers must be continuously monitored and periodically re-evaluated, normally every 12 month to three years. Appropriate KPIs for measuring supplier performance are, for example the quality of incoming goods or services, complaints or on-time-delivery. Further possibilities of the ongoing supplier evaluation are e.g. supplier audits or material tests. It is important that a procedure with objective criteria for the type and scope of supplier evaluation and release exists. A systematic approach must also be defined, which is effective if external providers do not meet the quality requirements.

Systematic monitoring excludes only those services and their providers that have no influence on their own products and services (e.g. usually office supplies).

Type and Extent of Control

The organization as principal must ensure that the purchased products or outsourced services are of a quality that allows it to assume full responsibility for them. In this respect, the products and services supplied and, if applicable, the associated activities of the external provider must be monitored. This includes above all the capabilities of the external provider as well as the products and services supplied. The following aspects influence the scope of monitoring during or at the end of a service provision or procurement:

a) the nature of the products or the service package to be provided. The scope depends on whether the service provision is characterized by a stable, simple, possibly repetitive value creation process or whether it is a complex, moderately transparent work package.

b) the organization's experience with the external provider. A reduction of the supplier monitoring is possible if it can be proven that the provider has established an effective quality management system with own appropriate monitoring and testing activities.

Necessary controls can range from random acceptance/final inspections (e.g. for standard parts or in mass production, with well-known suppliers) to ongoing monitoring of service provision and detailed acceptance tests (e.g. shipbuilding, construction sector, complex engineering services or new suppliers of critical components).

Information for External Providers

The most important criterion for purchased products and services is their compliance with the procurement requirements. Particular attention should therefore be paid to the procurement details in the order (specification, contract, etc.), as this clearly defines the product to be procured. Typically, this takes place by means of catalog description and order number of the supplier. For non-standard products and services, specifications are used. These should be as precise and unambiguous as possible.

The first step is to describe the service or product to be provided externally (8.4.3 a), including associated measurement and testing activities, if necessary. Furthermore, for example, special requirements must be specified for the manufacturing processes (e.g. for special processes) as well as shipping, storage and transport conditions. If work steps or processes are outsourced, the (formal) qualification of the staff employed by the supplier can also play a role. Further typical order requirements can be the vendor's obligations:

- to have further subcontracting (supplier cascade) approved by the organisation,
- to impose the same quality requirements on the subcontractors,
- to inform about changes to sources of supply or the obligation to have them released by the organization,
- to notify changes to the delivered product or service or the obligation to have them released by the organization,
- to maintain a QM system certified according to the ISO 9001 standard.

8.5 Production and Service Provision

Control of Production and Service Provision
Section 8.5.1 summarizes the essential requirements for systematically organized production and service provision. Guaranteeing of controlled conditions is in the foreground here. The provision of services must therefore be planned and structured, controlled and adequately documented. This requires, in particular

- all necessary products, services, processes and activities are defined by means of specifications and instructions so that the staff is clearly aware of the process results in terms of what, how and has to be done and which characteristics should be achieved,
- structured planning, monitoring of service provision and testing or inspection of products and services is ensured and takes place
- the necessary infrastructure and equipment is available and used. Acceptable environmental conditions must also be in place,
- the personnel is sufficiently qualified to carry out the assigned work, measures are taken to prevent human errors. In this way, the important field of human factors is taken into account in the standard,
- a regular validation of any special processes is ensured.

Identification and Traceability

Labelling
Certified organizations must be able to ensure a reliable identification of their products and services, including the current processing status or degree of completion, at all times. Accompanying documentation remains on the product during the period of service provision or storage. After completion, it is archived and replaced by a certificate or an acceptance confirmation, if required.

Tracebility
Organizations must assume responsibility for quality and liability towards their own customers, even if material or parts of the product or service spectrum are purchased from external. More and more customers are demanding traceability from their suppliers. However, traceability is not generally mandatory from ISO 9001 point of view. It depends on whether this is required by the customer, the legislator or the authorities.

When it comes to the traceability of products, this means for materials management that the parts, materials and substances used in them must be traceable from their source of manufacturing or origin to their installation, scrapping or transfer of ownership. Moreover, all product movements and processing must be documented. This means, for example, that:

- Traceability down to the serial, lot or badge number must be guaranteed.
- The traceability of the product development is to be ensured and differences between the target and actual status of the product are to be shown.
- All products manufactured from a raw material or production batch must be traceable from the source of purchase to delivery or scrapping.

Property Belonging to Customers or External Providers

Property of customers, suppliers and partners can be found in most organizations and is therefore part of daily practice. Third-party ownership plays a role in particular with regard to materials provided by customers as well as repair returns, product modifications and on-site service assignments. Intangible and intellectual property includes especially electronic and paper-based design documentation (drawings, analyses, parts lists, etc.) or production instructions.

Each organization must define rules for dealing with third-party property. Condition and completeness inspections during takeover are part of the standard procedure. Subsequently, appropriate protection must be provided against access by unauthorized persons and against deterioration due to environmental conditions (dust, ESD, UV light, etc.). If there is a risk of incorrect use or handling, instructions must be provided or even trainings given if necessary. Third-party property must be marked or made recognizable as such.

Preservation

Section 8.5.4 of the standard lays down requirements for the general handling of products and services during own operational control and responsibility. Each organization must demonstrate activities and measures to prevent deterioration of process results and to ensure compliance with customer requirements. In the case of products, the focus is on handling, storage, transport, packaging and shipping requirements. Services may involve data loss and data protection against accidental changes or compliance with hygiene or safety regulations.

Handling and Transport

- Order and cleanliness in the workspaces. Documentation should be organized and objects should be protected and returned to their intended place of storage when not in use for a longer period of time.
- Minimization of contamination and foreign objects (FOD),
- ensuring a professional working environment, e.g. through ESD-protected areas,
- the production of products is only to be carried out at designated workstations.
- Provisioning of transport and packaging specifications for sensitive parts and materials.

Storage

- Definition of storage requirements and storage conditions, tracking of storage and retrieval processes and product inspections.
- Defective stock material or material with unknown status shall be marked and placed in a restricted area to prevent unintended use.
- Materials with limited shelf life require monitoring of storage times.
- Protection against product or material damage during storage or during warehousing and stock removals,
- hazardous goods must be labelled with a warning notice and stored separately and associated safety data sheets must be kept available.

Post-delivery Activities

The provision of services does not end with the delivery, but also extends to the period thereafter—at least in the case of complaints or guarantees. The type and scope of after sales support are primarily based on the product or service. The reasons for activities after delivery can be triggered by the customer, by the legislator or by interested parties. As a rule, the causes are

- contract requirements,
- customer expectations that are not contractually fixed (including customer feedback),
- legal or official requirements (e.g. safety requirements, condition monitoring).

Operational requirements can also require extensive post-delivery activities, e.g. tracking the long-term quality of products and services. The necessary information can, for example, be provided by transmitted customer performance data on product or services, customer complaints or, fault analyses of repair devices.

Control of Changes

Products and services as well as processes must be controlled in a structured manner not only in their design/development phase and during ramp-up. Later changes during product or service provision also require a systematic approach. Reasons may be modifications to products or services, changes to the production process, new machines and equipment, tools or software updates, new production/performance parameters and the use of new materials, or operating supplies.

From the point of the ISO standard, it is important that changes are first assessed and planned in a structured manner and then systematically implemented.

The changes may only be released once the planned result and the fulfilment of the requirements have been established, checked an released in a traceable manner. Finally, the approval must be done by an authorized person.

Records must be kept to such an extent that the decision in favor of the change as well as the planning and implementation process can be traced at a later.

8.6 Release of Products and Services

The standard requires a systematic procedure for the control of product and service characteristics during value chain, in particular before dispatch and customer acceptance. For this purpose, a structured inspection/release procedure with clearly defined test requirements and acceptance criteria must exist and executed by qualified and authorized personnel.

Within the scope of product and service releases, the following has to be defined:

a) acceptance or rejection criteria,
b) at which point or at which process step tests shall be performed,
c) requirements for the recording of test results,
d) specifications regarding the measuring and test equipment to be used and, if applicable, instructions for their use.

Adequate evidence shall be provided for release activities.

The measurement and testing activities can also be used to derive useful indicators for evaluating process performance (see Chap. 9).

8.7 Control of Nonconforming Outputs

A general accompanying symptom of the provision of products and services is occasionally an improper execution of work. This can occur in the processes of the organization's own value creation, but also in the supply chain. If this results in defects or damage, action is required. In addition to the minimization of the damage, the focus here is on troubleshooting through replacement or through corrective (and service) measures in order to keep the nonconformity to the customer as low as possible.

If a defective process output, a nonconforming product or service has been identified, immediate action must be taken. This includes the separation and unambiguous identification of the object concerned and, if necessary, a stop at the corresponding work step or the blocking of the associated material batch. Troubleshooting requires both, a search for the error incl. a determination of its effect as well as a root cause analysis.

In principle, the following alternatives are possible for dealing with defective products or services:

- use as is with customer release,
- reclassification (e.g. due to restricted use),
- correction or rework,
- return to the supplier,
- scrapping/destruction

In the event of repair or rework, the product or service must be re-verified prior to concession. If the product no longer complies with the agreed specification after concession, the customer must be involved in the decision.

Records must be kept of non-conformities incl. their handling to such an extent that the decision-making process can be traced at a later date.

Performance Evaluation

9

9.1 Monitoring, Measurement, Analysis and Evaluation

General

During and after the provision of products and services, processes performance must be monitored and measured to determine if the planned results are archived. The "C" (check) of the PDCA cycle is in the foreground here. The type, scope and frequency of monitoring and measurement must be defined and aligned with the size of the organization and the service portfolio. With regard to frequency, it will be necessary to carry out some measurements daily (e.g. acceptance tests), while others only need to be carried out once a quarter or every six month.

In this respect, suitable measurement methods or key performance indicators (KPIs) must be available and survey frequencies must be determined. The following KPIs can be defined for this purpose, for example:

- machine downtimes, alternatively also machine utilization,
- waste, rejections, reworking,
- cycle/lead and processing times,
- stamp rate of employees or booking rate on orders,
- time span from receipt of order to delivery,
- complaint rate, error statistics of all kinds, cost of non-quality,
- delivery times, waiting and lay times,
- staff turnover rate,
- IT downtime.

M. Hinsch, *ISO 9001:2015 for Everyday Operations*, essentials,
https://doi.org/10.1007/978-3-658-25550-3_9

Customer Satisfaction
The achievement and improvement of customer satisfaction is a core concern of the ISO 9001. For this reason, it must be measured on a regular basis. The starting point for this is the determination of parameters, KPIs and intervals for customer satisfaction measurement. Typical criteria/indicators are:

- the delivery performance (On-Time-Delivery, OTD),
- product conformity (e.g. through acceptance tests, rejection rates or rate of complaints),
- claims from guarantees, complaints from customers,
- results of surveys,
- order or sales development.

If deficits in customer satisfaction are identified, a systematic procedure must be initiated in accordance with the requirements of Sect. 10.2 and 10.3.

Analysis and Evaluation
From the analysis and evaluation of the collected QM data, direct statements on performance can be derived e.g.: regarding product, service and process quality, customer satisfaction and the performance of the QM system. According to Sect. 9.1.3 of the standard, the following data must be evaluated:

a) *Products and services*: e.g. product testing, claims, rejection rates, requests for corrective action.
b) *Customer satisfaction*: e.g. sales figures, type and number of corrective actions and customer complaints, surveys and feedback.
c) *Performance of the QM system*: speed of implementation of audit findings, cost-of-non quality.
d) *Planning quality*: compliance with schedules/deadlines or utilization of resources: e.g. plan to actual hours, on-time delivery.
e) *Risks and opportunities*: Expected deviations in hours/days, rework, downtime, order extensions.
f) *Supplier performance*: e.g. on-time delivery, incoming goods findings, costs, innovation capability.
g) *need for improvements*: e.g. past developments to the examples given here.

The results either provide evidence of compliance with all quality requirements or form the starting point for the initiation of improvement measures (Sect. 10.3). In addition, the results of the data analysis are an important input for the management review (Sect. 9.3).

9.2 Internal Audit

Internal audits serve the purpose of checking whether operational processes and procedures are applied in daily practice and whether they meet the ISO 9001 and all other relevant requirements. An audit is a management instrument for structured and independent investigations that provides information on the effectiveness and performance of the QM system. At the same time, internal auditing can help to identify weak points and deviations from organizational quality objectives and can be the starting for improvement measures.

Internal auditing is structured via an audit program. The aim is to ensure that all elements of the QM system are checked regularly, at least every 3 years, for compliance with the ISO 9001 requirements.

When carrying out audits, care must be taken to ensure that internal auditors remain independent and neutral and not to audit their own range of activities. Auditor qualification plays a particularly important role in audit quality. The efficiency of this tool stands and falls with it. As an alternative to having own auditors, it is for know-how reasons possible and sensible to rely on the support of an external auditor for 2–3 days per year.

If non-compliance with standard requirements is identified during the audit, this is to be documented as an audit-finding, which must be closed immediately.

The audit results shall be submitted individually or in summary form to top management. This must be done at least once a year as part of the management review.

9.3 Management Review

The top management must regularly carry out so-called management reviews. This term is sometimes misunderstood, because it is not the top management that is evaluated, but it has to assess the performance of the QM system. The review should therefore give the organizational management the opportunity to obtain an up-to-date overview regarding the status of the quality management. At the same time, this review serves to instruct corrections and improvement measures in the QM system.

During the review, internal and external issues, process and delivery performance, achievement of quality objectives, supplier performance and operational risks and opportunities are to be reflected.

The standard makes no statements about the scope and frequency of management reviews. Some topics should be evaluated monthly by the management, for others a quarterly or six month review is sufficient. The reviews usually last 2–4 h.

A management review must always have an output. If objectives have not been achieved, effective measures must be instructed. Therefore, the Plan-Do-Check-Act cycle is to be applied. This has to be shown during the certification audit.

Records of last years' management reviews are checked during each certification audit.

Improvement 10

10.1 General

In order to maintain and enhance customer satisfaction and competitiveness, organizations must improve their products and services as well as the QM system itself wherever possible. In addition to the "typical" QM measures, which take place under QM control, the following activities are also be defined as (strategic) improvements in the sense of the ISO 9001:

- reorganizations,
- investment in staff or qualification as well as
- measures in the field of IT/infrastructure and tools,
- adjustments to production process,
- instruction for a training measure, or
- the decision to purchase a new, more powerful machine.

Whether the continuous improvement takes place in a formalized manner or is largely based on verbal agreement, measure have strong QM orientation or take place informally under a "name" other than QM is irrelevant from the ISO point of view. Auditor's expectations are also not high here. No revolutionary measures are expected. The concept of constant or continuous improvement is based on small steps.

M. Hinsch, *ISO 9001:2015 for Everyday Operations*, essentials,
https://doi.org/10.1007/978-3-658-25550-3_10

10.2 Nonconformity and Corrective Action

In everyday operations, non-conformities or incidents are quickly rectified in order to return to the path of production or service provision as fast as possible. In doing so, however, a look at the deeper root causes, at error patterns, such as accumulations or similarities, falls behind. The standard therefore requires that after identifying an error, a nonconformity or a customer complaint, measures be taken to further contain the damage, analyze the cause, remedy the situation and, if necessary, prevent it.

In a first step it has to be determined how serious the incident is, in particular whether other products or services are affected by the same defect. An important step for this is the root-cause analysis. So that corrected nonconformity do not occur again, the source, the period, the responsibilities and influences must be determined. Where appropriate, recognized quality management methods such as 8D reports, FMEA analyses, Ishikawa diagrams or the 5W procedure should be applied for root-cause analysis and the derivation of suitable measures. This is because not only symptoms should be eliminated, but also the actual sources of the nonconformity.

As soon as the roots-causes and effects of incidents have been fully determined, corrective measures must be derived and implemented. The measures can, for example, be as follows:

- changes of processes, procedures and QM-documentation,
- adjustment of the QM system,
- improvement of training content,
- changes to material specifications,
- design changes,
- change of suppliers.

In order to determine the effectiveness of the corrective measures (Sect. 10.2.1 d), check on the effectiveness must be carried out after their implementation; any risks and opportunities must be kept in mind during the implementation process. Finally, it must be ensured that the nonconformity, the measures taken and their results are recorded.

10.3 Continual Improvement

This section of the standard is an explicit demand to permanently improve the QM system. At its core, the requirements mentioned here aim on systematic and active measures to improving the performance of the QM system and thus of all processes involved in the value chain. In order to identify improvements, information from audits, management reviews, evaluations of process measurements and other quality parameters should be used.

What you can take with you from this *essential*

- Knowledge of the basic elements and focal points of ISO 9001:2015
- Understanding of the structure, objectives and basic requirements of the standard
- Basic knowledge of the requirements of the individual standard chapters
- Useful tips for transferring the standard requirements into your QM system
- An interpretation of the most important standard requirements

M. Hinsch, *ISO 9001:2015 for Everyday Operations,* essentials,
https://doi.org/10.1007/978-3-658-25550-3

References

Deutsches Institut für Normung. e. V. (2015). *Quality management systems – Requirements (ISO 9001:2015); German and English version EN ISO 9001:2015*. Berlin.

Hinsch, M. (2018). *Die ISO 9001: 2015 – Ein Ratgeber für die Einführung und tägliche Praxis*. Berlin: Springer.

M. Hinsch, *ISO 9001:2015 for Everyday Operations,* essentials,
https://doi.org/10.1007/978-3-658-25550-3