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Quality management systems — Guidelines for the application of ISO 9001:2015

Systèmes de management de la qualité — Lignes directrices pour l'application de l'ISO 9001:2015

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on the meaning of ISO specific terms and expressions related to conformity assessment, as well as information about ISO's adherence to the World Trade Organization (WTO) principles in the Technical Barriers to Trade (TBT) see the following URL: www.iso.org/iso/foreword.html.

The committee responsible for this document is Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

Introduction

This document has been developed to assist users to apply the quality management system requirements of ISO 9001:2015 *Quality management systems – Requirements*.

This document provides guidance, with a clause by clause correlation to Clauses 4 to 10 of ISO 9001:2015, however it does not provide guidance on ISO 9001:2015, Annexes A and B. Where there is direct correlation between list items (i.e. bullet points) in a clause in ISO 9001:2015 and the guidance, this is indicated within the clause of this document.

This document gives examples of what an organization can do, but it does not add new requirements to ISO 9001. The examples in this document are not definitive and only represent possibilities, not all of which are necessarily suitable for every organization.

ISO 9001 contains requirements that can be objectively audited or evaluated. This document includes examples, descriptions and options that aid both in the implementation of a quality management system and in strengthening its relation to the overall management system of an organization. While the guidelines in this document are consistent with the ISO 9001 quality management system model, they are not intended to provide interpretations of the requirements of ISO 9001 or be used for audit or evaluation purposes.

As the requirements of ISO 9001 are generic, this document can be used by organizations of all types, sizes, levels of maturity and in all sectors and geographic locations. However, the way an organization applies the guidance can vary based on factors such as the size or the complexity of the organization, the management model it adopts, the range of the organization's activities and the nature of the risks and opportunities it encounters.

Risk is the level of uncertainty inherent in a quality management system. There are risks in all systems, processes and functions. Risk-based thinking ensures these risks are determined, considered and controlled throughout the design and use of the quality management system.

Risk-based thinking has been implicit in previous editions of ISO 9001 in such requirements as determining the type and extent of control for external providers based on the effect of the product that is going to be provided, or taking corrective action based on the potential effect of an identified nonconformity.

In addition, in previous editions of ISO 9001, a clause on preventive action was included. By using risk-based thinking the consideration of risk is integral. It becomes proactive rather than reactive in preventing or reducing undesired effects through early identification and action. Preventive action is built-in when a management system is risk-based.

Not all the processes of a quality management system represent the same level of risk in terms of the organization's ability to meet its quality objectives. Some need more careful and formal planning and control than others.

There is no requirement in ISO 9001 to use formal risk management in determining and addressing risks and opportunities. An organization can choose the methods that suit its needs. IEC 31010 provides a list of risk assessment tools and techniques that can be considered, depending on the organization's context.

In some cases, an organization might have a formal risk management process in place that is required by customers or statutory and regulatory requirements. In such circumstances, the organization can adapt its formal risk management process to meet the intent of the requirements in ISO 9001 concerning risks and opportunities.

In addition to ISO 9001:2015, Annex A, ISO has published a number of other quality management standards and informative resources which can assist the user and provide information on additional implementation methods, including:

— the ISO handbook: ISO 9001:2015 *for Small Enterprises – What to do ? Advice from ISO/TC 176*

— the ISO 9001 Auditing Practices Group (APG) papers: www.iso.org/tc176/ISO9001AuditingPracticesGroup

— public information on the ISO/TC 176/SC2 website: https://committee.iso.org/tc176sc2

— the ISO handbook: *The Integrated Use of Management System Standards*.

Additional standards and documents are listed in the Bibliography.

Quality management systems — Guidelines for the application of ISO 9001:2015

1 Scope

This document provides guidance on the intent of the requirements in ISO 9001:2015, with examples of possible steps an organization can take to meet the requirements. It does not add to, subtract from, or in any way modify those requirements.

This document does not prescribe mandatory approaches to implementation, or provide any preferred method of interpretation.

2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

ISO 9001:2015, *Quality management systems — Requirements*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 apply.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at http://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Context of the organization

4.1 Understanding the organization and its context

The intent of this subclause is to understand the external and internal issues that are relevant to the organization's purpose and strategic direction and that can affect, either positively or negatively, the organization's ability to achieve the intended results of its quality management system. The organization should be aware that external and internal issues can change, and therefore, should be monitored and reviewed. An organization might conduct reviews of its context at planned intervals and through activities such as management review.

Information about external and internal issues can be found from many sources, such as through internal documented information and meetings, in the national and international press, websites, publications from national statistics offices and other government departments, professional and technical publications, conferences and meetings with relevant agencies, meetings with customers and relevant interested parties, and professional associations.

Examples of external and internal issues relevant to the organization's context can include, but are not limited to:

a) external issues related to:

   1) economic factors such as money exchange rates, economic situation, inflation forecast, credit availability;

   2) social factors such as local unemployment rates, safety perception, education levels, public holidays and working days;

   3) political factors such as political stability, public investments, local infrastructure, international trade agreements;

   4) technological factors such as new sector technology, materials and equipment, patent expirations, professional code of ethics;

   5) market factors such as competition, including the organization's market share, similar products or services, market leader trends, customer growth trends, market stability, supply chain relationships;

   6) statutory and regulatory factors which affect the work environment (see ISO 9001:2015, 7.1.4) such as trade union regulations and regulations related to an industry;

b) internal issues related to:

   1) overall performance of the organization;

   2) resource factors, such as infrastructure (see ISO 9001:2015, 7.1.3), environment for the operation of the processes (see ISO 9001:2015, 7.1.4), organizational knowledge (see ISO 9001:2015, 7.1.6);

   3) human aspects such as competence of persons, organizational behaviour and culture, relationships with unions;

   4) operational factors such as process or production and service provision capabilities, performance of the quality management system, monitoring customer satisfaction;

   5) factors in the governance of the organization, such as rules and procedures for decision making or organizational structure.

At the strategic level, tools such as Strengths, Weaknesses, Opportunities and Threats analysis (SWOT) and Political, Economic, Social, Technological, Legal, Environmental analysis (PESTLE) can be used. A simple approach can be useful for organizations dependent on the size and complexity of their operations, such as brainstorming and asking "what if" questions.

4.2 Understanding the needs and expectations of interested parties

The intent of this subclause is to ensure that the organization considers the relevant requirements of relevant interested parties, beyond just those of its direct customers. The intention is to focus on only those relevant interested parties which can have an impact on the organization's ability to provide products and services that meet requirements. While not directly stated in ISO 9001, the organization could consider its external and internal issues (see ISO 9001:2015, 4.1) before, and to assist in, determining its relevant interested parties.

The list of relevant interested parties can be unique to the organization. The organization can develop criteria for determining relevant interested parties by considering their:

a) possible influence or impact on the organization's performance or decisions;

b) ability to create risks and opportunities;

c) possible influences or impact on the market;

d) ability to affect the organization through their decisions or activities.

EXAMPLE 1 Examples of relevant interested parties that can be considered relevant by an organization include, but are not limited to:

— customers;

— end users or beneficiaries;

— joint venture partners;

— franchisors;

— owners of intellectual property;

— parent and subsidiary organizations;

— owners, shareholders;

— bankers;

— unions;

— external providers;

— employees and others working on behalf of the organization;

— statutory and regulatory authorities (local, regional, national or international);

— trade and professional associations;

— local community groups;

— non-governmental organizations;

— neighbouring organizations;

— competitors.

To understand the needs and expectations of relevant interested parties, several activities and methods can be carried out. They include working with those responsible for the processes or by using methods that allow the gathering of information. Methods include, but are not limited to:

— reviewing orders received;

— reviewing statutory and regulatory requirements with compliance or legal departments;

— lobbying and networking;

— participating in relevant associations;

— benchmarking;

— market surveillance;

— reviewing supply chain relationships;

— conducting customer or user surveys;

— monitoring customer needs, expectations and satisfaction.

EXAMPLE 2 Examples of relevant interested party requirements include, but are not limited to:

— customer requirements regarding conformity, price, availability or delivery;

— contracts which have been entered into with customer or external providers;

— industry codes and standards;

— agreements with community groups or non-governmental organizations;

— statutory and regulatory requirements for the product or service provided, and those that affect the organization's ability to provide that product or service;

— memoranda of understanding;

— permits, licenses or other forms of authorization;

— orders issued by regulatory agencies;

— treaties, conventions and protocols;

— agreements with public authorities and customers;

— voluntary principles or codes of practice;

— voluntary labelling or environmental commitments;

— obligations arising under contractual arrangements with the organization;

— policies for employees.

The information resulting from these activities should be considered in planning the quality management system (see ISO 9001:2015, Clause 6).

The organization should be aware that the relevant interested parties and their relevant requirements can be different for the different products and services provided, and can change due to unforeseen circumstances or intentional reactions to markets.

The organization should have robust systems in place to monitor and review the relevant requirements of its interested parties. Monitoring and reviewing can be done by using the organization's processes related to customer requirements, design and development of products and services, and (at a more strategic level) during management review.

4.3 Determining the scope of the quality management system

The intent of this subclause is to determine the boundaries of the quality management system so that it is defined in a manner that helps the organization meet requirements and the intended results of the system.

For ISO 9001:2015, 4.3, bullets a) to c), the scope should be established based on:

a) the external and internal issues as determined by the requirements of ISO 9001:2015, 4.1;

b) the relevant requirements of relevant interested parties (such as regulators as well as customers) as determined in accordance with the requirements in ISO 9001:2015, 4.2;

c) the products and services provided by the organization.

In determining the scope, the organization should also establish the boundaries of the quality management system by considering such issues as:

— the infrastructure of the organization;

— the organization's different sites and activities;

— commercial policies and strategies;

— centralized or externally provided functions, activities, processes, products and services.

All requirements of ISO 9001 are considered applicable unless they do not have an effect on the organization's ability to provide a product or deliver a service that meets requirements or on its enhancement of customer satisfaction.

In determining the application of requirements in ISO 9001, the organization should consider each individual requirement, and not just decide that a whole clause is not applicable. At times, some of the requirements may be applicable in a clause, or all of the requirements within a clause may, or may not, be applicable.

The scope should be maintained as documented information. The scope should include details of the products and services covered. It should also include justification for any requirements that are determined not to be applicable. This documented information can be maintained in whatever method the organization determines to meet its needs, such as a manual or a website.

4.4 Quality management system and its processes

4.4.1 The intent of this subclause is to ensure that the organization determines the processes needed for its quality management system in accordance with ISO 9001. This includes not only the processes for production and service provision, but also the processes that are needed for the effective implementation of the system, such as internal audit, management review and others (including processes that are performed by external providers). For example, if the organization determines the need for a process for monitoring and measuring resources, the process will need to meet the requirements of ISO 9001:2015, 7.1.5. The level to which processes need to be determined and detailed can vary according to the context of the organization and the application of risk-based thinking – taking into consideration the extent to which the process affects the organization's ability to achieve its intended results, the likelihood of problems occurring with the process and the potential consequences of such problems.

A process is a set of interrelated or interacting activities that use inputs in order to deliver intended results. For ISO 9001:2015, 4.4.1, bullets a) to h):

a) the organization should determine the inputs required and the outputs expected from its processes; inputs required for the processes should be considered from the viewpoint of what is required for the implementation of the processes as planned; expected outputs should be considered from the viewpoint of what is expected either by the customers or the subsequent processes; inputs and outputs can be tangible (e.g. materials, components or equipment) or intangible (e.g. data, information or knowledge);

b) when determining the sequence and interaction of these processes, the links with the inputs and outputs of the previous and subsequent processes should be considered; the methods for providing details of the sequence and interaction of the processes depends on the nature of the organization; different methods can be used, such as retaining or maintaining documented information (e.g. process maps or flow diagrams), or a more simple approach, such as a verbal explanation of the sequence and interaction of the processes;

c) to make sure that processes are effective (i.e. deliver the planned results), the process control criteria and methods should be determined and applied by the organization; criteria for monitoring and measurement could be process parameters, or specifications for products and services; performance indicators should be related to monitoring and measurement, or can be related to the

organization's quality objectives (criteria); other methods for performance indicators include, but are not limited to, reports, charts or the results of audits;

d) the organization should determine the resources needed for processes, such as people, infrastructure, environment for the operation of the processes, organizational knowledge and monitoring and measuring resources (see ISO 9001:2015, 7.1); considerations on the availability of resources should include the capabilities and constraints of existing internal resources and those that are obtainable from external providers;

e) the organization should assign the responsibilities and authorities for its processes by first determining the activities of the process and then determining the persons who will perform the activity; the responsibilities and authorities can be established in documented information, such as organization charts, documented procedures, operational policies and job descriptions, or by using a simple approach of verbal instructions;

f) the organization should ensure that any actions needed to address risks and opportunities associated with the processes are implemented (see ISO 9001:2015, 6.1);

g) the organization should consider the performance data obtained through the review of criteria established for monitoring and measuring; analyse and evaluate this data; and implement any changes needed to ensure that these processes consistently achieve their intended results;

h) the organization can use the results of analysis and evaluation to determine the necessary actions for improvement; improvements can be made at the process level (e.g. by reducing variations in the way an activity is performed) or at the quality management system level (e.g. by reducing the paperwork associated with the system, allowing persons to concentrate more on managing the processes).

4.4.2 The intent of this subclause is to ensure that the organization determines the extent of documented information that is needed.

Documented information is information required to be controlled and maintained by an organization and the medium on which it is contained.

The appropriate person (e.g. process owner, process output owner, process control person) should review what information is used for the process to perform consistently to deliver the intended output. For information (e.g. procedures, work instructions, visual aids, information and communication systems, drawings, specifications, metrics, reports, key performance indicators [KPIs], meeting minutes, representative samples, verbal conversations) that is used, an analysis/review of the value to support the process needs to be carried out. The result will be the decision as to which information will be treated as documented information. For example, when top management does strategic planning, they could consult and review relevant information on the internet, such as reports on the current and future status of the organization's industry sector that have been developed by governmental agencies and other relevant parties. This information should not be considered as documented information, as it is available from the public domain. In contrast, a business plan that includes quality objectives, risk and opportunities, strategies, among other relevant elements (e.g. the organization's mission, vision, values and process map) would need to be considered as documented information.

It is up to the organization to specify the different types of documented information needed to support the operation of its processes and its quality management system. In determining the type and extent of documented information needed, the organization should evaluate its own needs and apply risk-based thinking. It should also give consideration to its size, activities, types of products or services, complexity of its processes, resources, etc., as well as the potential consequences of nonconformities.

While ISO 9001 specifies the use of documented information in a number of its requirements, there can be a need for the organization to have additional documented information (such as documented procedures, websites, work instructions, manuals, regulations, standards, forms, guides, computer software, telephone "apps") to control the operation of its processes.

