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Quality management systems — Guidance for documented information

Systèmes de management de la qualité — Recommandations pour les informations documentées

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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 of the voluntary nature of standards, 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 www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 3, *Supporting technologies*.

This first edition of ISO 10013 cancels and replaces ISO/TR 10013:2001, which has been technically revised. The main changes compared with ISO/TR 10013:2001 are as follows:

— it has been aligned with the new structure and requirements of ISO 9001:2015, notably the documentation requirements;

— the original hierarchy of documentation is no longer used but left open for the user.

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www.iso.org/members.html.

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Introduction

ISO 9001 requires an organization to maintain and retain documented information to support the operation of its processes and to have confidence that the processes are being carried out as planned.

Documented information is information required to be controlled and maintained by an organization and the medium on which it is contained. Documented information can be used to communicate, to provide objective evidence or for sharing knowledge.

Documented information enables the knowledge and experiences of the organization to be preserved and can generate value to support the improvement of products or services.

This document provides guidance for the development and maintenance of documented information.

The adoption of a quality management system is a strategic decision for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives. It is applicable to all organizations, regardless of size, complexity or business model. Its aim is to increase an organization's awareness of its duties and commitment in fulfilling the needs and expectations of its customers and interested parties, and in achieving satisfaction with its products and services.

It is important to consider the context of the organization, including the legal and regulatory framework, needs and expectations of interested parties, risks and opportunities, and strategic direction of the organization, when an organization plans what documented information to maintain and retain for its quality management system. While the adoption of a quality management system is strategic, this also applies to its documented information.

Documented information can relate to an organization's total activities or to a selected part of those activities, e.g. specified requirements depending upon the nature of products and services, processes, contractual requirements, statutory and regulatory requirements, the context of the organization itself.

It is important that the content of the documented information also conforms to the requirements of the standards they intend to satisfy, e.g. sector-specific requirements.

Organizations have been moving from paper-based systems to electronic media in the last two decades. ISO 9001 has reflected this change, replacing terminology such as "documentation, quality manual, documented procedures, and records" with "documented information." This guidance document uses the word "documented information" to refer to information that needs to be controlled by the organization and "documents" to refer to information. It also uses the word "document" as a verb in a few places.

ISO management system standards use a high-level structure to encourage the use of integrated management systems. This guidance document by its design and scope is focused on the quality management system and uses terminology from ISO 9000:2015. However, nothing prohibits its use in other management system standards.

In the previous version of this document, a hierarchy of documentation, such as a quality manual, procedures, work instructions and forms/checklists, was suggested as a way of documenting the quality management system. This document does not prescribe a particular hierarchy but reflects the ability of electronic media to organize itself in a multitude of ways. It is important to realize that while a quality manual is not required, it can still be useful, and many sector-specific standards still require "quality manuals and documented procedures".

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Quality management systems — Guidance for documented information

1 Scope

This document gives guidance for the development and maintenance of the documented information necessary to support an effective quality management system, tailored to the specific needs of the organization.

This document can also be used to support other management systems, e.g. environmental or occupational health and safety management systems.

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*

3 Terms and definitions

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

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

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

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

3.1
work instruction
detailed description of how to perform tasks

EXAMPLE Detailed written descriptions, flow charts, templates, models, technical notes incorporated into drawings, specifications, equipment instruction manuals, pictures, audios and videos, checklists or combinations thereof.

Note 1 to entry: Work instructions can be documented.

Note 2 to entry: Work instructions describe any materials, equipment and documented information to be used. When relevant, work instructions include acceptance criteria.

3.2
form
documented information to be maintained and used to record data required by the quality management system

Note 1 to entry: A form becomes documented information to be retained (i.e. a record) when data are entered.

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3.3
workflow
series of activities necessary to complete a task

Note 1 to entry: A workflow that is partially or completely carried out without manual interference can be referred to as an "automated workflow".

Note 2 to entry: Workflows can be documented.

4 Documented information

4.1 General

4.1.1 Structure

Documented information can be structured and created in many ways based on the needs of the organization and other factors such as leadership, intended results of the management system, context (including statutory and regulatory requirements) and interested parties.

The structure of the documented information used in the quality management system can be described in a hierarchy. This structure facilitates the distribution, maintenance and understanding of the documented information. Electronic systems provide additional choices for structuring documented information. Annex A illustrates examples of documented information structures. Smaller organizations may choose a simplified documented information structure to meet their needs.

The type and extent of the documented information needed for the quality management system should be based on an analysis of processes and can differ from one organization to another due to, for example:

a) the size of the organization and type of activities;

b) the complexity of processes and their interactions;

c) the maturity of the quality management system;

d) risks and opportunities;

e) the competence of persons;

f) statutory and regulatory requirements;

g) customer and other interested party requirements;

h) the need for evidence of results achieved;

i) the need to support accessibility and retrievability remotely.

4.1.2 Definitions

Documented information can include definitions. To enhance comprehension, the organization should consider using vocabulary that is in accordance with standard terms and definitions which are referenced in ISO 9000, in general dictionary usage or which can be specific to the organization. An organization's quality management system may use different terminology for the defined types of documented information.

4.1.3 Content

An organization's documented information should include the following:

a) the scope of the quality management system (see 4.2.1);

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b) a quality policy (see 4.2.2);

c) quality objectives (see 4.2.3);

d) information that the organization determined necessary to support the operation of the quality management system and its processes, including, as applicable:

   1) a quality manual (see 4.2.4.2);

   2) organizational charts (see 4.2.4.3);

   3) process maps, process flow charts and/or process descriptions (see 4.2.4.4);

   4) procedures and work instructions (see 4.2.4.5);

   5) automated workflows (see 4.2.4.6);

   6) product and service specifications (see 4.2.4.7);

   7) internal and external communications (see 4.2.4.8);

   8) plans, schedules and lists (see 4.2.4.9);

   9) forms and checklists (see 4.2.4.10);

   10) documented information of external origin (see 4.2.4.11);

e) documented information to be retained (i.e. records) for providing evidence of results achieved (see 4.3).

Documented information can be in any type of media, such as paper, electronic, photograph or physical sample.

NOTE The advantages of electronic media are, for example:

— easier access to relevant versions including access from remote locations;

— easier control of changes, including the withdrawal of obsolete documented information;

— immediate and controlled distribution;

— retrievability and retention versus paper or other physical media.

4.1.4 Purpose

The purpose of having documented information for an organization includes:

a) communication of information;

b) evidence of achieving results or activities performed;

c) knowledge sharing;

d) knowledge preservation;

e) describing the quality management system of the organization.

4.1.5 Benefits

The benefits of having documented information for an organization include:

a) demonstrating compliance with statutory and regulatory requirements:

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b) providing information for cross-functional groups so that they can better understand interrelationships;

c) communicating the organization's commitment to quality to relevant interested parties;

d) helping persons to understand their role within the organization, thus providing a basis for expectations of work performance;

e) facilitating mutual understanding between different levels in the organization;

f) providing objective evidence that specified requirements have been achieved;

g) addressing risks and opportunities to improve organizational performance, product or service conformity, and customer satisfaction;

h) providing organizational knowledge, including the basis for competency and training for persons and other relevant interested parties;

i) stating how things are to be done to consistently meet specified requirements, thus promoting controlled conditions and providing a basis for continual improvement;

j) demonstrating to interested parties the capabilities within the organization, thus providing confidence;

k) providing requirements for external providers;

l) providing a basis for auditing and evaluating the effectiveness and continuing suitability of the quality management system.

4.2 Documented information to be maintained

4.2.1 Scope of the quality management system

The scope of the quality management system should be documented based on the organization's determination of the boundaries and applicability of the quality management system. The scope of a management system can include the whole of the organization, specific and identified functions of the organization, specific and identified sections of the organization, or one or more functions across a group of organizations. The scope should state the types of products and services covered and, if required, provide justification for any requirement of the relevant quality standard that the organization determines is not applicable to the scope of its quality management system. The scope of the quality management system should be based on the nature of the organization's products and services, their operational processes, issues raised in establishing the context of the organization and relevant requirements from interested parties, the results of risk-based thinking, commercial considerations, and contractual, statutory and regulatory requirements.

4.2.2 Quality policy

The quality policy helps an organization engage its people in the culture of quality of the organization. It should be aligned with the organization's strategic direction, mission and vision. It provides a verifiable commitment to quality to relevant interested parties.

An organization can have other policies besides the quality policy relating to the quality management system.

4.2.3 Quality objectives

Quality objectives should reflect the results to be achieved by the organization with respect to its strategic direction, quality policy, risks and opportunities, and applicable requirements to the quality management system.

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4.2.4 Information that the organization determined necessary to support the operation of the quality management system and its processes

4.2.4.1 General

The organization should determine the type and extent of documented information necessary to support the operation of its processes, the formats to be used and the media for communicating with users. The organization may decide what terms it uses for its documented information. While terms such as “procedures”, “work instructions” and “quality manual” are used in this document, the organization is not obliged to adopt such terminology.

4.2.4.2 Quality manual

There are many ways in which an organization can document its quality management system. Organizations can choose to use a quality manual, or a quality manual can be mandated by the organization’s external requirements. A quality manual is unique to each organization. It can provide the structure, format, content or method of presentation for documenting the quality management system and its processes for all types of organizations.

A small organization can find it appropriate to include the description of its entire quality management system within a single manual, including all the documented information it maintains. Large, multinational organizations can need manuals at different levels (e.g. the global, national or regional level) and a more complex hierarchy of documented information. If the organization chooses to implement a quality manual, it may include documented procedures or a reference to them, and a description of the processes of the quality management system and their interactions.

Information about the organization, such as name, location, context and means of communication including relevant specific terms and definitions, should be included in the quality manual. Additional information such as its line of business, a brief description of its background, history and size may also be included.

The quality manual can provide a description of the quality management system and its implementation in the organization. Descriptions of the processes and their interactions or a reference to them should be included in the manual. The processes of the organization should be designed to meet the overall objectives of the organization, its policies, context, and relevant expectations of interested parties. In large organizations, the processes can link the functional areas of the organization (see Annex A). The organization should document its specific quality management system following the sequence of the flow of the processes or any sequencing appropriate to the organization. Cross-referencing between the selected standard and the processes of the organization can be useful. The sequence and interaction of the processes within the quality management system can be documented using a process map.

NOTE 1 Manuals are also referred to as “quality manual”, “policy manual”, “reference manual”, “procedure manual” or any other suitable title.

NOTE 2 Although ISO 9001:2015 does not require a quality manual, some sector-specific standards do.

4.2.4.3 Organizational charts

Organizational charts are often graphical depictions of the roles, responsibilities and authorities within an organization. They can illustrate how roles, responsibilities and authorities flow through the organization and how different people or groups of people interact within the organization.

4.2.4.4 Process maps, process flow charts and/or process descriptions

A process map identifies the processes and visually describes the sequence and interaction of the processes in the organization. The processes can be further described using flow charts.

A process flow chart is a visual description of the process or procedure. It shows the process steps an organization performs, what triggers the process or procedure (i.e. start of the process and its input)

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and what is the final step of the process or its output. Some process flow chart formats document the input and output for each process step, the control points and the related acceptance criteria.

A process description is a textual description of the process. It explains the process steps in words.

Process owners should be identified for quality management system processes. Process owners are usually assigned by top management and given the authority and responsibility for a process from start to finish, and therefore should understand their role and be competent in the process. This is especially important since processes can cut across functional or departmental boundaries.

4.2.4.5 Procedures and work instructions

The structure and format of documented procedures should be defined by the organization either through text, flow charts, automated workflows, tables, a combination of the above or any other suitable method according to the needs of the organization. A procedure generally answers questions such as who, what, when, where and with what resources. Documented procedures should contain the information necessary to properly carry out the activities that comprise the process and reference any requirements to retain documented information and should be uniquely identified.

The level of detail can vary depending on the complexity of the activities, risks and opportunities, the methods used, and the levels of competency of people that is necessary to perform the activities. Irrespective of the level of detail, the following aspects should be considered, as applicable:

— defining the needs of the organization and its relevant interested parties;

— describing the process(es) in terms of text, or other methods (e.g. flow charts, photos, videos) related to the required activities;

— describing what is to be done, by whom or by which organizational function, why, when and where;

— describing process controls and controls of the identified activities;

— addressing risks and opportunities in a process as it affects the overall objectives of the organization;

— defining the resources needed for the activities (e.g. in terms of people, infrastructure and materials);

— defining the appropriate internal and external documented information related to the required activities;

— defining the inputs required and outputs expected of these interrelated or interacting activities;

— defining the measurements to be taken and the criteria to apply to ensure the effective operation and control of these processes.

Documented procedures should refer to related work instructions that define how an activity is performed. Documented procedures generally describe activities that can cross different functions, while work instructions generally apply to tasks within one function. The organization can decide that some of the above information is more appropriate in a work instruction.

Documented work instructions should be developed and maintained when the expected outcomes of the activity would be adversely affected by lack of such instructions. There are many ways to prepare and present instructions, therefore the organization should determine the most effective way to fulfil its purposes.

The structure, format and level of detail used in the work instructions should be tailored to the needs of the persons performing the activities and also depend on their skills and qualifications, the training undertaken, the complexity of the work, risks and opportunities, and the methods used. The structure of the work instructions can vary from that of documented procedures. Work instructions can be contained in various forms of media and languages as appropriate.

The work instructions can be included or referenced in the documented procedures.

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Work instructions should provide details of how to perform tasks and are typically function- and job-specific. Training can reduce the need for detailed instructions, provided the persons concerned have the information necessary to do their tasks effectively. The work instructions should be in the order or sequence of the operations, accurately reflecting the requirements and relevant activities. To reduce confusion and uncertainty, a consistent format or structure should be established and maintained as appropriate.

A documented procedure or work instruction should define any need to retain documented information related to the activities described therein. Any forms to be used should be identified as applicable. The method required to complete, file and retain the documented information should be stated.

4.2.4.6 Automated workflows

Automated workflows are processes that can manage and control the flow of activities in a defined sequence of tasks with pre-determined human intervention. When executing the activity, context-specific drop-down menus or pop-ups can guide the user in completing the transaction. Automated workflows can enhance process consistency (i.e. mistake-proofing) and performance through the workflow design, and can result in automated decision-making through analysis of data in interrelated areas.

An automated workflow typically starts with an initiator or a reminder from the automated system for an action. The needed action or data input needs to be completed, and the information is then sent to a receiver of the information either directly or through an approval process. Ultimately, through a series of automated actions, the input is transformed electronically into the needed output. For example, a reminder for an activity from a planned schedule of activities will result in the activity being completed automatically.

When an automated workflow activity is transacted, it can generate documented information to be retained. Automated workflows can provide traceability to all the participants of a specific transaction within a process.

Automated workflows can include the following constituent parts:

— digital forms;

— review and approvals;

— a notification to person or groups of persons to act;

— documented information of actions taken;

— electronic traceability;

— the storage and retention of documented information;

— data analysis tools.

Processes suitable for automated workflows include:

— risk and opportunity management;

— sales and contract review;

— product, process and service risk;

— training and competence;

— audit management;

— documented information management;

— performance management;

— management review;

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— equipment calibration and maintenance;

— new product development;

— change management process;

— purchasing;

— monitoring and measuring activities;

— supplier management;

— corrective action activities;

— continual improvement programmes.

4.2.4.7 Product and service specifications

Product and service specifications are documented information that state requirements for the products and services provided.

EXAMPLE Technical drawings, service delivery instructions, internal operating manuals, engineering specifications.

These are not further detailed in this document because they are unique to the product or service provided.

4.2.4.8 Internal and external communications

Internal and external communications include electronic and non-electronic communications, such as notifications, reports or recordings regarding the quality management system and its processes. These communications can be related to specific situations, time-sensitive matters or the routine dissemination of information. Emails and other electronic messaging systems are typical means of internal and external communication. When these messages represent evidence of actions taken or results achieved, they should be controlled as documented information to facilitate distribution, access, retrieval, storage, retention and disposition.

4.2.4.9 Plans, schedules and lists

A plan can be a detailed proposal for carrying out a set of activities. Plans should identify responsibilities and authorities, deadlines, resources and objectives to be achieved.

Schedules can be used to describe the timelines for proceeding with a sequence of activities within the quality management system. Lists are a selection of connected items, usually pre-determined and ordered, that can be used to support activities, e.g. approved supplier lists, equipment lists, master document list.

NOTE Documented information can be developed to describe how an organization will provide a specific intended output, whether that output is a process, product, service, project or contract. This can be termed a quality plan (see ISO 10005).

4.2.4.10 Forms and checklists

Forms are documented information that contain fields to prompt a user to provide certain information as an input or output to a process.

Checklists are a special kind of form that are developed and maintained to have confidence that the processes are being carried out as planned and to provide a consistent means of recording results of activities. They should be referenced in any associated documented information.

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Forms and checklists can be considered documented information to be maintained, while completed forms and checklists can be considered documented information to be retained.

4.2.4.11 Documented information of external origin

Documented information of external origin is information created by a party outside of the organization but kept by the organization for its use. This can include, for example, customer drawings, specifications, statutory and regulatory requirements, standards, codes and maintenance manuals.

The organization should consider documented information of external origin and control the relevant version(s) of it within the quality management system. The organization should consider the risks and opportunities associated with the adoption of external documented information.

4.3 Documented information to be retained

Documented information to be retained provides evidence of results achieved or that the activities are performed as planned. Reasons for retaining documented information include:

a) to have confidence that processes are being carried out as planned;

b) to demonstrate conformity to the quality management system requirements;

c) to demonstrate the performance and effectiveness of the quality management system;

d) to meet customer, statutory and regulatory, or other relevant interested party requirements.

The retention period of the documented information should be defined as well as the method of disposition at the end of the retention period.

Documented information that provides evidence of results achieved is not generally under revision control as it is not usually subject to change (see 5.2.5.).

5 Creating and updating documented information

5.1 Implementation

5.1.1 General

Organizations that are in the process of implementing, or have yet to implement, a quality management system should:

a) determine the documented information that applies according to the selected quality management system standard and the organization's scope and context;

b) conduct gap analyses to the determined scope and requirements by:

   1) identifying and listing existing documented information and analysing it;

   2) obtaining data about the existing quality management system and processes by various means, such as questionnaires and interviews;

   3) comparing the existing documented information to the requirements to determine what documented information needs to be developed or improved in order to support the organization's strategic direction and meet its needs and objectives;

c) when appropriate, train the individuals involved in the creation of documented information and the applicable quality management system standard requirements or other selected criteria;

d) determine the structure and levels of documented information (see Annex A), considering the factors provided in Clause 4;

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e) prepare documented information covering the scope of the quality management system and the results of the gap analysis by:

   1) identifying the sequence and interaction of processes necessary for the organization;

   2) documenting the processes to the extent necessary to ensure their effective operation and control;

   3) ensuring the processes conform to the quality management system requirements;

f) analyse the documented information for possible improvements and implement the improvements;

g) verify the documented information against the requirements of the chosen quality management system standard;

h) validate the documented information through trial implementation where necessary;

i) review and approve the documented information;

j) release and control the documented information;

k) train the person(s) doing work under the organization's control on new or updated documented information and retain documented information on the training provided;

l) update documented information as appropriate.

5.1.2 Use of references

The review and use of existing documents and references can significantly shorten the time to develop the documented information within a quality management system, as well as being an aid in identifying those areas where quality management system inadequacies need to be addressed and corrected. References should be used when appropriate to keep documented information concise. Unless required, specifying the revision status of referenced documents should be avoided in order to preclude changing the referencing documented information when the revision status of the referenced document is changed.

5.1.3 Responsibility for creation of documented information

Responsibility for developing documented information should be defined. It should be developed with the participation of the process owner and person(s) involved with the processes and activities for a better understanding of the necessary requirements and to provide a sense of involvement and ownership.

5.1.4 Identification and description

The organization should identify documented information with a unique identifier to enhance accessibility and retrievability. The organization should consider an identification system appropriate to the complexity of its quality management system. Organizations with a simpler structure can consider a simple system of identification, whereas organizations with a more complex structure can require greater detail or degrees of classification of types of documented information.

5.1.5 Format and media

The organization should consider documented information media and a format that will support the effective implementation of the quality management system with respect to when, where, how and by whom the documented information will be accessed and used when needed, and how the media interacts within the organization.

Documented information stored in electronic media can be managed digitally, allowing multiple methods to be used to communicate the documented information. The format should be configured to

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suit the end user. The organization should consider how the data will be configured, analysed and/or communicated when determining the media and format used.

5.1.6 Review and approval

The organization should control the review and approval of documented information to ensure that it is suitable and adequate for use. The release of documented information should be approved by authorized personnel and evidence of approval retained.

5.2 Control of documented information

5.2.1 Availability

Documented information should be available for use when and where it is needed. The availability of documented information for those performing activities is key to whether the quality management system is integrated and adopted into the routine.

5.2.2 Protection

Documented information should be adequately protected to ensure its legibility and accessibility and to prevent loss of confidentiality, improper use or loss of integrity. Documented information is susceptible to security issues. Organizations should consider their information security risks (e.g. related to cyber security).

NOTE For additional information, see ISO/IEC 27001 and related standards.

5.2.3 Distribution, access, retrieval and use

Access to the documented information should be granted to the appropriate personnel of the organization. A process should be established to ensure that only the appropriate documented information is in use. Under certain circumstances, the appropriate documented information to be used is not always the latest revision.

Proper distribution and control of documented information in physical media can be aided, e.g. by using serial numbers of each copy. The distribution of documented information can include relevant interested parties such as customers, certification bodies and regulatory authorities.

5.2.4 Storage and preservation

Documented information that is to be retained should be stored and preserved in an appropriate format or medium. The organization should consider the length of storage, the conditions under which the documented information will be stored, and the technological development and evolution of hardware and software when determining the media and storage conditions. For electronically stored documented information, the organization should ensure that appropriate backup and restore systems are in place.

5.2.5 Updating documented information and control of changes

The decision to update documented information can come from many sources, including management reviews, changes to products, services or the quality management system, changes to customer, statutory or regulatory requirements, or changes in the needs and expectations of relevant interested parties.

An organization should have a process for the control of changes, including the development, review, version control, approval, release and distribution of the updated documented information. The organization should consider keeping the history of changes to documented information for knowledge preservation purposes. Various methods can be considered for facilitating the process of updating documented information. The organization should consider whether configuration management of its

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documented information is required to meet the identification and traceability needs of its products and services.

When the organization uses documented information managed by software-based systems, it should control its changes as well as address information security issues (e.g. cyber security).

NOTE For additional information, see ISO/IEC 27001 and related standards, as well as ISO 10007.

5.2.6 Retention and disposition

The organization should consider customer, statutory and regulatory, and its own requirements when determining the retention period and disposition methods for documented information. It should also take into consideration the life cycle of the product or service provided.

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Annex A
(informative)

Examples of documented information structures

ISO 9001:2015 does not require a documented information hierarchy. Organizations may define their own documented information structure(s). Several structural aspects are shown in Table A.1. As organizations move towards electronic document management systems, it is possible to view documented information in multiple structures. The viewed structure can be sorted and filtered for the intended use of the documented information.

Table A.1 — Examples of documented information structures

Documented information type	Functional	Interested parties	Improvement flow	Production and service provision
— Quality policy — Quality objectives — Quality manual — Procedures — Automated workflows — Work instructions — Forms — Retained documents (i.e. records)	— Human resources — Sales — Manufacturing — Design — Purchasing — Operational — Cross-functional projects — Cross-functional processes	— Customers — End users — External providers — Society — Regulatory bodies — Workforce — Shareholders — Other interested parties	— Policies — Objectives — Action plans — Results	— Specifications — Requirements — Operational requirements — Operational controls — Meeting minutes

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