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Quality management — Guidelines for quality plans

Management de la qualité — Lignes directrices pour les plans qualité



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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 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 the following URL: www.iso.org/iso/foreword.html.

This document was prepared by Technical Committee ISO/TC 176, *Quality management and quality assurance*, Subcommittee SC 2, *Quality systems*.

This third edition cancels and replaces the second edition (ISO 10005:2005), which has been technically revised.

The main changes compared with the previous edition are as follows.

- a) It applies the terminology from ISO 9000:2015, which includes changes to key definitions, such as:
 - 1) for the definition of "quality plan" (see [3.2](#)), which has been modified to replace the phrase "procedures and associated resources to be applied when and by whom" by "actions, responsibilities and associated resources";
 - 2) for the definition of "specific case" (see [3.3](#)), which has been modified to make reference to "service", as ISO 9001:2015 now refers to "products and services" and no longer just to "products";
 - 3) the replacement of the terms "documentation" and "record" by the term "documented information", which is generally used in ISO management system standards to include both "procedures" and "records" which are not necessarily distinct from each other in a digital environment (documented information needed to support process operation is "maintained", which means that it is established and updated as required; documented information that provides evidence of conformity with requirements is "retained" which means that it is protected from unintended alterations).

Table 1 — Major changes to terms in this document since its previous edition

ISO 10005:2005	This document
Products	Products and services
Documentation Quality manual Documented procedures Records	Documented information
Purchased product	Externally provided processes, products and services
Supplier	External provider
Monitoring and measuring equipment	Monitoring and measuring resources

- b) It is aligned to ISO 9001:2015, leading to:
- 1) a significant revision in the clause/subclause sequence, titles and the addition of new material, e.g. the inclusion of “[5.2](#) Context of a quality plan”, or the extension of [7.2](#) to also reference the monitoring of a quality plan;
 - 2) the incorporation of “risk-based thinking”.
- c) A new clause ([Clause 4](#)) on using a quality plan.

Introduction

0.1 General

This document was prepared to address the need for guidance on quality plans, either in the context of an established quality management system or as an independent management activity. In either case, quality plans provide a means of relating specific requirements of the process, product, service, project or contract to work methods and practices. Quality plans are most effective when they are compatible with other associated plans. The guidance in this document can also be used where quality plans are integrated with other management plans or quality management systems.

Benefits of establishing a quality plan include increased confidence that requirements will be met, greater assurance that processes are in control and the motivation it can give to those involved. It might also give insight into opportunities for innovation and improvement.

The guidance on quality plans in this document is based on the quality management principles described in ISO 9000 and the concepts used in ISO 9001 for the establishment of quality management systems. [Clause 6](#), which describes the typical contents of a quality plan, includes guidance to applying relevant ISO 9001 requirements. The guidance is limited to quality plans and does not replace guidance given in ISO 9000 on quality management concepts or ISO/TS 9002 on the application of ISO 9001 requirements within an organization.

This document does not replace the guidance given in industry-specific documented information. Where quality plans are required for project applications, the guidance provided in this document is intended to be complementary to the guidance provided in ISO 10006. Some terms used in this document have been changed with respect to its previous edition to improve alignment with ISO 9001:2015 and other management system standards. There is no need for the terms used by an organization, whether in specifying quality plan requirements or developing a quality plan, to be replaced by the terms used in this document.

In this document, the following verbal forms are used:

- “should” indicates a recommendation;
- “may” indicates a permission;
- “can” indicates a possibility or a capability.

Information marked as “NOTE” is for guidance in understanding or clarifying the associated text.

NOTE See <https://committee.iso.org/home/tc176sc2> for guidance on the topics in this Introduction.

0.2 Using this document

This Introduction explains some underlying concepts and changes to terms used in the previous edition of this document.

[Clauses 1 to 3](#) provide basic information (Scope, Normative references, and Terms and definitions).

[Clause 4](#) summarizes how quality plans can be used.

[Clause 5](#) describes the process of developing a quality plan.

[Clause 6](#) describes the typical contents of a quality plan.

[Clause 7](#) describes the operation and control of a quality plan.

[Annex A](#) provides examples of simple quality plans.

[Annex B](#) provides a schematic representation of a process approach applied to a quality plan

[Annex C](#) provides a correlation matrix between the clauses of this document and those of ISO 9001:2015.

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[Annex D](#) provides a correlation matrix between the clauses of this document and the quality management principles from ISO 9000:2015.

The Bibliography includes a list of standards and other relevant information.

0.3 Process approach

The process approach means the systematic management of processes and their interactions to achieve intended results. Applying the process approach to quality plans assists organizations to manage the inputs, activities and outputs of each process within a coherent system of interrelated processes.

Processes referenced in a quality plan can interact with:

- each other (interactions among quality plan processes);
- other processes operated within the organization's management system;
- processes operated within other organizations (such as customers and external providers).

When considering how to manage its processes and their interactions, the organization can address these through a quality plan whether or not it has a quality management system.

[Annex B](#) provides a schematic representation of a process approach applied to quality plans.

0.4 Risk-based thinking

Risk-based thinking means applying a systematic approach to considering risk (the effect of uncertainty) so that risks can be understood and managed appropriately.

The application of risk-based thinking to the development and use of a quality plan enables an organization to determine the importance of particular issues and take appropriate actions to manage both risks and opportunities.

A customer requesting that a provider prepares a quality plan can apply risk-based thinking to determine the minimum requirements for the type and extent of the monitoring activities.

When developing a quality plan, the organization can apply risk-based thinking in deciding the processes, resources and control methods to be used. Particularly where an organization uses a standard model or template for different quality plans, risk-based thinking can assist those involved to make each quality plan fit for its intended purpose.

Quality management — Guidelines for quality plans

1 Scope

This document gives guidelines for establishing, reviewing, accepting, applying and revising quality plans.

This document is applicable to quality plans for any intended output, whether a process, product, service, project or contract, and any type or size of organization.

It is applicable whether or not the organization has a management system in conformity with ISO 9001.

This document provides guidance and does not specify requirements.

It is focused primarily on the provision of outputs and is not a guide to the planning of quality management system development.

NOTE To avoid undue repetition of “process, product, service, project or contract”, this document uses the term “specific case”.

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

documented information

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

Note 1 to entry: Documented information can be in any format and media and from any source.

Note 2 to entry: Documented information can refer to:

- the management system, including related *quality plans* (3.2) and processes;
- information created in order for the organization to operate (documentation);
- evidence of results achieved.

[SOURCE: ISO 9000:2015, 3.8.6, modified — In Note 2 to entry, the first list item has been modified, and Note 3 to entry has been deleted.]

3.2 quality plan

specification of the actions, responsibilities and associated resources to be applied to a specific object

[SOURCE: ISO 9000:2015, 3.8.9, modified — The phrase “procedures and associated resources to be applied when and by whom” has been replaced by “actions, responsibilities and associated resources”, and the notes to entry have been deleted.]

3.3 specific case

<quality plans> subject of a *quality plan* (3.2)

Note 1 to entry: The specific case can be a process, product, service, project, contract or other intended output for the quality plan.

4 Using a quality plan

4.1 Introduction

A quality plan describes how an organization will provide an intended output, whether that output is a process, product, service, project or contract (termed the “specific case” in this document).

Quality plans are developed where they are considered necessary to meet needs and expectations related to a specific case.

Where the organization has an established management system, quality plans might be necessary if requested by a customer or considered useful for other reasons. On the other hand, where no established management system exists, quality plans can provide a framework for meeting the requirements of the specific case. They can also assist the organization to develop its own management system and its processes.

The organization should decide where there is need for quality plans. There are a number of situations where quality plans can be useful or necessary, for example:

- a) to show how the organization’s quality management system applies to a specific case;
- b) to meet customer, other interested parties or the organization’s own requirements;
- c) to develop and validate new products, services or processes;
- d) to demonstrate, internally and/or externally, how requirements will be met;
- e) to organize and manage activities to meet requirements and quality objectives;
- f) to optimize the use of resources in meeting quality objectives;
- g) to minimize the risk of not meeting requirements;
- h) to control the establishment of a new or modified organization, site or partnering arrangement;
- i) as a basis for monitoring and assessing compliance with the requirements for quality;
- j) in the absence of an established management system.

4.2 Requesting external provider quality plans

An organization may choose to request that an external provider or a prospective external provider submit a quality plan related to a specific case (this can relate to external providers who are part of the same organization, e.g. a separate division). Both the organization requesting a quality plan and the prospective external provider should consider the reasons for using a quality plan and the benefits that might be achieved through its use.

The organization requesting an external provider quality plan should apply risk-based thinking to the nature of the specific case, the evaluation and selection of external provider(s) and opportunities for benefits. There can be benefits to both the organization and potential external providers in using risk-based thinking.

Consideration of risks related to the specific case can increase the options for requesting quality plans from external providers, for example:

- a) specifying intended results rather than the methods and resources to be applied to the specific case (such as in performance-based contracts) can allow external providers to introduce innovation in methods, practices and resources;
- b) specifying minimum requirements for controls and documented information allows an external provider to apply their own processes and experience;
- c) defining quality plan requirements for the specific case rather than requiring conformity with a management system standard, such as ISO 9001, can enable participation by a broader range of potential external providers with different levels of maturity of their management systems.

Examples of specifications of requirements for external provider quality plans relevant to particular sectors can often be found in industry codes of practice, requests for offers of products and services or other publicly available sources. However, care should be taken to ensure that such examples are appropriately adapted to the specific case.

Requirements for external provider quality plans can be included in specifications for other management plans such as service management plans, project management plans, construction management plans or production and installation plans.

4.3 Managing external provider quality plans

A quality plan can ensure that an organization has a common understanding with an external provider about how its requirements will be met. The organization should decide what level of monitoring is required to assess external provider performance, such as ongoing monitoring, acceptance checks, assessment and auditing.

The monitoring approach can be decided based on various factors, such as:

- a) the nature and scope of the specific case;
- b) risks associated with the specific case;
- c) the capability of the external provider;
- d) knowledge and expertise held by the organization requesting the quality plan.

Establishing a common understanding of the quality plan between the organization and the external provider is particularly important where the specific case involves high levels of risk and complexity. A common understanding means that the organization has a basis for confidence in satisfactory performance by the external provider and the external provider has a basis for communicating with the organization about potential problems.

Achieving such a relationship can facilitate:

- clarity of roles, including those of independent assessors used by the organization;
- maintaining the confidentiality of shared information and intellectual property;
- deciding on effective methods and responsibilities for communication;
- responding to supply chain and contract issues.

5 Development of a quality plan

5.1 Context of the quality plan

Understanding the context of the quality plan and its intended results provides a basis for determining risks and opportunities to be addressed.

The context of the quality plan can include:

- a) existing management plans or processes which will support the quality plan, whether or not these processes are part of an established management system;
- b) internal issues that can affect the ability of the organization to achieve the intended results, such as constraints on resources, how the quality plan will be communicated to its users and whether work will be carried out at different sites;
- c) external issues related to the specific case, such as statutory and regulatory requirements, competitive and market issues;
- d) the aspects of both the internal and external issues of the organization that relate to the specific case, for example quality and market objectives;
- e) the needs and expectations of relevant interested parties, including customers, employees, external providers, etc.

NOTE 1 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social, environmental and economic factors, whether international, national, regional or local.

NOTE 2 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

Risks should be determined and addressed, in order to provide confidence that intended results will be achieved and undesired effects will be prevented or reduced.

Opportunities for improvement should be considered, for example to meet customer expectations or increase effectiveness and efficiency. Opportunities for innovation can also be important, for example where draft quality plans are submitted as part of a tendering process for provision of products and services.

Once the context for the quality plan and its intended results are understood, the scope and objectives of the quality plan can be defined. The format and level of detail needed for the quality plan can also be decided.

5.2 Inputs to the quality plan

The organization should determine the inputs to the quality plan, for example:

- a) customer requirements, statutory, regulatory and industry specifications;
- b) information on the needs of users of the quality plan;
- c) other relevant quality plans;
- d) requirements of the specific case;
- e) assessments of risks and opportunities related to the specific case;
- f) requirements for and availability of resources;
- g) management system requirements of the organization;

- h) documented information relevant to the quality plan;
- i) communication requirements for the quality plan.

5.3 Defining the scope of the quality plan

The organization should determine what is to be covered by the quality plan. The scope of the quality plan will depend on several factors, including:

- a) the requirements of customers and other relevant interested parties;
- b) the types of products and services to be provided;
- c) the organization's processes and their quality characteristics;
- d) the resources needed to achieve the intended results;
- e) the extent to which the quality plan is supported by an established quality management system.

There can be benefits from reviewing the scope of the quality plan with the customer or other relevant interested parties.

5.4 Preparation of the quality plan

5.4.1 Initiation

In preparing the quality plan, the organization should determine the respective roles, responsibilities and authorities within the organization and, where applicable, the relevant responsibilities and authorities of external parties.

The quality plan should be prepared with the participation of people who are involved in the specific case, both within the organization and, where appropriate, relevant interested parties. Where a particular resource has limited availability, the quality plan might need to specify how the demand for resources will be satisfied.

5.4.2 Defining the quality plan

The quality plan should indicate how the required activities will be carried out, either directly or by reference to appropriate documented information (e.g. project plan, work instruction, checklist, software application).

Where an organization has an established management system, it may select, adapt, or supplement existing documented information for use in, or reference by, the quality plan.

Where a requirement results in a deviation from the organization's management system the resulting risks and opportunities associated with the deviation should be considered; such deviations should be justified, agreed and approved.

A quality plan may be included as part of other documented information, for example, project quality plans are often included in project management plans (see ISO 10006).

5.4.3 Consistency and compatibility

The content and format of the quality plan should be consistent with the scope, the inputs, the needs of the users of the quality plan and its intended outputs.

The level of detail in the quality plan should be consistent with any agreed requirements, the organization's methods of operation and the complexity of the activities to be performed. The need for compatibility with other management plans applicable to the specific case should also be considered.

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An organization may decide to prepare a quality plan that conforms to applicable requirements of ISO 9001. A correlation matrix to ISO 9001:2015 is provided in [Annex C](#) for guidance.

5.4.4 Presentation and structure

A quality plan may be formally defined and presented using different methods, for example:

- a) graphical representations (e.g. process map, work flow charts);
- b) written work instructions (e.g. textual description, table, document matrix, checklists, manual);
- c) visual media, electronic methods;
- d) software applications;
- e) combination of methods.

These methods should be appropriate to the application and users of the quality plan.

The quality plan may contain a number of distinct plans, for example for particular aspects, processes or functions. Control of the interfaces between the different plans needs to be clearly defined.

NOTE Examples of quality plans are provided in [Annex A](#).

6 Content of the quality plan

6.1 General

The guidance in [6.2](#) to [6.17](#) indicates what should be considered for inclusion in a quality plan. Documented information necessary for the intended users of the quality plan may be contained within the quality plan or, where available from other sources (e.g. an intranet or extranet), may be referenced or linked electronically.

Some topics not mentioned in [6.2](#) to [6.17](#) could be added depending on the nature and the scope of the specific case. Where a customer requires specific topics or a specific structure, the quality plan should be prepared in accordance with those requirements.

The quality plan for a specific case should cover the topics examined in [6.2](#) to [6.17](#) as appropriate. Some topics in this guidance might not be applicable, for example where design and development are not involved.

6.2 Scope of the quality plan

The scope should be clearly stated in the quality plan (see [5.3](#)). This should include:

- a) a simple statement of the purpose and expected output of the specific case;
- b) the aspects of the specific case to which it will be applied, including particular restrictions to its applicability;
- c) the conditions of its validity (e.g. dimensions, temperature range, hardware platform/operating system, market conditions, resource availability or quality management systems certification/registration status).

6.3 Quality plan inputs

It can be necessary to list or describe the inputs to the quality plan (see [5.2](#)), to facilitate, for example:

- a) reference to inputs by users of the quality plan;

- b) reviewing consistency with inputs during maintenance of the quality plan;
- c) reviewing changes to inputs for impact on the quality plan.

The quality plan should include or make reference to the requirements to be met for the specific case. A simple overview of the requirements may be included to help users to understand the context of their work, for example an outline of a project. In other cases, a comprehensive list of requirements developed from input documented information can be used.

6.4 Quality objectives

The quality plan should state the quality objectives for the specific case and how they will be achieved. Quality objectives may be established, for example, in relation to:

- a) quality characteristics for the specific case;
- b) important issues for satisfaction of the customer, organization or other interested parties;
- c) opportunities for improvement.

These quality objectives should be expressed in measurable terms. Any required measurement processes needed to determine achievement of the quality objectives should be included or referenced in the quality plan.

6.5 Quality plan responsibilities

The quality plan should identify people within the organization who are responsible for:

- a) ensuring that the activities and resources required for the quality plan or contract are planned, implemented and controlled, and their progress monitored;
- b) reviewing quality plan inputs, recording these reviews and resolving conflicts and ambiguities;
- c) communicating requirements to all affected departments and functions, external providers and customers, and resolving problems that arise at the interfaces between such groups;
- d) reviewing the results of any audits conducted;
- e) reviewing and authorizing changes to, or deviations from, the quality plan.

Reporting lines of those involved in implementing the quality plan may be presented in the form of an organizational chart.

6.6 Control of documented information

6.6.1 For documented information applicable to the specific case, the quality plan should state:

- a) how the documented information will be identified;
- b) by whom the documented information will be reviewed and approved;
- c) how distribution of, and access to, the documented information will be controlled;
- d) how the documented information will be maintained and protected.

6.6.2 The quality plan should define what documented information should be retained to provide evidence of conformity with requirements. Such documented information can include quality plan inputs, design and development reviews, inspection and test results, process monitoring and measurement

outputs, work or service orders, drawings, minutes of meetings, assessment and audit reports. Matters to be considered include:

- a) how, where and for how long evidence of conformity will be retained;
- b) what the customer, statutory and regulatory requirements are, and how they will be applied;
- c) what methods will be used to ensure that documented information retained as evidence of conformity is protected from unintended alteration and made available when required;
- d) what documented information will be supplied to the customer, when and by what means;
- e) where applicable, in what language, format and media documented information will be provided.

6.7 Resources

6.7.1 Provision of resources

The quality plan should specify the type and amount of resources needed for the successful implementation of the quality plan. These resources can include people, internally or externally provided processes, products or services, infrastructure and environment for the operation of processes, monitoring and measurement resources, and specialized knowledge and expertise.

6.7.2 Materials, products and services

Where there are specific characteristics for required materials, products and services, the specifications or standards to which these resources need to conform should be stated or referenced in the quality plan.

6.7.3 People

The quality plan should specify, where applicable, the competence required for defined roles or activities within the specific case. The quality plan should define any specific training, organizational knowledge or other actions required for personnel. This should include:

- a) the need for, and training of, new personnel;
- b) the training of existing personnel in new or revised operating methods.

The need or applicability of individual learning, team development and motivational strategies should also be considered.

NOTE Training in the use of quality plans is addressed in [7.2](#).

6.7.4 Infrastructure and environment for the operation of processes

The quality plan should state the requirements of the specific case with regard to buildings and associated utilities, workspace, tools and equipment, information and communication technology, support services and transportation.

Where the operational environment has a direct effect on product, service or process quality, the quality plan should specify the relevant environmental characteristics to be considered.

6.7.5 Monitoring and measuring resources

The quality plan should specify the resources needed to ensure valid and reliable results when monitoring or measuring to verify the conformity of products and services to requirements.

The quality plan should specify the controls to be used for monitoring and measuring resources intended for use for the specific case, including requirements for calibration or verification, or reference to relevant documented information.

NOTE Guidance on the management of measurement systems can be found in ISO 10012.

6.8 Customers and other interested parties communication

The quality plan should state or make reference to:

- a) who is responsible for communication with customers and other interested parties;
- b) the methods to be used for communication;
- c) when the communication is needed;
- d) the process to be followed when customer feedback is received;
- e) the documented information that should be retained from communications and/or on complaints received from customers and other interested parties.

6.9 Design and development

6.9.1 Design and development process

The quality plan should reference applicable plan(s) for design and development.

The quality plan should take account of applicable specifications, codes, industry standards, quality characteristics, statutory and regulatory requirements.

It should specify the criteria by which the design and development inputs and outputs should be accepted, and how, at what stage(s), and by whom, the outputs should be reviewed, verified and validated.

In some cases, design and development is a complex process and guidance should be sought from appropriate sources, including internal documented information on design and development. In others, the level of complexity will be low but still require a planned process to ensure that risks associated with the use of design and development outputs are controlled. For projects, the design and development process can be applied to the establishment and subsequent change control of project plans, as well as to the intended result of the project.

In the service sector, the design and development process can apply to the development of a service specification which forms the basis for subsequent service provision. However, where services are unique to a specific customer transaction, for example research and advisory services, the design and development process can be applied to the entire service provision process.

NOTE ISO/TS 9002 provides general guidance on the design and development process. ISO/IEC 90003 and ISO/IEC/IEEE 24748-5 provide specific guidance for the software sector.

6.9.2 Control of design and development changes

The quality plan should state:

- a) how requests for changes to the design and development outputs will be controlled;
- b) who is authorized to initiate a change request;
- c) how changes will be reviewed in terms of their impact;
- d) who is authorized to approve or reject changes;

- e) how the implementation of changes will be verified.

In some cases, there might be no requirement in the quality plan for design and development. However, the organization might need to control changes to planned design and development outputs, for example to approve the use of alternative materials, respond to changes in available resources or adjust service outputs to meet specific customer needs.

6.10 Externally provided processes, products and services

The quality plan should specify:

- a) the critical characteristics of externally provided processes, products and services that can affect the specific case;
- b) how those characteristics will be communicated to external providers;
- c) the methods to be used for the evaluation and control of external providers including, when necessary, alternative or supplementary external providers;
- d) requirements for, and reference to, external provider quality plans or other plans, where appropriate;
- e) the methods to be used to satisfy the requirements, including statutory and regulatory requirements, that apply to externally provided products and services;
- f) how the organization intends to verify that externally provided products and services conform to specified requirements.

6.11 Production and service provision

Production and service provision, together with the relevant monitoring and measurement processes, commonly form the main part of the quality plan. The processes involved will vary, depending on the nature of the work. The interrelationship between the various processes involved can be effectively expressed through the preparation of process maps or flow charts.

Production and service processes might need to be validated to ensure they are capable of delivering the required output, especially if the process output cannot be verified by subsequent monitoring or measurement.

The quality plan should specify the inputs, processes and outputs required for carrying out production and/or service provision. The organization should apply risk-based thinking when deciding whether to include or refer to:

- a) the process steps;
- b) relevant documented information;
- c) the tools, equipment, software, information technology platform and methods to be used to achieve the specified requirements, including details of any necessary material, product, service, process, software application, certification or validation;
- d) required controlled conditions to meet planned arrangements, methods for verifying compliance with such conditions, including any specified statistical or other process controls;
- e) requirements for competence and/or qualification (see [6.7.3](#));
- f) criteria for the acceptance of products, services and/or other process outputs;
- g) applicable statutory and regulatory requirements;
- h) industry codes and practices;

- i) implementation of actions to prevent human error;
- j) arrangements for release, delivery and post-delivery activities.

Where installation or commissioning is a requirement, the quality plan should state how the output will be installed and which characteristics need to be verified and validated at that time.

Where the specific case includes post-delivery activities (e.g. maintenance, support or training services), the quality plan should state how the organization intends to assure conformity with applicable requirements, such as:

- statutes and regulations;
- industry codes and practices;
- the competence of personnel, including trainees;
- the availability of initial and on-going technical support during the agreed time period.

NOTE ISO 10006 provides guidance on project management processes for production and service provision.

6.12 Identification and traceability

Where identification of outputs is appropriate to ensure requirements for the specific case are met, the quality plan should specify methods to be used. Where traceability is a requirement, the quality plan should define its scope and extent, including how affected outputs will be identified.

The quality plan should state:

- a) how contractual, or other relevant traceability requirements are identified and incorporated into documented information;
- b) what documented information is to be retained to provide evidence of meeting traceability requirements, and how it will be controlled;
- c) specific requirements and methods for the identification of the inspection and test status of outputs.

NOTE Identification and traceability is part of configuration management. For further guidance on configuration management see ISO 10007.

6.13 Property belonging to customers or external providers

The quality plan should state:

- a) how products and services provided by customers or external providers are identified and controlled;
- b) the methods to be used to verify that these products and services meet specified requirements;
- c) how nonconforming products and services will be controlled.

NOTE 1 Customer's or external provider's property can include materials, components, tools and equipment, premises, intellectual property and personal data.

NOTE 2 ISO/IEC 27002 provides guidance on information security.

6.14 Preservation of outputs

The quality plan should state:

- a) requirements for preservation and how these requirements will be met;

- b) where the organization is responsible for delivery, how the output will be delivered in a manner that will ensure that its required characteristics are not degraded.

NOTE Preservation can include identification, handling, contamination control, storage, packaging and delivery, transmission or transportation and protection.

6.15 Control of nonconforming outputs

The quality plan should define how nonconforming outputs will be identified and controlled to prevent unintended use, until proper disposition or acceptance by concession is completed.

The quality plan might need to define specific limitations, such as the degree or type of rework or repair allowed, and how such rework or repair will be authorized.

Where service provision is carried out at the interface with the customer, preventing use of nonconforming service outputs might not be feasible. Where applicable, the quality plan should define or make reference to the actions and communications that are appropriate to the effects, or potential effects, of such nonconformities.

6.16 Monitoring and measurement

Monitoring and measurement processes should define how objective evidence of conformity will be obtained. In some instances, customers request submission of monitoring and measurement plans (sometimes termed “inspection and test plans”), without other quality plan information, as a basis for monitoring conformity with specified requirements.

The quality plan should specify:

- a) process and output monitoring and measurements to be applied;
- b) the stages at which they should be applied;
- c) the characteristics to be monitored and measured at each stage;
- d) the acceptance criteria to be used;
- e) any statistical process control methods to be applied;
- f) where inspections or tests are required to be witnessed or performed by interested parties, for example:
 - 1) a test, or series of tests (sometimes referred to as “type tests”), directed towards the approval of a design and conducted to determine if the design is capable of meeting the requirements of the product and service specification;
 - 2) site testing including acceptance;
 - 3) product and service verification;
 - 4) product and service validation;
- g) where, when and how the organization intends to use external providers to perform inspections or tests;
- h) the criteria for release of products, services or other outputs.

NOTE ISO/TR 10017 provides guidance on the selection of statistical methods.

6.17 Audits

The quality plan should specify the type of audits to be performed for the specific case, the nature and extent of such audits and how the results of the audits should be used.

Audits may be used for several purposes, such as:

- a) to monitor the implementation and effectiveness of quality plans;
- b) to monitor and verify conformity with specified requirements;
- c) for surveillance of external providers to the organization;
- d) to provide independent objective assessment, when required, to meet the needs of customers or other interested parties.

NOTE ISO 19011 provides guidance for the auditing of management systems.

7 Operation and control of the quality plan

7.1 Review and acceptance of the quality plan

The quality plan should be reviewed for adequacy and effectiveness, and should be formally approved by an authorized person or a group that includes representatives from relevant functions within the organization.

In contractual situations, a quality plan might need to be submitted to the customer by the organization for review and acceptance, either as part of a pre-contract consultation process or after a contract has been awarded. Once a contract is awarded, the quality plan should be reviewed and, where appropriate, revised to reflect any changes in requirements.

Where a project or contract is conducted in stages, the organization might be expected to submit a quality plan to the customer for each stage, prior to the start of that stage.

7.2 Implementation and monitoring of the quality plan

In the implementation and monitoring of the quality plan, the organization should consider the following issues:

- a) distribution of the quality plan to all relevant people; care should be taken to distinguish between copies that are distributed under the control provisions for documented information (to be updated as appropriate), and those that are supplied for information only;
- b) training in the use of quality plans; in some organizations (e.g. those engaged in project management) quality plans may be used as a routine part of the quality management system, while in others, quality plans may be used only occasionally (in this case, special training could be needed to assist users in applying the quality plan correctly);
- c) monitoring conformity with quality plans; the organization is responsible for monitoring conformity with each quality plan that it operates, which can include:
 - 1) operational supervision of the planned arrangements;
 - 2) milestone reviews;
 - 3) audits.

Audits are generally undertaken on a sampling basis, especially where many short-term quality plans are used.

Where quality plans are submitted to customers or other interested parties, these interested parties might establish provisions for monitoring conformity with the quality plans.

Whether carried out by internal or external interested parties, such monitoring can assist in:

- assessing the commitment of the organization to the effective implementation of the quality plan;

- evaluating the practical implementation of the quality plan;
- determining where risks can arise in relation to the requirements of the specific case;
- taking corrective action where appropriate;
- finding opportunities for improvement in the quality plan and associated activities.

7.3 Revision of the quality plan

The organization should revise the quality plan:

- a) to reflect any changes to quality plan inputs or risks, including:
 - 1) the specific case for which the quality plan is established;
 - 2) the processes for production and service provision;
 - 3) the organization's management system;
 - 4) statutory or regulatory requirements;
- b) to incorporate agreed improvements to the quality plan.

An authorized person or persons should review changes to the quality plan for impact, adequacy and effectiveness. Revisions to the quality plan should be made known to users, customers, interested parties and/or external providers. Communication with customers and other interested parties should be consistent with the requirements for externally provided products and services. Any documented information that is affected by changes in the quality plan should be revised as necessary.

The organization should consider how and under what circumstances the organization would authorize a deviation from the quality plan, including:

- who will have the authority to request such deviations;
- how such a request will be made;
- what information will be provided and in what form;
- who will be identified as having the responsibility and authority to accept or reject such deviations.

7.4 Feedback and improvement

Where appropriate, experience gained from the application of a quality plan should be reviewed and evaluated. The organization can also review the application of the quality plan in consultation with customers, external providers and other relevant interested parties.

Lessons learned should be used to improve the organization's quality plan(s) and the respective management system(s).

Annex A (informative)

Examples of formats for quality plans

This annex provides examples of some of the formats in which quality plans may be presented.

The examples shown should not be taken as being complete in relation to the quality plan contents described in [Clause 6](#).

Actual quality plans may be more complex. It would normally be expected that all the processes applicable to the specific case would be covered.

Presentation of quality plans may be in any format deemed suitable for meeting the agreed requirements. A textual presentation rather than a diagrammatic one may be more appropriate in certain circumstances. Similarly, a diagrammatic format may be supplemented with text. Other formats better suited to a specific case may be used.

Where the quality plan is available electronically, referenced documented information, such as standard operating procedures (SOPs) or process management software, may be accessible via hyperlinks.

The following examples include:

- Example 1: A “text” type of quality plan; this could be used, for example, as a template for a quality plan for an engineering project;
- Example 2: A “table” type of quality plan; this could be used, for example, as a quality plan for processed materials;
- Example 3: A “Flow chart” type of quality plan; this could be used, for example, as a quality plan for a service.

EXAMPLE 1 A template for a “text” type of quality plan.

1. Introduction

1.1 Purpose and scope of the project quality plan

The purpose of this project quality plan is to document the quality processes that XYZ will follow in order to effectively manage project quality from planning to delivery. It defines the procedures, processes and management systems to be used for the management of engineering and project management services.

[Describe relationship to project management plan, XYZ quality management system, etc.]

1.2 Project overview

[Include a description of the project including planned stages and schedule]

1.3 Scope of services

[Define the scope of the services included in the project quality plan]

1.4 Specific project risks

[List/describe specific project risks e.g. unusual characteristics related to client context, project context, project partners, requirements, deliverables, resources, communications, confidentiality]

2. Resourcing and communication

2.1 Roles, responsibilities and authorities

[Define roles, responsibilities and authorities – consider table to summarize]

2.2 Communication

[Define communication pathways and authorities, especially where multiple parties are involved in the project]

2.3 Competence, awareness and training

[To be included where there are specific competence, awareness and training needs for the project]

3. Quality management

3.1 Quality policy and QMS

A copy of the XYZ quality policy statement is included in Appendix A.

[Define application of XYZ quality management system to this project quality plan]

3.2 Quality objectives and KPIs

The key quality objectives for this project are to...

Key performance indicators (KPIs) are listed in...

3.3 Audits

To ensure that the project is delivered in accordance with the XYZ quality management system, the project will be audited as part of the internal audit programme.

[If project audits are planned as part of the project control process, outline the intended schedule]

3.4 Nonconformity management

Nonconformity records (NCRs) are retained in the...

Summaries and reviews for corrective action and continual improvement are maintained and updated by the project team in accordance with...

4. Project delivery**4.1 Project inputs**

[Define handling and management of project inputs]

4.2 Scope changes

Any changes to the scope of the work shall be addressed via the change management process. It is the responsibility of all team members to notify the project leader of any potential or actual changes to the scope of the work.

4.3 Project control

[Include a description of the processes used for project control]

4.4 Manage project deliverables

[Describe or list deliverables, together with responsibilities for controlling completion]

4.5 Check, review, verify and approve

[Describe processes and responsibilities for checking (including checking of methods and application of standards/previous design solutions/validation strategies), reviews, verification and approval]

5. Documented information management**5.1 Computer network file structure**

A computer network file structure has been adopted for this project within XYZ...

5.2 Documented information management process

[Describe/list how different types of documents are controlled]

5.3 Inputs, outputs and transmittals

[Describe/list how different types of documents are controlled. Define how incoming documents, change requests, outgoing documents and transmittal records are managed and registered]

6. Project deliverables

[Include description, list or table of deliverables and related information]

7. Approval requirements

[XYZ and client approval requirements, plus relationship to other interested parties where applicable]

8. Distributing the deliverables

[Define the process for transmittal of deliverables and the documented information to be retained]

9. Change management

[Define internal and external change management requirements, including changes occurring after delivery of documented information]

10. Identification and traceability

[Define or reference identification and retention requirements for quality plan outputs]

Appendices

For example:

— *Appendix A - XYZ quality policy*

— *Appendix B - Contract management plan table of contents*

EXAMPLE 2 A “table” type quality plan					
QPL - 005	Product/product line: Specification grade chemicals	Originated by:	Approved by:	Rev:	Date:
Activity	Description	Document/ Procedure	Area/ Dept.		
Scope	This quality plan is applicable to the processes of production and distribution of specification-grade chemicals.	—	—		
Quality objectives	Our quality objectives are yield (93 %); on-time delivery (+/-1 day).	QSP - 005	Various		
Management responsibilities	Job descriptions and organization charts of the responsibilities of personnel involved in the planning, executing, controlling and monitoring the progress of the activities covered by this plan are to be found in referenced documents.	QSP - 020 SOP - 800	MGMT/ HRS		
Documentation	There are no special document control requirements. Contractual documents will be retained for a minimum of five years.	QSP - 050	TSS		
Records	Identifiable and retrievable records will be maintained to furnish evidence of activities affecting quality. Records will be retained for a minimum of five years.	QSP - 055	QA		
Resources	The requirements for storage, process and transportation of raw materials and components are specified in //VSB\materials.doc.	QSP - 020	MGMT		
Resources	All staff are required to have successfully completed training on the handling of the materials specified in the contract.	SOP - 810	HRS		
Resources	No special infrastructure or work environment conditions apply.				
Requirements review/ Customer specifications	All quotations given and all customer specifications and orders received will be reviewed prior to acceptance, to ensure that the requirements are properly defined, all differences satisfactorily resolved, and the company has the capacity to meet the requirements involved.	SOP - 100 SOP - 110 SOP - 120	MKT/ TSS/ MFG/QA		
Customer communication	Customer feedback is collected either by visiting the website or using form SOP-190F1 and is discussed at monthly meetings between the customer and the contract management team.	SOP - 150 SOP - 190	MKT		

Design and development	All accepted customer specifications that differ significantly from regular company specifications require review and approval (SOP-200). This may require customer prototype approval, and process verification and validation.	SOP - 200 SOP - 220	TSS
Purchasing	All critical products purchased by the company are subject to receiving inspection and testing as required in the current raw material and package specifications. Bulk tank cars will not be unloaded until all required testing is satisfactorily completed. Nonconforming materials may be approved by concession, disposed of, or returned to the supplier.	SOP - 300 SOP - 310 SOP - 400 SOP - 470 SOP - 490	PUR/ MAT
Production	Standard operating procedures apply.	SOP - 500	MFG
Identification and traceability	Standard operating procedures apply.	SOP - 440 SOP - 540	MAT/ MFG
Customer property	Customer specifications and proprietary test methods will be processed and protected through the formal specification system to preserve their integrity and ensure the confidentiality of the information contained therein.	SOP - 110	MKT/ TSS
	Standard operating procedures apply to special packaging materials provided by the customer.	SOP - 410	MAT/ MFG
Storage and handling	Purchased materials, intermediates and finished products will be stored in secure containers, tanks and warehouse facilities. Careful handling methods will be used to prevent damage, deterioration or contamination of the product. Bulk products will be shipped in dedicated tank cars.	SOP - 400 SOP - 700 SOP - 750	MAT
Nonconforming products	Products failing to pass the final lot acceptance requirements will be diverted to a special quarantine area or tank. A written concession from the customer will be required before any nonconforming product can be shipped.	SOP - 570 SOP - 580 SOP - 590	MFG/ TSS/QA
Monitoring and measurement	Sampling and testing plans exist or will be prepared to cover all product realization processes.	SOP - 600	QA

Inspection and testing equipment	The company maintains a range of measuring and testing equipment to cover the scope of its development, production and control activities. All required calibration is done in-house or by the equipment manufacturer.	SOP - 610	QA
Audit	The facilities may receive internal, customer and regulatory audits.	SOP - 675	QA
<p>Key</p> <p>HRS: human resources MAT: materials control MFG: manufacturing MGMT: top management MKT: marketing and sales PUR: purchasing QA: quality assurance QSP: quality system procedure SOP: standard operating procedure TSS: technical services</p>			

EXAMPLE 3 A “flowchart” type quality plan

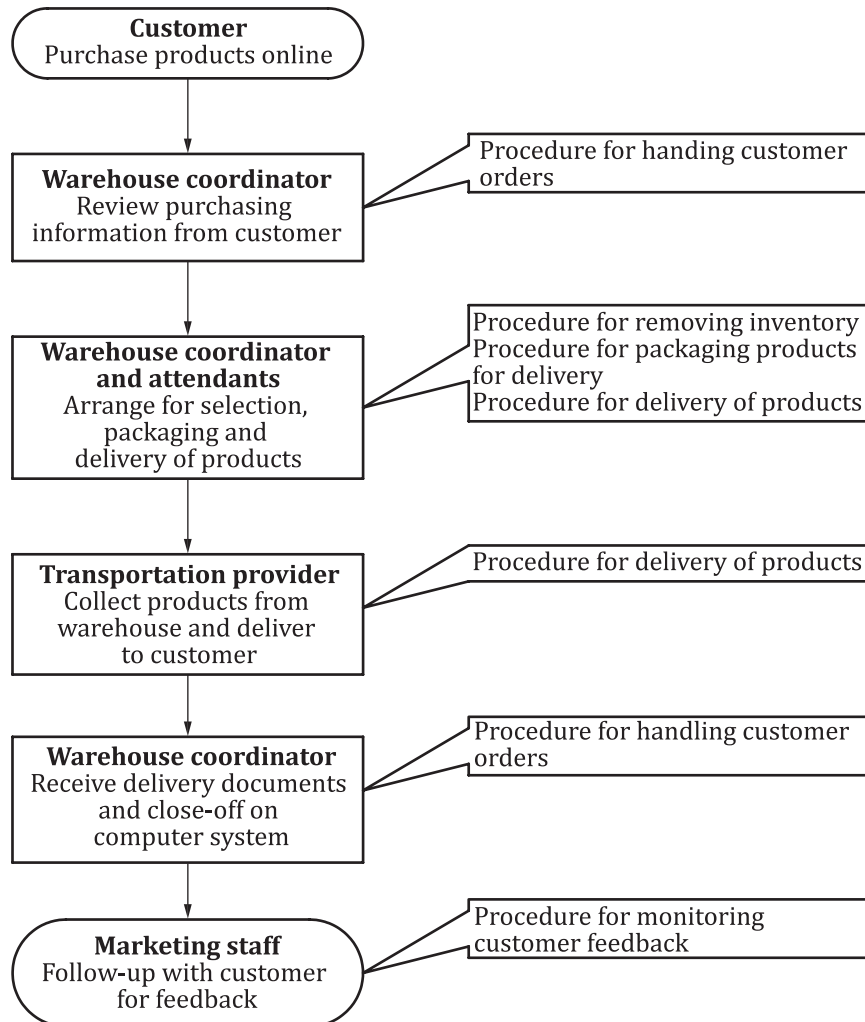


Figure A.1 — Example of a “flowchart” type quality plan

Annex B (informative)

Schematic representation of a process approach applied to quality plans

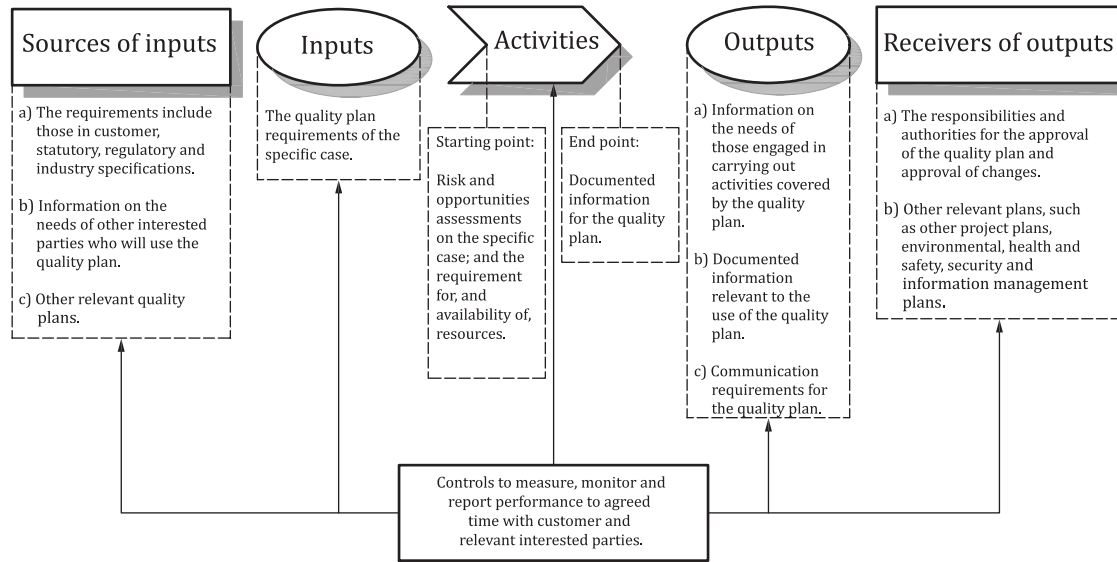


Figure B.1 — Schematic representation of a process approach applied to a quality plan

Annex C (informative)

Correlation matrix between the clauses in this document and those in ISO 9001:2015

Table C.1 — Correspondence between the clauses in this document and those in ISO 9001:2015

Clause in this document	Heading	Clause in ISO 9001:2015
Clause 5	Development of a quality plan	4.1, 4.2, 6.1, 7.1.1, 8.1
Clause 6	Content of the quality plan	7, 8, 9, 10
6.1	General	8.1
6.2	Scope of the quality plan	4.3, 8.2
6.3	Quality plan inputs	8.1, 8.2, 8.6, 9.1.1
6.4	Quality objectives	6.2, 9.1.1
6.5	Quality plan responsibilities	5.3
6.6	Control of documented information	7.5
6.7	Resources	7.1
6.7.1	Provision of resources	7.1.1
6.7.2	Materials, products and services	8.2
6.7.3	People	7.1.2, 7.2, 7.3
6.7.4	Infrastructure and environment for the operation of processes	7.1.3, 7.1.4
6.7.5	Monitoring and measuring resources	7.1.5
6.8	Interested party communication	7.4, 8.2.1, 8.4.3
6.9	Design and development	8.3
6.9.1	Design and development process	8.3.1 to 8.3.5
6.9.2	Control of design and development changes	8.3.6
6.10	Externally provided processes, products and services	8.4
6.11	Production and service provision	8.5.1, 8.5.5, 8.5.6
6.12	Identification and traceability	8.5.2
6.13	Property belonging to customers or external providers	8.5.3
6.14	Preservation of outputs	8.5.4
6.15	Control of nonconforming outputs	8.7, 10.2
6.16	Monitoring and measurement	8.1, 8.6, 9.1
6.17	Audits	9.2
Clause 7	Operation and control of the quality plan	7, 8, 9, 10
7.1	Review and acceptance of the quality plan	7.5.2, 8.1, 8.2.1, 8.2.3
7.2	Implementation and monitoring of the quality plan	7.2, 7.3, 7.5.3, 8.1, 9.1.3, 9.2
7.3	Revision of the quality plan	7.5.3, 8.2.4, 8.5.6
7.4	Feedback and improvement	9.3, 10.1
NOTE Correspondence between clauses does not imply conformity.		

Annex D (informative)

Correlation matrix between the clauses of this document and the quality management principles from ISO 9000:2015

Table D.1 — Correlation between the clauses of this document and the quality management principles from ISO 9000:2015

Clause No.	Clause title	Quality management principle						
		Customer focus	Leadership	Engagement of people	Process approach	Improvement	Evidence-based decision-making	Relationship management
Clause 4	Using a quality plan							
4.1	Reasons for using a quality plan	Y	N	Y	Y	N	N	Y
4.2	Requesting external provider quality plans	N	N	N	Y	Y	Y	Y
4.3	Managing external provider quality plans	N	N	Y	Y	N	Y	Y
Clause 5	Development of a quality plan							
5.1	Context of the quality plan	Y	N	N	Y	Y	Y	Y
5.2	Inputs to the quality plan	Y	N	Y	Y	N	N	Y
5.3	Defining the scope of the quality plan	Y	N	N	Y	N	N	Y
5.4	Preparation of the quality plan							
5.4.1	Initiation	Y	N	Y	Y	N	N	Y
5.4.2	Defining the quality plan	N	N	N	Y	N	N	N
5.4.3	Consistency and compatibility	Y	N	N	Y	N	N	N
5.4.4	Presentation and structure	N	N	N	Y	N	N	N
Clause 6	Content of the quality plan							
6.1	General	N	N	N	N	N	N	Y
6.2	Scope of the quality plan	Y	N	N	Y	N	N	N
6.3	Quality plan inputs	Y	N	N	Y	N	Y	N
6.4	Quality objectives	Y	N	N	Y	Y	Y	Y
6.5	Quality plan responsibilities	Y	Y	Y	Y	N	Y	Y
6.6	Control of documented information	Y	Y	Y	Y	N	Y	N

Table D.1 (continued)

Clause No.	Clause title	Quality management principle						
		Customer focus	Leadership	Engagement of people	Process approach	Improvement	Evidence-based decision-making	Relationship management
6.7	Resources							
6.7.1	Provision of resources	N	N	Y	Y	N	N	Y
6.7.2	Materials, products and services	N	N	N	N	N	Y	N
6.7.3	People	N	N	Y	N	Y	N	N
6.7.4	Infrastructure and environment for the operation of processes	N	N	Y	Y	N	N	N
6.7.5	Monitoring and measuring resources	N	N	N	Y	N	N	N
6.8	Interested party communication	Y	N	Y	Y	N	N	Y
6.9	Design and development							
6.9.1	Design and development process	N	N	N	Y	N	N	Y
6.9.2	Control of design and development changes	N	Y	Y	Y	N	Y	N
6.10	Externally provided processes, products and services	N	N	N	Y	N	N	Y
6.11	Production and service provision	N	N	Y	Y	N	Y	Y
6.12	Identification and traceability	Y	N	N	Y	N	N	N
6.13	Property belonging to customers or external providers	Y	N	N	Y	N	Y	Y
6.14	Preservation of outputs	N	N	N	Y	N	N	N
6.15	Control of nonconforming outputs	N	N	Y	Y	Y	N	Y
6.16	Monitoring and measurement	Y	N	N	Y	N	Y	Y
6.17	Audits	Y	N	N	N	N	Y	Y

Table D.1 (continued)

Clause No.	Clause title	Quality management principle						
		Customer focus	Leadership	Engagement of people	Process approach	Improvement	Evidence-based decision-making	Relationship management
Clause 7	Operation and control of the quality plan							
7.1	Review and acceptance of the quality plan	Y	Y	N	N	N	Y	Y
7.2	Implementation and monitoring of the quality plan	Y	N	Y	N	Y	Y	Y
7.3	Revision of the quality plan	Y	Y	Y	Y	Y	N	Y
7.4	Feedback and improvement	Y	N	N	N	Y	Y	Y

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- [4] ISO 10004, *Quality management — Customer satisfaction — Guidelines for monitoring and measuring*
- [5] ISO 10006, *Quality management systems — Guidelines for quality management in projects*
- [6] ISO 10007, *Quality management — Guidelines for configuration management*
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- [8] ISO/TR 10013, *Guidelines for quality management system documentation*
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1) Under revision.

