TECHNICAL SPECIFICATION

ISO/IEC TS 33053

First edition
2019-11

Information technology — Process assessment — Process Reference Model (PRM) for quality management

Technologies de l'information — Évaluation du processus — Modèle de référence de processus pour la gestion de la qualité

Reference number
ISO/IEC TS 33053:2019(E)

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Published in Switzerland

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Foreword

ISO (the International Organization for Standardization) and IEC (the International Electrotechnical Commission) form the specialized system for worldwide standardization. National bodies that are members of ISO or IEC participate in the development of International Standards through technical committees established by the respective organization to deal with particular fields of technical activity. ISO and IEC technical committees collaborate in fields of mutual interest. Other international organizations, governmental and non-governmental, in liaison with ISO and IEC, also take part in the work.

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 document 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 and IEC 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) or the IEC list of patent declarations received (see http://patents.iec.ch).

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 Joint Technical Committee ISO/IEC JTC 1, *Information technology*, Subcommittee SC 7, *Systems and Software Engineering*.

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.

Introduction

The purpose of this document is to facilitate the development of a process assessment model described in ISO/IEC TS 33073.

ISO/IEC 33002 describes the requirements for the conduct of an assessment. ISO/IEC 33004 describes the requirements for process reference, process assessment and maturity models. ISO/IEC 33020 describes the measurement scale for assessing the process quality characteristic of process capability. ISO/IEC 33001 describes the concepts and terminology used for process assessment.

A process reference model is a model comprising definitions of processes described in terms of process purpose and outcomes, together with an architecture describing the relationships between the processes. Using the process reference model in a practical application can require additional elements suited to the environment and circumstances.

The process reference model specified in this document describes the processes including the quality management system processes implied by ISO 9001. Each process of this process reference model is described in terms of a purpose and outcomes, and provides traceability to requirements. The process reference model does not attempt to place the processes in any specific environment nor does it pre-determine any level of process capability required to fulfil the ISO 9001 requirements. The process reference model is not intended to be used for a conformity assessment audit or as a process implementation reference guide.

The relationships between ISO 9001, ISO/IEC TR 24774, ISO/IEC 33002, ISO/IEC 33004, ISO/IEC 33020, ISO/IEC TS 33053 and ISO/IEC TS 33073 are shown in Figure 1.

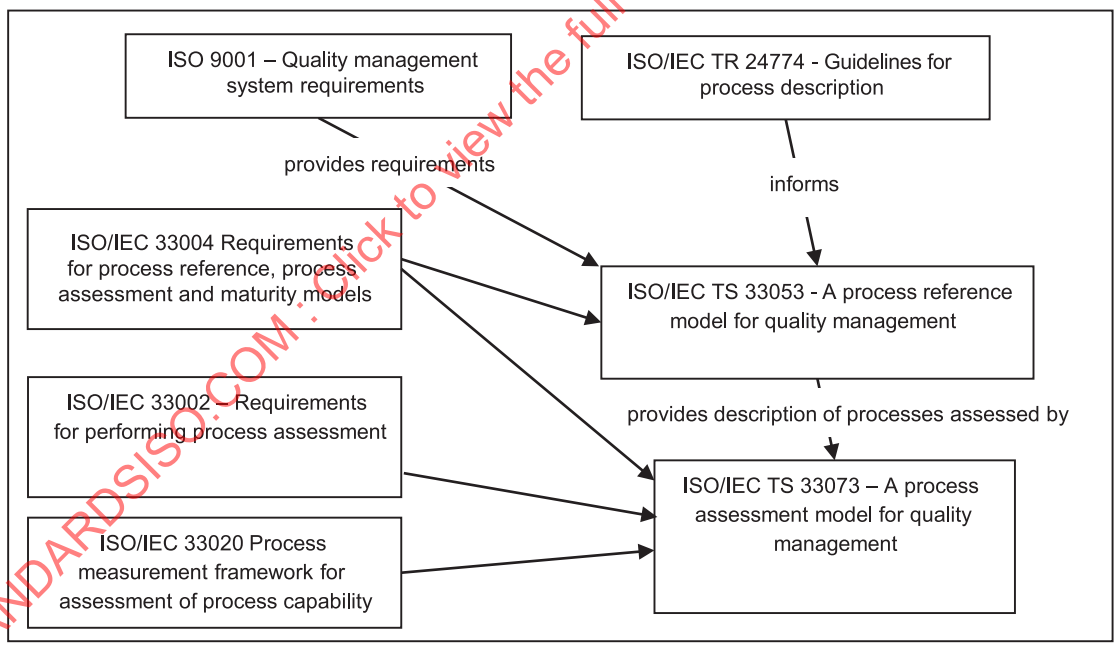

Figure 1 — Relationships between relevant standards

Any organization can define processes with additional elements in order to suit it to its specific environment and circumstances. Some processes cover general management aspects of an organization. These processes have been identified in order to give coverage to the requirements of ISO 9001.

The process reference model does not provide the evidence required by ISO 9001. The process reference model does not specify the interfaces between the processes.

This document describes a process reference model for quality management with descriptions of processes in Clause 5. Annex A describes the relationship between management system requirements

and process model elements. Annex B provides the statement of conformity in accordance with ISO/IEC 33004.

Information technology — Process assessment — Process Reference Model (PRM) for quality management

1 Scope

This document defines a process reference model for the domain of quality management.

The model specifies a process architecture for the domain and comprises a set of processes. Each process is described in terms of process purpose and outcomes.

NOTE Users of this document can freely reproduce the detailed descriptions contained in this process reference model as part of any tool or other material to support the performance of process assessments, so that it can be used for its intended purpose.

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/IEC 33001, *Information technology — Process assessment — Concepts and terminology*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO/IEC 33001 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/

4 Overview of the process reference model

This clause describes the structure of a process reference model to support quality management. The process reference model includes processes, which can already exist in the context of a quality management system of a service provider.

Figure 2 identifies the processes derived from ISO 9001 requirements. Three process groups are identified, namely, common processes, technical processes and organizational processes. The term "common processes" refers to those processes identified with the text in the management system subclauses that is common to all management system standards. The term "technical processes" refers to processes associated with the technical domain of the application standard. In the present case of ISO 9001, the technical processes underpin the implementation of those requirements associated with the creation or support of products and services. "organizational processes" refers to those processes that support the implementation of the requirements for products and services.

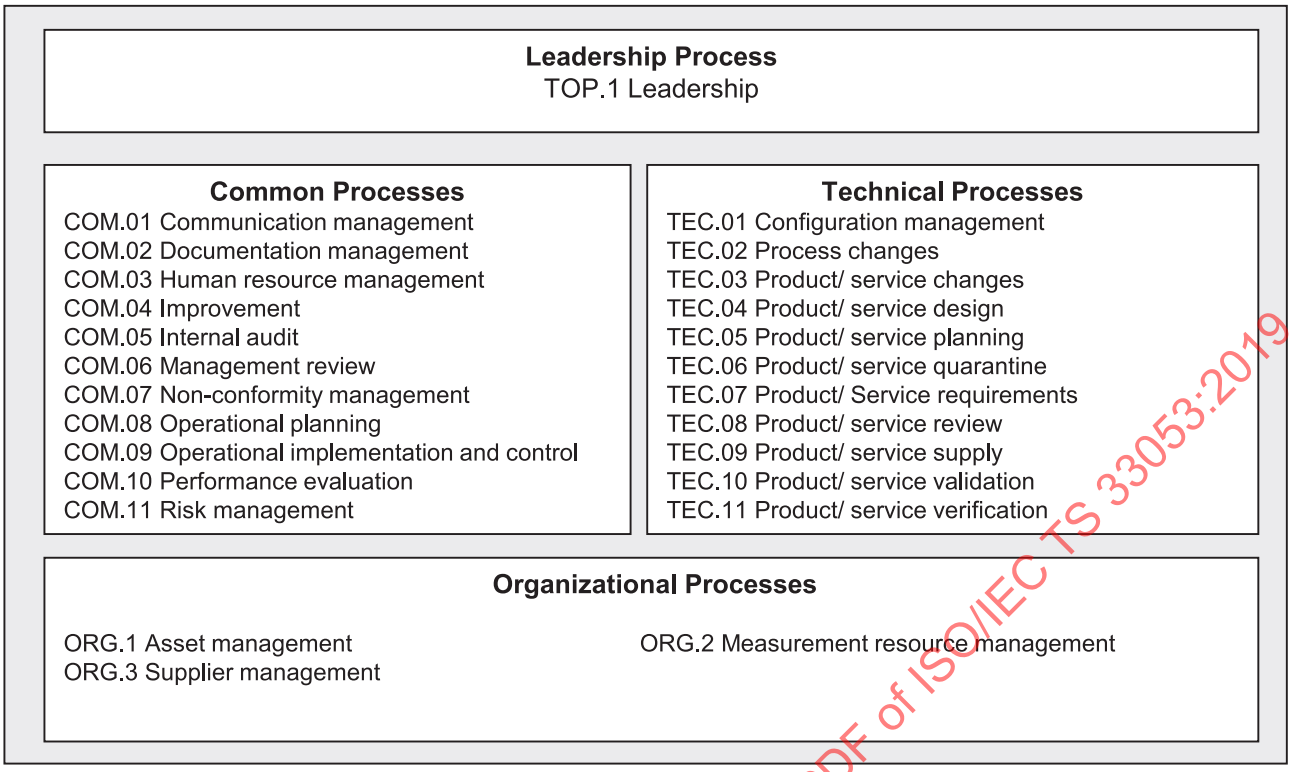

Figure 2 — Processes in the process reference model

5 Process descriptions

5.1 General

The process descriptions in this process reference model are defined following the guidance set out in ISO/IEC TR 24774. Each process in the process reference model has the following descriptive elements.

a) Process ID: each process belonging to a group is identified with a process identifier (ID) consisting of the group abbreviated name and a sequential number of the process in that group.

b) Name: the name of a process is a short phrase that summarizes the scope of the process, identifying the principal concern of the process, and distinguishes it from other processes within the scope of the process reference model.

c) Purpose: the purpose of the process is a high level, overall goal for performing the process.

d) Outcomes: an outcome is an observable result of the successful achievement of the process purpose. Outcomes are measurable, tangible, technical or business results that are achieved by a process. Outcomes are observable and assessable.

e) Requirements traceability: the outcomes are based on the requirements of ISO 9001. The references identify the applicable subclauses of ISO 9001, the subclause heading, and the outcomes that are supported.

In 5.2 to 5.27, all entries in the requirements traceability row end with numbers in square brackets, (i.e. [n]). Each number in the square brackets is a reference to a numbered outcome. These outcomes are directly linked to the requirements of ISO 9001.

Some outcomes are shown in square brackets. These are only indirectly linked to requirements of ISO 9001. The outcomes in square brackets are not referenced by any of the entries in the requirements traceability row. These additional outcomes have been included because they are considered necessary

in order for this type of process reference model to serve as the basis of the process assessment model (ISO/IEC TS 33073). With these additional outcomes, the process is complete and the process purpose can be achieved.

5.2 COM.01 Communication management

Process ID	COM.01
Name	Communication management
Purpose	The purpose of communication management is to produce timely and accurate information products to support effective communication and decision making.
Outcomes	As a result of successful implementation of this process: [1) Information content is defined in terms of identified communication requirements.] 2) Parties to communicate with are identified. 3) The party responsible for the communication is identified. 4) Events that require communication actions are identified. 5) The channel for the communication is selected. 6) Information products are communicated to relevant interested parties.
Requirements traceability	ISO 9001:2015, 5.1.1, General [6] ISO 9001:2015, 5.2.2, Communicating the quality policy [6] ISO 9001:2015, 7.4, Communication [2][3][4][5] ISO 9001:2015, 8.2.4, Changes to requirements for products and services [6] ISO 9001:2015, 8.4.3, Information for external providers [6] ISO 9001:2015, 8.7.1 [6] ISO 9001:2015, 9.2.2 [6]

5.3 COM.02 Documentation management

Process ID	COM.02
Name	Documentation management
Purpose	The purpose of document management is to provide relevant, timely, complete, valid documented information to designated parties.
Outcomes	As a result of successful implementation of this process: 1) Documented information to be documented is identified. 2) The forms of documented information representation are defined. 3) The documented information content status is known. 4) Documented information is current, complete and valid. 5) Documented information is released according to defined criteria. 6) Documented information is available to relevant interested parties. 7) Documented information is archived, or disposed of, as required.

Requirements traceability	ISO 9001:2015, 4.3, Determining the scope of the quality management system [1][3] ISO 9001:2015, 5.2.2, Communicating the quality policy [1][4][6] ISO 9001:2015, 6.2.1 [3][4] ISO 9001:2015, 7.1.5.1, General [1] ISO 9001:2015, 7.1.6, Organizational knowledge [4][6] ISO 9001:2015, 7.2, Competence [1] ISO 9001:2015, 7.5.2, Creating and updating [2][5] ISO 9001:2015, 7.5.3.1 [4][6] ISO 9001:2015, 7.5.3.2 [2][4][6][7] ISO 9001:2015, 8.1, Operational planning and control [1] ISO 9001:2015, 8.2.3.2 [1] ISO 9001:2015, 8.2.4, Changes to requirements for products and services [3][4] ISO 9001:2015, 8.3.2, Design and development planning [1] ISO 9001:2015, 8.3.3, Design and development inputs [1] ISO 9001:2015, 8.3.4, Design and development controls [1] ISO 9001:2015, 8.3.5, Design and development outputs [1] ISO 9001:2015, 8.3.6, Design and development changes [1] ISO 9001:2015, 8.4.1, General [1] ISO 9001:2015, 8.5.1, Control of production and service provision [1] ISO 9001:2015, 8.5.2, Identification and traceability [1] ISO 9001:2015, 8.5.3, Property belonging to customers or external providers [1] ISO 9001:2015, 8.5.6, Control of changes [1] ISO 9001:2015, 8.6, Release of products and services [5] ISO 9001:2015, 8.7.2 [1] ISO 9001:2015, 9.1.1, General [1] ISO 9001:2015, 9.2.2 [1] ISO 9001:2015, 9.3.3, Management review outputs [1] ISO 9001:2015, 10.2.2 [1]

5.4 COM.03 Human resource management

Process ID	COM.03
Name	Human resource management
Purpose	The purpose of human resource management is to provide the organization with necessary competent human resources and to improve their competencies, in alignment with business needs.
Outcomes	As a result of successful implementation of this process: 1) The competencies required by the organization to produce products and services are identified. 2) Identified competency gaps are filled through training or recruitment. 3) Understanding of roles and activities in achieving organisational objectives in product and service provision is demonstrated by each person.

Requirements traceability	ISO 9001:2015, 7.2, Competence [1][2] ISO 9001:2015, 7.3, Awareness [3]

5.5 COM.04 Improvement

Process ID	COM.04
Name	Improvement
Purpose	The purpose of improvement is to continually improve the management system, its processes, products and services.
Outcomes	As a result of successful implementation of this process: 1) Opportunities for improvement are identified. 2) Opportunities for improvement are evaluated against defined criteria. [3) Improvements are prioritized.] [4) Improvements are implemented.] [5) The effectiveness of implemented improvements is evaluated.]
Requirements traceability	ISO 9001:2015, 9.1.3, Analysis and evaluation [2] ISO 9001:2015, 9.3.3, Management review outputs [1] ISO 9001:2015, 10.1, General [1] ISO 9001:2015, 10.3, Continual improvement [1]

5.6 COM.05 Internal audit

Process ID	COM.05
Name	Internal audit
Purpose	The purpose of internal audit is to independently determine conformity of the management system, products, services, and processes to the requirements, policies, plans and agreements, as appropriate.
Outcomes	As a result of successful implementation of this process: 1) The scope and purpose of each audit is defined. 2) The objectivity and impartiality of the conduct of audits and selection of auditors are assured. 3) Conformity of selected services, products and processes with requirements, plans and agreements is determined.
Requirements traceability	ISO 9001:2015, 9.2.1 [3] ISO 9001:2015, 9.2.2 [1][2][3]

5.7 COM.06 Management review

Process ID	COM.06
Name	Management review
Purpose	The purpose of management review is to assess the performance of the management system, to identify and make decisions regarding potential improvements.
Outcomes	As a result of successful implementation of this process: 1) The objectives of the review are established. 2) The status and performance of an activity or process are assessed in terms of the established objectives. 3) Risks, problems and opportunities for improvement are identified.
Requirements traceability	ISO 9001:2015, 9.3.1, General [2] ISO 9001:2015, 9.3.2, Management review inputs [1] ISO 9001:2015, 9.3.3, Management review outputs [3]

5.8 COM.07 Non-conformity management

Process ID	COM.07
Name	Non-conformity management
Purpose	The purpose of the non-conformity management process is to resolve non-conformities and to eliminate their causes when appropriate.
Outcomes	As a result of successful implementation of this process: 1) Non-conformities are identified. 2) Non-conformities are resolved and closed. 3) The cause(s) of selected non-conformities is determined. 4) The need for action to eliminate the causes of non-conformities is evaluated. 5) A selected action proposal is implemented. 6) The effectiveness of changes to eliminate the non-conformities is confirmed.
Requirements traceability	ISO 9001:2015, 7.1.5.2, Measurement traceability [1] ISO 9001:2015, 7.4, Communication [5] ISO 9001:2015, 9.2.2 [1] ISO 9001:2015, 10.2.1 [1][2][3][4][5][6]

5.9 COM.08 Operational planning

Process ID	COM.08
Name	Operational planning
Purpose	The purpose of operational planning is to define the characteristics of all operational and organizational processes, and to plan their execution.

Outcomes	As a result of successful implementation of this process: 1) Process requirements are identified. 2) Process input and output products are determined. 3) The set of activities that transform the inputs into outputs is determined. 4) The sequence and interaction of the process with other processes is determined. 5) The required competencies and roles for performing the process are identified. 6) The required resources for performing the process are identified. 7) Methods for monitoring the effectiveness and suitability of the process are determined. 8) Plans for the deployment of the process are developed.
Requirements traceability	ISO 9001:2015, 4.4.1, [2][4][5][6][7] ISO 9001:2015, 5.2.1, Establishing the quality policy [1] ISO 9001:2015, 5.3, Organizational roles, responsibilities and authorities [5] ISO 9001:2015, 6.1.1 [1][8] ISO 9001:2015, 6.1.2 [8] ISO 9001:2015, 6.2.2 [1][5][6][7][8] ISO 9001:2015, 6.3, Planning of changes [1] ISO 9001:2015, 7.1.1, General [6] ISO 9001:2015, 7.1.3, Infrastructure [1] ISO 9001:2015, 7.1.4, Environment for the operation of processes [1] ISO 9001:2015, 7.1.5.1, General [1] ISO 9001:2015, 7.5.2, Creating and updating [1] ISO 9001:2015, 8.1, Operational planning and control [1][2][4][6] ISO 9001:2015, 8.2.1, Customer communication [1] ISO 9001:2015, 8.3.2, Design and development planning [8] ISO 9001:2015, 8.3.4, Design and development controls [1] ISO 9001:2015, 8.5.1, Control of production and service provision [3][4][5][6][7] ISO 9001:2015, 9.1.1, General [8] ISO 9001:2015, 9.2.1 [8] ISO 9001:2015, 9.2.2 [8] ISO 9001:2015, 9.3.1, General [8] ISO 9001:2015, 9.3.2, Management review inputs [8]

5.10 COM.09 Operational implementation and control

Process ID	COM.09
Name	Operational implementation and control
Purpose	The purpose of the operational implementation and control process is to deploy and control the execution and performance of operational and organizational processes.

Outcomes	As a result of successful implementation of this process: 1) The required roles, responsibilities and authorities are allocated. 2) The required resources are allocated and applied. 3) Actions required to achieve the management system objectives are implemented. 4) Suitability and effectiveness of the actions taken to achieve the management system objectives are reviewed. 5) Deviations from planned arrangements are corrected when targets are not achieved. 6) Data is collected and analysed as a basis for understanding the behaviour of, and to demonstrate the suitability and effectiveness of the processes.
Requirements traceability	ISO 9001:2015, 4.1, Understanding the organization and its context [4] ISO 9001:2015, 4.2, Understanding the needs and expectations of interested parties [4] ISO 9001:2015, 5.2.1, Establishing the quality policy [3][4] ISO 9001:2015, 5.3, Organizational roles, responsibilities and authorities [1] ISO 9001:2015, 7.1.1, General [2] ISO 9001:2015, 7.1.2, People [2] ISO 9001:2015, 7.1.3, Infrastructure [3] ISO 9001:2015, 7.1.4, Environment for the operation of processes [3][4] ISO 9001:2015, 7.1.5.1, General [2][3] ISO 9001:2015, 7.2, Competence [4] ISO 9001:2015, 8.1, Operational planning and control [3][4][5] ISO 9001:2015, 8.2.3.1 [4] ISO 9001:2015, 8.4.3, Information for external providers [4] ISO 9001:2015, 8.5.1, Control of production and service provision [3] ISO 9001:2015, 9.1.3, Analysis and evaluation [6] ISO 9001:2015, 9.2.2 [3][4]

5.11 COM.10 Performance evaluation

Process ID	COM.10
Name	Performance evaluation
Purpose	The purpose of performance evaluation is to collect and analyse data that will be used to evaluate the performance of the management system and the business processes in terms of the defined objectives.
Outcomes	As a result of successful implementation of this process: 1) Performance monitoring and measurement needs are defined. [2) Performance measures, derived from the performance measurement needs, are identified.] 3) Performance measurement methods, supportive of the performance measures, are identified. 4) Data is collected using the identified performance measurement methods. 5) The collected performance data is analysed.

Requirements traceability	ISO 9001:2015, 9.1.1, General [1][3][4] ISO 9001:2015, 9.1.2, Customer satisfaction [1][3] ISO 9001:2015, 9.1.3, Analysis and evaluation [5]

5.12 COM.11 Risk management

Process ID	COM.11
Name	Risk management
Purpose	The purpose of risk management is to identify, analyse, evaluate, treat and monitor risks.
Outcomes	As a result of successful implementation of this process: [1) Criteria for the assessment of risks and the acceptable level of risk are identified.] 2) Risks are identified. [3) Identified risks are analysed.] [4) Risks are evaluated against defined criteria.] [5) Risks are selected for treatment.] 6) Selected risks are treated.
Requirements traceability	ISO 9001:2015, 6.1.2 [6] ISO 9001:2015, 10.2.1 [2]

5.13 ORG.01 Asset management

Process ID	ORG.01
Name	Asset management
Purpose	The purpose of the asset management process is to establish and maintain the integrity of all identified product assets.
Outcomes	As a result of successful implementation of this process: 1) Items requiring asset management are identified. 2) Asset status is known. [3) Changes to assets under management are controlled.] 4) The integrity of assets is assured.
Requirements traceability	ISO 9001:2015, 8.5.3, Property belonging to customers or external providers [1][2][4]

5.14 ORG.02 Measurement resource management

Process ID	ORG.02
Name	Measurement resource management
Purpose	The purpose of the measurement resource management process is to ensure that measurement resources used to perform tests and calibrations is acquired, controlled and maintained.

Outcomes	As a result of successful implementation of this process: [1) Requirements for measurement resources are defined.] [2) Measurement resources for performing tests and calibrations is acquired.] 3) Measurement resource items are identified. 4) The calibration status of measurement resource items is confirmed at appropriate intervals. [5) Measurement resources are maintained in accordance with defined requirements.] 6) Mal-performing measurement resources are segregated and controlled in order to avoid unintended use.
Requirements traceability	ISO 9001:2015, 7.1.5.2, Measurement traceability [3][4][6]

5.15 ORG.03 Supplier management

Process ID	ORG.03
Name	Supplier management
Purpose	The purpose of the supplier management process is to ensure supplier products/services are managed and integrated into the delivered product/service to meet the agreed requirements.
Outcomes	As a result of successful implementation of this process: [1) Suppliers are identified.] [2) Products/services to be provided are negotiated with each supplier.] [3) Determine the roles and relationships between the organization and its suppliers and, where applicable, between suppliers.] [4) The capability of subcontracted suppliers to meet obligations is confirmed.] [5) Supplier obligations to meet requirements are monitored.] 6) Supplier performance against agreed criteria is monitored.
Requirements traceability	ISO 9001:2015, 9.1.3 Analysis and evaluation [6]

5.16 TEC.01 Configuration management

Process ID	TEC.01
Name	Configuration management
Purpose	The purpose of the configuration management process is to identify, control, record, track, report and verify all identified product/service components.
Outcomes	As a result of successful implementation of this process: 1) Items requiring configuration management are identified. 2) The status of configuration items and modifications is known. [3) Changes to items under configuration management are controlled.] [4) The integrity of systems, products/services and product/service components is assured.] [5) The configuration of released items is controlled.]

Requirements traceability	ISO 9001:2015, 8.5.2, Identification and traceability [1][2]

5.17 TEC.02 Process changes

Process ID	TEC.02
Name	Process changes
Purpose	The purpose of the process change process is to manage changes in order to improve the effectiveness and/or efficiency of the process.
Outcomes	As a result of successful implementation of this process: 1) Process change requests are classified. 2) Process change requests are assessed using defined criteria. 3) Process changes are implemented, as appropriate.
Requirements traceability	ISO 9001:2015, 8.5.6, Control of changes [1][2][3]

5.18 TEC.03 Product/service changes

Process ID	TEC.03
Name	Product/service changes
Purpose	The purpose of the product/service change process is to manage changes through the product/service lifecycle.
Outcomes	As a result of successful implementation of this process: 1) Product/service change requests are identified and classified. 2) Product/service change requests are assessed using defined criteria. 3) Product/service changes are implemented, as appropriate.
Requirements traceability	ISO 9001:2015, 8.3.6, Design and development changes [1][2][3]

5.19 TEC.04 Product/service design

Process ID	TEC.04
Name	Product/service design
Purpose	The purpose of the product/service design process is to provide a design for the product/service that implements the requirements and can be verified against the requirements.
Outcomes	As a result of successful implementation of this process: 1) Design for each product/service component is developed in accordance with defined requirements. 2) External and internal interfaces for each product/service component are defined.
Requirements traceability	ISO 9001:2015, 8.3.5, Design and development outputs [1][2]

5.20 TEC.05 Product/service planning

Process ID	TEC.05
Name	Product/service planning

Purpose	The purpose of the product/service planning process is to produce effective and workable plans to direct product and/or service plan implementation.
Outcomes	As a result of successful implementation of this process: [1) The objectives for the scope of the work associated with the development of the product/service are defined.] [2) The feasibility of achieving the objectives of the product/service development with available resources and constraints are evaluated.] [3) The tasks and resources necessary to complete the product/service development are sized and estimated.] [4) The responsibilities and authorities needed at each stage of product/service development are identified.] [5) Interfaces between customer and relevant interested parties are identified.] 6) Plans for the development of the product/service are developed.
Requirements traceability	ISO 9001:2015, 8.3.4, Design and development controls [6]

5.21 TEC.06 Product/service quarantine

Process ID	TEC.06
Name	Product/service quarantine
Purpose	The purpose of the product/service quarantine process is to ensure that products/services that do not meet customer requirements are controlled with a view to prevent unintended use.
Outcomes	As a result of successful implementation of this process: 1) Product/service that does not conform to requirements is identified. 2) Nonconforming product/service is placed under quarantine. 3) Alternative approaches are identified regarding disposition of the nonconforming product/service. 4) Agreed actions are taken regarding disposition of nonconforming product/service. 5) Product/service that has been corrected is re-verified to demonstrate conformity to requirements. [6) Action is taken to prevent re-occurrence of the identified product/service nonconformity.] 7) Product/service is released from quarantine when authorised.
Requirements traceability	ISO 9001:2015, 8.7.1 [1][2][3][4][5][7]

5.22 TEC.07 Product/service requirements

Process ID	TEC.07
Name	Product/service requirements
Purpose	The purpose of the product/service requirements process is to establish and agree the requirements for products and/or services.

Outcomes	As a result of successful implementation of this process: 1) The required characteristics and context of use of products/services are identified. 2) The constraints for a product/service solution are defined. 3) The requirements for the product/service are defined. [4) The requirements for validating the product/service are defined.]
Requirements traceability	ISO 9001:2015, 8.1, Operational planning and control [3] ISO 9001:2015, 8.2.2, Determining the requirements for products and services [3] ISO 9001:2015, 8.2.3.2 [3] ISO 9001:2015, 8.3.3, Design and development inputs [1][2][3]

5.23 TEC.08 Product/service review

Process ID	TEC.08
Name	Product/service review
Purpose	The purpose of the product/service review process is to maintain a common understanding with customer what should be done to help ensure development of a product/service that meets the customer and relevant interested party requirements. Product/service reviews are held at both management and technical levels throughout the product/service lifecycle.
Outcomes	As a result of successful implementation of this process: [1) Criteria for the review of product/service is identified.] [2) Review participants are identified.] 3) Required review activities are performed. 4) Action items are identified.
Requirements traceability	ISO 9001:2015, 8.3.4, Design and development controls [3][4]

5.24 TEC.09 Product/service supply

Process ID	TEC.09
Name	Product/service supply
Purpose	The purpose of the product/service supply process is to provide product/service to meet the agreed customer requirements.
Outcomes	As a result of successful implementation of this process: [1) Product/service request(s) received from the customer are confirmed.] 2) Product/service request(s) are evaluated in terms of mandated product/service delivery criteria. 3) A response to a customer's product/service request is produced. 4) An agreement is established between the customer and the supplier for providing the product/service. 5) The product/service is provided to the customer in accordance with the agreed requirements. 6) Conformity to applicable stated and implied customer and supplier requirements by internal processes and/or product/service provided is verified.

Requirements traceability	ISO 9001:2015, 8.2.2, Determining the requirements for products and services [2] ISO 9001:2015, 8.2.3.1 [2][3] ISO 9001:2015, 8.2.3.2 [2] ISO 9001:2015, 8.3.5, Design and development outputs [4][6] ISO 9001:2015, 8.6, Release of products and services [5][6]

5.25 TEC.10 Product/service validation

Process ID	TEC.10
Name	Product/service validation
Purpose	The purpose of the product/service validation process is to confirm that the requirements for a specific intended use of the product/service are fulfilled.
Outcomes	As a result of successful implementation of this process: [1) Products/services to be validated are selected.] [2) Criteria for validation of all required process results are identified.] 3) Required validation activities are performed. [4) Problems are identified.]
Requirements traceability	ISO 9001:2015, 8.3.4, Design and development controls [3]

5.26 TEC.11 Product/service verification

Process ID	TEC.11
Name	Product/service verification
Purpose	The purpose of the product/service verification process is to confirm that each product/service properly reflects the specified requirements.
Outcomes	As a result of successful implementation of this process: [1) Products/services to be verified are selected.] [2) Criteria for verification of all required process results is identified.] 3) Required verification activities are performed. [4) Defects are identified.]
Requirements traceability	ISO 9001:2015, 8.3.4, Design and development controls [3] ISO 9001:2015, 8.6, Release of products and services [3]

5.27 TOP.01 Leadership

Process ID	TOP.01
Name	Leadership
Purpose	The purpose of Leadership is to direct the organization in the achievement of its vision, mission, strategy and goals, through assuring the definition of a management system, a management system policy, and management system objectives.

Outcomes	As a result of successful implementation of this process: 1) The context of the organization, including the expectations of its relevant interested parties, are understood and analysed. 2) The scope of management system activities is defined, taking the context of the organization into consideration. 3) The management system policy and objectives are defined. 4) The management system and operational process strategy is determined. 5) Commitment and leadership with respect to the management system is demonstrated.
Requirements traceability	ISO 9001:2015, 4.1, Understanding the organization and its context [1] ISO 9001:2015, 4.2, Understanding the needs and expectations of interested parties [1] ISO 9001:2015, 4.3, Determining the scope of the quality management system [2] ISO 9001:2015, 4.4.1 [4] ISO 9001:2015, 4.4.2 [4] ISO 9001:2015, 5.1.1, General [3][5] ISO 9001:2015, 5.1.2, Customer focus [5] ISO 9001:2015, 5.2.1, Establishing the quality policy [3] ISO 9001:2015, 6.2.1 [3] ISO 9001:2015, 6.3, Planning of changes [4] ISO 9001:2015, 7.1.6, Organizational knowledge [4] ISO 9001:2015, 7.5.1, General [4] ISO 9001:2015, 7.5.3.2 [4] ISO 9001:2015, 8.1, Operational planning and control [4] ISO 9001:2015, 8.3.1, General [4] ISO 9001:2015, 8.4.1, General [4] ISO 9001:2015, 8.4.2, Type and extent of control [4] ISO 9001:2015, 8.5.1, Control of production and service provision [4] ISO 9001:2015, 8.5.3, Property belonging to customers or external providers [4] ISO 9001:2015, 8.5.4, Preservation [4] ISO 9001:2015, 8.5.5, Post-delivery activities [4] ISO 9001:2015, 9.1.1, General [4] ISO 9001:2015, 10.3, Continual improvement [4]

Annex A
(informative)

The relationship between management system requirements and a process reference model

A.1 General

This annex examines the similarities, differences and relationships between a quality management system used in ISO 9001, a process reference model (process reference model) in this document and the assessment of the process quality characteristic of process capability.

ISO 9001 defines a quality management system as that part of the overall management system, based on a business risk approach, to establish, implement, operate, monitor, review, maintain and improve product and services.

Process reference models are used as a basis for developing process assessment models that are used to assess process capability. A consistent description of processes within and across process reference models allows the combination of processes from different reference models that can ease the development of new models and facilitate comparison of models.

A.2 Processes and process models

A.2.1 Process seen in terms of inputs and outputs

To function effectively, an organization has to determine and manage numerous linked activities. An activity or set of activities using resources, and managed in order to enable the transformation of inputs into outputs, can be considered a process. Often the output from one process forms the input to the next as shown in Figure A.1.

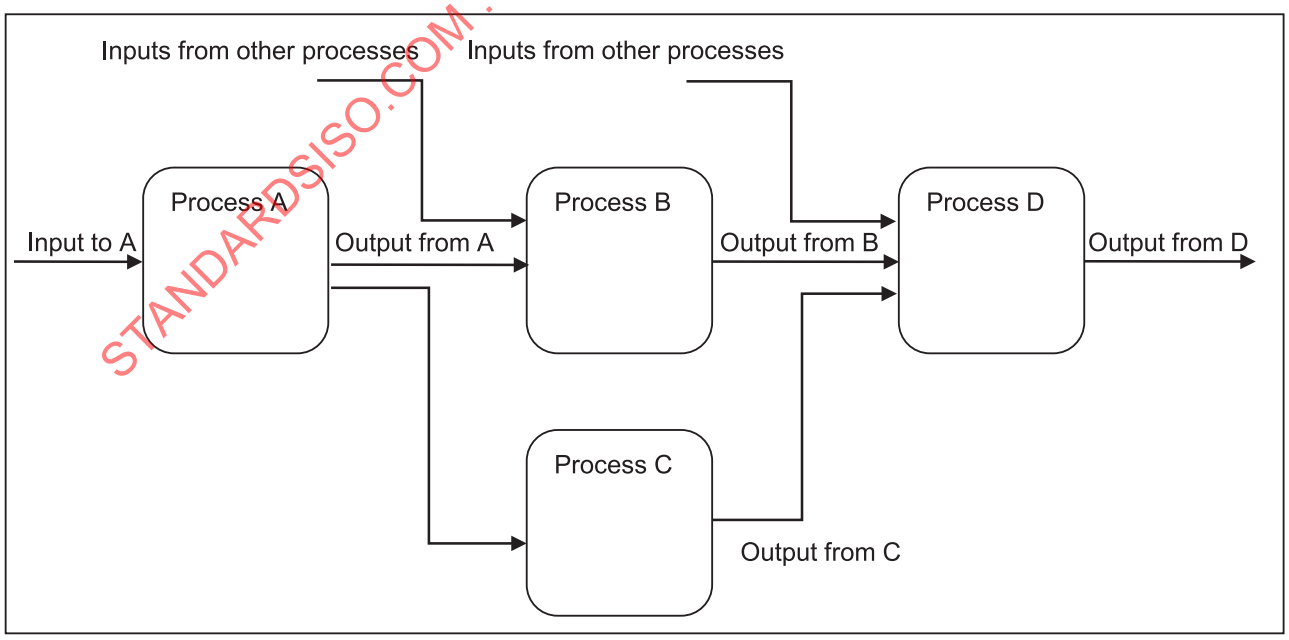

Figure A.1 — Process seen as a transformation of inputs to outputs

A.2.2 Using a Process Reference Model as a basis for understanding capability

Capability is defined in ISO 9000 as the "ability of an object to realize an output that will fulfil the requirements for that output". In ISO/IEC 33020, process capability is considered to be "a characterization of the ability of a process to meet current or projected business goals".

Whereas the view of ISO 9000 is on customer satisfaction and process outputs, ISO/IEC 33002 focuses on process outcomes, which are defined to be "observable results of a process". ISO/IEC TR 24774 elaborates with a definition of a process outcome as "an observable result of the successful achievement of the process purpose". Outcomes are measurable, tangible, technical or business results that are achieved by a process, for example the results that are used by other processes. Outcomes are observable and assessable for a specific process.

A.3 Nature of requirements for a management system

The requirements for management systems are generic and applicable to organizations in any industry or economic sector. ISO 9000 identifies requirements as a "need or expectation that is stated, generally implied or obligatory".

A.4 Relationship of requirements to a process reference model

The process reference model describes individual processes whereas ISO 9001 exemplifies part of the overall management system, based on a business risk approach, to establish, implement, operate, monitor, review, maintain and improve product and services.

Processes are instantiated within an organization — often within a quality management system.

ISO 9001 defines the requirements for a quality management system. Some of the requirements in ISO 9001 are broader than the requirements for individual processes that can be represented in a process reference model.

Some requirements are general requirements for a QMS that apply across all processes.

For example, ISO 9001:2015, 5.1.1, Leadership and commitment for the quality management system:

> Top management shall demonstrate leadership and commitment with respect to the quality management system by:
>
> a) taking accountability for the effectiveness of the quality management system;
>
> b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;
>
> c) ensuring the integration of the quality management system requirements into the organization's business processes;
>
> d) promoting the use of the process approach and risk-based thinking;
>
> e) ensuring that the resources needed for the quality management system are available;
>
> f) communicating the importance of effective quality management and of conforming to the quality management system requirements;
>
> g) ensuring that the quality management system achieves its intended results;

h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;

i) promoting improvement;

j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

Management system standards include general requirements and specific requirements. They include specific requirements for a process including requirements for the interaction of processes.

A.5 Illustrative example

An example is presented to explain the relationship between the requirements perspective of processes (i.e. from the viewpoint of ISO 9001), and the process perspective of ISO/IEC 33002. The example is that of the internal audit process. This process is well understood in terms of its expected outcomes (i.e. in terms of the needs of conformity assessment), and it also has a comprehensive set of requirements in ISO 9001.

A.5.1 Internal audit requirements and the internal audit process

Each process in 5.2 to 5.27 is supported by a requirements traceability section. This section provides information about requirements that are supported by the process outcomes in this document. In most cases, the process outcomes are supported by requirements from several subclauses, indicating that requirements for a process that is implemented within a QMS are generally wider than the headline subclause associated with it.

Table A.1 illustrates the relationship between the process reference model process perspective (i.e. as indicated by the outcomes) and the requirements perspective, as indicated by the defined requirements.

Table A.1 — The internal audit process: process outcome and requirements perspective

Process reference model perspective		ISO 9001:2015 requirements perspective	
Process outcome	**Process outcome description**	**Reference**	**Requirement definition**
1	The scope and purpose of each audit is defined.	9.2.2	The organization shall: b) define the audit criteria and scope for each audit;
2	The objectivity and impartiality of the conduct of audits and selection of auditors are assured.	9.2.2	The organization shall: c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
3	Conformity of selected services, products and processes with requirements, plans and agreements is determined.	9.2.1	The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system: a) conforms to: 1) the organization's own requirements for its quality management system; 2) the requirements of this International Standard; b) is effectively implemented and maintained.
4	Audit results are produced.	9.2.2	The organization shall: a) ... results of [previous] audits;

A.6 Mappings of requirements with process outcomes

Table A.2 identifies subclauses and singular requirements, and associated outcomes.

Table A.2 — Mappings of ISO 9001 requirements with process outcomes

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
Understanding the organization and its context The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.	4.1	TOP.01	**Leadership** 1. The context of the organization, including the expectations of its relevant interested parties, are understood and analysed.
Understanding the organization and its context The organization shall monitor and review information about these external and internal issues.	4.1	COM.09	**Operational implementation and control** 4. Suitability and effectiveness of the actions taken to achieve the management system objectives are reviewed.
Understanding the needs and expectations of interested parties Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine: a) the interested parties that are relevant to the quality management system;	4.2	TOP.01	**Leadership** 1. The context of the organization, including the expectations of its relevant interested parties, are understood and analysed.
Understanding the needs and expectations of interested parties Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, the organization shall determine: b) the requirements of these interested parties that are relevant to the quality management system.	4.2	TOP.01	**Leadership** 1. The context of the organization, including the expectations of its relevant interested parties, are understood and analysed.
Understanding the needs and expectations of interested parties The organization shall monitor and review information about these interested parties and their relevant requirements.	4.2	COM.09	**Operational implementation and control** 4. Suitability and effectiveness of the actions taken to achieve the management system objectives are reviewed.
Determining the scope of the quality management system The organization shall determine the boundaries and applicability of the quality management system to establish its scope.	4.3	TOP.01	**Leadership** 2. The scope of management system activities is defined, taking the context of the organization into consideration.
Determining the scope of the quality management system When determining this scope, the organization shall consider: a) the external and internal issues referred to in 4.1; b) the requirements of relevant interested parties referred to in 4.2; c) the products and services of the organization.	4.3	TOP.01	**Leadership** 2. The scope of management system activities is defined, taking the context of the organization into consideration.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
Determining the scope of the quality management system The organization shall apply all the requirements of this International Standard if they are applicable within the determined scope of its quality management system.	4.3	TOP.01	**Leadership** 2. The scope of management system activities is defined, taking the context of the organization into consideration.
Determining the scope of the quality management system The scope of the organization's quality management system shall be available [and be maintained] as [documented] information.	4.3	COM.02	**Documentation management** 1. Documented information to be documented is identified.
Determining the scope of the quality management system The scope of the organization's quality management system shall be [available and be] maintained as documented information.	4.3	COM.02	**Documentation management** 3. The documented information content status is known.
Determining the scope of the quality management system The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.	4.3	TOP.01	**Leadership** 2. The scope of management system activities is defined, taking the context of the organization into consideration.
Determining the scope of the quality management system Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.	4.3	TOP.01	**Leadership** 2. The scope of management system activities is defined, taking the context of the organization into consideration.
The organization shall establish, implement, maintain and continually improve a quality management system, including the processes needed and their interactions, in accordance with the requirements of this International Standard.	4.4.1	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
The organization shall determine the processes needed for the quality management system and their application throughout the organization,	4.4.1	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
.. and shall: a) determine the inputs required and the outputs expected from these processes;	4.4.1	COM.08	**Operational planning** 2. Process input and output products are determined.
.. and shall: b) determine the sequence and interaction of these processes;	4.4.1	COM.08	**Operational planning** 4. The sequence and interaction of the process with other processes is determined.
.. and shall: c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;	4.4.1	COM.08	**Operational planning** 7. Methods for monitoring the effectiveness and suitability of the process are determined.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
.. and shall: d) determine the resources needed for these processes ensure their availability;	4.4.1	COM.08	**Operational planning** 6. The required resources for performing the process are identified.
.. and shall: e) assign the responsibilities and authorities for these processes;	4.4.1	COM.08	**Operational planning** 5. The required competencies and roles for performing the process are identified.
.. and shall: f) address the risks and opportunities as determined in accordance with the requirements of 6.1;	4.4.1	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
.. and shall: g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;	4.4.1	COM.08	**Operational planning** 7. Methods for monitoring the effectiveness and suitability of the process are determined.
.. and shall: h) improve the processes and the quality management system.	4.4.1	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
To the extent necessary, the organization shall: a) maintain documented information to support the operation of its processes;	4.4.2	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
To the extent necessary, the organization shall: b) retain documented information to have confidence that the processes are being carried out as planned.	4.4.2	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
General Top management shall demonstrate leadership and commitment with respect to the quality management system [by:[	5.1.1	TOP.01	**Leadership** 5. Commitment and leadership with respect to the management system is demonstrated.
General ..by: a) taking accountability for the effectiveness of the quality management system;	5.1.1	TOP.01	**Leadership** 5. Commitment and leadership with respect to the management system is demonstrated.
General ..by: b) ensuring that the quality policy [and quality objectives] are established for the quality management system and are compatible with the context and strategic direction of the organization;	5.1.1	TOP.01	**Leadership** 3. The management system policy and objectives are defined.
General ..by: b) ensuring that the [quality policy and] quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;	5.1.1	TOP.01	**Leadership** 3. The management system policy and objectives are defined.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
General ..by: c) ensuring the integration of the quality management system requirements into the organization's business processes;	5.1.1	TOP.01	**Leadership** 5. Commitment and leadership with respect to the management system is demonstrated.
General ..by: d) promoting the use of the process approach and risk-based thinking;	5.1.1	TOP.01	**Leadership** 5. Commitment and leadership with respect to the management system is demonstrated.
General ..by: e) ensuring that the resources needed for the quality management system are available;	5.1.1	TOP.01	**Leadership** 5. Commitment and leadership with respect to the management system is demonstrated.
General ..by: f) communicating the importance of effective quality management and of conforming to the quality management system requirements;	5.1.1	COM.01	**Communication management** 6. Information products are communicated to relevant interested parties.
General ..by: g) ensuring that the quality management system achieves its intended results;	5.1.1	TOP.01	**Leadership** 5. Commitment and leadership with respect to the management system is demonstrated.
General ..by: h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;	5.1.1	TOP.01	**Leadership** 5. Commitment and leadership with respect to the management system is demonstrated.
General ..by: i) promoting improvement;	5.1.1	TOP.01	**Leadership** 5. Commitment and leadership with respect to the management system is demonstrated.
General ..by: j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.	5.1.1	TOP.01	**Leadership** 5. Commitment and leadership with respect to the management system is demonstrated.
Customer focus Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that: a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met; b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed; c) the focus on enhancing customer satisfaction is maintained.	5.1.2	TOP.01	**Leadership** 5. Commitment and leadership with respect to the management system is demonstrated.
Establishing the quality policy Top management shall establish, [implement and maintain] a quality policy that:..	5.2.1	TOP.01	**Leadership** 3. The management system policy and objectives are defined.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
Establishing the quality policy Top management shall [establish], implement [and maintain] a quality policy that:..	5.2.1	COM.09	**Operational implementation and control** 3. Actions required to achieve the management system objectives are implemented.
Establishing the quality policy Top management shall [establish, implement and] maintain a quality policy that:..	5.2.1	COM.09	**Operational implementation and control** 4. Suitability and effectiveness of the actions taken to achieve the management system objectives are reviewed.
Establishing the quality policy .. that: a) is appropriate to the purpose and context of the organization and supports its strategic direction;	5.2.1	COM.08	**Operational planning** 1. Process requirements are identified.
Establishing the quality policy .. that: b) provides a framework for setting quality objectives;	5.2.1	COM.08	**Operational planning** 1. Process requirements are identified.
Establishing the quality policy .. that: c) includes a commitment to satisfy applicable requirements;	5.2.1	COM.08	**Operational planning** 1. Process requirements are identified.
Establishing the quality policy .. that: d) includes a commitment to continual improvement of the quality management system.	5.2.1	COM.08	**Operational planning** 1. Process requirements are identified.
Communicating the quality policy The quality policy shall: a) be available [and be maintained] as documented information;	5.2.2	COM.02	**Documentation management** 1. Documented information to be documented is identified.
Communicating the quality policy The quality policy shall: a) be [available and be] maintained as documented information;	5.2.2	COM.02	**Documentation management** 4. Documented information is current, complete and valid.
Communicating the quality policy The quality policy shall: b) be communicated, understood and applied within the organization;	5.2.2	COM.01	**Communication management** 6. Information products are communicated to relevant interested parties.
Communicating the quality policy The quality policy shall: c) be available to relevant interested parties, as appropriate.	5.2.2	COM.02	**Documentation management** 6. Documented information is available to relevant interested parties.
Organizational roles, responsibilities and authorities Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, [communicated and understood within the organization.]	5.3	COM.08	**Operational planning** 5. The required competencies and roles for performing the process are identified.
Organizational roles, responsibilities and authorities Top management shall ensure that the responsibilities and authorities for relevant roles are [assigned], communicated and understood within the organization.	5.3	COM.09	**Operational implementation and control** 1. The required roles, responsibilities and authorities are allocated.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
Organizational roles, responsibilities and authorities Top management shall assign the responsibility and authority for: a) ensuring that the quality management system conforms to the requirements of this International Standard;	5.3	COM.08	**Operational planning** 5. The required competencies and roles for performing the process are identified.
Organizational roles, responsibilities and authorities Top management shall assign the responsibility and authority for: b) ensuring that the processes are delivering their intended outputs;	5.3	COM.08	**Operational planning** 5. The required competencies and roles for performing the process are identified.
Organizational roles, responsibilities and authorities Top management shall assign the responsibility and authority for: c) reporting on the performance of the quality management system and on opportunities for improvement (see 10.1), in particular to top management;	5.3	COM.08	**Operational planning** 5. The required competencies and roles for performing the process are identified.
Organizational roles, responsibilities and authorities Top management shall assign the responsibility and authority for: d) ensuring the promotion of customer focus throughout the organization;	5.3	COM.08	**Operational planning** 5. The required competencies and roles for performing the process are identified.
Organizational roles, responsibilities and authorities Top management shall assign the responsibility and authority for: e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.	5.3	COM.08	**Operational planning** 5. The required competencies and roles for performing the process are identified.
When planning for the quality management system, [the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to: a) give assurance that the quality management system can achieve its intended result(s); b) enhance desirable effects; c) prevent, or reduce, undesired effects; d) achieve improvement.]	6.1.1	COM.08	**Operational planning** 8. Plans for the deployment of the process are developed.
[When planning for the quality management system], the organization shall consider the issues referred to in 4.1 and the requirements referred to in 4.2 and determine the risks and opportunities that need to be addressed to: a) give assurance that the quality management system can achieve its intended result(s); b) enhance desirable effects; c) prevent, or reduce, undesired effects; d) achieve improvement.	6.1.1	COM.08	**Operational planning** 1. Process requirements are identified.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
The organization shall plan: a) actions to address these risks and opportunities; b) how to: 1) integrate and implement the actions into its quality management system processes (see 4.4); 2) evaluate the effectiveness of these actions.	6.1.2	COM.08	**Operational planning** 8. Plans for the deployment of the process are developed.
Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services.	6.1.2	COM.11	**Risk management** 6. Selected risks are treated.
The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.	6.2.1	TOP.01	**Leadership** 3. The management system policy and objectives are defined.
The quality objectives shall: a) be consistent with the quality policy;	6.2.1	TOP.01	**Leadership** 3. The management system policy and objectives are defined.
The quality objectives shall: b) be measurable;	6.2.1	TOP.01	**Leadership** 3. The management system policy and objectives are defined.
The quality objectives shall: c) take into account applicable requirements;	6.2.1	TOP.01	**Leadership** 3. The management system policy and objectives are defined.
The quality objectives shall: d) be relevant to conformity of products and services and to enhancement of customer satisfaction;	6.2.1	TOP.01	**Leadership** 3. The management system policy and objectives are defined.
The quality objectives shall: e) be monitored;	6.2.1	TOP.01	**Leadership** 3. The management system policy and objectives are defined.
The quality objectives shall: f) be communicated;	6.2.1	TOP.01	**Leadership** 3. The management system policy and objectives are defined.
The quality objectives shall: g) be updated as appropriate.	6.2.1	COM.02	**Documentation management** 3. The documented information content status is known.
The organization shall maintain documented information on the quality objectives.	6.2.1	COM.02	**Documentation management** 4. Documented information is current, complete and valid.
When planning how to achieve its quality objectives, the organization shall determine: a) what will be done;	6.2.2	COM.08	**Operational planning** 1. Process requirements are identified.
When planning how to achieve its quality objectives, the organization shall determine: b) what resources will be required;	6.2.2	COM.08	**Operational planning** 6. The required resources for performing the process are identified.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
When planning how to achieve its quality objectives, the organization shall determine: c) who will be responsible;	6.2.2	COM.08	**Operational planning** 5. The required competencies and roles for performing the process are identified.
When planning how to achieve its quality objectives, the organization shall determine: d) when it will be completed;	6.2.2	COM.08	**Operational planning** 8. Plans for the deployment of the process are developed.
When planning how to achieve its quality objectives, the organization shall determine: e) how the results will be evaluated.	6.2.2	COM.08	**Operational planning** 7. Methods for monitoring the effectiveness and suitability of the process are determined.
Planning of changes When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).	6.3	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
Planning of changes The organization shall consider: a) the purpose of the changes and their potential consequences; b) the integrity of the quality management system; c) the availability of resources; d) the allocation or reallocation of responsibilities and authorities.	6.3	COM.08	**Operational planning** 1. Process requirements are identified.
General The organization shall determine [and provide] the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.	7.1.1	COM.08	**Operational planning** 6. The required resources for performing the process are identified.
General The organization shall [determine and] provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.	7.1.1	COM.09	**Operational implementation and control** 2. The required resources are allocated and applied.
General The organization shall consider: a) the capabilities of, and constraints on, existing internal resources;	7.1.1	COM.08	**Operational planning** 6. The required resources for performing the process are identified.
General The organization shall consider: b) what needs to be obtained from external providers.	7.1.1	COM.08	**Operational planning** 6. The required resources for performing the process are identified.
People The organization shall determine [and provide] the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.	7.1.2	COM.09	**Operational implementation and control** 2. The required resources are allocated and applied.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
People The organization shall [determine and] provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.	7.1.2	COM.09	**Operational implementation and control** 2. The required resources are allocated and applied.
Infrastructure The organization shall determine, [provide and maintain] the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.	7.1.3	COM.08	**Operational planning** 1. Process requirements are identified.
Infrastructure The organization shall [determine], provide [and maintain] the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.	7.1.3	COM.09	**Operational implementation and control** 3. Actions required to achieve the management system objectives are implemented.
Infrastructure The organization shall [determine, provide and] maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.	7.1.3	COM.09	**Operational implementation and control** 3. Actions required to achieve the management system objectives are implemented.
Environment for the operation of processes The organization shall determine, [provide and maintain] the environment necessary for the operation of its processes and to achieve conformity of products and services.	7.1.4	COM.08	**Operational planning** 1. Process requirements are identified.
Environment for the operation of processes The organization shall [determine,] provide [and maintain] the environment necessary for the operation of its processes and to achieve conformity of products and services.	7.1.4	COM.09	**Operational implementation and control** 3. Actions required to achieve the management system objectives are implemented.
Environment for the operation of processes The organization shall [determine, provide and] maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.	7.1.4	COM.09	**Operational implementation and control** 4. Suitability and effectiveness of the actions taken to achieve the management system objectives are reviewed.
General The organization shall determine [and provide] the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.	7.1.5.1	COM.08	**Operational planning** 1. Process requirements are identified.
General The organization shall [determine and] provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.	7.1.5.1	COM.09	**Operational implementation and control** 3. Actions required to achieve the management system objectives are implemented.
General The organization shall ensure that the resources provided: a) are suitable for the specific type of monitoring and measurement activities being undertaken;	7.1.5.1	COM.09	**Operational implementation and control** 2. The required resources are allocated and applied.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
General The organization shall ensure that the resources provided: b) are maintained to ensure their continuing fitness for their purpose.	7.1.5.1	COM.09	**Operational implementation and control** 2. The required resources are allocated and applied.
General The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.	7.1.5.1	COM.02	**Documentation management** 1. Documented information to be documented is identified.
Measurement traceability When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be: a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards;	7.1.5.2	ORG.02	**Measurement resource management** 4. The calibration status of measurement resource items is confirmed at appropriate intervals.
Measurement traceability When no such standards exist, the basis used for calibration or verification shall be retained as documented information;	7.1.5.2	ORG.02	**Measurement resource management** 4. The calibration status of measurement resource items is confirmed at appropriate intervals.
Measurement traceability When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be: b) identified in order to determine their status;	7.1.5.2	ORG.02 ORG.02	**Measurement resource management** 3. Measurement resource items are identified. **Measurement resource management** 4. The calibration status of measurement resource items is confirmed at appropriate intervals.
Measurement traceability When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be: c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.	7.1.5.2	ORG.02	**Measurement resource management** 4. The calibration status of measurement resource items is confirmed at appropriate intervals.
Measurement traceability The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, [and shall take appropriate action as necessary.]	7.1.5.2	ORG.02	**Measurement resource management** 6. Mal-performing measurement resources are segregated and controlled in order to avoid unintended use.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
Measurement traceability [The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose,] and shall take appropriate action as necessary.	7.1.5.2	COM.07	**Non-conformity management** 1. Non-conformities are identified.
Organizational knowledge The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.	7.1.6	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
Organizational knowledge This knowledge shall be maintained [and be made available to the extent necessary.]	7.1.6	COM.02	**Documentation management** 4. Documented information is current, complete and valid.
Organizational knowledge This knowledge shall be [maintained and be] made available to the extent necessary.	7.1.6	COM.02	**Documentation management** 6. Documented information is available to relevant interested parties.
Organizational knowledge When addressing changing needs and trends, the organization shall consider its current knowledge and determine how to acquire or access any necessary additional knowledge and required updates.	7.1.6	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
Competence The organization shall: a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;	7.2	COM.03	**Human resource management** 1. The competencies required by the organization to produce products and services are identified.
Competence The organization shall: b) ensure that these persons are competent on the basis of appropriate education, training, or experience;	7.2	COM.03	**Human resource management** 2. Identified competency gaps are filled through training or recruitment.
Competence The organization shall: c) where applicable, take actions to acquire the necessary competence, [and evaluate the effectiveness of the actions taken;]	7.2	COM.09	**Operational implementation and control** 4. Suitability and effectiveness of the actions taken to achieve the management system objectives are reviewed.
Competence The organization shall: c) where applicable, [take actions to acquire the necessary competence,] and evaluate the effectiveness of the actions taken;	7.2	COM.09	**Operational implementation and control** 4. Suitability and effectiveness of the actions taken to achieve the management system objectives are reviewed.
Competence The organization shall: d) retain appropriate documented information as evidence of competence.	7.2	COM.02	**Documentation management** 1. Documented information to be documented is identified.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
Awareness The organization shall ensure that persons doing work under the organization's control are aware of: a) the quality policy; b) relevant quality objectives; c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance; d) the implications of not conforming with the quality management system requirements.	7.3	COM.03	**Human resource management** 3. Understanding of roles and activities in achieving organisational objectives in product and service provision is demonstrated by each person.
Communication The organization shall determine the internal and external communications relevant to the quality management system, including: b) when to communicate;	7.4	COM.01	**Communication management** 4. Events that require communication actions are identified.
Communication The organization shall determine the internal and external communications relevant to the quality management system, including: c) with whom to communicate;	7.4	COM.01	**Communication management** 2. Parties to communicate with are identified.
Communication The organization shall determine the internal and external communications relevant to the quality management system, including: d) how to communicate;	7.4	COM.01	**Communication management** 5. The channel for the communication is selected.
Communication The organization shall determine the internal and external communications relevant to the quality management system, including: e) who communicates.	7.4	COM.01	**Communication management** 3. The party responsible for the communication is identified.
General The organization's quality management system shall include: a) documented information required by this International Standard;	7.5.1	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
General The organization's quality management system shall include: b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.	7.5.1	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
Creating and updating a) When creating and updating documented information, the organization shall ensure appropriate: a) identification and description (e.g. a title, date, author, or reference number);	7.5.2	COM.08	**Operational planning** 1. Process requirements are identified.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
Creating and updating When creating and updating documented information, the organization shall ensure appropriate: b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);	7.5.2	COM.02	**Documentation management** 2. The forms of documented information representation are defined.
Creating and updating c) When creating and updating documented information, the organization shall ensure appropriate: c) review [and approval] for suitability and adequacy.	7.5.2	COM.02	**Documentation management** 2. The forms of documented information representation are defined.
Creating and updating c) When creating and updating documented information, the organization shall ensure appropriate: c) [review and] approval for suitability and adequacy.	7.5.2	COM.02	**Documentation management** 5. Documented information is released according to defined criteria.
Documented information required by the quality management system and by this International Standard shall be controlled [to ensure: a) it is available and suitable for use, where and when it is needed;]	7.5.3.1	COM.02	**Documentation management** 4. Documented information is current, complete and valid.
Documented information required by the quality management system and by this International Standard shall be controlled to ensure: a) it is available and suitable for use, where and when it is needed;	7.5.3.1	COM.02	**Documentation management** 6. Documented information is available to relevant interested parties.
Documented information required by the quality management system and by this International Standard shall be controlled to ensure: b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).	7.5.3.1	COM.02	**Documentation management** 4. Documented information is current, complete and valid.
a) For the control of documented information, the organization shall address the following activities, as applicable: a) distribution, access, retrieval and use;	7.5.3.2	COM.02	**Documentation management** 6. Documented information is available to relevant interested parties.
b) For the control of documented information, the organization shall address the following activities, as applicable: b) storage and preservation, including preservation of legibility;	7.5.3.2	COM.02	**Documentation management** 4. Documented information is current, complete and valid.
c) For the control of documented information, the organization shall address the following activities, as applicable: c) control of changes (e.g. version control);	7.5.3.2	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
d) For the control of documented information, the organization shall address the following activities, as applicable: d) retention and disposition.	7.5.3.2	COM.02	**Documentation management** 7. Documented information is archived, or disposed of, as required.
Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system shall be identified as appropriate, [and be controlled.]	7.5.3.2	COM.02	**Documentation management** 2. The forms of documented information representation are defined.
Documented information of external origin determined by the organization to be necessary for the planning and operation of the quality management system [shall be identified as appropriate], and be controlled.	7.5.3.2	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
Documented information retained as evidence of conformity shall be protected from unintended alterations.	7.5.3.2	COM.02	**Documentation management** 4. Documented information is current, complete and valid.
Operational planning and control The organization shall plan, [implement and control] the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:..	8.1	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
Operational planning and control The organization shall [plan,] implement [and control] the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:..	8.1	COM.09	**Operational implementation and control** 3. Actions required to achieve the management system objectives are implemented.
Operational planning and control The organization shall [plan, implement and] control the processes (see 4.4) needed to meet the requirements for the provision of products and services, and to implement the actions determined in Clause 6, by:..	8.1	COM.09	**Operational implementation and control** 4. Suitability and effectiveness of the actions taken to achieve the management system objectives are reviewed.
Operational planning and control The organization shall .. by: a) determining the requirements for the products and services;	8.1	TEC.07	**Product/service requirements** 3. The requirements for the product/service are defined.
Operational planning and control The organization shall .. by: b) establishing criteria for: 1) the processes;	8.1	COM.08	**Operational planning** 2. Process input and output products are determined.
Operational planning and control The organization shall .. by: b) establishing criteria for: 2) the acceptance of products and services;	8.1	COM.08	**Operational planning** 4. The sequence and interaction of the process with other processes is determined.
Operational planning and control The organization shall .. by: c) determining the resources needed to achieve conformity to the product and service requirements;	8.1	COM.08	**Operational planning** 6. The required resources for performing the process are identified.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
Operational planning and control The organization shall .. by: d) implementing control of the processes in accordance with the criteria;	8.1	COM.09	**Operational implementation and control** 3. Actions required to achieve the management system objectives are implemented.
Operational planning and control The organization shall .. by: e) determining and maintaining and retaining documented information to the extent necessary: 1) to have confidence that the processes have been carried out as planned;	8.1	COM.02	**Documentation management** 1. Documented information to be documented is identified.
Operational planning and control The organization shall .. by: e) determining and maintaining and retaining documented information to the extent necessary: 2) to demonstrate the conformity of products and services to their requirements.	8.1	COM.02	**Documentation management** 1. Documented information to be documented is identified.
Operational planning and control The output of this planning shall be suitable for the organization's operations.	8.1	COM.08	**Operational planning** 1. Process requirements are identified.
Operational planning and control The organization shall control planned changes [and review the consequences of unintended changes], taking action to mitigate any adverse effects, as necessary.	8.1	COM.09	**Operational implementation and control** 5. Deviations from planned arrangements are corrected when targets are not achieved.
Operational planning and control The organization shall [control planned changes and] review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.	8.1	COM.09	**Operational implementation and control** 5. Deviations from planned arrangements are corrected when targets are not achieved.
Operational planning and control The organization shall ensure that outsourced processes are controlled (see 8.4).	8.1	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
Customer communication Communication with customers shall include: a) providing information relating to products and services; b) handling enquiries, contracts or orders, including changes; c) obtaining customer feedback relating to products and services, including customer complaints; d) handling or controlling customer property; e) establishing specific requirements for contingency actions, when relevant.	8.2.1	COM.08	**Operational planning** 1. Process requirements are identified.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
Determining the requirements for products and services a) 0) When determining the requirements for the products and services to be offered to customers, the organization shall ensure that: a) the requirements for the products and services are defined, ..	8.2.2	TEC.07	**Product/service requirements** 3. The requirements for the product/service are defined.
Determining the requirements for products and services a) 1) When determining the requirements for the products and services to be offered to customers, the organization shall ensure that: a) the requirements for the products and services are defined, including: [1) any applicable statutory and regulatory requirements;] 2) those considered necessary by the organization;	8.2.2	TEC.07	**Product/service requirements** 3. The requirements for the product/service are defined.
Determining the requirements for products and services a) 2) When determining the requirements for the products and services to be offered to customers, the organization shall ensure that: [a) the requirements for the products and services are defined], including:] 1) any applicable statutory and regulatory requirements; [2) those considered necessary by the organization;]	8.2.2	TEC.07	**Product/service requirements** 3. The requirements for the product/service are defined.
Determining the requirements for products and services b) When determining the requirements for the products and services to be offered to customers, the organization shall ensure that: b) the organization can meet the claims for the products and services it offers.	8.2.2	TEC.09	**Product/service supply** 2. Product/service request(s) are evaluated in terms of mandated product/service delivery criteria.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
The organization shall conduct a review before committing to supply products and services to a customer, to include: a) requirements specified by the customer, including the requirements for delivery and post delivery activities; b) requirements not stated by the customer, but necessary for the specified or intended use, when known; c) requirements specified by the organization; d) statutory and regulatory requirements applicable to the products and services; e) contract or order requirements differing from those previously expressed.	8.2.3.1	TEC.09	**Product/service supply** 2. Product/service request(s) are evaluated in terms of mandated product/service delivery criteria.
The organization shall ensure that contract or order requirements differing from those previously defined are resolved.	8.2.3.1	COM.09	**Operational implementation and control** 4. Suitability and effectiveness of the actions taken to achieve the management system objectives are reviewed.
The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.	8.2.3.1	TEC.09	**Product/service supply** 3. A response to a customer's product/service request is produced.
The organization shall retain [documented] information, as applicable: a) on the results of the review;	8.2.3.2	TEC.09	**Product/service supply** 2. Product/service request(s) are evaluated in terms of mandated product/service delivery criteria.
[The organization shall retain] documented information, [as applicable: a) on the results of the review;]	8.2.3.2	COM.02	**Documentation management** 1. Documented information to be documented is identified.
The organization shall retain [documented] information, as applicable: b) on any new requirements for the products and services.	8.2.3.2	TEC.07	**Product/service requirements** 3. The requirements for the product/service are defined.
[The organization shall retain [documented information, [as applicable: b) on any new requirements for the products and services]	8.2.3.2	COM.02	**Documentation management** 1. Documented information to be documented is identified.
Changes to requirements for products and services The organization shall ensure that [relevant documented] information is amended, [and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.]	8.2.4	COM.02	**Documentation management** 4. Documented information is current, complete and valid.
Changes to requirements for products and services [The organization shall ensure that relevant] documented information is amended [, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.]	8.2.4	COM.02	**Documentation management** 3. The documented information content status is known.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
Changes to requirements for products and services [The organization shall ensure that relevant documented information is amended,] and that relevant persons are made aware of the changed requirements, [when the requirements for products and services are changed.	8.2.4	COM.01	**Communication management** 6. Information products are communicated to relevant interested parties.
General The organization shall establish, [implement and maintain] a design and development process that is appropriate to ensure the subsequent provision of products and services.	8.3.1	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
General The organization shall [establish], implement [and maintain] a design and development process that is appropriate to ensure the subsequent provision of products and services.	8.3.1	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
General The organization shall [establish, implement and] maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.	8.3.1	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
Design and development planning a) In determining the stages and controls for design and development, the organization shall consider: a) the nature, duration and complexity of the design and development activities;	8.3.2	COM.08	**Operational planning** 8. Plans for the deployment of the process are developed.
Design and development planning b) In determining the stages and controls for design and development, the organization shall consider: b) the required process stages, including applicable design and development reviews;	8.3.2	COM.08	**Operational planning** 8. Plans for the deployment of the process are developed.
Design and development planning c) In determining the stages and controls for design and development, the organization shall consider: c) the required design and development verification and validation activities;	8.3.2	COM.08	**Operational planning** 8. Plans for the deployment of the process are developed.
Design and development planning d) In determining the stages and controls for design and development, the organization shall consider: d) the responsibilities and authorities involved in the design and development process;	8.3.2	COM.08	**Operational planning** 8. Plans for the deployment of the process are developed.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
Design and development planning e) In determining the stages and controls for design and development, the organization shall consider: e) the internal and external resource needs for the design and development of products and services;	8.3.2	COM.08	**Operational planning** 8. Plans for the deployment of the process are developed.
Design and development planning f) In determining the stages and controls for design and development, the organization shall consider: f) the need to control interfaces between persons involved in the design and development process;	8.3.2	COM.08	**Operational planning** 8. Plans for the deployment of the process are developed.
Design and development planning g) In determining the stages and controls for design and development, the organization shall consider: g) the need for involvement of customers and users in the design and development process;	8.3.2	COM.08	**Operational planning** 8. Plans for the deployment of the process are developed.
Design and development planning h) In determining the stages and controls for design and development, the organization shall consider: h) the requirements for subsequent provision of products and services;	8.3.2	COM.08	**Operational planning** 8. Plans for the deployment of the process are developed.
Design and development planning i) In determining the stages and controls for design and development, the organization shall consider: i) the level of control expected for the design and development process by customers and other relevant interested parties;	8.3.2	COM.08	**Operational planning** 8. Plans for the deployment of the process are developed.
Design and development planning j) In determining the stages and controls for design and development, the organization shall consider: j) the documented information needed to demonstrate that design and development requirements have been met.	8.3.2	COM.02	**Documentation management** 1. Documented information to be documented is identified.
Design and development inputs The organization shall determine the requirements essential for the specific types of products and services to be designed and developed.	8.3.3	TEC.07	**Product/service requirements** 1. The required characteristics and context of use of products/services are identified.
Design and development inputs The organization shall consider: a) functional and performance requirements;	8.3.3	TEC.07	**Product/service requirements** 3. The requirements for the product/service are defined.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
Design and development inputs The organization shall consider: b) information derived from previous similar design and development activities;	8.3.3	TEC.07	**Product/service requirements** 3. The requirements for the product/service are defined.
Design and development inputs The organization shall consider: c) statutory and regulatory requirements;	8.3.3	TEC.07	**Product/service requirements** 2. The constraints for a product/service solution are defined.
Design and development inputs The organization shall consider: d) standards or codes of practice that the organization has committed to implement;	8.3.3	TEC.07	**Product/service requirements** 2. The constraints for a product/service solution are defined.
Design and development inputs The organization shall consider: e) potential consequences of failure due to the nature of the products and services.	8.3.3	TEC.07	**Product/service requirements** 2. The constraints for a product/service solution are defined.
Design and development inputs Inputs shall be adequate for design and development purposes, complete and unambiguous.	8.3.3	TEC.07	**Product/service requirements** 3. The requirements for the product/service are defined.
Design and development inputs Conflicting design and development inputs shall be resolved.	8.3.3	TEC.07	**Product/service requirements** 3. The requirements for the product/service are defined.
Design and development inputs The organization shall retain documented information on design and development inputs.	8.3.3	COM.02	**Documentation management** 1. Documented information to be documented is identified.
Design and development controls a) The organization shall apply controls to the design and development process to ensure that: a) the results to be achieved are defined;	8.3.4	COM.08	**Operational planning** 1. Process requirements are identified.
Design and development controls b) The organization shall apply controls to the design and development process to ensure that: b) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;	8.3.4	TEC.05	**Product/service planning** 6. Plans for the development of the product/service are developed.
		TEC.08	**Product/service review** 3. Required review activities are performed.
Design and development controls c) The organization shall apply controls to the design and development process to ensure that: c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;	8.3.4	TEC.11	**Product/service verification** 3. Required verification activities are performed.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
Design and development controls d) The organization shall apply controls to the design and development process to ensure that: d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;	8.3.4	TEC.10	**Product/service validation** 3. Required validation activities are performed.
Design and development controls e) The organization shall apply controls to the design and development process to ensure that: e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;	8.3.4	TEC.08	**Product/service review** 4. Action items are identified.
Design and development controls f) The organization shall apply controls to the design and development process to ensure that: f) documented information of these activities is retained.	8.3.4	COM.02	**Documentation management** 1. Documented information to be documented is identified.
Design and development outputs a) The organization shall ensure that design and development outputs: a) meet the input requirements;	8.3.5	TEC.04	**Product/service design** 1. Design for each product/service component is developed in accordance with defined requirements.
Design and development outputs b) The organization shall ensure that design and development outputs: b) are adequate for the subsequent processes for the provision of products and services;	8.3.5	TEC.04	**Product/service design** 2. External and internal interfaces for each product/service component are defined.
Design and development outputs c) The organization shall ensure that design and development outputs: c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;	8.3.5	TEC.09	**Product/service supply** 4. An agreement is established between the customer and the supplier for providing the product/ service.
Design and development outputs d) The organization shall ensure that design and development outputs: d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.	8.3.5	TEC.09	**Product/service supply** 6. Conformity to applicable stated and implied customer and supplier requirements by internal processes and/or product/service provided is verified.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
Design and development outputs The organization shall retain documented information on design and development outputs.	8.3.5	COM.02	**Documentation management** 1. Documented information to be documented is identified.
Design and development changes The organization shall identify, [review and control] changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.	8.3.6	TEC.03	**Product/service changes** 1. Product/service change requests are identified and classified.
Design and development changes The organization shall [identify], review and [control] changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.	8.3.6	TEC.03	**Product/service changes** 2. Product/service change requests are assessed using defined criteria.
Design and development changes The organization shall [identify, review and] control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.	8.3.6	TEC.03	**Product/service changes** 3. Product/service changes are implemented, as appropriate.
Design and development changes The organization shall retain documented information on: a) design and development changes; b) the results of reviews; [c) the authorization of the changes; d) the actions taken to prevent adverse impacts.]	8.3.6	COM.02	**Documentation management** 1. Documented information to be documented is identified.
Design and development changes The organization shall retain documented information on: [a) design and development changes; b) the results of reviews;] c) the authorization of the changes; [d) the actions taken to prevent adverse impacts.]	8.3.6	COM.02	**Documentation management** 1. Documented information to be documented is identified.
Design and development changes The organization shall retain documented information on: [a) design and development changes; b) the results of reviews; c) the authorization of the changes;] d) the actions taken to prevent adverse impacts.	8.3.6	COM.02	**Documentation management** 1. Documented information to be documented is identified.
General The organization shall ensure that externally provided processes, products and services conform to requirements.	8.4.1	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
General a) The organization shall determine the controls to be applied to externally provided processes, products and services when: a) products and services from external providers are intended for incorporation into the organization's own products and services;	8.4.1	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
General b) The organization shall determine the controls to be applied to externally provided processes, products and services when: b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;	8.4.1	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
General c) The organization shall determine the controls to be applied to externally provided processes, products and services when: c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.	8.4.1	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
General The organization shall determine [and apply] criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements.	8.4.1	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
General The organization shall [determine and] apply criteria for the evaluation, selection, monitoring of performance, and re-evaluation of external providers, based on their ability to provide processes or products and services in accordance with requirements.	8.4.1	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
General The organization shall retain [documented] information of these activities and any necessary actions arising from the evaluations.	8.4.1	COM.02	**Documentation management** 1. Documented information to be documented is identified.
General [The organization shall retain] documented information [of these activities and any necessary actions arising from the evaluations.]	8.4.1	COM.02	**Documentation management** 1. Documented information to be documented is identified.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
Type and extent of control The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.	8.4.2	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
Type and extent of control The organization shall: a) ensure that externally provided processes remain within the control of its quality management system;	8.4.2	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
Type and extent of control The organization shall: b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;	8.4.2	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
Type and extent of control The organization shall: c) take into consideration: 1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;	8.4.2	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
Type and extent of control The organization shall: c) take into consideration: 2) the effectiveness of the controls applied by the external provider;	8.4.2	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
Type and extent of control The organization shall: d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.	8.4.2	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
Information for external providers The organization shall ensure the adequacy of requirements prior to their communication to the external provider.	8.4.3	COM.09	**Operational implementation and control** 4. Suitability and effectiveness of the actions taken to achieve the management system objectives are reviewed.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
Information for external providers The organization shall communicate to external providers its requirements for: a) the processes, products and services to be provided; b) the approval of: 1) products and services; 2) methods, processes and equipment; 3) the release of products and services; c) competence, including any required qualification of persons; d) the external providers' interactions with the organization; e) control and monitoring of the external providers' performance to be applied by the organization; f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.	8.4.3	COM.01	**Communication management** 6. Information products are communicated to relevant interested parties.
Control of production and service provision The organization shall implement production and service provision under controlled conditions.	8.5.1	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
Control of production and service provision A. a) 1) Controlled conditions shall include, as applicable: a) the availability of [documented] information that defines: 1) the characteristics of the products to be produced, the services to be provided, [or the activities to be performed; 2) the results to be achieved;]	8.5.1	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
Control of production and service provision B. a) 2) Controlled conditions shall include, as applicable: a) [the availability of [documented] information that defines: 1) the characteristics of the products to be produced, the services to be provided,] or the activities to be performed; 2) the results to be achieved;	8.5.1	COM.02	**Documentation management** 1. Documented information to be documented is identified.
Control of production and service provision C. Controlled conditions shall include, as applicable: a) the availability of [documented] information that defines: [1) the characteristics of the products to be produced, the services to be provided, or] the activities to be performed; 2) the results to be achieved;	8.5.1	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
Control of production and service provision D. [Controlled conditions shall include, as applicable: a) the availability of] documented [information that defines: 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed; 2) the results to be achieved;]	8.5.1	COM.02	**Documentation management** 1. Documented information to be documented is identified.
Control of production and service provision Controlled conditions shall include, as applicable: b) the availability and use of suitable monitoring and measuring resources;	8.5.1	COM.08	**Operational planning** 3. The set of activities that transform the inputs into outputs is determined.
Control of production and service provision Controlled conditions shall include, as applicable: c) the implementation of monitoring and measurement activities at appropriate stages to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;	8.5.1	COM.08 COM.09	**Operational planning** 7. Methods for monitoring the effectiveness and suitability of the process are determined. **Operational implementation and control** 3. Actions required to achieve the management system objectives are implemented.
Control of production and service provision Controlled conditions shall include, as applicable: d) the use of suitable infrastructure and environment for the operation of processes;	8.5.1	COM.08	**Operational planning** 6. The required resources for performing the process are identified.
Control of production and service provision Controlled conditions shall include, as applicable: e) the appointment of competent persons, including any required qualification;	8.5.1	COM.08	**Operational planning** 5. The required competencies and roles for performing the process are identified.
Control of production and service provision Controlled conditions shall include, as applicable: f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;	8.5.1	COM.08	**Operational planning** 4. The sequence and interaction of the process with other processes is determined.
Control of production and service provision Controlled conditions shall include, as applicable: g) the implementation of actions to prevent human error;	8.5.1	COM.08	**Operational planning** 4. The sequence and interaction of the process with other processes is determined.

Table A.2 *(continued)*

ISO 9001:2015		ISO/IEC TS 33054 process reference model	
Control of production and service provision Controlled conditions shall include, as applicable: h) the implementation of release, delivery and post-delivery activities.	8.5.1	COM.08	**Operational planning** 4. The sequence and interaction of the process with other processes is determined.
Identification and traceability The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.	8.5.2	TEC.01	**Configuration management** 1. Items requiring configuration management are identified.
Identification and traceability The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.	8.5.2	TEC.01	**Configuration management** 2. The status of configuration items and modifications is known.
Identification and traceability The organization shall control the unique identification of the outputs when traceability is a requirement, [and shall retain the documented information necessary to enable traceability.]	8.5.2	TEC.01	**Configuration management** 1. Items requiring configuration management are identified.
Identification and traceability [The organization shall control the unique identification of the outputs when traceability is a requirement], and shall retain the documented information necessary to enable traceability.	8.5.2	COM.02	**Documentation management** 1. Documented information to be documented is identified.
Property belonging to customers or external providers The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.	8.5.3	TOP.01	**Leadership** 4. The management system and operational process strategy is determined.
Property belonging to customers or external providers The organization shall identify, [verify, protect and safeguard] customers' or external providers' property provided for use or incorporation into the products and services.	8.5.3	ORG.01	**Asset management** 1. Items requiring asset management are identified.
Property belonging to customers or external providers The organization shall [identify,] verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.	8.5.3	ORG.01	**Asset management** 4. The integrity of assets is assured.
Property belonging to customers or external providers When the property of a customer or external provider is lost, damaged or otherwise found to be unsuitable for use, the organization shall report this to the customer or external provider [and retain documented information on what has occurred.]	8.5.3	ORG.01	**Asset management** 2. Asset status is known.