TECHNICAL SPECIFICATION

# ISO/IEC TS 33073

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# Information technology — Process assessment — Process capability assessment model for quality management

*Technologies de l'information — Évaluation des processus — Modèle d'évaluation de l'aptitude des processus pour le management de la qualité*



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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. In the field of information technology, ISO and IEC have established a joint technical committee, ISO/IEC JTC 1.

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).

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

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

This document was prepared by Technical Committee ISO/IEC JTC 1, *Information technology*, Subcommittee SC 7, *Software and systems engineering*.

# Introduction

This document provides a Quality Management Process Assessment Model (PAM) for use in performing a conformant assessment of process capability in accordance with the requirements of ISO/IEC 33002. It is structured in accordance with the requirements of ISO/IEC 33004 to reflect processes that enable implementation of ISO 9001. The scale for assessing the extent of achievement of process capability is based on ISO/IEC 33020.

The publication of the revised edition of ISO 9001:2015 has rendered the publication of this document as both timely and appropriate.

An integral part of conducting an assessment is to use a PAM that is constructed for that purpose. A PAM is related to a Process Reference Model (PRM) and is conformant with ISO/IEC 33004. ISO/IEC 33002 identifies the minimum requirements for performing an assessment in order to ensure consistency and repeatability of the ratings. ISO/IEC 33002 addresses the assessment of process and the application of process assessment for improvement and capability determination. Results of conformant process assessments may be compared when the scopes of the assessments are considered to be similar.

The requirements for process assessment defined in ISO/IEC 33002 form a structure which:

a) facilitates self-assessment;

b) provides a basis for use in process improvement and capability determination;

c) takes into account the context in which the assessed process is implemented;

d) produces a process rating;

e) addresses the ability of the process to achieve its purpose;

f) is applicable across all application domains and sizes of organization;

g) may provide an objective benchmark between organizations.

The relationship between ISO/IEC TR 24774, ISO 9001, ISO/IEC 33002, ISO/IEC 33004, ISO/IEC 33020, and this document is shown in Figure 1.



 

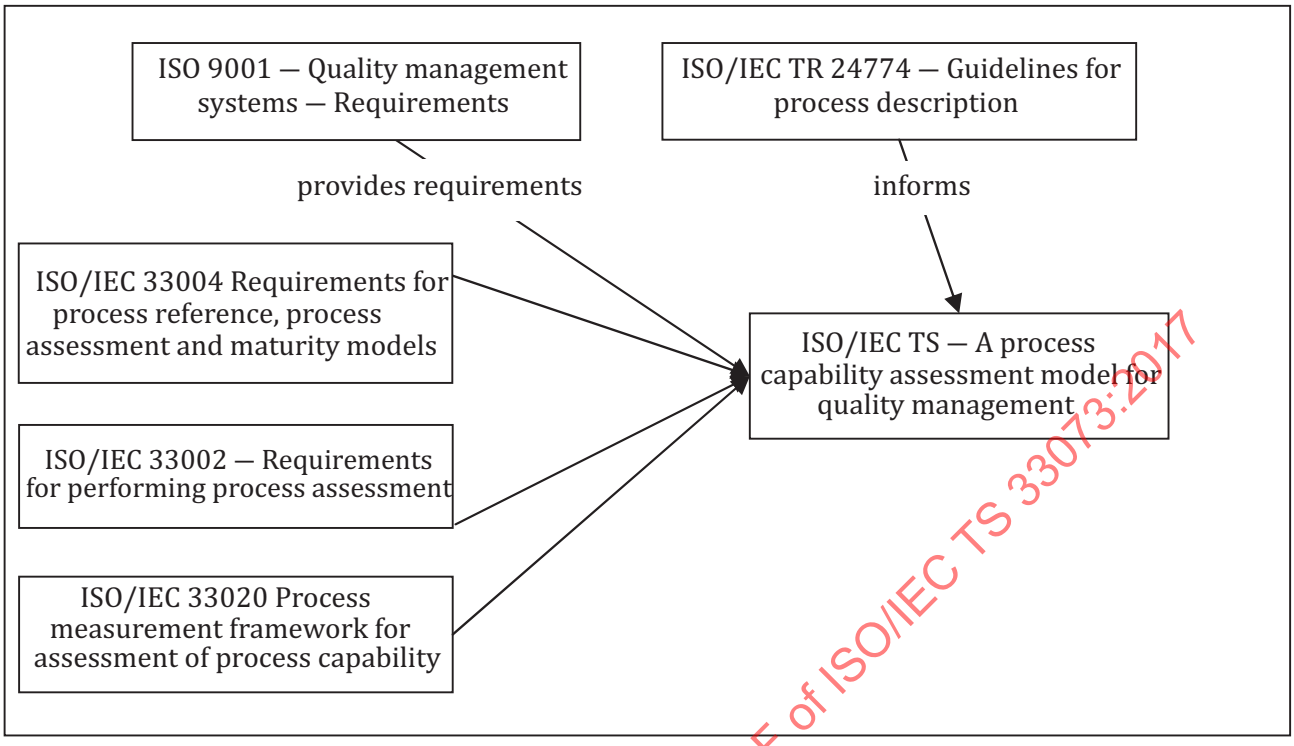


**Figure 1 — Relationships between relevant standards**

Any organization may use processes with additional elements in order to suit it to the environment and circumstances. This PAM contains a set of indicators to be considered when interpreting the intent of its PRM. It provides greater detail to indicate process performance and capability. The indicators may also be used when implementing a process improvement program or to help evaluate and select an assessment model, method, methodology or tools.

As an exemplar, this PAM embodies the core characteristics that could be expected of any PAM consistent with ISO/IEC 33004. Nevertheless, any other PAMs meeting the requirements of ISO/IEC 33004 may be used in a conformant assessment.

This document has a similar structure to ISO/IEC 15504-5 and ISO/IEC 15504–6. It may be used in conjunction with these process assessment models to support joint assessment of quality management processes and system/software life cycle processes.

Within this document:

— Clause 4 provides a detailed description of the structure and key components of a PAM, which includes two dimensions: a process dimension and a capability dimension. Assessment indicators are introduced in this clause.

— Clause 5 addresses the process dimension. The processes are described in the PAM in terms of purpose and outcomes. The PAM includes a set of process performance indicators called base practices for each process. The PAM also defines a second set of indicators of process performance by associating inputs and outputs with each process. Clause 5 is also linked directly to Annex B, which defines the inputs/outputs characteristics.

— Clause 6 addresses the capability dimension. It duplicates the definitions of the capability levels and process attributes from ISO/IEC 33020 and expands each of the nine attributes through the inclusion of a set of generic practices. These generic practices belong to a set of indicators of process capability, in association with generic resource indicators, and generic inputs/outputs indicators. Annex B is also linked directly to Clause 6 as it defines the inputs/outputs characteristics.

— Annex A provides a statement of conformance of the PAM to the requirements defined in ISO/IEC 33004.

— Annex B provides selected characteristics for typical inputs/outputs to assist the assessor in evaluating the capability level of processes.

— Annex C contains three tables. Table C.1 identifies the base practices linked to requirements; Table C.2 identifies the requirements linked to base practices; and lastly, Table C.3 identifies the base practices not linked to requirements.

— Bibliography contains a list of informative references.

# Information technology — Process assessment — Process capability assessment model for quality management

## 1 Scope

This document:

— defines an integrated PRM and PAM that meets the requirements of ISO/IEC 33004 and that supports the performance of an assessment by providing indicators for guidance on the interpretation of the process purposes and outcomes and the process attributes as defined in ISO/IEC 33020;

— provides guidance, by example, on the definition, selection and use of assessment indicators.

A PAM comprises a set of indicators of process performance and process capability. The indicators are used as a basis for collecting the objective evidence that enables an assessor to assign ratings. The set of indicators included in this document is not intended to be an all-inclusive set nor is it intended to be applicable in its entirety.

The PAM in this document is directed at assessment sponsors and competent assessors who wish to select a model and associated documented process method for assessment (for either capability determination or process improvement). Additionally, it can be of use to developers of assessment models in the construction of their own model, by providing examples of good service management practices. It can be used by:

a) service providers to assess and improve a Quality Management System (QMS);

b) service providers to demonstrate their capability for the design, development, transition and delivery of services that fulfil Quality Management requirements.

Any PAM meeting the requirements defined in ISO/IEC 33004 concerning models for process assessment may be used for assessment. Different models and methods can be needed to address differing business needs. The assessment model in this document is provided as an assessment model meeting all the requirements expressed in ISO/IEC 33004.

NOTE **Copyright release for the PAM:** Users of this document can freely reproduce the detailed descriptions contained in the assessment 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

There are no normative references in this document.

## 3 Terms and definitions

No terms and definitions are listed in this document.

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

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

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

# 4 Overview of the Process Assessment Model (PAM)

## 4.1 General

This document provides a PAM that includes examples of assessment indicators.

The PRM defined in this document, associated with the process attributes defined in ISO/IEC 33020, establish a PAM used as a common basis for performing assessments of Quality Management system process capability, allowing for the reporting of results using a common rating scale.

This PAM is a two-dimensional model of the process quality characteristic of process capability. In one dimension, the process dimension, the processes are defined. In the other dimension, the capability dimension, a set of process attributes grouped into capability levels is defined. The process attributes provide the measurable features of the process quality characteristic of process capability.

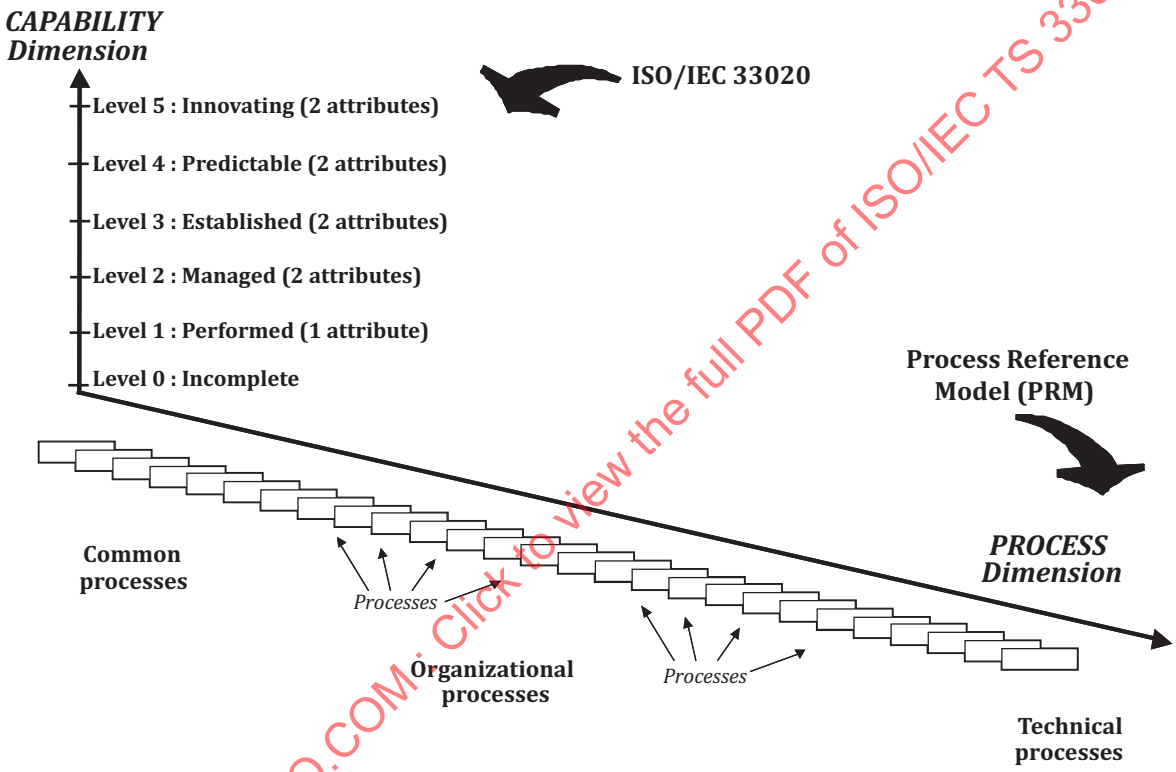


**Figure 2 — Relationship between the Process Assessment Model and its inputs**

Figure 2 shows the relationship between the general structure of the PAM and ISO/IEC 33020.

A PRM conformant with the requirements defined in ISO/IEC 33004 and a capability dimension defined in ISO/IEC 33020 cannot be used alone as the basis for conducting reliable and consistent assessments of process capability since the level of detail provided is not sufficient. The descriptions of process purpose and outcomes in a PRM, and the process attribute definitions in ISO/IEC 33020, need to be supported with a comprehensive set of indicators of process performance and process capability that are used for assessment performance.

The PAM defined in this document is conformant with the ISO/IEC 33004 requirements for a PAM and can be used as the basis for conducting an assessment of Quality Management process capability.

In order to meet the PAM requirements of ISO/IEC 33004, a documented process supporting other requirements of ISO/IEC 33002 is also required. This need may be met, for example, by the adoption of a supporting method for conducting assessments.

## 4.2 Structure of the Process Assessment Model

This subclause describes the detailed structure of the PAM and its key components.

This PAM expands upon the PRM by including a defined set of assessment indicators. Assessment indicators comprise indicators of process performance and process capability and are defined to support an assessor's judgment of the performance and capability of an implemented process.

Clause 5, together with its associated Annex B, describes the components of the process dimension, and Clause 6 describes the components of the capability dimension. Annex A provides a statement of conformance of the PAM to the requirements defined in ISO/IEC 33004.

ISO/IEC 33004 requires that processes included in a PRM satisfy the following.

"*The fundamental elements of a process reference model are the descriptions of the processes within the scope of the model.*

*The process descriptions in the process reference model incorporate a statement of the purpose of the process which describes at a high level the overall objectives of performing the process, together with the set of outcomes which demonstrate successful achievement of the process purpose.*

*A process description shall meet the following requirements:*

a) *a process shall be described in terms of its purpose and process outcomes;*

b) *the set of process outcomes shall be necessary and sufficient to achieve the purpose of the process;*

c) *process descriptions shall not contain or imply aspects of the process quality characteristic beyond the basic level of any relevant process measurement framework conformant with ISO/IEC 33003."*

### 4.2.1 Processes

Figure 3 shows the processes included in the process dimension of the PAM for quality management.

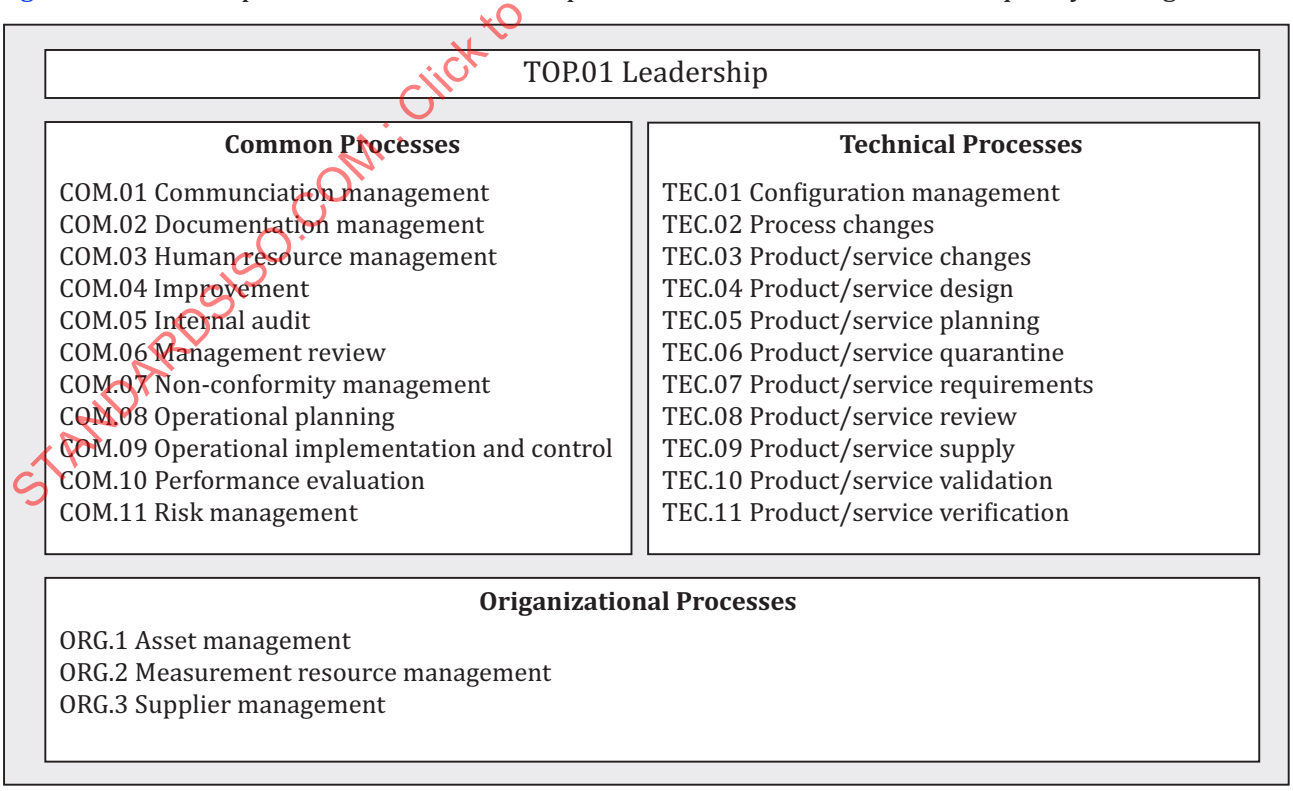


**Figure 3 — Processes in the Process Assessment Model**

### 4.2.2 Process dimension

The process dimension of the PAM includes all processes and shown in Figure 3. Each process in the PAM is described in terms of a purpose statement. These statements contain the unique functional objectives of the process when performed in a particular environment. A list of specific outcomes is associated with each of the process purpose statements, as a list of expected positive results of the performance of the processes.

Satisfying the purpose statements of a process represents the first step in building a level 1 process capability where the expected outcomes are observable. The processes are described in Clause 5.

### 4.2.3 Capability dimension

For the capability dimension, the process capability levels and process attributes are identical to those defined in ISO/IEC 33020.

Evolving process capability is expressed in the PAM in terms of process attributes grouped into capability levels. Process attributes are features of a process that can be evaluated on a scale of achievement, providing a measure of the capability of the process. They are applicable to all processes. Each process attribute describes a facet of the overall capability of managing and improving the effectiveness of a process in achieving its purpose and contributing to the business goals of the organization.

A capability level is a set of process attribute(s) that work together to provide a major enhancement in the capability to perform a process. The levels constitute a rational way of progressing through improvement of the capability of any process and are defined in ISO/IEC 33020.

There are six capability levels, incorporating nine process attributes.

— **Level 0: Incomplete process**

  The process is not implemented or fails to achieve its process purpose.

  At this level, there is little or no evidence of any systematic achievement of the process purpose.

— **Level 1: Performed process**

  The implemented process achieves its process purpose.

— **Level 2: Managed process**

  The previously described Performed process is now implemented in a managed fashion (planned, monitored and adjusted) and its work products are appropriately established, controlled and maintained.

— **Level 3: Established process**

  The previously described Managed process is now implemented using a defined process that is capable of achieving its process outcomes.

— **Level 4: Predictable process**

  The previously described Established process now operates predictably within defined limits to achieve its process outcomes. Quantitative management needs are identified, measurement data are collected and analysed to identify assignable causes of variation. Corrective action is taken to address assignable causes of variation.

— **Level 5: Innovating process**

  The previously described Predictable process is now continually improved to respond to change aligned with organizational goals.



 

Within the PAM, the measure of capability is based upon the nine process attributes (PA) defined in ISO/IEC 33020. Process attributes are used to determine whether a process has reached a given capability. Each attribute measures a particular aspect of the process capability.

At each level, there is no ordering between the process attributes; each attribute addresses a specific aspect of the capability level. The list of process attributes is shown in Table 1.

**Table 1 — Capability levels and process attributes**

| Process Attribute ID | Capability Levels and Process Attributes |
|---|---|
| | **Level 0: Incomplete process** |
| | **Level 1: Performed process** |
| **PA 1.1** | Process performance |
| | **Level 2: Managed process** |
| **PA 2.1** | Performance management |
| **PA 2.2** | Work Products management |
| | **Level 3: Established process** |
| **PA 3.1** | Process definition |
| **PA 3.2** | Process deployment |
| | **Level 4: Predictable process** |
| **PA 4.1** | Quantitative analysis |
| **PA 4.2** | Quantitative control |
| | **Level 5: Innovating process** |
| **PA 5.1** | Process innovation |
| **PA 5.2** | Process innovation implementation |

The process attributes are evaluated on a four point ordinal scale of achievement, as defined in ISO/IEC 33020. They provide insight into the specific aspects of process capability required to support process improvement and capability determination.

## 4.3 Assessment indicators

The PAM is based on the principle that the capability of a process can be assessed by demonstrating the achievement of process attributes on the basis of evidence related to assessment indicators.

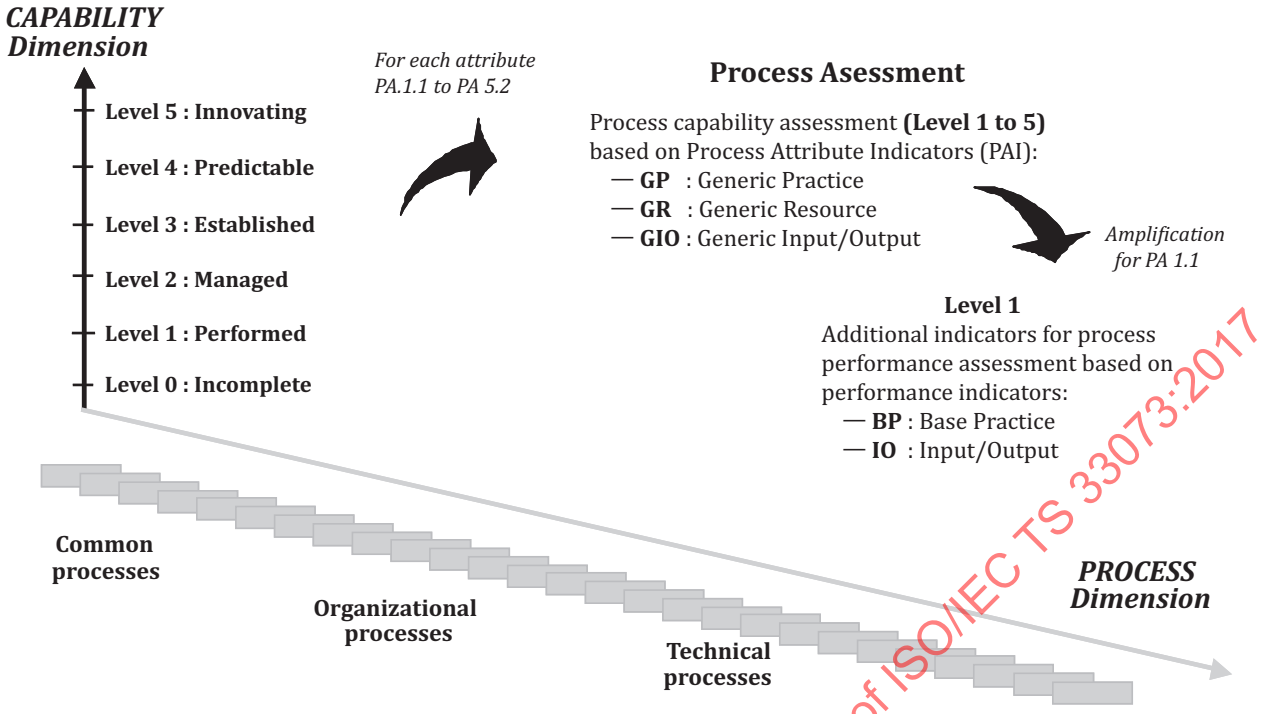


**Figure 4 — Assessment indicators**

There are two types of assessment indicators: process capability indicators, which apply to capability levels 1 to 5 and process performance indicators, which apply exclusively to capability level 1. These indicators are defined in 4.3.2.

The process attributes in the capability dimension have a set of process capability indicators that provide an indication of the extent of achievement of the attribute in the instantiated process. These indicators concern significant activities, resources or results associated with the achievement of the attribute purpose by a process.

The process capability indicators are:

— Generic Practice (GP);

— Generic Resource (GR);

— Generic Input/Output (GIO).

As additional indicators for supporting the assessment of a process at Level 1, each process in the process dimension has a set of process performance indicators which is used to measure the degree of achievement of the process performance attribute for the process assessed.

The process performance indicators are:

— Base Practice (BP);

— Input/output (IO).

The performance of Base Practices (BPs) provides an indication of the extent of achievement of the process purpose and process outcomes. Input/Outputs (IOs) are either used or produced (or both), when performing the process.

The process performance and process capability indicators defined in the PAM represent types of objective evidence that might be found in an instantiation of a process and therefore could be used to judge achievement of capability.



 

Figure 4 shows how the assessment indicators are related to process performance and process capability.

### 4.3.1 Process Capability Indicators

The three types of process capability indicators related to levels 1 to 5 are identified in Figure 5. They are intended to be applicable to all processes.

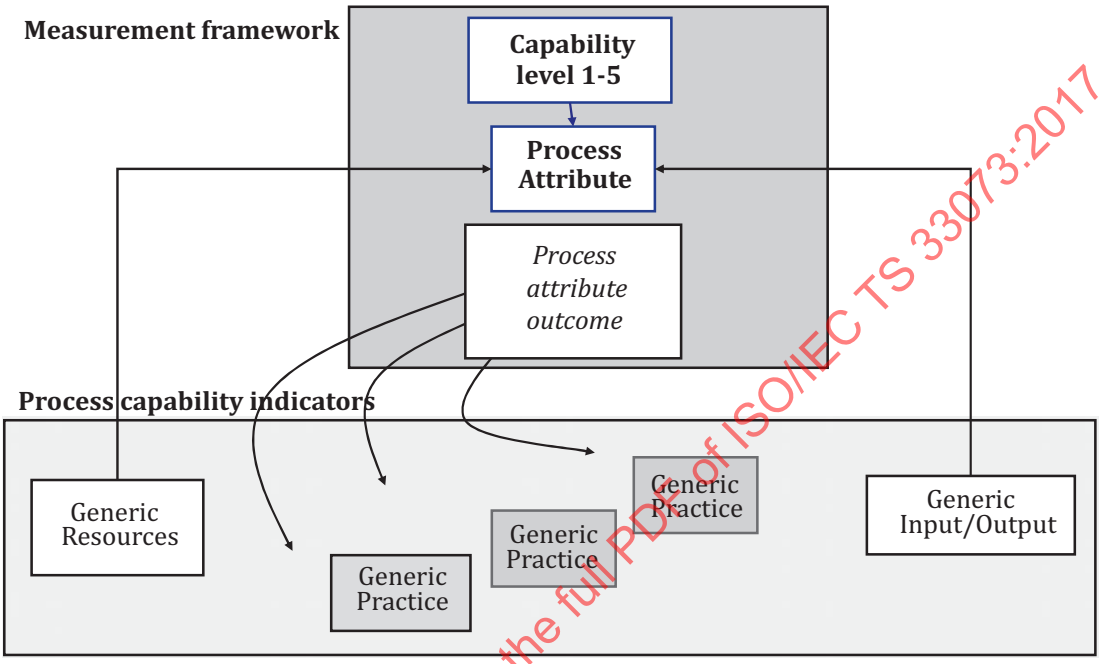


**Figure 5 — Process capability indicators**

All the process capability indicators relate to the process attributes defined in the capability dimension of the PAM. They represent the type of evidence that would support judgments of the extent to which the attributes are achieved. Evidence of their effective performance or existence supports the judgment of the degree of achievement of the attribute. The generic practices are the principal indicators of process capability.

The **Generic Practice (GP)** indicators are indicators of activities of a generic type and provide guidance on the implementation of the attribute's characteristics. They support the achievement of the process attribute and many of them concern management practices, i.e. practices that are established to support the process performance as it is characterized at level 1.

During the evaluation of process capability, the primary focus is on the performance of the generic practices. In general, performance of all generic practices is expected for full achievement of the process attribute.

The **Generic Resource (GR)** indicators are associated resources that may be used when performing the process in order to achieve the attribute. These resources may include human resources, tools, methods and infrastructure. The availability of a resource indicates the potential to fulfil the purpose of a specific attribute.

The assessor should interpret the generic resources according to the process assessed, e.g. for PA2.1 resources (with identified objectives, responsibilities and authorities), an assessor would look for roles (with identified objectives, responsibilities and authorities) in primary and supporting processes, but for organizational processes, would look for governance structures (e.g. mandated committees, positions) with identified objectives, responsibilities and authorities.

The **Generic Input/Output (GIO)** indicators are sets of characteristics that would be expected to be evident in inputs/outputs of generic types as a result of achievement of an attribute. The generic inputs/outputs form the basis for the classification of the inputs/outputs defined as process performance indicators; they represent basic types of inputs/outputs from all types of processes.

These three types of indicators help to establish objective evidence of the extent of achievement of the specified process attribute.

Due to the fact that Level 1 capability of a process is only characterized by the measure of the extent to which the process purpose is achieved, the process performance attribute (PA.1.1) has a single generic practice indicator (GP.1.1.1). In order to support the assessment of PA.1.1 and to amplify the process performance achievement analysis, additional process performance indicators are defined in the PAM.

### 4.3.2 Process Performance Indicators

There are two types of process performance indicators: **Base Practice (BP)** indicators and **Input/Output (IO)** indicators. Process performance indicators relate to individual processes defined in the process dimension of the PAM and are chosen to explicitly address the achievement of the defined process outcomes.

Evidence of performance of the base practices, and the presence of inputs/outputs with their expected characteristics, provide objective evidence of the achievement of the process outcomes.

A base practice is an activity that addresses the purpose of a particular process. Consistently performing the base practices associated with a process will help the consistent achievement of its purpose. A coherent set of base practices is associated with each process in the process dimension. The base practices are described at an abstract level, identifying "what" should be done without specifying "how". Implementing the base practices of a process should achieve the basic outcomes that reflect the process purpose. Base practices represent only the first step in building process capability, but the base practices represent the unique, functional activities of the process, even if that performance is not systematic.

In this particular PAM, the base practices have been used as a vehicle to link the outcomes of each process in the PRM with the requirements defined for that process in ISO 9001. This has been achieved using the following strategy.

— Singular requirements from ISO 9001 have been identified and assigned a unique identifier (process number plus sequential numbering within the subclause).

— Each process outcome has been linked to a single base practice.

This approach provides insight on how the singular requirements from ISO 9001 contribute to the achievement of the process purpose and outcomes. The performance of a process requires inputs and produces outputs that are identifiable and usable in achieving the purpose of the process. In this assessment model, each input/output has a defined set of example characteristics that may be used when reviewing the input/output to assess the effective performance of a process. Input/output characteristics may be used to identify the corresponding input/output produced/used by the assessed organization.

Clause 5 contains a complete description of the processes, including the base practices and the associated inputs and outputs.

Annex B contains a list of generic inputs/outputs together with their characteristics.

## 4.4 Measuring process capability

The process performance and process capability indicators in this model give examples of evidence that an assessor might obtain or observe in the performance of an assessment. The evidence obtained in the assessment, through observation of the implemented process, can be mapped onto the set of indicators to enable correlation between the implemented process and the processes defined in this



 

assessment model. These indicators provide guidance for assessors in accumulating the necessary objective evidence to support judgments of capability. They are not mandatory.

An indicator is defined as an objective characteristic of a practice or input/output that supports performing a conformant assessment in accordance with the requirements of ISO/IEC 33004. The assessment indicators and their relationship to process performance and process capability are shown in Figure 6.

Observable (objective) evidence collected during an assessment is used to confirm the indicators (e.g. practices were performed). All such evidence comes either from the examination of inputs/outputs of the processes assessed or from statements made by the performers and managers of the processes.

The existence of base practices, inputs/outputs, and input/output characteristics, provide evidence of the performance of the processes associated with them. Similarly, the existence of process capability indicators provides evidence of process capability.

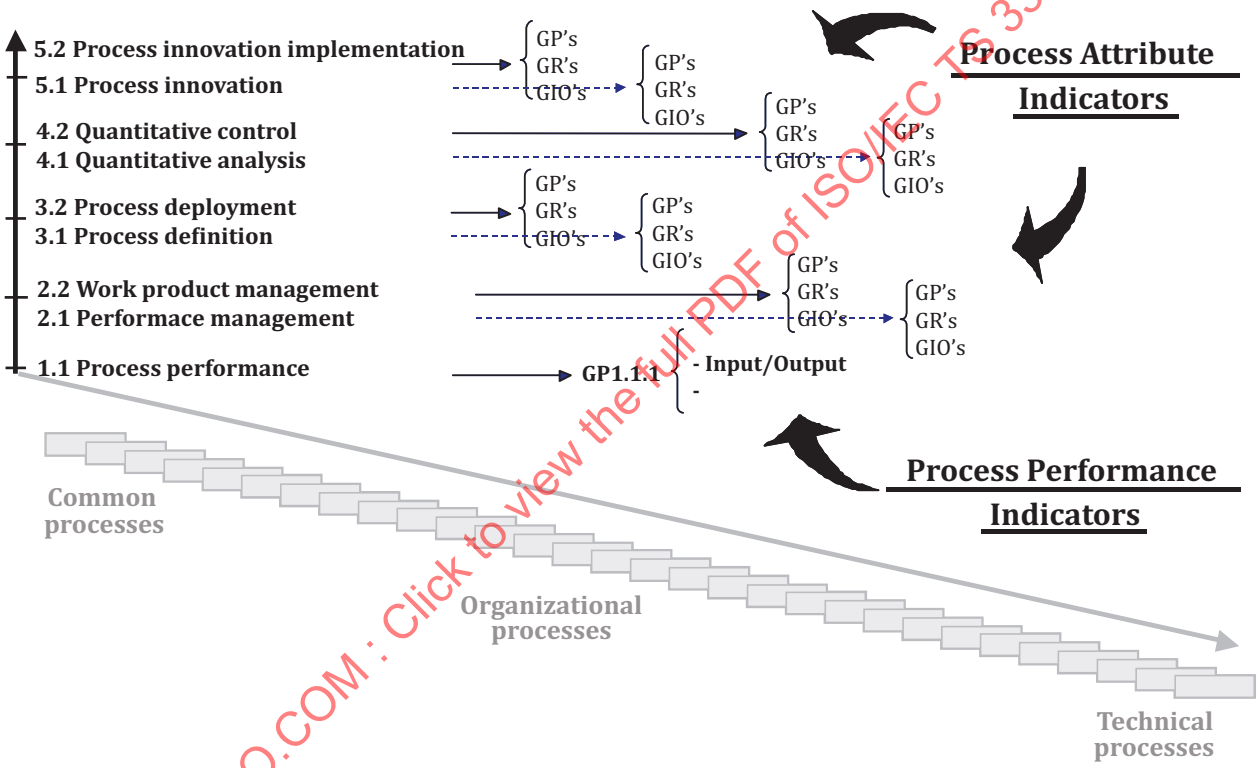


**Figure 6 — Relationship between assessment indicators and process capability**

The evidence obtained should be recorded in a form that clearly relates to an associated indicator, so that the support for the assessor's judgment can be readily confirmed or verified as required by ISO/IEC 33002.

The output from a process assessment is a set of process profiles, one for each process within the scope of the assessment. Each process profile consists of a set of the process attribute ratings for an assessed process. Each attribute rating represents a judgment by the assessor of the extent to which the attribute is achieved. To improve the reliability and repeatability of the assessment, the judgments of the assessor are based on a coherent set of recorded objective evidences.

# 5 The process dimension and process performance indicators (Level 1)

## 5.1 General

This clause defines the processes and the process performance indicators, also known as the process dimension, of the PAM. The processes in the process dimension can be directly mapped to the processes defined in the PRM.

The processes are classified into Process Groups which are shown in Figure 3. The process purposes, outcomes, the practices, the inputs and outputs of processes are included in this clause.

The individual processes are described in terms of process name, process purpose, and process outcomes:

a) name: a short noun phrase that summarizes the scope of the process, identifying the principle concern of the process, and distinguishes it from other processes within the scope of the PRM;

b) purpose: describes at a high level the overall objectives of performing the process;

c) outcomes: 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.

In addition, the process dimension of the PAM provides information in the form of:

a) a set of base practices for the process needed to accomplish the process outcomes; a single base practice is explicitly associated with a process outcome;

b) a number of inputs/outputs associated with each process and their relationship to one or more of its outcomes by numbers in square brackets (i.e. [n]);

c) characteristics associated with each input/output.

The input/output identifiers and characteristics are contained in Annex B.

The base practices and the inputs/outputs constitute the set of indicators of process performance. The associated inputs/outputs listed in this clause may be used when reviewing potential inputs and outputs of an organization's process implementation. They provide objective guidance for potential inputs and outputs to look for and objective evidence supporting the assessment of a particular process. A documented assessment process and assessor judgment is needed to ensure that process context (application domain, business purpose, development methodology, size of the organization, etc.) is explicitly considered when using this information. This list should not be considered as a checklist of what each organization must have but rather as an example and starting point for considering whether, given the context, the inputs/outputs are necessary and contributing to the intended purpose of the process.

NOTE Some outcomes are not linked to specific requirements of ISO 9001. These additional outcomes have been included in order to present a complete process so that the process purpose can be achieved. The complete list of affected base practices is shown in Table C.2.



 

## 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:<br>a) information content is defined in terms of identified communication requirements;<br>b) parties to communicate with are identified;<br>c) the party responsible for the communication is identified;<br>d) events that require communication actions are identified;<br>e) the channel for the communication is selected;<br>f) information products are communicated to relevant interested parties. |
| **Base Practices** | COM.01.BP.1 **Define information content.** Define information content in terms of identified communication needs and requirements. [Outcome 1]<br>COM.01.BP.2 **Identify parties to communicate to.** Identify parties to communicate with. [Outcome 2]<br>COM.01.BP.3 **Identify party responsible for communication.** Identify the party responsible for the communication. [Outcome 3]<br>COM.01.BP.4 **Identify communication events.** Identify the events that require communication actions. [Outcome 4]<br>COM.01.BP.5 **Select communication channel.** Select the channel for the communication. [Outcome 5]<br>COM.01.BP.6 **Communicate information products.** Communicate information products to relevant interested parties. [Outcome 6] |
| **Inputs** | |
| 12-02 Communication requirements [Outcome 6] | |
| **Outputs** | |
| 08-03 Audit result communication record [Outcome 6] | |
| 12-02 Communication requirements [Outcomes 1,2,3,4,5] | |
| 08-13 Improvement communication record [Outcome 6] | |
| 08-25 Nonconforming product customer communication record [Outcome 6] | |
| 08-44 Product/service requirements communication record [Outcome 6] | |
| 08-53 QMS Communication records [Outcome 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:<br>a) documented information to be documented is identified;<br>b) the forms of documented information representation are defined;<br>c) the documented information content status is known;<br>d) documented information is current, complete and valid;<br>e) documented information is released according to defined criteria;<br>f) documented information is available to relevant interested parties;<br>g) documented information is archived, or disposed of, as required. |
| **Base Practices** | COM.02.BP.1 **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. [Outcome 1]<br>COM.02.BP.2 **Define the forms of documented information representation.** Identify the forms of information to be stored in the repository. For example, this may include documents, records, audio content, video content, image content. [Outcome 2]<br>COM.02.BP.3 **Determine the documented information content status.** The status of the documented information content refers to the timeliness of the information content. This includes the control of changes, for example, by using version control techniques. [Outcome 3]<br>COM.02.BP.4 **Determine whether the documented information is current, complete and valid.** The documented information contained in the repository is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). [Outcome 4]<br>COM.02.BP.5 **Release documented information according to defined criteria.** The documented information release status refers to those situations typically where authorization is needed, such as in situations where a) agreements are in force, and b) policies and procedures are approved by management and their use in the organization is thereby obligatory. [Outcome 5]<br>COM.02.BP.6 **Make documented information available to relevant interested parties.** Manage the distribution, access, retrieval and use of documented information towards interested parties. [Outcome 6]<br>COM.02.BP.7 **Archive, or dispose of documented information, as required.** Manage documented information, including records, through its lifecycle by addressing the following activities: a) storage and preservation, including preservation of legibility; b) retention and disposition. Records should be protected in accordance with statutory, regulatory, contractual and business requirements. [Outcome 7] |
| **Inputs** | |
| 03-08 Management system strategy: documentation [Outcomes 1,2] | |

| Outputs | |
|---|---|
| 08-11 | Corrective action record [Outcome 1] |
| 11-01 | Corrective action request [Outcome 1] |
| 08-12 | Customer asset communication record [Outcome 1] |
| 12-03 | Documentation management requirements [Outcome 2] |
| 08-17 | Information item approval record [Outcome 5] |
| 03-02 | Information item identification [Outcome 2] |
| 12-05 | Information management requirements [Outcomes 4,6,7] |
| 08-20 | Management review record [Outcome 1] |
| 03-04 | Management system (MS) scope [Outcomes 1,3] |
| 03-12 | Management system strategy: knowledge [Outcomes 4,6] |
| 03-14 | Management system strategy: measurement [Outcome 1] |
| 03-15 | Management system strategy: outsourcing [Outcome 1] |
| 08-21 | Measurement resources effectiveness review result [Outcome 1] |
| 08-22 | MS Implementation log [Outcome 1] |
| 02-5 | MS Measurement information collection log [Outcome 1] |
| 08-29 | Non-conformity disposition record [Outcome 1] |
| 11-04 | Nonconforming product corrective action request [Outcome 1] |
| 08-25 | Nonconforming product customer communication record [Outcome 1] |
| 08-27 | Nonconforming product quarantine release authorization [Outcome 1] |
| 08-31 | Personnel competency records [Outcome 1] |
| 08-32 | Process change approval record [Outcome 1] |
| 02-7 | Process change implementation log [Outcome 1] |
| 08-34 | Process change request review record [Outcome 1] |
| 04-6 | Product/service process lifecycle model [Outcome 1] |
| 12-15 | Product/service characteristics [Outcome 1] |
| 08-35 | Product/service design change log [Outcome 1] |
| 08-36 | Product/service release approval record [Outcome 5] |
| 12-18 | Product/service requirements [Outcome 1] |
| 11-10 | Product/service requirements change request [Outcome 4] |
| 08-45 | Product/service requirements review record [Outcome 1] |
| 08-46 | Product/service requirements status record [Outcome 3] |
| 03-27 | Product/service taxonomy [Outcome 1] |
| 08-49 | Product/service validation record [Outcome 1] |
| 03-34 | Quality objectives [Outcomes 3,4] |
| 05-2 | Quality policy [Outcomes 1,4,6] |
| 09-10 | Risk analysis report [Outcome 1] |
| 08-55 | Risk assessment review record [Outcome 1] |

## 5.4 COM.03 Human resource management

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|---|---|
| **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:<br>a) the competencies required by the organization to produce products and services are identified;<br>b) identified competency gaps are filled through training or recruitment;<br>c) understanding of roles and activities in achieving organsational objectives in product and service provision is demonstrated by each individual. |
| **Base Practices** | COM.03.BP.1 **Identify organizational competencies.** Identify the competencies required by the organization. [Outcome 1]<br>COM.03.BP.2 **Fill competency gaps.** Fill identified competency gaps through training or recruitment. [Outcome 2]<br>COM.03.BP.3 **Demonstrate awareness of understanding of role.** Each individual demonstrates their understanding of their role and activities in achieving organizational objectives. [Outcome 3] |
| **Inputs** | |
| 12-10 Organizational competence requirements [Outcome 2] | |
| 08-31 Personnel competency records [Outcome 2] | |
| **Outputs** | |
| 12-10 Organizational competence requirements [Outcome 1] | |
| 08-61 Training effectiveness evaluation result [Outcome 3] | |
| 08-62 Training record [Outcomes 2,3] | |

## 5.5 COM.04 Improvement

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|---|---|
| **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:<br>a) opportunities for improvement are identified;<br>b) opportunities for improvement are evaluated against defined criteria;<br>c) improvements are prioritized;<br>d) improvements are implemented;<br>e) the effectiveness of implemented improvements is evaluated. |

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| **Base Practices** | COM.04.BP.1 **Identify improvement opportunities.** These might arise from the following sources:<br>a) the decisions and actions arising from the outputs of the management reviews;<br>b) feedback arising from actions to meet customer requirements and assess customer satisfaction;<br>c) actions arising from:<br>1) improving products and services to meet requirements as well as to address future needs and expectations;<br>2) correcting, preventing or reducing undesired effects;<br>3) improving the performance and effectiveness of the quality management system. [Outcome 1]<br>COM.11.BP.6 **Identify opportunities.** One of the options for treating risk involve taking or increasing the risk in order to pursue an opportunity. [Outcome 1]<br>COM.04.BP.2 **Evaluate improvement opportunities.** Evaluate opportunities for improvement against defined criteria. The results of analysis are used to evaluate the need for improvements to the quality management system, and to the business processes. [Outcome 2]<br>COM.04.BP.3 **Prioritize improvements.** Prioritize the improvements to be made. [Outcome 3]<br>COM.04.BP.4 **Implement improvements.** Implement the selected improvements. [Outcome 4]<br>COM.04.BP.5 **Evaluate improvement effectiveness.** Evaluate the effectiveness of implemented improvements. [Outcome 5] |
| **Inputs** | |
| 11-03 | Improvement opportunity approval request [Outcome 5] |
| 12-04 | Improvement opportunity evaluation criteria [Outcomes 2,4] |
| 08-14 | Improvement opportunity evaluation result [Outcomes 3,4] |
| 08-16 | Improvement opportunity record [Outcomes 2,3] |
| 05-1 | Improvement policy [Outcome 2] |
| 06-1 | Improvement procedure [Outcomes 2,3] |
| 03-01 | Improvement target [Outcomes 4,5] |
| **Outputs** | |
| 04-4 | Improvement implementation schedule [Outcome 4] |
| 11-02 | Improvement opportunity [Outcome 1] |
| 11-03 | Improvement opportunity approval request [Outcome 3] |
| 09-02 | Improvement opportunity evaluation report [Outcome 2] |
| 08-14 | Improvement opportunity evaluation result [Outcome 2] |
| 08-15 | Improvement opportunity implementation log [Outcome 5] |
| 08-16 | Improvement opportunity record [Outcome 1] |
| 03-01 | Improvement target [Outcome 3] |
| 03-09 | Management system strategy: Establish the management system [Outcome 1] |

## 5.6 COM.05 Internal audit

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| **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:<br>a) the scope and purpose of each audit is defined;<br>b) the objectivity and impartiality of the conduct of audits and selection of auditors are assured;<br>c) conformity of selected services, products and processes with requirements, plans and agreements is determined. |
| **Base Practices** | COM.05.BP.1 **Define the criteria and scope of each audit.** Define the audit criteria and the scope of each audit. [Outcome 1]<br>COM.05.BP.2 **Select auditors .** Select auditors to ensure objectivity and the impartiality of the audit process. [Outcome 2]<br>COM.05.BP.3 **Conduct audits.** Conduct audits according to the defined criteria ensuring objectivity and the impartiality of the audit process. [Outcome 3] |
| **Inputs** | |
| 04-2 Audit plan [Outcomes 2,3] | |
| 08-05 Auditor list [Outcome 3] | |
| **Outputs** | |
| 08-01 Audit (MS) log [Outcome 3] | |
| 04-2 Audit plan [Outcome 1] | |
| 08-04 Audit results [Outcome 3] | |
| 08-05 Auditor list [Outcome 2] | |

## 5.7 COM.06 Management review

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| **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:<br>a) the objectives of the review are established;<br>b) the status and performance of an activity or process are assessed in terms of the established objectives;<br>c) risks, problems and opportunities for improvement are identified. |

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| **Base Practices** | COM.06.BP.1 **Identify the objectives for management system review.** Objectives for management review include:<br>a) the status of actions from previous management reviews;<br>b) changes in external and internal issues that are relevant to the quality management system including its strategic direction;<br>c) information on the quality performance, including trends and indicators for:<br>1) nonconformities and corrective actions;<br>2) monitoring and measurement results;<br>3) audit results;<br>4) customer satisfaction;<br>5) issues concerning external providers and other relevant interested parties;<br>6) adequacy of resources required for maintaining an effective quality management system;<br>7) process performance and conformity of products and services;<br>d) the effectiveness of actions taken to address risks and opportunities;<br>e) new potential opportunities for continual improvement. [Outcome 1]<br>COM.06.BP.2 **Assess status and performance of activities.** Top management conduct reviews of the organization's quality management system to ensure its continuing suitability, adequacy and effectiveness. [Outcome 2]<br>COM.06.BP.3 **Identify risks, problems and opportunities for improvement.** Identify risks, problems, and opportunities related to improvement, and the need for changes to the quality management system. [Outcome 3] |
| **Inputs** | |
| 03-03 Management review objectives [Outcome 2] | |
| 08-20 Management review record [Outcome 3] | |
| **Outputs** | |
| 11-02 Improvement opportunity [Outcome 3] | |
| 08-19 Management review action log [Outcome 3] | |
| 03-03 Management review objectives [Outcome 1] | |
| 08-20 Management review record [Outcome 2] | |

## 5.8 COM.07 Non-conformity management

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| **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. |

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| **Outcomes** | As a result of successful implementation of this process:<br>a) non-conformities are identified;<br>b) non-conformities are resolved and closed;<br>c) the cause(s) of selected non-conformities is determined;<br>d) the need for action to eliminate the causes of non-conformities is evaluated;<br>e) a selected action proposal is implemented;<br>f) the effectiveness of changes to eliminate the non-conformities is confirmed. |
| **Base Practices** | COM.07.BP.1 **Identify non-conformities.** Non-conformities are identified. These might arise during development and/or production of the product/service, or from post-production activities e.g. feedback from customers. [Outcome 1]<br>COM.07.BP.2 **Resolve and close non-conformities.** Resolve and close non-conformities. When a nonconformity occurs, including any arising from complaints, the organization reacts to the nonconformity and, as applicable: take action to control and correct it; and deal with the consequences. [Outcome 2]<br>COM.07.BP.3 **Determine cause of non-conformities.** Determine the cause of selected non-conformities. The organization evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by: reviewing and analysing the nonconformity; determining the causes of the nonconformity; determining if similar nonconformities exist, or could potentially occur. [Outcome 3]<br>COM.07.BP.4 **Determine the need for action.** Determine the need for action to eliminate the causes of non-conformities. Corrective actions are appropriate to the effects of the nonconformities encountered. [Outcome 4]<br>COM.07.BP.5 **Implement selected action proposals.** Implement a selected action proposal. The organization implements any action needed. If necessary, changes are made to the quality management system. [Outcome 5]<br>COM.07.BP.6 **Confirm change effectiveness.** Confirm the effectiveness of changes to eliminate the non-conformities. The organization reviews the effectiveness of any corrective action taken. [Outcome 6] |
| **Inputs** | |
| 08-02 | Audit corrective action record [Outcome 2] |
| 08-08 | Corrective action cause analysis record [Outcome 4] |
| 08-11 | Corrective action record [Outcome 5] |
| 08-29 | Non-conformity disposition record [Outcome 3] |
| 08-30 | Non-conformity record [Outcome 2] |
| **Outputs** | |
| 08-02 | Audit corrective action record [Outcome 1] |
| 08-07 | Correction action log [Outcome 5] |
| 08-08 | Corrective action cause analysis record [Outcome 3] |
| 08-09 | Corrective action change proposal approval record [Outcome 5] |
| 08-10 | Corrective action change proposal verification record [Outcome 6] |
| 08-11 | Corrective action record [Outcome 4] |
| 08-29 | Non-conformity disposition record [Outcome 2] |
| 08-30 | Non-conformity record [Outcome 1] |

## 5.9 COM.08 Operational planning

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|---|---|
| **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:<br>a) process requirements are identified;<br>b) process input and output products are determined;<br>c) the set of activities that transform the inputs into outputs is determined;<br>d) the sequence and interaction of the process with other processes is determined;<br>e) the required competencies and roles for performing the process are identified;<br>f) the required resources for performing the process are identified;<br>g) methods for monitoring the effectiveness and suitability of the process are determined;<br>h) plans for the deployment of the process are developed. |
| **Base Practices** | COM.08.BP.1 **Identify process requirements.** Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. [Outcome 1]<br>COM.08.BP.2 **Determine process input and output products.** Determine process input and output products expected from these processes. [Outcome 2]<br>COM.08.BP.3 **Determine the set of activities that transform the inputs into outputs.** Determine the set of activities that transform the inputs into outputs. Controlled conditions include, as applicable, the availability and use of suitable monitoring and measuring resources. [Outcome 3]<br>COM.08.BP.4 **Determine the sequence and interaction of the process with other processes.** Determine the sequence and interaction of the process with other processes by establishing criteria for the acceptance of products and services, the need for 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, the implementation of actions to prevent human error, and the implementation of release, delivery and post-delivery activities. [Outcome 4] |

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| | COM.08.BP.5 **Identify the required competencies and roles for performing the process.** Identify the required competencies and roles for performing the process. These include:<br>a) ensuring that the quality management system conforms to the management system requirements;<br>b) ensuring that the processes are delivering their intended outputs;<br>c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;<br>d) ensuring the promotion of customer focus throughout the organization;<br>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented;<br>f) who will be responsible for meeting quality system objectives;<br>g) the appointment of competent persons, including any required qualification. [Outcome 5]<br>COM.08.BP.6 **Identify the required resources for performing the process.** Determine what resources will be required by the quality management system to achieve its quality objectives. This includes determining:<br>a) the resources needed for these processes;<br>b) the capabilities of, and constraints on, existing internal resources;<br>c) what needs to be obtained from external providers;<br>d) the resources needed to achieve conformity to the product and service requirements;<br>e) the use of suitable infrastructure and environment for the operation of processes. [Outcome 6]<br>COM.08.BP.7 **Determine the methods for monitoring the effectiveness and suitability of the process.** Determine the methods for monitoring the effectiveness and suitability of the process. [Outcome 7]<br>COM.08.BP.8 **Plan the deployment of the process.** Plan that the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. [Outcome 8] |

| **Inputs** | |
|---|---|
| 06-1 | Improvement procedure [Outcome 4] |
| 04-6 | Product/service process lifecycle model [Outcome 3] |
| 03-26 | Product/service provision lifecycle model [Outcome 4] |
| **Outputs** | |
| 04-1 | Audit (MS) schedule [Outcome 8] |
| 04-3 | Audit programme plan [Outcome 8] |
| 12-01 | Communication process requirements [Outcome 1] |
| 12-03 | Documentation management requirements [Outcome 1] |
| 12-04 | Improvement opportunity evaluation criteria [Outcome 2] |
| 05-1 | Improvement policy [Outcome 1] |
| 06-1 | Improvement procedure [Outcome 3] |
| 12-06 | Infrastructure requirements [Outcome 1] |
| 04-5 | Management review schedule [Outcome 8] |
| 12-07 | Management system change evaluation criteria [Outcome 1] |
| 03-20 | Management system strategy: roles and responsibilities [Outcome 5] |
| 03-22 | MS Measurement information gathering events [Outcome 8] |
| 03-24 | MS Measurement methods [Outcome 7] |
| 12-09 | MS Resource requirements [Outcome 6] |
| 12-10 | Organizational competence requirements [Outcome 5] |
| 12-11 | Organizational roles and responsibilities [Outcome 5] |
| 12-12 | Process environment requirements [Outcome 1] |
| 04-6 | Product/service process lifecycle model [Outcomes 1,2,4,7,8] |
| 03-29 | Product/service objectives [Outcome 1] |
| 03-26 | Product/service provision lifecycle model [Outcomes 3,4,5,6,7] |
| 03-30 | Project/service measures [Outcome 7] |
| 03-31 | Project/service resource needs [Outcome 6] |
| 03-32 | Project/service roles and responsibilities [Outcome 5] |
| 03-33 | Project/service schedule [Outcome 8] |
| 05-2 | Quality policy [Outcome 1] |
| 08-54 | Risk and opportunity identification [Outcome 8] |
| 03-36 | Risk and opportunity identification criteria [Outcome 1] |
| 04-7 | Risk management plan [Outcome 8] |

## 5.10 COM.09 Operational implementation and control

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|---|---|
| **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:<br>a) the required roles, responsibilities and authorities are allocated;<br>b) the required resources are allocated and applied;<br>c) actions required to achieve the management system objectives are implemented;<br>d) suitability and effectiveness of the actions taken to achieve the management system objectives are reviewed;<br>e) deviations from planned arrangements are corrected when targets are not achieved;<br>f) data is collected and analysed as a basis for understanding the behaviour of and to demonstrate the suitability and effectiveness of the processes. |
| **Base Practices** | COM.09.BP.1 **Allocate roles, responsibilities and authorities.** Allocate the required roles, responsibilities and authorities. Top management ensures that the responsibilities and authorities for relevant roles are communicated and understood within the organization. [Outcome 1]<br>COM.09.BP.2 **Allocate resources.** Allocate and apply the required resources. The organization:<br>a) provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system;<br>b) determines the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>c) provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>d) ensures that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken;<br>e) ensure that the resources provided are maintained to ensure their continuing fitness for their purpose. [Outcome 2] |

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| | COM.09.BP.3 **Perform process activities.** Perform process activities. The organization:<br>a) monitors and reviews information about these external and internal issues;<br>b) monitors and reviews information about interested parties and their relevant requirements;<br>c) evaluates the effectiveness of the actions taken;<br>d) ensures that contract or order requirements differing from those previously defined are resolved;<br>e) ensures the adequacy of requirements prior to their communication to the external provider;<br>f) maintains an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits. [Outcome 3]<br>COM.09.BP.4 **Review process activities.** Review process activities. [Outcome 4]<br>COM.09.BP.5 **Correct deviations.** Correct deviations from planned arrangements when targets are not achieved. [Outcome 5]<br>COM.09.BP.6 **Collect and analyse data.** Collect and analyse data as a basis for understanding the behaviour of, and to demonstrate the suitability and effectiveness of the processes. [Outcome 6]<br>COM.10.BP.5 **Analyse the collected data.** Analyse the collected data in order to evaluate the quality management system performance, the effectiveness of the quality management system, as well as the effectiveness of any action taken within the scope of the quality management system. [Outcome 6] |
| **Inputs** | |
| 08-33 Process change evaluation record [Outcome 6] | |
| 11-07 Process change request [Outcome 6] | |
| **Outputs** | |
| 03-09 Management system strategy: Establish the management system [Outcomes 3,4] | |
| 02-3 Measuring equipment asset list [Outcome 2] | |
| 02-4 Measuring equipment maintenance log [Outcome 2] | |
| 08-22 MS Implementation log [Outcome 3] | |
| 08-23 MS Implementation review record [Outcomes 3,4] | |
| 02-5 MS Measurement information collection log [Outcome 3] | |
| 02-6 MS Performance measurement data [Outcome 6] | |
| 08-24 MS Resources provision record [Outcome 2] | |
| 08-31 Personnel competency records [Outcome 4] | |
| 08-33 Process change evaluation record [Outcome 5] | |
| 11-07 Process change request [Outcome 5] | |
| 08-45 Product/service requirements review record [Outcome 4] | |
| 03-34 Quality objectives [Outcome 4] | |
| 08-57 Roles and responsibilities assignment record [Outcome 1] | |
| 08-62 Training record [Outcome 4] | |

## 5.11 COM.10 Performance evaluation

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|---|---|
| **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:<br>a) performance monitoring and measurement needs are defined;<br>b) performance measures derived from the performance measurement needs are identified;<br>c) performance measurement methods supportive of the performance measures are identified;<br>d) data is collected using the identified performance measurement methods.<br>e) the collected performance data is analysed. |
| **Base Practices** | COM.10.BP.1 **Determine what needs to be monitored.** Determine what needs to be monitored and measured. [Outcome 1]<br>COM.10.BP.2 **Determine appropriate performance measures.** Determine appropriate performance measures that support the performance measurement needs. [Outcome 2]<br>COM.10.BP.3 **Determine the appropriate methods for monitoring, measurement, analysis and evaluation.** Determine the appropriate methods for monitoring, measurement, analysis and evaluation, as well as how the results will be evaluated. [Outcome 3]<br>COM.10.BP.4 **Monitor and measure the quality management system performance.** Collect and verify data on the quality management system performance of the organization. [Outcome 4]<br>COM.10.BP.5 **Analyse the collected data.** Analyse the collected data in order to evaluate the quality management system performance, the effectiveness of the quality management system, as well as the effectiveness of any action taken within the scope of the quality management system. [Outcome 5] |

| Inputs | |
|---|---|
| 03-23 | MS Measurement information needs [Outcome 2] |
| 03-24 | MS Measurement methods [Outcome 4] |
| 02-6 | MS Performance measurement data [Outcome 5] |
| 03-30 | Project/service measures [Outcome 3] |
| 03-34 | Quality objectives [Outcome 2] |
| **Outputs** | |
| 09-01 | Customer satisfaction evaluation report [Outcome 5] |
| 09-03 | Management system conformity evaluation report [Outcome 5] |
| 03-23 | MS Measurement information needs [Outcome 1] |
| 03-24 | MS Measurement methods [Outcome 3] |
| 02-6 | MS Performance measurement data [Outcomes 4,5] |
| 09-04 | Planning performance evaluation report [Outcome 5] |
| 09-05 | Process capability assessment report [Outcome 5] |
| 09-08 | Product/service conformity evaluation report [Outcome 5] |
| 03-30 | Project/service measures [Outcome 2] |
| 03-34 | Quality objectives [Outcome 1] |

## 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:<br>a) risks are identified;<br>b) identified risks are analysed;<br>c) risks are evaluated against defined criteria;<br>d) risks are selected for treatment;<br>e) selected risks are treated. |

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| Base Practices | COM.11.BP.1 **Identify risks.** Identify risks and opportunities. The following may be considered for identifying such uncertainties:<br>— potential occurrence of set of circumstances and their consequences;<br>— set of circumstances and their consequences which may potentially not occur;<br>— potential consequences, which may affect objectives but where such consequences do not appear to be linked to specific risk source, type or sequence of events;<br>— changes in the internal or external environment leading to a state consisting of factors previously unknown to the organization. These are sometimes also referred to as "known unknowns";<br>— changes in the internal or external environment leading to a state where knowledge of the organization about its environment may become invalidated or irrelevant;<br>— gradual changes in the internal or external environment which individually may not have any effect on objectives but their repetitive occurrences overtime can result in significant changes to one or more factors resulting in a single or chain of events and consequences. [Outcome 1]<br>COM.11.BP.2 **Analyse risks.** Analyse risks. The analysis of risks may include:<br>— likelihood of events and consequences occurring/not occurring;<br>— scale of consequences, which can result from events<br>— speed and duration at which events or uncertainties can occur and progress<br>— duration over which events or uncertainties can occur;<br>— level of effectiveness of the design of existing risk treatments;<br>— level of effectiveness of the operation of existing risk treatments;<br>— change in other risk analysis measures, if some or all of existing treatments were absent or are assumed to be ineffective;<br>— likelihood of achieving the objectives considering all other inputs captured during risk analysis;<br>— level of confidence on the various measures captured during risk analysis<br>— the level of sensitivity of the various measures to preconditions and assumptions. [Outcome 2]<br>COM.11.BP.3 **Evaluate risks.** Evaluate risks against defined criteria. The purpose of risk evaluation is to decide whether a risk is acceptable or unacceptable to the organization in relation to its objectives. This involves comparing the level of risk found during the analysis process with the previously defined risk criteria. Based on this comparison, treatment should be considered. [Outcome 3]<br>COM.11.BP.4 **Select risks for treatment.** Select risks for treatment. [Outcome 4]<br>COM.11.BP.5 **Treat risks.** Treat selected risks. Risk treatment involves selecting one or more options for responding to risks and implementing those options. Risk treatment involves a cyclical process of:<br>— formulating and selecting risk treatment;<br>— implementing risk treatment;<br>— deciding whether residual risk levels are acceptable;<br>— if not acceptable, generating further risk treatment;<br>— assessing the effectiveness of that treatment;<br>— potential evolution over time. [Outcome 5]<br>COM.11.BP.6 **Identify opportunities.** One of the options for treating risk involve taking or increasing the risk in order to pursue an opportunity. [Outcome 5] |

| Inputs | |
|---|---|
| 09-10 | Risk analysis report [Outcome 3] |
| 08-54 | Risk and opportunity identification [Outcome 2] |
| 08-55 | Risk assessment review record [Outcome 4] |
| 04-8 | Risk treatment plan [Outcome 5] |
| Outputs | |
| 09-10 | Risk analysis report [Outcome 2] |
| 08-54 | Risk and opportunity identification [Outcome 1] |
| 08-55 | Risk assessment review record [Outcome 3] |
| 08-56 | Risk treatment action log [Outcome 5] |
| 04-8 | Risk treatment plan [Outcome 4] |

## 5.13 ORG.01 Asset management

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|---|---|
| **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:<br>a) items requiring asset management are identified;<br>b) asset status is known;<br>c) changes to assets under management are controlled;<br>d) the integrity of assets is assured. |
| **Base Practices** | ORG.01.BP.1 **Identify Items.** Identify Items requiring asset management. [Outcome 1]<br>ORG.01.BP.2 **Determine asset status.** Determine the status of the asset. [Outcome 2]<br>ORG.01.BP.3 **Control asset changes.** Control changes to assets under management. [Outcome 3]<br>ORG.01.BP.4 **Assure asset integrity.** Assure the integrity of assets. [Outcome 4] |
| **Inputs** | |
| 07-1 | Customer asset [Outcomes 2,3,4] |
| **Outputs** | |
| 07-1 | Customer asset [Outcomes 1,4] |
| 08-12 | Customer asset communication record [Outcome 2] |

## 5.14 ORG.02 Measurement resource management

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|---|---|
| **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. |

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|---|---|
| **Outcomes** | As a result of successful implementation of this process:<br>a) requirements for measurement resources are defined;<br>b) measurement resources for performing tests and calibrations is acquired;<br>c) measurement resource items are identified;<br>d) the calibration status of measurement resource items is confirmed at appropriate intervals;<br>e) measurement resources are maintained in accordance with defined requirements;<br>f) mal-performing measurement resources are segregated and controlled in order to avoid unintended use. |
| **Base Practices** | ORG.02.BP.1 **Define measurement resource requirements.** Define requirements for test and calibration measurement resources. [Outcome 1]<br>ORG.02.BP.2 **Acquire measurement resources.** Acquire measurement resources for performing tests and calibrations. [Outcome 2]<br>ORG.02.BP.3 **Identify measurement resources.** Identify measurement resources. [Outcome 3]<br>ORG.02.BP.4 **Confirm calibration status.** Confirm the calibration status of measurement resources, as applicable at appropriate intervals. [Outcome 4]<br>ORG.02.BP.5 **Maintain measurement resources.** Maintain measurement resources in accordance with defined requirements. [Outcome 5]<br>ORG.02.BP.6 **Segregate mal-performing measurement resources.** Segregate and control mal-performing measurement resources in order to avoid unintended use. [Outcome 6] |
| **Inputs** | |
| 02-2 | Measurement resource identification [Outcomes 4,5,6] |
| **Outputs** | |
| 02-1 | Measurement resource calibration log [Outcomes 4,6] |
| 02-2 | Measurement resource identification [Outcome 3] |
| 12-12 | Process environment requirements [Outcome 1] |

## 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:<br>a) suppliers are identified;<br>b) products/services to be provided are negotiated with each supplier;<br>c) determine the roles and relationships between the organization and its suppliers and, where applicable, between suppliers;<br>d) the capability of subcontracted suppliers to meet obligations is confirmed;<br>e) supplier obligations to meet requirements are monitored;<br>f) supplier performance against agreed criteria is monitored. |

| | |
|---|---|
| **Base Practices** | ORG.03.BP.1 **Identify suppliers.** Identify suppliers. [Outcome 1]<br>ORG.03.BP.2 **Negotiate products/services.** Negotiate products/services to be provided with each supplier. [Outcome 2]<br>ORG.03.BP.3 **Determine roles and relationships.** Determine the roles and relationships between the organization and its suppliers and, where applicable, between suppliers. [Outcome 3]<br>ORG.03.BP.4 **Confirm supplier capability.** Confirm the capability of subcontracted suppliers to meet obligations. [Outcome 4]<br>ORG.03.BP.5 **Monitor supplier obligations.** Monitor supplier obligations to meet requirements. [Outcome 5]<br>ORG.03.BP.6 **Monitor supplier performance.** Monitor supplier performance against agreed criteria. [Outcome 6] |
| **Inputs** | |
| 01-2 | Supplier agreement [Outcomes 3,4,5] |
| 03-38 | Supplier performance evaluation criteria [Outcome 6] |
| 08-60 | Supplier role assignments list [Outcome 2] |
| **Outputs** | |
| 01-1 | Service level agreement [Outcome 2] |
| 03-37 | Sub-contracted supplier roles and responsibilities [Outcome 3] |
| 01-2 | Supplier agreement [Outcome 2] |
| 08-58 | Supplier agreement review record [Outcome 5] |
| 08-59 | Supplier capability assessment record [Outcome 4] |
| 09-11 | Supplier performance evaluation report [Outcome 6] |
| 08-60 | Supplier role assignments list [Outcome 1] |

## 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:<br>a) items requiring configuration management are identified;<br>b) the status of configuration items and modifications is known;<br>c) changes to items under configuration management are controlled;<br>d) the integrity of systems, products/services and product/service components is assured;<br>e) the configuration of released items is controlled. |

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|---|---|
| **Base Practices** | TEC.01.BP.1 **Identify configuration items.** Identify items requiring configuration management. [Outcome 1]<br>TEC.01.BP.2 **Identify configuration item status.** Identify the status of configuration items and modifications. [Outcome 2]<br>TEC.01.BP.3 **Control changes.** Control changes to items under configuration management. [Outcome 3]<br>TEC.01.BP.4 **Assure the integrity of items.** Assure the integrity of systems, products/services and product/service components. [Outcome 4]<br>TEC.01.BP.5 **Control released items.** Control the configuration of released items. [Outcome 5] |
| **Inputs** | |
| 07-3 | Product/service component [Outcome 1] |
| 12-16 | Product/service component change evaluation criteria [Outcome 3] |
| 11-08 | Product/service component change request [Outcome 3] |
| 08-40 | Product/service component change request approval record [Outcome 3] |
| 10-1 | Product/service component repository [Outcomes 4,5] |
| 12-17 | Product/service release criteria [Outcome 5] |
| **Outputs** | |
| 08-06 | Configuration item change log [Outcome 3] |
| 07-2 | Product/service [Outcome 5] |
| 07-3 | Product/service component [Outcome 5] |
| 08-39 | Product/service component change evaluation result [Outcome 3] |
| 10-1 | Product/service component repository [Outcome 1] |
| 08-41 | Product/service component repository access log [Outcomes 3,4] |
| 09-06 | Product/service configuration evaluation report [Outcome 4] |
| 09-07 | Product/service configuration status report [Outcome 2] |
| 08-43 | Product/service release approval record [Outcome 5] |
| 03-27 | Product/service taxonomy [Outcome 1] |

## 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:<br>a) process change requests are classified;<br>b) process change requests are assessed using defined criteria;<br>c) process changes are implemented, as appropriate. |

| | |
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| **Base Practices** | TEC.02.BP.1 **Classify process change requests.** Classify process change requests. The organization reviews changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. [Outcome 1]<br>TEC.02.BP.2 **Assess process change requests.** Assess process change requests using defined criteria. [Outcome 2]<br>TEC.02.BP.3 **Implement process changes.** Implement process changes, as appropriate. [Outcome 3] |
| **Inputs** | |
| 08-32 Process change approval record [Outcome 3] | |
| 08-34 Process change request review record [Outcome 2] | |
| **Outputs** | |
| 08-32 Process change approval record [Outcome 2] | |
| 08-33 Process change evaluation record [Outcome 2] | |
| 02-7 Process change implementation log [Outcome 3] | |
| 08-34 Process change request review record [Outcome 1] | |

## 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:<br>a) product/service change requests are identified and classified;<br>b) product/service change requests are assessed using defined criteria;<br>c) product/service changes are implemented, as appropriate. |
| **Base Practices** | TEC.03.BP.1 **Identify product/service change requests.** Identify and classify product/service change requests. [Outcome 1]<br>TEC.03.BP.2 **Assess product/service change requests.** Assess product/service change requests using defined criteria. [Outcome 2]<br>TEC.03.BP.3 **Implement product/service changes.** Implement product/service changes, as appropriate. [Outcome 3] |
| **Inputs** | |
| 08-42 Product/service design change evaluation result [Outcome 3] | |
| 11-09 Product/service design change request [Outcome 2] | |
| **Outputs** | |
| 08-42 Product/service design change evaluation result [Outcome 2] | |
| 08-35 Product/service design change log [Outcome 3] | |
| 11-09 Product/service design change request [Outcome 1] | |

## 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:<br>a) design for each product/service component is developed in accordance with defined requirements;<br>b) external and internal interfaces for each product/service component are defined. |
| **Base Practices** | TEC.04.BP.1 **Design each product/service component.** Develop the design for each product/service component in accordance with defined requirements. [Outcome 1]<br>TEC.04.BP.2 **Define external and internal interfaces.** Define the external and internal interfaces for each product/service component. [Outcome 2] |
| **Inputs** | |
| 03-28 Product/service design [Outcome 2] | |
| **Outputs** | |
| 03-28 Product/service design [Outcomes 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:<br>a) the objectives for the scope of the work associated with the development of the product/service are defined;<br>b) the feasibility of achieving the objectives of the product/service development with available resources and constraints are evaluated;<br>c) the tasks and resources necessary to complete the product/service development are sized and estimated;<br>d) the responsibilities and authorities needed at each stage of product/service development are identified;<br>e) interfaces between customer and relevant interested parties are identified;<br>f) plans for the development of the product/service are developed. |

| | |
|---|---|
| **Base Practices** | TEC.05.BP.1 **Define objectives.** Define the objectives for the scope of the work associated with the development of the product/service. [Outcome 1]<br>TEC.05.BP.2 **Evaluate feasibility.** Evaluate the feasibility of achieving the objectives of the product/ service development with available resources and constraints. [Outcome 2]<br>TEC.05.BP.3 **Estimate tasks and resources.** Size and estimate the tasks and resources necessary to complete the product/service development. [Outcome 3]<br>TEC.05.BP.4 **Identify responsibilities and authorities.** Identify the responsibilities and authorities needed at each stage of product/service development. [Outcome 4]<br>TEC.05.BP.5 **Identify interfaces.** Identify interfaces between customer and relevant interested parties. [Outcome 5]<br>TEC.05.BP.6 **Develop plans.** Develop plans for the development of the product/ service. [Outcome 6] |
| **Inputs** | |
| 09-09 Product/service feasibility analysis report [Outcome 3] | |
| **Outputs** | |
| 09-09 Product/service feasibility analysis report [Outcome 2]<br>02-8 Product/service review schedule [Outcome 6]<br>03-30 Project/service measures [Outcome 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:<br>a) product/service that does not conform to requirements is identified;<br>b) nonconforming product/service is placed under quarantine;<br>c) alternative approaches are identified regarding disposition of the nonconforming product/service;<br>d) agreed actions are taken regarding disposition of nonconforming product/ service;<br>e) product/service that has been corrected is re-verified to demonstrate conformity to requirements;<br>f) action is taken to prevent re-occurrence of the identified product/service nonconformity;<br>g) product/service is released from quarantine when authorized. |

| | |
|---|---|
| **Base Practices** | TEC.06.BP.1 **Identify non-conforming product/services.** Identify product/service that does not conform to requirements. [Outcome 1]<br>TEC.06.BP.2 **Quarantine nonconforming product/services.** Place under quarantine nonconforming product/services. [Outcome 2]<br>TEC.06.BP.3 **Identify alternative approaches.** Identify alternative approaches regarding disposition of the nonconforming product/service. [Outcome 3]<br>TEC.06.BP.4 **Take agreed actions.** Take agreed actions regarding disposition of nonconforming product/service. [Outcome 4]<br>TEC.06.BP.5 **Re-verify corrected product/service.** Re-verify product/service that has been corrected to demonstrate conformity to requirements. [Outcome 5]<br>TEC.06.BP.6 **Take action to prevent re-occurrence.** Take action to prevent re-occurrence of the identified product/service nonconformity. [Outcome 6]<br>TEC.06.BP.7 **Release product/service from quarantine.** Release product/service from quarantine when authorized. [Outcome 7] |
| **Inputs** | |
| 08-29 Non-conformity disposition record [Outcome 4] | |
| 08-30 Non-conformity record [Outcome 2] | |
| 11-05 Nonconforming product corrective action request [Outcome 7] | |
| 08-26 Nonconforming product disposition evaluation result [Outcome 5] | |
| 11-06 Nonconforming product quarantine request [Outcome 3] | |
| 08-28 Nonconforming product re-verification record [Outcome 6] | |
| **Outputs** | |
| 08-29 Non-conformity disposition record [Outcome 3] | |
| 08-30 Non-conformity record [Outcome 1] | |
| 11-05 Nonconforming product corrective action request [Outcome 6] | |
| 11-04 Nonconforming product corrective action request [Outcome 4] | |
| 08-26 Nonconforming product disposition evaluation result [Outcome 4] | |
| 08-27 Nonconforming product quarantine release authorization [Outcome 7] | |
| 11-06 Nonconforming product quarantine request [Outcome 2] | |
| 08-28 Nonconforming product re-verification record [Outcome 5] | |

## 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:<br>a) the required characteristics and context of use of products/services are identified;<br>b) the constraints for a product/service solution are defined;<br>c) the requirements for the product/service are defined;<br>d) the requirements for validating the product/service are defined. |

| | |
|---|---|
| **Base Practices** | TEC.07.BP.1 **Identify product/service characteristics.** Identify the required characteristics and context of use of products/services. [Outcome 1]<br>TEC.07.BP.2 **Identify solution constraints.** Identify the constraints for a product/service solution. [Outcome 2]<br>TEC.07.BP.3 **Define requirements.** Define the requirements for the product/service. [Outcome 3]<br>TEC.07.BP.4 **Define validation requirements.** Define the requirements for validating the product/ service. [Outcome 4] |
| **Inputs** | |
| 12-18 Product/service requirements [Outcomes 2,3,4] | |
| **Outputs** | |
| 12-18 Product/service requirements [Outcomes 1,2,3] | |
| 08-45 Product/service requirements review record [Outcome 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:<br>a) criteria for the review of product/ service is identified;<br>b) review participants are identified;<br>c) required review activities are performed;<br>d) action items are identified. |
| Base Practices | TEC.08.BP.1 **Identify criteria.** Identify criteria for the review of product/service. [Outcome 1]<br>TEC.08.BP.2 **Identify participants.** Identify review participants. [Outcome 2]<br>TEC.08.BP.3 **Perform reviews.** Perform the required review activities [Outcome 3]<br>TEC.08.BP.4 **Identify action items.** Identify action items. [Outcome 4] |
| **Inputs** | |
| 12-13 Product review criteria [Outcome 3] | |
| 08-45 Product/service requirements review record [Outcome 4] | |
| 08-47 Product/service review participant list [Outcome 3] | |
| **Outputs** | |
| 12-13 Product review criteria [Outcome 1] | |
| 08-45 Product/service requirements review record [Outcomes 3,4] | |
| 08-52 Product/service review action log [Outcome 4] | |
| 08-47 Product/service review participant list [Outcome 2] | |

## 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:<br>a) product/service request(s) received from the customer are confirmed;<br>b) product/service request(s) are evaluated in terms of mandated product/service delivery criteria;<br>c) a response to a customer's product/service request is produced;<br>d) an agreement is established between the customer and the supplier for providing the product/service;<br>e) the product/service is provided to the customer in accordance with the agreed requirements;<br>f) conformity to applicable stated and implied customer and supplier requirements by internal processes and/or product/service provided is verified. |
| **Base Practices** | TEC.09.BP.1 **Confirm product/service request(s).** Confirm product/service request(s) received from the customers. [Outcome 1]<br>TEC.09.BP.2 **Evaluate product/service request(s).** Evaluate product/service request(s) in terms of mandated product/service delivery criteria. [Outcome 2]<br>TEC.09.BP.3 **Produce a response to a request.** Produce a response to a customer's product/ service request. [Outcome 3]<br>TEC.09.BP.4 **Establish an agreement.** Establish an agreement between the customer and the supplier for providing the product/service. [Outcome 4]<br>TEC.09.BP.5 **Provide product/service.** Provide the product/service to the customer in accordance with the agreed requirements. [Outcome 5]<br>TEC.09.BP.6 **Verify conformity to requirements.** Verify conformity to applicable stated and implied customer and supplier requirements by internal processes and/ or product provided. [Outcome 6] |
| **Inputs** | |
| 03-21 | Management system strategy: supplier capability [Outcome 3] |
| 12-14 | Product/service acceptance criteria [Outcomes 5,6] |
| 08-44 | Product/service requirements communication record [Outcome 4] |
| 08-45 | Product/service requirements review record [Outcome 3] |
| 03-35 | Request for proposal (RFP) [Outcome 2] |
| **Outputs** | |
| 03-21 | Management system strategy: supplier capability [Outcome 2] |
| 08-37 | Product delivery record [Outcome 5] |
| 12-14 | Product/service acceptance criteria [Outcome 4] |
| 08-36 | Product/service release approval record [Outcomes 5,6] |
| 08-44 | Product/service requirements communication record [Outcome 3] |
| 08-45 | Product/service requirements review record [Outcome 2] |
| 08-49 | Product/service validation record [Outcome 6] |
| 03-35 | Request for proposal (RFP) [Outcome 1] |

## 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:<br>a) products/ services to be validated are selected;<br>b) criteria for validation of all required process results are identified;<br>c) required validation activities are performed;<br>d) problems are identified. |
| **Base Practices** | TEC.10.BP.1 **Select validation results.** Select process results to be validated. [Outcome 1]<br>TEC.10.BP.2 **Identify criteria.** Identify criteria for validation of all required process results. [Outcome 2]<br>TEC.10.BP.3 **Perform validation activities.** Perform required validation activities. [Outcome 3]<br>TEC.10.BP.4 **Identify problems.** Identify problems. [Outcome 4] |
| **Inputs** | |
| 08-38 Product/service candidate list [Outcome 3] | |
| 12-19 Product/service validation criteria [Outcome 3] | |
| 08-49 Product/service validation record [Outcome 4] | |
| **Outputs** | |
| 08-38 Product/service candidate list [Outcome 1] | |
| 08-48 Product/service validation action log [Outcome 4] | |
| 12-19 Product/service validation criteria [Outcome 2] | |
| 08-49 Product/service validation record [Outcome 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:<br>a) products/services to be verified are selected;<br>b) criteria for verification of all required process results is identified;<br>c) required verification activities are performed;<br>d) defects are identified. |

| | |
|---|---|
| **Base Practices** | TEC.11.BP.1 **Select verification items.** Select products/services to be verified. [Outcome 1]<br>TEC.11.BP.2 **Identify criteria.** Identify criteria for verification of all required process results. [Outcome 2]<br>TEC.11.BP.3 **Perform verification.** Perform required verification activities. [Outcome 3]<br>TEC.11.BP.4 **Identify defects.** Identify defects. [Outcome 4] |
| **Inputs** | |
| 08-38 Product/service candidate list [Outcome 3] | |
| 12-20 Product/service verification criteria [Outcome 3] | |
| **Outputs** | |
| 08-38 Product/service candidate list [Outcome 1] | |
| 08-50 Product/service verification action log [Outcome 4] | |
| 12-20 Product/service verification criteria [Outcome 2] | |
| 08-51 Product/service verification record [Outcome 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:<br>a) the context of the organization, including the expectations of its relevant interested parties, are understood and analysed;<br>b) the scope of management system activities is defined, taking the context of the organization into consideration;<br>c) the management system policy and objectives are defined;<br>d) the management system and operational process strategy is determined;<br>e) commitment and leadership with respect to the management system is demonstrated. |

| | |
|---|---|
| **Base Practices** | TOP.01.BP.1 **Determine external and internal issues that are relevant to the organization and analyse their impacts.** Determine external and internal issues that are relevant to the purpose of the assessed organization and that affect its ability to achieve the intended outcome(s) of its quality management system. [Outcome 1]<br><br>TOP.01.BP.2 **Determine relevant the interested parties and analyse their requirements.** Determine the relevant interested parties that are relevant to the quality management system and establish appropriate contacts with them. [Outcome 1]<br><br>TOP.01.BP.3 **Determine the scope of the quality management system.** Determine the boundaries and applicability of the quality management system, taking into consideration the context of the organization, the requirements of relevant interested parties and the interfaces and dependencies between activities performed by the organization, and those that are performed by other organization. [Outcome 2]<br><br>TOP.01.BP.4 **Define a quality policy.** Define a quality policy that is appropriate to the purpose of the organization. [Outcome 3]<br><br>TOP.01.BP.5 **Define quality objectives.** Define quality objectives at relevant functions and levels, which are measurable, consistent with the quality policy. [Outcome 3]<br><br>TOP.01.BP.6 **Determine process strategy.** Determine the management system and operational process strategy. [Outcome 4]<br><br>TOP.01.BP.7 **Integrate the quality management system requirements into the business processes of the organization.** Ensure the integration of the quality management system requirements into the business processes of the organization. [Outcome 5]<br><br>TOP.01.BP.8 **Demonstrate leadership by enabling contributions to organizational effectiveness.** Direct and support persons to contribute to the effectiveness of the quality management system and support other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. [Outcome 5] |

| Inputs | |
|---|---|
| 03-04 | Management system (MS) scope [Outcome 3] |
| 03-10 | Management system strategy: external and internal issues [Outcome 2] |
| 03-25 | MS Relevant Interested parties [Outcome 2] |
| 12-08 | MS Relevant Interested parties MS expectations [Outcome 2] |
| 05-2 | Quality policy [Outcomes 4,5] |
| **Outputs** | |
| 08-18 | Information status record [Outcome 4] |
| 03-04 | Management system (MS) scope [Outcome 2] |
| 03-05 | Management system strategy: change management [Outcome 4] |
| 03-06 | Management system strategy: customer focus [Outcome 5] |
| 03-07 | Management system strategy: customer property [Outcome 4] |
| 03-08 | Management system strategy: documentation [Outcome 4] |
| 03-09 | Management system strategy: Establish the management system [Outcome 4] |
| 03-10 | Management system strategy: external and internal issues [Outcome 1] |
| 03-11 | Management system strategy: improvement [Outcome 4] |
| 03-12 | Management system strategy: knowledge [Outcome 4] |
| 03-13 | Management system strategy: management commitment [Outcomes 3,5] |
| 03-14 | Management system strategy: measurement [Outcome 4] |
| 03-15 | Management system strategy: outsourcing [Outcome 4] |
| 03-16 | Management system strategy: planning [Outcome 4] |
| 03-17 | Management system strategy: process environment [Outcome 4] |
| 03-18 | Management system strategy: product preservation [Outcome 4] |
| 03-25 | MS Relevant Interested parties [Outcome 1] |
| 12-08 | MS Relevant Interested parties MS expectations [Outcome 1] |
| 12-15 | Product/service characteristics [Outcome 4] |
| 03-34 | Quality objectives [Outcome 3] |
| 05-2 | Quality policy [Outcome 3] |

# 6 Process capability indicators

## 6.1 General

This clause presents the process capability indicators related to the process capability attributes (process attribute, PA) associated with capability levels 1 to 5 defined in the capability dimension of the process assessment model. Process capability indicators are the means of achieving the capabilities addressed by the considered process capability attributes. Evidence of process capability indicators supports the judgment of the degree of achievement of the process capability attribute. Clause 5 describes the assessment indicators for process performance which is characterized by Level 1 process capability.

## 6.2 Process capability levels and process attributes

### 6.2.1 General

The capability process quality characteristic of the process assessment model consists of capability levels as defined in ISO/IEC 33020. Process capability is defined on a six-point ordinal scale that enables capability to be assessed from the bottom of the scale, **Incomplete**, through to the top end of the scale, **Innovating**. The scale represents increasing capability of the implemented process, from failing to achieve the process purpose through to continually improve and responding to strategic organizational change.

NOTE 1 In the next paragraphs, ISO/IEC 33020 process attribute definitions and attribute outcomes are identified with italic font.

NOTE 2 Following each generic resource and generic work product is "[PA.x.y outcome]". This refers to process attribute x.y outcome n which is satisfied by this indicator.

### 6.2.2 Process capability Level 0: Incomplete process

The process is not implemented or fails to achieve its process purpose.

At this level, there is little or no evidence of any systematic achievement of the process purpose.

### 6.2.3 Process capability Level 1: Performed process

#### 6.2.3.1 General

The implemented process achieves its process purpose. The following process attribute demonstrates the achievement of this level.

#### 6.2.3.2 PA.1.1 Process performance process attribute

##### 6.2.3.2.1 General

*The process performance process attribute is a measure of the extent to which the process purpose is achieved. As a result of full achievement of this process attribute, the process achieves its defined process outcomes.*

##### 6.2.3.2.2 Generic practice for PA.1.1

| **PA.1.1.GP1 Achieve the process outcomes** |
| --- |
| Achieve the intent of the base practices. |
| Produce work products that evidence the process outcomes. |

NOTE The assessment of a performed process is based on process performance indicators, which are defined in Clause 5.

##### 6.2.3.2.3 Generic resources for PA.1.1

— Resources are used to perform the intent of process-specific base practices. [PA.1.1 outcome a]

##### 6.2.3.2.4 Generic work products for PA.1.1

7.0 Product [PA.1.1 outcome a]

— Work products exist that provide evidence of the achievement of the process outcomes.

### 6.2.4 Process capability Level 2: Managed process

#### 6.2.4.1 General

The previously described *performed process* is now implemented in a managed fashion (planned, monitored and adjusted) and its work products are appropriately established, controlled and maintained.

The following process attributes, together with the previously defined process attribute, demonstrate the achievement of this level.

#### 6.2.4.2 PA.2.1 Performance management process attribute

##### 6.2.4.2.1 General

*The performance management process attribute is a measure of the extent to which the performance of the process is managed. As a result of full achievement of this process attribute:*

b) *objectives for the performance of the process are identified;*

c) *performance of the process is planned;*

d) *performance of the process is monitored;*

e) *performance of the process is adjusted to meet plans;*

f) *responsibilities and authorities for performing the process are defined, assigned and communicated;*

g) *personnel performing the process are prepared for executing their responsibilities;*

h) *resources and information necessary for performing the process are identified, made available, allocated and used;*

i) *interfaces between the involved parties are managed to ensure both effective communication and clear assignment of responsibility.*

#### 6.2.4.2.2 Generic practices for PA.2.1

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|---|
| **PA.2.1.GP1 Identify the objectives** for the performance of the process.<br>NOTE Performance objectives may include quality of the artefacts produced, process cycle time or frequency, resource usage and boundaries of the process.<br>Performance objectives are identified based on process requirements.<br>The scope of the process performance is defined.<br>Assumptions and constraints are considered when identifying the performance objectives. |
| **PA.2.1.GP2 Plan the performance** of the process to fulfil the identified objectives.<br>Plan(s) for the performance of the process are developed. The process performance cycle is defined.<br>Key milestones for the performance of the process are established.<br>Estimates for process performance attributes are determined and maintained.<br>Process activities and tasks are defined.<br>Schedule is defined and aligned with the approach to performing the process.<br>Process work product reviews are planned. |
| **PA.2.1.GP3 Monitor the performance** of the process against the plans.<br>The process is performed according to the plan(s).<br>Process performance is monitored to ensure that planned results are achieved and to identify possible deviations. |
| **PA.2.1.GP4 Adjust** the performance of the process.<br>Process performance issues are identified.<br>Appropriate actions are taken when planned results and objectives are not achieved.<br>The plan(s) are adjusted, as necessary.<br>Rescheduling is performed as necessary. |
| **PA.2.1.GP5 Define responsibilities and authorities** for performing the process.<br>Responsibilities, commitments and authorities to perform the process are defined, assigned and communicated.<br>Responsibilities and authorities to verify process work products are defined and assigned.<br>The needs for process performance experience, knowledge and skills are defined. |

| |
|---|
| **PA.2.1.GP6 Prepare those performing the process** to execute their responsibilities.<br>Competencies for management and execution of the process are ensured by training or work-based learning.<br>Required competencies are identified based on the responsibilities. |
| **PA.2.1.GP7 Identify and make available resources** to perform the process according to plan.<br>The human and infrastructure resources necessary for performing the process are identified, made available, allocated and used.<br>The information necessary to perform the process is identified and made available. |
| **PA.2.1.GP8 Manage the interfaces** between involved parties.<br>The individuals and groups involved in the process performance are determined.<br>Responsibilities of the involved parties are assigned.<br>Interfaces between the involved parties are managed.<br>Communication is assured between the involved parties.<br>Communication between the involved parties is effective. |

#### 6.2.4.2.3 Generic resources for PA.2.1

— Human resources with identified objectives, responsibilities and authorities [PA.2.1 outcomes a, e, f, g, h].

— Facilities and infrastructure resources [PA.2.1 outcomes a, e, g, h].

— Project planning, management and control tools, including time and cost reporting [PA.2.1 outcomes b, c, d].

— Workflow management system [PA.2.1 outcomes e, h].

— Email and/or other communication mechanisms [PA.2.1 outcomes e, h].

— Information and/or experience repository [PA.2.1 outcomes b, c, f, g].

— Problem and issue management mechanisms [PA.2.1 outcome d].

#### 6.2.4.2.4 Generic work products for PA.2.1

4.0 Plan [PA 2.1 outcomes a, b, c, d, e, f, g, h]

— Defines objectives to perform the process.

— Describes assumptions and constraints considered in defining the objectives.

— Includes milestones and timetable to produce the work products of the process.

— Identifies tasks, resources, responsibilities and infrastructure needed to perform the process.

— Considers risks related to fulfil defined objectives.

— Identifies stakeholders and communication mechanisms to be used.

— Describes how the plan is controlled and adjusted when needed.

8.0 Record [PA.2.1 outcomes c, d, e, g, h]

— Contains status information about corrections; schedule and work breakdown structure.

— Monitors identified risks.

— States results achieved or provides evidence of activities performed in a process.

— Provides evidence of communication, meetings, reviews and corrections.

9.0 Report [PA.2.1 outcomes b, c, d]

— Monitors process performance against defined objectives and plans.

— Identifies deviations in process performance.

— Describes results and status of the process.

— Provides evidence of management activities.

#### 6.2.4.3 PA.2.2 Work product management process attribute

##### 6.2.4.3.1 General

*The work product management process attribute is a measure of the extent to which the work products produced by the process are appropriately managed. As a result of full achievement of this process attribute:*

a) *requirements for the work products of the process are defined;*

b) *requirements for documentation and control of the work products are defined;*

c) *work products are appropriately identified, documented and controlled;*

d) *work products are reviewed in accordance with planned arrangements and adjusted as necessary to meet requirements.*

*NOTE 1 Requirements for documentation and control of work products may include requirements for the identification of changes and revision status, approval and re-approval of work products, distribution of work products, and for making relevant versions of applicable work products available at points of use.*

*NOTE 2 The work products referred to in this clause are those that result from the achievement of the process purpose through the process outcomes.*

#### 6.2.4.3.2 Generic practices for PA.2.2

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|---|
| **PA.2.2.GP1 Define the requirements for the work products.**<br>The requirements for the work products to be produced are defined. Requirements may include defining contents and structure.<br>Quality criteria of the work products are identified.<br>Appropriate review and approval criteria for the work products are defined. |
| **PA.2.2.GP2 Define the requirements for documentation and control** of the work products**.**<br>Requirements for the documentation and control of the work products are defined. Such requirements may include requirements for distribution, identification of work products and their components traceability.<br>Dependencies between work products are identified and understood.<br>Requirements for the approval of work products to be controlled are defined. |
| **PA.2.2.GP3 Identify, document and control** the work products.<br>The work products to be controlled are identified.<br>Change control is established for work products.<br>The work products are documented and controlled in accordance with requirements.<br>Versions of work products are assigned to product configurations as applicable.<br>The work products are made available through appropriate access mechanisms.<br>The revision status of the work products may readily be ascertained. |
| **PA.2.2.GP4 Review and adjust work products** to meet the defined requirements.<br>Work products are reviewed against the defined requirements in accordance with planned arrangements.<br>Issues arising from work product reviews are resolved. |

#### 6.2.4.3.3 Generic resources for PA.2.2

— Requirement management method/toolset [PA.2.2 outcomes a, b, c].

— Configuration management system [PA.2.2 outcomes b, c].

— Documentation elaboration and support tool [PA.2.2 outcomes b, c].

— Document identification and control procedure [PA.2.2 outcomes b, c].

— Work product review methods and experiences [PA.2.2 outcome d].

— Review management method/toolset [PA.2.2 outcome d].

— Intranets, extranets and/or other communication mechanisms [PA.2.2 outcomes b, c].

— Problem and issue management mechanisms [PA.2.2 outcome d].

#### 6.2.4.3.4 Generic work products for PA.2.2

4.0 Plan [PA 2.2 outcome b]

— Expresses selected policy or strategy to manage work products.

— Describes requirements to develop, distribute, and maintain the work products.

— Defines quality control actions needed to manage the quality of the work product.

7.0 Product [PA 2.2 outcomes a, b, c, d]

— Demonstrates process-specific work products to be managed.

8.0 Record [PA 2.2 outcomes c, d]

— Records the status of documentation or work product.

— Demonstrates work product reviews and contributes to traceability.

— Describes non-conformance detected during work product reviews.

— Provides evidence that the changes are under control.

10.0 Repository [PA 2.2 outcome c]

— Contains and makes available work products and/or configuration items.

— Supports monitoring of changes to work products.

12.0 Specification [PA 2.2 outcomes a, b]

— Defines the attributes associated with a work product to be created.

— Defines the functional and non-functional requirements for work products.

— Identifies work product dependencies.

— Identifies approval criteria for documents.

### 6.2.5 Process capability Level 3: Established process

#### 6.2.5.1 General

The previously described *managed process* is now implemented using a defined process that is capable of achieving its process outcomes.

The following process attributes, together with the previously defined process attributes, demonstrate the achievement of this level.

#### 6.2.5.2 PA.3.1 Process definition process attribute

*The process definition process attribute is a measure of the extent to which a standard process is maintained to support the deployment of the defined process. As a result of full achievement of this process attribute:*

a) *a standard process, including appropriate tailoring guidelines, is defined and maintained that describes the fundamental elements that must be incorporated into a defined process;*

b) *the sequence and interaction of the standard process with other processes is determined;*

c) *required competencies and roles for performing the process are identified as part of the standard process;*

d) *required infrastructure and work environment for performing the process are identified as part of the standard process;*

e) *suitable methods and measures for monitoring the effectiveness and suitability of the process are determined.*

#### 6.2.5.2.1 Generic practices for PA.3.1

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| **PA.3.1.GP1 Define the standard process** that will support the deployment of the defined process.<br>A standard process is developed that includes the fundamental process elements.<br>The standard process identifies the deployment needs and deployment context.<br>Guidance and/or procedures are provided to support implementation of the process as needed.<br>Appropriate tailoring guideline(s) are available as needed. |
| **PA.3.1.GP2 Determine the sequence and interaction** between processes so that they work as an integrated system of processes.<br>The standard process's sequence and interaction with other processes are determined.<br>Deployment of the standard process as a defined process maintains integrity of processes. |
| **PA.3.1.GP3 Identify the roles and competencies** for performing the standard process.<br>Process performance roles are identified.<br>Competencies for performing the process are identified. |
| **PA.3.1.GP4 Identify the required infrastructure and work environment** for performing the standard process.<br>Process infrastructure components are identified (facilities, tools, networks, methods, etc.).<br>Work environment requirements are identified. |
| **PA.3.1.GP5 Determine suitable methods and measures** to monitor the effectiveness and suitability of the standard process.<br>Methods and measures for monitoring the effectiveness and suitability of the process are determined.<br>Appropriate criteria and data needed to monitor the effectiveness and suitability of the process are defined.<br>The need to conduct internal audit and management review is established.<br>Process changes are implemented to maintain the standard process. |

#### 6.2.5.2.2 Generic resources for PA.3.1

— Process modelling methods/tools [PA.3.1 outcomes a, b, c, d].

— Training material and courses [PA.3.1 outcomes a, b, c].

— Resource management system [PA.3.1 outcomes b, c].

— Process infrastructure [PA.3.1 outcomes a, b].

— Audit and trend analysis tools [PA.3.1 outcome e].

— Process monitoring method [PA.3.1 outcome e].

#### 6.2.5.2.3 Generic work products for PA.3.1

3.0 Description [PA 3.1 outcomes a, b, c, e]

— Describes the standard process, including the fundamental process elements, interactions with other processes and appropriate tailoring guidelines.

— Addresses the performance, management and deployment of the process, as described by capability levels 1 and 2 and the PA 3.2 Process deployment attribute.

— Addresses methods to monitor process effectiveness and suitability.

— Identifies data and records to be collected when performing the defined process, in order to improve the standard process.

— Identifies and communicates the personnel competencies, roles and responsibilities for the standard and defined process.

— Identifies the personnel performance criteria for the standard and defined process.

— Identifies the tailoring guidelines for the standard process.

— Identifies process measures.

4.0 Plan [PA 3.1 outcomes c, d]

— Identifies approaches for defining, maintaining and supporting a standard process, including infrastructure, work environment, training, internal audit and management review.

5.0 Policy [PA 3.1 outcomes a, b, c, d, e]

— Provides evidence of organizational commitment to maintain a standard process to support the deployment of the defined process.

10.0 Repository [PA 3.1 outcome d]

— Is used to support and maintain the standard process assets.

12.0 Specification [PA 3.1 outcome a]

— Provides reference for the standards used by the standard process and identification about how they are used.

#### 6.2.5.3 PA.3.2 Process deployment process attribute

##### 6.2.5.3.1 General

*The process deployment process attribute is a measure of the extent to which the standard process is deployed as a defined process to achieve its process outcomes. As a result of full achievement of this process attribute:*

a) *a defined process is deployed based upon an appropriately selected and/or tailored standard process;*

b) *required roles, responsibilities and authorities for performing the defined process are assigned and communicated;*

c) *personnel performing the defined process are competent on the basis of appropriate education, training, and experience;*

d) *required resources and information necessary for performing the defined process are made available, allocated and used;*

e) *required infrastructure and work environment for performing the defined process are made available, managed and maintained;*

f) *appropriate data are collected and analysed as a basis for understanding the behaviour of the process, to demonstrate the suitability and effectiveness of the process, and to evaluate where continual improvement of the process can be made.*

#### 6.2.5.3.2 Generic practices for PA.3.2

| |
|---|
| **PA.3.2.GP1 Deploy a defined process** that satisfies the context-specific requirements of the use of the standard process.<br>The defined process is appropriately selected and/or tailored from the standard process.<br>Conformance of defined process with standard process requirements is verified. |
| **PA.3.2.GP2 Assign and communicate roles, responsibilities and authorities** for performing the defined process.<br>The roles for performing the defined process are assigned and communicated.<br>The responsibilities and authorities for performing the defined process are assigned and communicated. |
| **PA.3.2.GP3 Ensure necessary competencies** for performing the defined process.<br>Appropriate competencies for assigned personnel are identified.<br>Suitable training is available for those deploying the defined process. |
| **PA.3.2.GP4 Provide resources and information** to support the performance of the defined process.<br>Required human resources are made available, allocated and used.<br>Required information to perform the process is made available, allocated and used. |
| **PA.3.2.GP5 Provide adequate process infrastructure** to support the performance of the defined process.<br>Required infrastructure and work environment is available.<br>Organizational support to effectively manage and maintain the infrastructure and work environment is available.<br>Infrastructure and work environment is used and maintained. |
| **PA.3.2.GP6 Collect and analyse data about performance of the process** to demonstrate its suitability and effectiveness.<br>Data required to understand the behaviour, suitability and effectiveness of the defined process are identified.<br>Data are collected and analysed to understand the behaviour, suitability and effectiveness of the defined process.<br>Results of the analysis are used to identify where continual improvement of the standard and/or defined process can be made. |

#### 6.2.5.3.3 Generic resources for PA.3.2

— Feedback mechanisms (customer, staff, other stakeholders) [PA.3.2 outcome f].

— Process repository [PA.3.2 outcomes a, b].

— Resource management system [PA.3.2 outcomes b, c, d].

— Knowledge management system [PA.3.2 outcome d].

— Problem and change management system [PA.3.2 outcome f].

— Working environment and infrastructure [PA.3.2 outcome e].

— Data collection analysis system [PA.3.2 outcome f].

— Process assessment framework [PA.4.1 outcome f].

— Audit/review system [PA.3.2 outcome f].

#### 6.2.5.3.4 Generic work products for PA.3.2

2.0 Data [PA 3.2 outcome f]

— Provides evidence that the project's defined process performance data was collected.

4.0 Plan [PA 3.2 outcomes a, b, f]

— Expresses the strategy for the organizational support, allocation and use of the process infrastructure.

— Describes the project's resources and the elements of the infrastructure needed to deploy the defined process.

— Expresses the strategy to satisfy the project's training needs.

— Identifies process improvement proposal(s) based on analysis of suitability and effectiveness.

3.0 Description [PA 3.2 outcome a]

— Describes the defined process for use by the project.

— Describes the verification activities needed to ensure the conformance of the project's defined process with the organization's standard process.

— Represents the interactions of the project's defined process with other processes.

8.0 Record [PA 3.2 outcomes a, b, c, d, e, f]

— Captures the project's work breakdown structure needed to define the tasks and their dependencies.

— Provides evidence that the project personnel possess the required authorities, skills, experience and knowledge.

— Provides evidence that project personnel have received the required training to satisfy the needs of the project.

— Provides evidence that project infrastructure and working environment are made available and maintained for performing the defined process.

— Records the status of required corrective actions.

9.0 Report [PA 3.2 outcome f]

— Provides results of the analysis, recommended corrective action, feedback to the process owner and to the organization's standard process.

— Identifies improvement opportunities of the defined process.

— Provides evidence on the suitability and effectiveness of the defined process.

10.0 Repository [PA 3.2 outcome d]

— Provides evidence that information is made available for performing the defined process.

12.0 Specification [PA 3.2 outcome f]

— Provides a basis to analyse data associated with the performance of the defined process.

### 6.2.6 Process capability Level 4: Predictable process

#### 6.2.6.1 General

The previously described *Established process* now operates predictively within defined limits to achieve its process outcomes. Quantitative management needs are identified, measurement data are collected and analysed to identify assignable causes of variation. Corrective action is taken to address assignable causes of variation.

The following process attributes, together with the previously defined process attributes, demonstrate the achievement of this level.

#### 6.2.6.2 PA.4.1 Quantitative analysis process attribute

##### 6.2.6.2.1 General

*The quantitative analysis process attributes a measure of the extent to which information needs are defined, relationships between process elements are identified and data are collected. As a result of full achievement of this process attribute:*

a) *the process is aligned with quantitative business goals;*

b) *process information needs in support of relevant defined quantitative business goals are established;*

c) *process measurement objectives are derived from process information needs;*

d) *measurable relationships between process elements that contribute to the process performance are identified;*

e) *quantitative objectives for process performance in support of relevant business goals are established;*

f) *appropriate measures and frequency of measurement are identified and defined in line with process measurement objectives and quantitative objectives for process performance;*

g) *results of measurement are collected, validated and reported in order to monitor the extent to which the quantitative objectives for process performance are met;*

*NOTE 1 Information needs typically reflect management, technical, project, process or product needs.*

*NOTE 2 Measures may be either process measures or product measures or both.*

##### 6.2.6.2.2 Generic practices for PA.4.1

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|---|
| **PA.4.1.GP1 Align the process with quantitative business goals.**<br>Quantitative business goals relevant to the process are identified.<br>The process supports achievement of the identified business goals. |
| **PA.4.1.GP2 Identify process information needs**, in relation to quantitative business goals.<br>Business goals relevant to establishing quantitative process measurement objectives for the process are identified.<br>Process stakeholders are identified and their information needs are defined.<br>Information needs are relevant to the quantitative business goals. |
| **PA.4.1.GP3 Derive process measurement objectives** from process information needs.<br>Process measurement objectives to satisfy defined process information needs are defined. |

| |
|---|
| **PA.4.1.GP4 Identify measurable relationships between process elements** that contribute to the process performance.<br>Relationships between process elements are determined.<br>Measures of process performance are justifiable. |
| **PA.4.1.GP5 Establish quantitative objectives** for the performance of the defined process, according to the alignment of the process with the business goals.<br>Process performance objectives are defined to explicitly reflect the quantitative business goals.<br>Process performance objectives are verified with process stakeholders to be realistic and useful. |
| **PA.4.1.GP6 Identify product and process measures** that support the achievement of the quantitative objectives for process performance.<br>Detailed measures are defined to support monitoring, analysis and verification needs of process and product goals.<br>Measures to satisfy process measurement and performance objectives are defined.<br>Frequency of data collection is defined.<br>Algorithms and methods to create derived measurement results from base measures are defined, as appropriate.<br>Verification mechanism for base and derived measures is defined. |
| **PA.4.1.GP7 Collect product and process measurement results** through performing the defined process.<br>Data collection mechanism is created for all identified measures.<br>Required data is collected in an effective and reliable manner.<br>Measurement results are created from the collected data within defined frequency.<br>Analysis of measurement results is performed within defined frequency.<br>Measurement results are validated to confirm that the results fulfil the process information needs.<br>Measurement results are reported to those responsible for monitoring the extent to which quantitative objectives are met. |

#### 6.2.6.2.3 Generic resources for PA.4.1

— Management information (cost, time, reliability, profitability, customer benefits, risks, etc.) [PA.4.1 outcomes a, b, c, d, e, f, g].

— Applicable measurement techniques [PA.4.1 outcome f].

— Product and process measurement tools and results databases [PA.4.1 outcomes f, g].

— Process measurement framework [PA.4.1 outcomes d, e, f, g].

— Tools for data analysis and measurement [PA.4.1 outcomes c, d, e, f, g].

#### 6.2.6.2.4 Generic work products for PA.4.1

2.0 Data [PA 4.1 outcome g]

— Defines data to be collected as specified in plans and measures.

3.0 Description [PA 4.1 outcomes a, b, d, f]

— Defines information needs for the process.

— Specifies candidate measures.

4.0 Plan [PA 4.1 outcomes a, b, c, e, f]

— Identifies the objective to be achieved.

— Describes process performance goals aligned with business goals and context-specific other relevant goals.

— Defines quantitative objectives for process performance.

— Specifies measures for the process.

— Defines tasks and schedules to collect and analyse data.

— Allocates responsibilities and resources for measurement.

9.0 Report [PA 4.1 outcome g]

— Provides results of process data analysis to identify process performance parameters.

12.0 Specification [PA 4.1 outcomes b, c, f]

— Describes information needs and performance objectives.

— Provides a basis for analysing process performance.

— Defines explicit criteria for data validation.

— Defines frequency of data collection.

#### 6.2.6.3 PA.4.2 Quantitative control process attribute

##### 6.2.6.3.1 General

*The quantitative control process attribute is a measure of the extent to which objective data are used to manage process performance that is predictable. As a result of full achievement of this process attribute:*

a) *techniques for analysing the collected data are selected;*

b) *assignable causes of process variation are determined through analysis of the collected data;*

c) *distributions that characterize the process performance are established;*

d) *corrective actions are taken to address assignable causes of variation;*

e) *separate distributions are established (as necessary) for analysing the process under the influence of assignable causes of variation.*

#### 6.2.6.3.2 Generic practices for PA.4.2

| |
|---|
| **PA.4.2.GP1 Select analysis techniques**, appropriate to collected data.<br>Process control analysis methods and techniques are defined.<br>Selected techniques are validated against process control objectives. |
| **PA.4.2.GP2 Determine assignable causes of process variation** by analysing the collected data.<br>Variation in process performance is attributed to a specific, unpredictable cause.<br>Assignable cause indicates a possible problem in the defined process. |
| **PA.4.2.GP3 Establish distributions** that characterize the process performance.<br>Variation in measurement results is used to analyse process performance.<br>Deviations are analysed to identify potential cause(s) of variation.<br>Trends of process performance are identified. |
| **PA.4.2.GP4 Identify and implement corrective actions** to address assignable causes.<br>Results are provided to those responsible for taking action.<br>Corrective actions are determined to address each assignable cause.<br>Corrective actions are implemented to address assignable causes of variation.<br>Corrective action results are monitored.<br>Corrective actions are evaluated to determine their effectiveness. |
| **PA.4.2.GP5 Establish separate distributions** for analysing the process under the influence of assignable causes of variation.<br>Consequences of process variation are analysed.<br>Distributions are used to quantitatively understand process performance. |

#### 6.2.6.3.3 Generic resources for PA.4.2

— Process control and analysis techniques [PA.4.2 outcomes a, b].

— Statistical analysis tools/applications [PA.4.2 outcomes b, c, e].

— Process control tools/applications [PA.4.2 outcomes c, d, e].

#### 6.2.6.3.4 Generic work products for PA.4.2

2.0 Data [PA 4.2 outcome b]

— Provides measurement data to identify assignable causes of variation.

3.0 Description [PA 4.2 outcomes b, c, e]

— Defines parameters for process control.

— Defines and maintains limits for variation.

4.0 Plan [PA 4.2 outcome a]

— Defines analysis methods and techniques at detailed level.

8.0 Record [PA 4.2 outcomes c, d, e]

— Provides information on defects and problems.

— Records the changes.

— Documents corrective actions to be implemented.

— Monitors the status of corrective actions.

9.0 Report [PA 4.2 outcomes a, c, d, e]

— Provides analysed measurement results of process performance.

— Identifies corrective actions to address assignable causes of variation.

— Ensures that selected techniques are effective and measures are validated.

10.0 Repository [PA 4.2 outcomes a, b, c, d, e]

— Collects the data and provides the basis for analysis, corrective actions and results reporting.

12.0 Specification [PA 4.2 outcomes a, b, e]

— Defines the method for collecting data.

— Measures the efficiency of the process.

### 6.2.7 Process capability Level 5: Innovating process

#### 6.2.7.1 General

The previously described *Predictable process* is now continually improved to respond to organizational change.

The following process attributes, together with the previously defined process attributes, demonstrate the achievement of this level.

#### 6.2.7.2 PA.5.1 Process innovation process attribute

##### 6.2.7.2.1 General

*The process innovation process attribute is a measure of the extent to which changes to the process are identified from investigations of innovative approaches to the definition and deployment of the process. As a result of full achievement of this process attribute:*

a) *process innovation objectives are defined that support the relevant business goals;*

b) *appropriate data are analysed to identify opportunities for best practice and innovation;*

c) *innovation opportunities derived from new technologies and process concepts are identified;*

d) *an implementation strategy is established to achieve the process innovation objectives.*



 

#### 6.2.7.2.2 Generic practices for PA.5.1

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| **PA.5.1.GP1 Define the process innovation objectives** for the process that support the relevant business goals.<br>Directions to process innovation are set.<br>New business visions and goals are analysed to give guidance for new process objectives and potential areas of process change.<br>Quantitative and qualitative process innovation objectives are defined and documented. |
| **PA.5.1.GP2 Analyse data** of the process to identify opportunities for best practice and innovation.<br>Feedback on opportunities for innovation is actively sought.<br>Innovation opportunities are identified.<br>Industry best practices are identified and evaluated. |
| **PA.5.1.GP3 Identify innovation opportunities** of the process from new technologies and process concepts.<br>Impact of new technologies on process performance is identified and evaluated.<br>Impact of new process concepts is identified and evaluated.<br>Innovation opportunities are identified.<br>Emergent risks are considered in identifying innovation opportunities |
| **PA.5.1.GP4 Define an implementation strategy** based on long-term innovation vision and objectives.<br>Commitment to innovation is demonstrated by organizational management and process owner(s).<br>Proposed process changes are evaluated and piloted to determine their benefits and expected impact on defined business objectives.<br>Changes are classified and prioritized based on their impact on defined innovation objectives.<br>Measures that validate the results of process changes are defined to determine expected effectiveness of the process change.<br>Implementation of the approved change(s) is planned as an integrated program or project.<br>Implementation plan and impact on business goals are discussed and reviewed by organizational management. |

#### 6.2.7.2.3 Generic resources for PA.5.1

— Process innovation framework [PA.5.1 outcomes a, c, d].

— Process feedback and analysis system (measurement data, causal analysis results, etc.) [PA.5.1 outcome b].

— Piloting and trialling mechanism [PA.5.1 outcomes b, c].

#### 6.2.7.2.4 Generic work products for PA.5.1

2.0 Data [PA 5.1 outcomes b, c]

— Provides analytical data to identify opportunities for best practice and innovation.

3.0 Description [PA 5.1 outcomes c, d]

— Identifies potential areas of innovation and new technology.

4.0 Plan [PA 5.1 outcomes a, d]

— Define and maintain business goals.

— Provides evidence of management commitment.

— Defines innovation objectives for the process

— Allocates resources for innovation activities.

— Schedules activities for root cause analysis.

— Defines an approach to implementing selected innovations.

— Identifies scope of pilot innovation activities.

5.0 Policy [PA 5.2 outcome a]

— Establishes expectations for conduct and evaluation of pilot innovations.

8.0 Record [PA 5.1 outcomes c, d]

— Identifies potential innovation opportunities.

— Records information on new technology and techniques.

9.0 Report [PA 5.1 outcomes b, c]

— Identifies potential innovations and process changes.

#### 6.2.7.3 PA.5.2 Process innovation implementation process attribute

##### 6.2.7.3.1 General

*The process innovation implementation process attribute is a measure of the extent to which changes to the definition, management and performance of the process achieves the relevant process innovation objectives. As a result of full achievement of this process attribute:*

a) *impact of all proposed changes is assessed against the objectives of the defined process and standard process;*

b) *implementation of all agreed changes is managed to ensure that any disruption to the process performance is understood and acted upon;*

c) *effectiveness of process change on the basis of actual performance is evaluated against the defined product requirements and process objectives.*

#### 6.2.7.3.2 Generic practices of PA.5.2

| |
|---|
| **PA.5.2.GP1 Assess the impact of each proposed change** against the objectives of the defined and standard process.<br>Objective priorities for process innovation are established.<br>Specified changes are assessed against product quality and process performance requirements and goals.<br>Impact of changes to other defined and standard processes is considered. |
| **PA.5.2.GP2**. **Manage the implementation of agreed changes** to selected areas of the defined and standard process according to the implementation strategy.<br>A mechanism is established for incorporating accepted changes into the defined and standard process(es) effectively and completely.<br>The factors that impact the effectiveness and full deployment of the process change are identified and managed, such as:<br>— economic factors (productivity, profit, growth, efficiency, quality, competition, resources, and capacity);<br>— human factors (job satisfaction, motivation, morale, conflict/cohesion, goal consensus, participation, training, span of control);<br>— management factors (skills, commitment, leadership, knowledge, ability, organizational culture and risks);<br>— technology factors (sophistication of system, technical expertise, development methodology, need of new technologies).<br>Training is provided to users of the process.<br>Process changes are effectively communicated to all affected parties.<br>Records of the change implementation are maintained. |
| **PA.5.2.GP3 Evaluate the effectiveness of process change** on the basis of actual performance against process performance and capability objectives and business goals.<br>Performance and capability of the changed process are measured and compared with historical data.<br>A mechanism is available for documenting and reporting analysis results to management and owners of standard and defined process.<br>Measures are analysed to evaluate the effectiveness of process changes.<br>Other feedback is recorded, such as opportunities for further innovation of the standard process. |

#### 6.2.7.3.3 Generic resources for PA.5.2

— Change management system [PA.5.2 outcomes a, b, c].

— Process evaluation system (impact analysis, etc.) [PA.5.2 outcomes a, c].

#### 6.2.7.3.4 Generic work products for PA.5.2

3.0 Description [PA 5.2 outcome b]

— Documents changes as a result of process innovation actions.

4.0 Plan [PA 5.2 outcomes a, b]

— Defines activities and schedule for pilot change implementation.

— Allocates resources for pilot implementation.

— Assigns responsibility for pilot implementation.

— Defines activities and schedule for organizational implementation of process change.

— Allocates resources and responsibilities for organizational implementation.

— Specifies scope of pilot implementation of proposed change.

8.0 Record [PA 5.2 outcome b]

— Contains records of all completed and in-progress pilot implementations.

— Records history of and justification for changes.

9.0 Report [PA 5.2 outcomes a, b, c]

— Describes results of pilot implementation of process change.

— Evaluates effectiveness of process compared to process innovation objectives.

— Provides details on implementation of organizational changes.

— Describes proposed changes to standard and defined process.

12.0 Specification [PA 5.2 outcome c]

— Specifies measures derived from process innovation objectives.

## 6.3 Related processes for process attributes

Certain processes support achievement of the capabilities addressed by a process attribute. Table 2 lists those processes and indicates the relation between those processes and each process attribute (PA). This information can be used in planning process assessments and in analysis and validation of the assessment results.

**Table 2 — Related processes for process attributes**

| | Process attributes | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| *Related processes* | PA 2.1 | PA 2.2 | PA 3.1 | PA 3.2 | PA 4.1 | PA 4.2 | PA 5.1 | PA 5.2 |
| Asset management | | | | X | | | | |
| Communication | X | | | | | | | |
| Configuration management | | X | | | | | | |
| Documentation management | | X | | X | | | | |
| Human resource management | X | | | X | | | | |
| Improvement | | | | X | | | | |
| Internal audit | | X | | | | | | |
| Leadership | | | | | | | X | X |
| Management review | | | | X | | | | |
| Measurement resource management | | | | X | | | | |
| Non-conformity management | | | | X | | | | |
| Operational implementation and control | | | | X | | | | |
| Operational planning | | | X | | | | | |
| Performance evaluation | | | | X | X | X | | |
| Process changes | | X | | | | | | |
| Product/service changes | | X | | | | | | |
| Product/service planning | X | | | | | | | |
| Product/service quarantine | | X | | | | | | |

**Table 2** *(continued)*

| | Process attributes | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| *Related processes* | PA 2.1 | PA 2.2 | PA 3.1 | PA 3.2 | PA 4.1 | PA 4.2 | PA 5.1 | PA 5.2 |
| Product/service reviews | X | | | | | | | |
| Product/service validation | | X | | | | | | |
| Product/service verification | | X | | | | | | |
| Risk management | X | | | X | | | | |
| Supplier management | X | | | | | | | |

# Annex A
(informative)

# Conformity of the process assessment model

## A.1 General

This document sets out a process assessment model that meets the requirements for conformance defined in ISO/IEC 33004. The process assessment model can be used in the performance of assessments that meet the requirements of ISO/IEC 33002. It may also be used as an example for a process assessment model developer.

This annex serves as the statement of conformance of the process assessment model to the requirements defined in ISO/IEC 33004. For ease of reference, the requirements from ISO/IEC 33004:2015, Clause 6 are embedded verbatim in the text of this annex. They should not be construed as normative elements of this document.

## A.2 Requirements for process assessment models

### A.2.1 General

> *This International Standard sets out the requirements that shall be met by process models used to support process assessment. A process assessment model shall be based upon a suitable reference source of process definitions based on one or more process reference model(s) as described in Clause 5. The requirements to be met by a process assessment model in order to claim conformance through its relationship with specific process reference model(s) are defined in Clause 6.*
>
> *[ISO/IEC 33004:2015, Clause 4]*

The purpose of this process assessment model is to support assessment of process capability using the process measurement framework defined in ISO/IEC 33020.

### A.2.2 Process assessment model scope

> *Processes in a process assessment model are based on the process descriptions provided in process reference model(s); process attributes and process quality levels (if applicable) are based on the process measurement framework.*
>
> *In order to assure that assessment results are translatable into a set of process profiles in a repeatable and reliable manner, process assessment models shall adhere to certain requirements.*
>
> *[ISO/IEC 33004:2015, 6.2]*

The process capability scope of this process assessment model is defined in the process measurement framework specified in ISO/IEC 33020, which defines a process measurement framework for process capability satisfying the requirements of ISO/IEC 33003.

### A.2.3 Requirements for process assessment models

*6.3.1 A process assessment model shall relate to a single process quality characteristic.*

*6.3.2 A process assessment model shall incorporate a single process measurement framework, conformant with ISO/IEC 33003:2015, based on the selected process quality characteristic.*

*6.3.3 A process assessment model shall be based on one or more process reference models and a process measurement framework.*

*6.3.4 A process assessment model shall relate to at least one process from the selected process reference model(s).*

*6.3.5 A process assessment model shall declare its scope of coverage in the terms of:*

*a) the selected process quality characteristic;*

*b) the selected process measurement framework;*

*c) the selected process reference model(s);*

*d) the selected processes from the process reference model(s);*

*e) the process attributes and (if relevant) the process quality levels of the process quality characteristic selected from the process measurement framework.*

*6.3.6 If the selected process measurement framework provides a nominal scale, then the process assessment model shall, for a given process, address all of the defined process attributes, including the process performance attribute.*

*6.3.7 If the process measurement framework provides an ordinal or interval scale, then the process assessment model shall address, for a given process, all, or a continuous subset, of the levels (starting at process quality level 1) of the process measurement framework for the process quality characteristic for each of the processes within its scope.*

*[ISO/IEC 33004:2015, 6.3]*

In the capability dimension of this process assessment model, the model addresses all of the process attributes and capability levels defined in the process measurement framework in ISO/IEC 33020:2015, Clause 5.

### A.2.4 Assessment indicators

*A process assessment model shall be based on a set of assessment indicators that:*

*a) explicitly address the purpose and process outcomes, as defined in the selected process reference model, of each of the processes within the scope of the process assessment model;*

*b) demonstrate the achievement of the process attributes within the scope of the process assessment model;*

*c) demonstrate the achievement (where relevant) of the process quality levels within the scope of the process assessment model.*

*The assessment indicators generally fall into three types:*

*a) practices that support achievement of either the process purpose or the specific process attribute;*

*b) information items and their characteristics that demonstrate the respective achievements;*

*c) resources and infrastructure that support the respective achievements.*

*[ISO/IEC 33004:2015, 6.3.8]*

The process assessment model provides a two-dimensional view of process capability for the processes in the process reference model, through the inclusion of assessment indicators as shown in Figure 4. The assessment Indicators used are:

— base practices and work products;

— generic practices, generic resources and generic work products

as shown in Figure 3. They support the judgment of the performance and capability of an implemented process.

### A.2.5 Mapping process assessment models to process reference models

*6.3.9 Mapping process assessment models*

*A process assessment model shall provide explicit mapping from the relevant elements of the process assessment model to the processes of the selected process reference model(s), and to the relevant process attributes of the selected process measurement framework. The mappings shall be complete, clear and unambiguous.*

*This enables process assessment models that are structurally different to be related to the same process reference model(s) and the process measurement framework.*

*6.3.9.1 Mapping to process reference models*

*The mapping of the assessment indicators within the process assessment model shall be to the purpose and process outcomes of the processes in the selected process reference model.*

*6.3.9.2 Mapping to process measurement framework*

*The mapping of the assessment indicators within the process assessment model shall be to the process attributes (including all the process attribute outcomes listed for each process attribute) in the process measurement framework.*

*[ISO/IEC 33004, 6.3.9]*

Each of the Processes in this process assessment model is identical in scope to the Process defined in the process reference model. Each base practice and work product is cross-referenced to the Process outcomes it addresses. All work products relate as Inputs or Outputs to the Process as a whole. See mappings in Clause 5.

Each of the process attributes in this process assessment model is identical to the process attribute defined in the process measurement framework. The generic practices address the process attribute outcomes from each process attribute. The generic resources and generic work products relate to the process attribute as a whole.

Table A.1 lists the mappings of the GPs to the achievements associated with each process attribute.

**Table A.1 — Mapping of generic practices**

| GP | Practice name | Maps to |
|---|---|---|
| **PA.1.1: Process performance process attribute** | | |
| PA.1.1.GP1 | Achieve the process outcomes. | PA.1.1 a |
| **PA.2.1: Performance management process attribute** | | |
| PA.2.1.GP1 | Identify the objectives for the performance of the process. | PA.2.1 a |
| PA.2.1.GP2 | Plan the performance of the process to fulfil the identified objectives. | PA.2.1 b |
| PA.2.1.GP3 | Monitor the performance of the process against the plans. | PA.2.1 c |
| PA.2.1.GP4 | Adjust the performance of the process. | PA.2.1 d |
| PA.2.1.GP5 | Define responsibilities and authorities for performing the process. | PA.2.1 e |
| PA.2.1.GP6 | Prepare those performing the process to execute their responsibilities. | PA.2.1 f |
| PA.2.1.GP7 | Identify and make available resources to perform the process according to plan. | PA.2.1 g |
| PA.2.1.GP8 | Manage the interfaces between involved parties. | PA.2.1 h |

**Table A.1** *(continued)*

| GP | Practice name | Maps to |
|---|---|---|
| **PA.2.2: Work product management process attribute** | | |
| PA.2.2.GP1 | Define the requirements for the work products. | PA.2.2 a |
| PA.2.2.GP2 | Define the requirements for documentation and control of the work products. | PA.2.2 b |
| PA.2.2.GP3 | Identify, document and control the work products. | PA.2.2 c |
| PA.2.2.GP4 | Review and adjust work products to meet the defined requirements. | PA.2.2 d |
| **PA.3.1: Process definition process attribute** | | |
| PA.3.1.GP1 | Define the standard process that will support the deployment of the defined process. | PA.3.1 a |
| PA.3.1.GP2 | Determine the sequence and interaction between processes so that they work as an integrated system of processes. | PA.3.1 b |
| PA.3.1.GP3 | Identify the roles and competencies for performing the standard process. | PA.3.1 c |
| PA.3.1.GP4 | Identify the required infrastructure and work environment for performing the standard process. | PA.3.1 d |
| PA.3.1.GP5 | Determine suitable methods and measures to monitor the effectiveness and suitability of the standard process. | PA.3.1 e |
| **PA.3.2: Process deployment process attribute** | | |
| PA.3.2.GP1 | Deploy a defined process that satisfies the context-specific requirements of the use of the standard process. | PA.3.2 a |
| PA.3.2.GP2 | Assign and communicate roles, responsibilities and authorities for performing the defined process. | PA.3.2 b |
| PA.3.2.GP3 | Ensure necessary competencies for performing the defined process. | PA.3.2 c |
| PA.3.2.GP4 | Provide resources and information to support the performance of the defined process. | PA.3.2 d |
| PA.3.2.GP5 | Provide adequate process infrastructure to support the performance of the defined process. | PA.3.2 e |
| PA.3.2.GP6 | Collect and analyse data about performance of the process to demonstrate its suitability and effectiveness. | PA.3.2 f |
| **PA.4.1 Quantitative analysis process attribute** | | |
| PA.4.1.GP1 | Align the process with quantitative business goals. | PA.4.1 a |
| PA.4.1.GP2 | Identify process information needs, in relation with quantitative business goals. | PA.4.1 b |
| PA.4.1.GP3 | Derive process measurement objectives from process information needs. | PA.4.1 c |
| PA.4.1.GP4 | Identify measurable relationships between process elements that contribute to the process performance. | PA.4.1 d |
| PA.4.1.GP5 | Establish quantitative objectives for the performance of the defined process, according to the alignment of the process with the business goals. | PA.4.1 e |
| PA.4.1.GP6 | Identify product and process measures that support the achievement of the quantitative objectives for process performance. | PA.4.1 f |
| PA.4.1.GP7 | Collect product and process measurement results through performing the defined process. | PA.4.1 g |
| **PA.4.2 Quantitative control process attribute** | | |
| PA.4.2.GP1 | Select analysis techniques, appropriate to collected data. | PA.4.2 a |
| PA.4.2.GP2 | Determine assignable causes of process variation by analysing the collected data. | PA.4.2 b |
| PA.4.2.GP3 | Establish distributions that characterize the process performance. | PA.4.2 c |
| PA.4.2.GP4 | Identify and implement corrective actions to address assignable causes. | PA.4.2 d |

**Table A.1** *(continued)*

| GP | Practice name | Maps to |
|---|---|---|
| PA.4.2.GP5 | Establish separate distributions for analysing the process under the influence of assignable causes of variation. | PA.4.2 e |
| **PA.5.1 Process innovation process attribute** | | |
| PA.5.1.GP1 | Define the process innovation objectives for the process that support the relevant business goals. | PA.5.1 a |
| PA.5.1.GP2 | Analyse data of the process to identify opportunities for best practice and innovation. | PA.5.1 b |
| PA.5.1.GP3 | Identify innovation opportunities of the process from new technologies and process concepts. | PA.5.1 c |
| PA.5.1.GP4 | Define an implementation strategy based on long-term innovation vision and objectives. | PA.5.1 d |
| **PA.5.2 Process innovation implementation process attribute** | | |
| PA.5.2.GP1 | Assess the impact of each proposed change against the objectives of the defined and standard process. | PA.5.2 a |
| PA.5.2.GP2 | Manage the implementation of agreed changes to selected areas of the defined and standard process according to the implementation strategy. | PA.5.2 b |
| PA.5.2.GP3 | Evaluate the effectiveness of process change on the basis of actual performance against process performance and capability objectives and business goals. | PA.5.2 c |

### A.2.6 Expression of assessment results

*A process assessment model shall provide a formal and verifiable mechanism for representing the results of an assessment as a set of process attribute ratings for each assessed process (the process profiles) selected from the process reference model(s).*

*[ISO/IEC 33004:2015, 6.3.10]*

The process attributes and the process attribute ratings in this process assessment model are identical to those defined in the Measurement Framework. Consequently, results of assessments based upon this process assessment model are expressed directly as a set of process attribute ratings for each process within the scope of the assessment. No translation or conversion is required.

# Annex B
(informative)

# Input and output characteristics

## B.1 General

Characteristics of inputs and outputs listed in this annex can be used when reviewing potential inputs and outputs of process implementation. The characteristics are provided as guidance for the attributes to look for to provide objective evidence supporting the assessment of a particular process.

A documented process and assessor judgment is needed to ensure that the process context (application domain, business purpose, development methodology, size of the organization, etc.) is considered when using this information. Inputs and outputs are defined using the schema in Table B.1. Inputs and outputs and their characteristics should be considered as a starting point for determining whether, given the context, they are contributing to the intended purpose of the process.

**Table B.1 — Input/Output identification**

| | |
|---|---|
| Input/Output identifier # | An identifier number for the input/output which is used to reference the input/output. |
| Input/Output name | Provides an example of a typical name associated with the input/output characteristics. This name is provided as an identifier of the type of input/output the practice or process might produce. Organizations may call these input/outputs by different names. The name of the input/output in the organization is not significant. Similarly, organizations may have several equivalent input/outputs which contain the characteristics defined in one input/output type. The formats for the input/outputs can vary. It is up to the assessor and the organizational unit coordinator to map the actual input/outputs produced in their organization to the examples given here. |
| Category | A group with which an item is associated. |
| Input/Output characteristics | Provides examples of the potential characteristics associated with the input/output types. The assessor may look for these in the samples provided by the organizational unit. |

## B.2 Generic input and outputs

The Generic Work Product Indicators are sets of characteristics that would be expected to be evident in input/outputs of a generic type as a result of achievement of an attribute. The generic input/outputs support the class structure of the input/outputs defined as process performance indicators. These input/output types are basic input types to process owners of all types of processes. See Table B.2.

**Table B.2 — Generic inputs and outputs**

| Reference | Category | Purpose | Typical Input/Output characteristics |
|---|---|---|---|
| 1.0 | Contract | A contract (or agreement) is the formal agreement between an acquirer and a supplier. Informally, commitments or agreements may be specified between parts of the same organization (sometimes called a memorandum of understanding).<br>[ISO/IEC/IEEE 15289] | A contract or agreement addresses the following:<br>a) identification of the performing organizations and their responsibilities;<br>b) statement of work to be performed, with tasks based on a service management process or a system or software life-cycle model, and scope of tasks;<br>c) system requirements and software requirements definition and analysis results;<br>d) negotiated price and payment schedule;<br>e) deliverables, including documentation, records, and off-the-shelf products identified;<br>f) schedule for suppliers to deliver the product or service;<br>g) proprietary rights to systems and technical data and software intellectual property rights: usage, ownership, warranty and licensing rights;<br>h) provisions for monitoring; reporting, verification, validation, and acceptance criteria;<br>i) procedures for contract changes, exceptions, resolving disputes, and closeout, such as supplier responsibilities in the event of expected or early termination of the contract or formal agreement and the transfer of services to another party.<br>The contract may specify best practices, to include standards and strategies for processes, activities and tasks. |
| 2.0 | Data | Ordered informational content | — Result of applying a measure<br>— Available to those who need to know within defined timeframe |
| 3.0 | Description | Information item that represents a planned or actual concept, function, design, or object.<br>[ISO/IEC/IEEE 15289] | A description shall include the following elements:<br>a) date of issue and status;<br>b) scope;<br>c) issuing organization;<br>d) references;<br>e) context;<br>f) notation for description;<br>g) body;<br>h) summary;<br>i) glossary;<br>j) change history. |

**Table B.2** *(continued)*

| Reference | Category | Purpose | Typical Input/Output characteristics |
|---|---|---|---|
| 4.0 | Plan | Information item that presents a systematic course of action for achieving a declared purpose, including when, how, and by whom specific activities are to be performed.<br>[ISO/IEC/IEEE 15289] | A plan shall include the following elements:<br>a) date of issue and status;<br>b) scope;<br>c) issuing organization;<br>d) references (applicable policies, laws, standards, contracts, requirements, and other plans and procedures);<br>e) approval authority;<br>f) introduction, containing the purpose, audience, and scope of the plan;<br>g) planned activities and tasks;<br>h) identification of tools, methods, and techniques;<br>i) schedules;<br>j) budgets and cost estimates;<br>k) resources and their allocation, including human resources, technical resources (infrastructure), and tools;<br>l) responsibilities and authority, including the senior responsible owner and immediate process or service owner;<br>m) interfaces among parties involved;<br>n) risks and risk identification, assessment and mitigation activities;<br>o) quality assurance and performance measures;<br>p) environment, infrastructure, security, and safety;<br>q) training;<br>r) approach for technical and management review and reporting;<br>s) other plans (plans or task descriptions that expand on the details of a plan);<br>t) glossary;<br>u) change procedures and history;<br>v) termination process. |

**Table B.2** *(continued)*

| Reference | Category | Purpose | Typical Input/Output characteristics |
|---|---|---|---|
| 5.0 | Policy | Clear and measurable statement of preferred direction and behaviour to condition the decisions made within an organization.<br>[ISO/IEC/IEEE 15289] | A policy shall include the following elements:<br>a) date of issue, effective date, and status scope;<br>c) issuing organization;<br>d) approval authority and identification of those accountable for enforcing the policy;<br>e) authoritative references for compliance or conformance (such as policies, laws and regulations, standards, contracts, requirements, and vision or mission statements);<br>f) body, including objectives;<br>g) glossary;<br>h) change history. |
| 6.0 | Procedure | Information item that presents an ordered series of steps to perform a process, activity, or task.<br>[ISO/IEC/IEEE 15289] | A procedure shall include the following elements:<br>a) date of issue and status;<br>b) scope;<br>c) issuing organization;<br>d) approval authority;<br>e) relationship to plans and other procedures;<br>f) authoritative references;<br>g) inputs and outputs;<br>h) ordered description of steps to be taken by each participant;<br>i) error and problem resolution;<br>j) glossary;<br>k) change history. |
| 7.0 | Product | Output of an organization that can be produced without any transaction taking place between the organization and the customer.<br>[ISO 9000:2015, 3.7.6] | Production of a product is achieved without any transaction necessarily taking place between provider and customer, but can often involve this service element upon its delivery to the customer.<br>The dominant element of a product is that it is generally tangible.<br>Hardware is tangible and its amount is a countable characteristic (e.g. tyres). Processed materials are tangible and their amount is a continuous characteristic (e.g. fuel and soft drinks). Hardware and processed materials are often referred to as goods. Software consists of information regardless of delivery medium (e.g. computer programme, mobile phone app, instruction manual, dictionary content, musical composition copyright, driver's license). |

**Table B.2** *(continued)*

| Reference | Category | Purpose | Typical Input/Output characteristics |
|---|---|---|---|
| 8.0 | Record | Set of related data items treated as a unit.<br>[ISO/IEC/IEEE 15289] | A record shall include the following elements:<br>a) date of record, date recorded, and status;<br>b) scope;<br>c) subject or category;<br>d) issuing organization;<br>e) references;<br>f) body;<br>g) unique record identifier. |
| 9.0 | Report | Information item that describes the results of activities such as investigations, observations, assessments, or tests.<br>[ISO/IEC/IEEE 15289] | A report shall include the following elements:<br>a) date of issue and status;<br>b) scope;<br>c) issuing organization;<br>d) contributors;<br>e) summary;<br>f) introduction, including the purpose, audience, and scope of the report;<br>g) context (assumptions);<br>h) body (including methods of obtaining results);<br>i) conclusions and recommendations;<br>j) references;<br>k) bibliography. |

**Table B.2** *(continued)*

| Reference | Category | Purpose | Typical Input/Output characteristics |
|---|---|---|---|
| 10.0 | Repository | Storage facility for data | — Repository for components<br>— Storage and retrieval capabilities<br>— Ability to browse content<br>— Listing of contents with description of attributes<br>— Sharing and transfer of components between affected groups<br>— Effective controls over access<br>— Maintain component descriptions<br>— Recovery of archive versions of components<br>— Ability to report component status<br>— Changes to components are tracked to change/user requests |
| 11.0 | Request | Record information needed to solicit a response.<br>[ISO/IEC/IEEE 15289] | A request shall include the following elements:<br>a) date of initiation;<br>b) scope;<br>c) subject;<br>d) originator of request;<br>e) identification of requested item, service, or response;<br>f) detailed description of requested item, service, or response, including due date;<br>g) justifications. |
| 12.0 | Specification | Provide requirements for a required service, product, or process.<br>[ISO/IEC/IEEE 15289] | A specification shall include the following elements:<br>a) date of issue and status;<br>b) scope;<br>c) issuing organization;<br>d) references;<br>e) approval authority;<br>f) body;<br>g) assurance requirements;<br>h) conditions, constraints, and characteristics;<br>i) glossary;<br>j) change history. |



## B.3 Specific inputs and outputs

Specific outputs are typically created by process owners and applied by process deployers in order to satisfy an outcome of a particular process purpose. See Table B.3.

NOTE 1 The reference scheme for the specific inputs and outputs associates the item to the first reference (direct or implied) to an informational element in a subclause of ISO 9001. The set of items in a category is ordered alphabetically.

NOTE 2 The term “normative” that appears under the Characteristics column refers to a requirement in ISO 9001 to create an item that contains at least the defined informational characteristics. Where the term “informative” appears, it implies that the defined characteristics are recommended good practice.

NOTE 3 In some cases, there are multiple elements to an information item. A single item (for example, 01-2) can have more than one descriptive component to it. These elements are differentiated from each other by means for an element reference. For example, in 01-2 there are two descriptive elements.

**Table B.3 — Specific inputs and outputs**

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 01-1 | Service level agreement | Contract | The organization shall communicate to external providers its requirements for:<br>a) the processes, products and services to be provided;<br>b) the approval of:<br>1) products and services;<br>2) methods, processes and equipment;<br>3) the release of products and services;<br>c) competence, including any required qualification of persons;<br>d) the external providers’ interactions with the organization;<br>e) control and monitoring of the external providers’ performance to be applied by the organization;<br>f) verification or validation activities that the organization, or its customer, intends to perform at the external providers’ premises. |
| 01-2 | Supplier agreement | Contract | The generic considerations of the Generic Work Product category of 'Contract' apply. |
| 02-1 | Measurement resource calibration log | Data | a) 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:<br>1) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards;<br>2) when no such standards exist, the basis used for calibration or verification shall be retained as documented information;<br>b) 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 identified in order to determine their status; |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| | | | c) 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 safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.<br>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). |
| 02-2 | Measurement resource identification | Data | b) 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:<br>— identified in order to determine their status;<br>— identified in order to determine their calibration status. |
| 02-3 | Measuring equipment asset list | Data | The organization shall ensure that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken. |
| 02-4 | Measuring equipment maintenance log | Data | The organization shall ensure that the resources provided are maintained to ensure their continuing fitness for their purpose. |
| 02-5 | MS Measurement information collection log | Data | Controlled conditions shall include, as applicable, 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.<br>The organization shall ensure that monitoring and measurement activities are implemented in accordance with the determined requirements [and shall retain appropriate documented information as evidence of the results.]<br>[The organization shall ensure that monitoring and measurement activities are implemented in accordance with the determined requirements] and shall retain appropriate documented information as evidence of the results. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 02-6 | MS Performance measurement data | Data | [The organization shall retain appropriate documented information as] evidence of the results.<br>[The organization shall ensure that monitoring and measurement activities are implemented in accordance with the determined requirements and shall retain appropriate documented information as] evidence of the results.<br>The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement. |
| 02-7 | Process change implementation log | Data | The organization shall retain [documented] information describing the [results of the review of changes, the person(s) authorizing the change, and] any necessary actions arising from the review.<br>[The organization shall retain] documented [information describing the results of the review of changes, the person(s) authorizing the change, and] any necessary actions arising from the review. |
| 02-8 | Product/service review schedule | Data | Design and development reviews are planned. |
| 03-01 | Improvement target | Description | The generic considerations of the Generic Work Product category of 'Description' apply. |
| 03-02 | Information item identification | Description | 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]. |
| 03-03 | Management review objectives | Description | Top management shall review the organization's quality management system, [at planned intervals], to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.<br>The management review shall [be planned and carried out] taking into consideration:<br>a) the status of actions from previous management reviews;<br>b) changes in external and internal issues that are relevant to the quality management system;<br>c) information on the performance and effectiveness of the quality management system, including trends in: |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| | | | 1) customer satisfaction and feedback from relevant interested parties;<br>2) the extent to which quality objectives have been met;<br>3) process performance and conformity of products and services;<br>4) nonconformities and corrective actions;<br>5) monitoring and measurement results;<br>6) audit results;<br>7) the performance of external providers;<br>d) the adequacy of resources;<br>e) the effectiveness of actions taken to address risks and opportunities (see 6.1);<br>f) opportunities for improvement. |
| 03-04 | Management system (MS) scope | Description | The organization shall determine the boundaries and applicability of the quality management system to establish its scope.<br>When determining this scope, the organization shall consider:<br>a) the external and internal issues referred to in 4.1;<br>b) the requirements of relevant interested parties referred to in 4.2;<br>c) the products and services of the organization.<br>The organization shall apply all the requirements of this document if they are applicable within the determined scope of its quality management system. |
| | | | The scope of the organization's quality management system shall be available [and be maintained] as documented information.<br>The scope of the organization's quality management system shall be [available and be] maintained as documented information.<br>The scope shall state the types of products and services covered, and provide justification for any requirement of this document that the organization determines is not applicable to the scope of its quality management system.<br>Conformity to this document 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. |
| 03-05 | Management system strategy: change management | Description | The organization shall ensure that outsourced processes are controlled (see ISO 9001:2015, 8.4). |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 03-06 | Management system strategy: customer focus | Description | Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:<br>a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;<br>b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;<br>c) the focus on enhancing customer satisfaction is maintained. |
| 03-07 | Management system strategy: customer property | Description | 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. |
| 03-08 | Management system strategy: documentation | Description | The organization's quality management system shall include:<br>a) documented information required by this document;<br>b) documented information determined by the organization as being necessary for the effectiveness of the quality management system. |
| 03-09 | Management system strategy: Establish the management system | Description | 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 document.<br>The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall address the risks and opportunities as determined in accordance with the requirements of 6.1.<br>To the extent necessary, the organization shall: |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| | | | a) maintain documented information to support the operation of its processes;<br>b) retain documented information to have confidence that the processes are being carried out as planned.<br>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:..<br>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:..<br>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:..<br>The organization shall meet requirements for post-delivery activities associated with the products and services.<br>In determining the extent of post-delivery activities that are required, the organization shall consider:<br>a) statutory and regulatory requirements;<br>b) the potential undesired consequences associated with its products and services;<br>c) the nature, use and intended lifetime of its products and services;<br>d) customer requirements;<br>e) customer feedback. |
| 03-10 | Management system strategy: external and internal issues | Description | 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. |
| 03-11 | Management system strategy: improvement | Description | The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system and shall improve the processes and the quality management system. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 03-12 | Management system strategy: knowledge | Description | The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services.<br>This knowledge shall be maintained [and be made available to the extent necessary.]<br>This knowledge shall be [maintained and be] made available to the extent necessary.<br>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. |
| 03-13 | Management system strategy: management commitment | Description | Top management shall demonstrate leadership and commitment with respect to the quality management system by:<br>a) taking accountability for the effectiveness of the quality management system;<br>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;<br>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;<br>c) ensuring the integration of the quality management system requirements into the organization's business processes;<br>d) promoting the use of the process approach and risk-based thinking;<br>e) ensuring that the resources needed for the quality management system are available;<br>g) ensuring that the quality management system achieves its intended results;<br>h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;<br>i) promoting improvement;<br>j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. |
| 03-14 | Management system strategy: measurement | Description | The organization shall evaluate the performance and the effectiveness of the quality management system.<br>The organization shall retain appropriate documented information as evidence of the results. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 03-15 | Management system strategy: outsourcing | Description | a) The organization shall determine the controls to be applied to externally provided processes, products and services when products and services from external providers are intended for incorporation into the organization's own products and services;<br><br>b) The organization shall determine the controls to be applied to externally provided processes, products and services when products and services are provided directly to the customer(s) by external providers on behalf of the organization; |
| | | | c) The organization shall determine the controls to be applied to externally provided processes, products and services when a process, or part of a process, is provided by an external provider as a result of a decision by the organization.<br><br>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.<br><br>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.<br><br>The organization shall retain [documented] information of these activities and any necessary actions arising from the evaluations.<br><br>The organization shall take into consideration 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.<br><br>[The organization shall retain] documented information [of these activities and any necessary actions arising from the evaluations.]<br><br>The organization shall take into consideration the effectiveness of the controls applied by the external provider. |
| 03-16 | Management system strategy: planning | Description | 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). |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 03-17 | Management system strategy: process environment | Description | The organization shall establish, [implement and maintain] a design and development process that is appropriate to ensure the subsequent provision of products and services.<br><br>The organization shall [establish], implement [and maintain] a design and development process that is appropriate to ensure the subsequent provision of products and services.<br><br>The organization shall [establish, implement and] maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.<br><br>The organization shall ensure that externally provided processes, products and services conform to requirements. |
| | | | 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.<br><br>The organization shall:<br><br>a) ensure that externally provided processes remain within the control of its quality management system;<br><br>b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;<br><br>c) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.<br><br>The organization shall implement production and service provision under controlled conditions. |
| 03-18 | Management system strategy: product preservation | Description | The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. |
| 03-19 | Management system strategy: resources | Description | The organization shall [determine and] provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 03-20 | Management system strategy: roles and responsibilities | Description | Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, [communicated and understood within the organization] and shall assign the responsibilities and authorities for these processes.<br><br>Normative: Annex SL 5.3 Top management shall assign the responsibility and authority for:<br>a) ensuring that the XXX management system conforms to the requirements of this International Standard/this part of ISO XXXX/this Technical Specification;<br>b) reporting on the performance of the XXX management system to top management. |
| 03-21 | Management system strategy: supplier capability | Description | b) When determining the requirements for the products and services to be offered to customers, the organization shall ensure that the organization can meet the claims for the products and services it offers. |
| 03-22 | MS Measurement information gathering events | Description | The organization shall determine:<br><br>a) when the monitoring and measuring shall be performed;<br><br>b) when the results from monitoring and measurement shall be analysed and evaluated. |
| 03-23 | MS Measurement information needs | Description | The organization shall determine what needs to be monitored and measured;<br><br>The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. |
| 03-24 | MS Measurement methods | Description | The organization shall determine:<br><br>a) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;<br><br>b) apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes.<br><br>The organization shall determine the methods for obtaining, monitoring and reviewing this information. |
| 03-25 | MS Relevant Interested parties | Description | 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 the interested parties that are relevant to the quality management system; |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 03-26 | Product/service provision lifecycle model | Description | Controlled conditions shall include, as applicable:<br>a) the availability and use of suitable monitoring and measuring resources;<br>b) 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;<br>c) the use of suitable infrastructure and environment for the operation of processes;<br>d) the appointment of competent persons, including any required qualification;<br>e) 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;<br>f) the implementation of actions to prevent human error;<br>g) the implementation of release, delivery and post-delivery activities. |
| 03-27 | Product/service taxonomy | Description | The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.<br>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.]<br>[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. |
| 03-28 | Product/service design | Description | The organization shall ensure that design and development outputs:<br>a) meet the input requirements;<br>b) are adequate for the subsequent processes for the provision of products and services. |
| 03-29 | Product/service objectives | Description | When planning how to achieve its quality objectives, the organization shall determine what will be done.<br>The organization shall apply controls to the design and development process to ensure that the results to be achieved are defined. |
| 03-30 | Project/service measures | Description | When planning how to achieve its quality objectives, the organization shall determine how the results will be evaluated. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 03-31 | Project/service resource needs | Description | When planning how to achieve its quality objectives, the organization shall determine what resources will be required. |
| 03-32 | Project/service roles and responsibilities | Description | When planning how to achieve its quality objectives, the organization shall determine: who will be responsible; |
| 03-33 | Project/service schedule | Description | When planning how to achieve its quality objectives, the organization shall determine when it will be completed; |
| 03-34 | Quality objectives | Description | The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.<br>The quality objectives shall:<br>a) be consistent with the quality policy;<br>b) be measurable;<br>c) take into account applicable requirements;<br>d) be relevant to conformity of products and services and to enhancement of customer satisfaction;<br>e) be monitored;<br>f) be communicated;<br>g) be updated as appropriate.<br>The organization shall maintain documented information on the quality objectives. |
| 03-35 | Request for proposal (RFP) | Description | The request for proposal (RFP) is the acquirer's request for information and commitments needed from the supplier that are required to be included in the potential supplier's proposal. It announces the acquirer's intention to potential bidders to acquire a specified system, software product or software service. It includes the following:<br>a) the stakeholders' system requirements;<br>b) scope statement;<br>c) bidder instructions;<br>d) the scope of tasks to be referenced in the draft contract;<br>e) deliverable product list; |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| | | | f) terms and conditions;<br>g) contract milestones (for example, review and audit of supplier progress);<br>h) control of subcontracts;<br>i) procedural and technical constraints (for example, target environment);<br>j) supporting processes and their performing organizations, including responsibilities (if other than supplier), so suppliers may, in their proposals, define the approach to each of the specified supporting processes. It may outline the supplier selection criteria. |
| 03-36 | Risk and opportunity identification criteria | Description | [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:<br>a) give assurance that the quality management system can achieve its intended result(s);<br>b) enhance desirable effects;<br>c) prevent, or reduce, undesired effects;<br>d) achieve improvement. |
| 03-37 | Sub-contracted supplier roles and responsibilities | Description | The generic considerations of the Generic Work Product category of 'Description' apply. |
| 03-38 | Supplier performance evaluation criteria | Description | The generic considerations of the Generic Work Product category of 'Description' apply. |
| 04-1 | Audit (MS) schedule | Plan | [The organization shall conduct internal audits] at planned intervals [to provide information on whether the quality management system:<br>a) conforms to:<br>1) the organization's own requirements for its quality management system;<br>2) the requirements of this document;<br>b) is effectively implemented and maintained.] |
| 04-2 | Audit plan | Plan | The organization shall define the audit criteria and scope for each audit; |
| 04-3 | Audit programme plan | Plan | The organization shall plan, establish, [implement and maintain] an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits. |
| 04-4 | Improvement implementation schedule | Plan | The generic considerations of the Generic Work Product category of 'Plan' apply. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 04-5 | Management review schedule | Plan | The management review shall be planned [and carried out taking into consideration:]<br>[Top management shall review the organization's quality management system,] at planned intervals, [to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.] |
| 04-6 | Product/service process lifecycle model | Plan | a) Evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results.<br>b) Determine the inputs required and the outputs expected from these processes.<br>c) Determine the sequence and interaction of these processes.<br>The organization shall .. by establishing criteria for:<br>a) the processes;<br>b) the acceptance of products and services;<br>The organization shall .. by determining and keeping documented information to the extent necessary:<br>a) to have confidence that the processes have been carried out as planned;<br>b) to demonstrate the conformity of products and services to their requirements.<br>The output of this planning shall be suitable for the organization's operations.<br>In determining the stages and controls for design and development, the organization shall consider:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process; |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| | | | g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties;<br>j) the documented information needed to demonstrate that design and development requirements have been met. |
| 04-7 | Risk management plan | Plan | The organization shall plan:<br>a) actions to address these risks and opportunities;<br>b) how to:<br>1) integrate and implement the actions into its quality management system processes (see 4.4);<br>2) evaluate the effectiveness of these actions. |
| 04-8 | Risk treatment plan | Plan | The generic considerations of the Generic Work Product category of 'Plan' apply. |
| 05-1 | Improvement policy | Policy | The generic considerations of the Generic Work Product category of 'Policy' apply. |
| 05-2 | Quality policy | Policy | Top management shall establish, [implement and maintain] a quality policy that:<br>a) is appropriate to the purpose and context of the organization and supports its strategic direction;<br>b) provides a framework for setting quality objectives;<br>c) includes a commitment to satisfy applicable requirements;<br>d) includes a commitment to continual improvement of the quality management system.<br>The quality policy shall:<br>a) be available [and be maintained] as documented information;<br>b) be [available and be] maintained as documented information;<br>c) be available to relevant interested parties, as appropriate. |
| 06-1 | Improvement procedure | Procedure | The generic considerations of the Generic Work Product category of 'Procedure' apply. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 07-1 | Product asset | Product | The organization shall identify, [verify, protect and safeguard] customers' or external providers' property provided for use or incorporation into the products and services.<br>The organization shall [identify,] verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services. |
| 07-2 | Product/service | Product | The generic considerations of the Generic Work Product category of 'Product' apply. |
| 07-3 | Product/service component | Product | The generic considerations of the Generic Work Product category of 'Product' apply. |
| 08-01 | Audit (MS) log | Record | The organization shall conduct internal audits [at planned intervals] to provide information on whether the quality management system:<br>a) conforms to:<br>1) the organization's own requirements for its quality management system;<br>2) the requirements of this document;<br>b) is effectively implemented and maintained. |
| 08-02 | Audit corrective action record | Record | The organization shall take appropriate correction and corrective actions without undue delay. |
| 08-03 | Audit result communication record | Record | The organization shall ensure that the results of the audits are reported to relevant management. |
| 08-04 | Audit results | Record | The organization shall: a) .. results of [previous] audits;<br>The organization shall: a) .. results of previous audits; |
| 08-05 | Auditor list | Record | The organization shall select auditors and conduct audits to ensure objectivity and the impartiality of the audit process. |
| 08-06 | Configuration item change log | Record | The generic considerations of the Generic Work Product category of 'Record' apply. |
| 08-07 | Correction action log | Record | When a nonconformity occurs, including any arising from complaints, the organization shall evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:<br>[a) reviewing and analysing the nonconformity;<br>b) determining the causes of the nonconformity;<br>c) determining if similar nonconformities exist, or could potentially occur.] |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 08-08 | Corrective action cause analysis record | Record | [When a nonconformity occurs, including any arising from complaints, the organization shall evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:<br>a) reviewing and analysing the nonconformity];<br>b) determining the causes of the nonconformity;<br>c) determining if similar nonconformities exist, or could potentially occur. |
| 08-09 | Corrective action change proposal approval record | Record | When a nonconformity occurs, including any arising from complaints, the organization shall:<br>a) implement any action needed;<br>b) make changes to the quality management system, if necessary. |
| 08-10 | Corrective action change proposal verification record | Record | When a nonconformity occurs, including any arising from complaints, the organization shall review the effectiveness of any corrective action taken; |
| 08-11 | Corrective action record | Record | The organization shall retain documented information as evidence of:<br>a) the nature of the nonconformities and any subsequent actions taken;<br>b) the results of any corrective action.<br>Corrective actions shall be appropriate to the effects of the nonconformities encountered. |
| 08-12 | Product asset communication record | Record | 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.]<br>[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. |
| 08-13 | Improvement communication record | Record | The generic considerations of the Generic Work Product category of 'Record' apply. |
| 08-14 | Improvement opportunity evaluation result | Record | The generic considerations of the Generic Work Product category of 'Record' apply. |
| 08-15 | Improvement opportunity implementation log | Record | The generic considerations of the Generic Work Product category of 'Record' apply. |
| 08-16 | Improvement opportunity record | Record | The generic considerations of the Generic Work Product category of 'Record' apply. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 08-17 | Information item approval record | Record | When creating and updating documented information, the organization shall ensure appropriate: [review and] approval for suitability and adequacy. |
| 08-18 | Information status record | Record | For the control of documented information, the organization shall address the following activities, as applicable control of changes (e.g. version control).<br>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. |
| 08-19 | Management review action log | Record | The outputs of the management review shall include decisions and actions related to:<br>a) opportunities for improvement;<br>b) any need for changes to the quality management system;<br>c) resource needs. |
| 08-20 | Management review record | Record | Top management shall review the organization's quality management system, [at planned intervals], to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.<br>The organization shall retain documented information as evidence of the results of management reviews.<br>The management review shall [be planned] and carried out taking into consideration. |
| 08-21 | Measurement resources effectiveness review result | Record | The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources. |
| 08-22 | MS implementation log | Record | Top management shall [establish,] implement [and maintain] a quality policy that:..<br>The organization shall [determine], provide [and maintain] the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.<br>The organization shall [determine,] provide [and maintain] the environment necessary for the operation of its processes and to achieve conformity of products and services. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| | | | 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.<br>The organization shall:<br>a) [plan, establish], implement [and maintain] an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits;<br>b) retain documented information as evidence of the implementation of the audit programme [and the audit results];<br>c) retain documented information as evidence of the implementation of the [audit programme and] the audit results.<br>The management review shall [be planned] and carried out taking into consideration:<br>a) the status of actions from previous management reviews;<br>b) changes in external and internal issues that are relevant to the quality management system;<br>c) information on the performance and effectiveness of the quality management system, including trends in:<br>1) customer satisfaction and feedback from relevant interested parties;<br>2) the extent to which quality objectives have been met;<br>3) process performance and conformity of products and services;<br>4) nonconformities and corrective actions;<br>5) monitoring and measurement results;<br>6) audit results;<br>7) the performance of external providers;<br>d) the adequacy of resources;<br>e) the effectiveness of actions taken to address risks and opportunities (see 6.1);<br>f) opportunities for improvement. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 08-23 | MS Implementation review record | Record | The organization shall monitor and review information about these external and internal issues.<br><br>The organization shall monitor and review information about these interested parties and their relevant requirements.<br><br>Top management shall [establish, implement and] maintain a quality policy that...<br><br>The organization shall [determine, provide and] maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.<br><br>The organization shall [determine, provide and] maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.<br><br>The organization shall .. by implementing control of the processes in accordance with the criteria;<br><br>The organization shall [plan, establish, implement and] maintain [an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization], and the results of previous audits. |
| 08-24 | MS Resources provision record | Record | 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.<br><br>The organization shall [determine and] provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.<br><br>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. |
| 08-25 | Nonconforming product customer communication record | Record | The organization shall retain documented information that describes any concessions obtained.<br><br>The organization shall deal with nonconforming outputs by informing the customer. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 08-26 | Nonconforming product disposition evaluation result | Record | The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services.<br>This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services. |
| 08-27 | Nonconforming product quarantine release authorization | Record | The organization shall retain documented information that identifies the authority deciding the action in respect of the nonconformity.<br>The organization shall deal with nonconforming outputs by obtaining authorization for acceptance under concession. |
| 08-28 | Nonconforming product re-verification record | Record | Conformity to the requirements shall be verified when nonconforming outputs are corrected. |
| 08-29 | Non-conformity disposition record | Record | The organization shall retain documented information that describes the actions taken.<br>The organization shall deal with nonconforming outputs through segregation, containment, return or suspension of provision of products and services;.<br>When a nonconformity occurs, including any arising from complaints, the organization shall react to the nonconformity and, as applicable, take action to control and correct it and deal with the consequences. |
| 08-30 | Non-conformity record | Record | The organization shall ensure that outputs that do not conform to their requirements are identified [and controlled] to prevent their unintended use or delivery.<br>When a nonconformity occurs, [including any arising from complaints, the organization shall<br>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. |
| 08-31 | Personnel competency records | Record | The organization shall<br>a) where applicable, [take actions to acquire the necessary competence], and evaluate the effectiveness of the actions taken;<br>b) retain appropriate documented information as evidence of competence. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 08-32 | Process change approval record | Record | The organization shall retain [documented] information describing [the results of the review of changes], the person(s) authorizing the change, [and any necessary actions arising from the review].<br><br>[The organization shall retain] documented [information describing the results of the review of changes], the person(s) authorizing the change, [and any necessary actions arising from the review]. |
| 08-33 | Process change evaluation record | Record | The organization shall [review and] control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.<br><br>The organization shall [control planned changes] and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. |
| 08-34 | Process change request review record | Record | The organization shall review [and control] changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.<br><br>The organization shall retain documented information describing the results of the review of changes, [ the person(s) authorizing the change, and any necessary actions arising from the review]. |
| 08-35 | Product/service design change log | Record | 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.<br><br>The organization shall retain documented information on:<br><br>a) design and development changes;<br><br>b) the results of reviews;<br><br>[c) the authorization of the changes;<br><br>d) the actions taken to prevent adverse impacts.] |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| | | | The organization shall retain documented information on:<br>[a) design and development changes;<br>b) the results of reviews;]<br>c) the authorization of the changes;<br>[d) the actions taken to prevent adverse impacts.]<br>The organization shall retain documented information on:<br>[a) design and development changes;<br>b) the results of reviews;<br>c) the authorization of the changes;]<br>d) the actions taken to prevent adverse impacts. |
| 08-36 | Product/service release approval record | Record | The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, [unless otherwise approved by a relevant authority and, as applicable, by the customer.]<br>[The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed,] unless otherwise approved by a relevant authority and, as applicable, by the customer.<br>The documented information shall include:<br>a) evidence of conformity with the acceptance criteria;<br>b) traceability to the person(s) authorizing the release. |
| 08-37 | Product delivery record | Record | The generic considerations of the Generic Work Product category of 'Record' apply. |
| 08-38 | Product/service candidate list | Record | The generic considerations of the Generic Work Product category of 'Record' apply. |
| 08-39 | Product/service component change evaluation result | Record | The generic considerations of the Generic Work Product category of 'Record' apply. |
| 08-40 | Product/service component change request approval record | Record | The generic considerations of the Generic Work Product category of 'Record' apply. |
| 08-41 | Product/service component repository access log | Record | The generic considerations of the Generic Work Product category of 'Record' apply. |
| 08-42 | Product/service design change evaluation result | Record | 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. |
| 08-43 | Product/service release approval record | Record | The generic considerations of the Generic Work Product category of 'Record' apply. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 08-44 | Product/service requirements communication record | Record | The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.<br>[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. |
| 08-45 | Product/service requirements review record | Record | The organization shall conduct a review before committing to supply products and services to a customer, to include:<br>a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;<br>b) requirements not stated by the customer, but necessary for the specified or intended use, when known;<br>c) requirements specified by the organization;<br>d) statutory and regulatory requirements applicable to the products and services;<br>e) contract or order requirements differing from those previously expressed.<br>The organization shall ensure that contract or order requirements differing from those previously defined are resolved.<br>The organization shall retain [documented] information, as applicable on the results of the review.<br>[The organization shall retain] documented information, [as applicable on the results of the review].<br>The organization shall retain [documented] information, as applicable, on any new requirements for the products and services.<br>[The organization shall retain] documented information, [as applicable, on any new requirements for the products and services].<br>The organization shall apply controls to the design and development process to ensure that: |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| | | | a) reviews are conducted to evaluate the ability of the results of design and development to meet requirements;<br>b) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;<br>c) documented information of these activities is retained.<br>The organization shall ensure the adequacy of requirements prior to their communication to the external provider. |
| 08-46 | Product/service requirements status record | Record | [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.] |
| 08-47 | Product/service review participant list | Record | The generic considerations of the Generic Work Product category of 'Record' apply. |
| 08-48 | Product/service validation action log | Record | The generic considerations of the Generic Work Product category of 'Record' apply. |
| 08-49 | Product/service validation record | Record | The organization shall apply controls to the design and development process to ensure that validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use.<br>The organization shall ensure that design and development outputs specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.<br>The organization shall retain documented information on design and development outputs.<br>The organization shall retain documented information on the release of products and services. |
| 08-50 | Product/service verification action log | Record | The generic considerations of the Generic Work Product category of 'Record' apply. |
| 08-51 | Product/service verification record | Record | The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.<br>The organization shall apply controls to the design and development process to ensure that verification activities are conducted to ensure that the design and development outputs meet the input requirements. |
| 08-52 | Product/service review action log | Record | The generic considerations of the Generic Work Product category of 'Record' apply. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 08-53 | QMS Communication records | Record | Communicating the importance of effective quality management and of conforming to the quality management system requirements.<br>The organization shall communicate to external providers its requirements for:<br>a) the processes, products and services to be provided;<br>b) the approval of:<br>1) products and services;<br>2) methods, processes and equipment;<br>3) the release of products and services;<br>c) competence, including any required qualification of persons;<br>d) the external providers' interactions with the organization;<br>e) control and monitoring of the external providers' performance to be applied by the organization;<br>f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.<br>The quality policy shall be communicated, understood and applied within the organization. |
| 08-54 | Risk and opportunity identification | Record | 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:<br>a) give assurance that the quality management system can achieve its intended result(s);<br>b) enhance desirable effects;<br>c) prevent, or reduce, undesired effects;<br>d) achieve improvement.]<br>When a nonconformity occurs, including any arising from complaints, the organization shall update risks and opportunities determined during planning, if necessary. |
| 08-55 | Risk assessment review record | Record | The generic considerations of the Generic Work Product category of 'Record' apply. |
| 08-56 | Risk treatment action log | Record | Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services. |
| 08-57 | Roles and responsibilities assignment record | Record | Top management shall ensure that the responsibilities and authorities for relevant roles are [assigned], communicated and understood within the organization. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 08-58 | Supplier agreement review record | Record | The generic considerations of the Generic Work Product category of 'Record' apply. |
| 08-59 | Supplier capability assessment record | Record | The generic considerations of the Generic Work Product category of 'Record' apply. |
| 08-60 | Supplier role assignments list | Record | The generic considerations of the Generic Work Product category of 'Record' apply. |
| 08-61 | Training effectiveness evaluation result | Record | The organization shall ensure that persons doing work under the organization's control are aware of:<br>a) the quality policy;<br>b) relevant quality objectives;<br>c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;<br>d) the implications of not conforming with the quality management system requirements. |
| 08-62 | Training record | Record | The organization shall:<br>a) ensure that these persons are competent on the basis of appropriate education, training, or experience;<br>b) where applicable, take actions to acquire the necessary competence, [and evaluate the effectiveness of the actions taken.] |
| 09-01 | Customer satisfaction evaluation report | Report | The results of analysis shall be used to evaluate the degree of customer satisfaction |
| 09-02 | Improvement opportunity evaluation report | Report | The results of analysis shall be used to evaluate the need for improvements to the quality management system. |
| 09-03 | Management system conformity evaluation report | Report | The results of analysis shall be used to evaluate the performance and effectiveness of the quality management system. |
| 09-04 | Planning performance evaluation report | Report | The results of analysis shall be used to evaluate if planning has been implemented effectively. |
| 09-05 | Process capability assessment report | Report | The results of analysis shall be used to evaluate the effectiveness of actions taken to address risks and opportunities. |
| 09-06 | Product/service configuration evaluation report | Report | The generic considerations of the Generic Work Product category of 'Report' apply. |
| 09-07 | Product/service configuration status report | Report | The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. |
| 09-08 | Product/service conformity evaluation report | Report | The results of analysis shall be used to evaluate conformity of products and services. |
| 09-09 | Product/service feasibility analysis report | Report | The generic considerations of the Generic Work Product category of 'Report' apply. |
| 09-10 | Risk analysis report | Report | The generic considerations of the Generic Work Product category of 'Report' apply. |
| 09-11 | Supplier performance evaluation report | Report | The results of analysis shall be used to evaluate the performance of external providers. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 10-1 | Product/service component repository | Repository | The generic considerations of the Generic Work Product category of 'Repository' apply. |
| 11-01 | Corrective action request | Request | The organization shall retain documented information as evidence of the nature of the nonconformities and any subsequent actions taken. |
| 11-02 | Improvement opportunity | Request | The outputs of the management review shall include decisions and actions related t opportunities for improvement.<br>The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.<br>These shall include:<br>a) improving products and services to meet requirements as well as to address future needs and expectations;<br>b) correcting, preventing or reducing undesired effects;<br>c) improving the performance and effectiveness of the quality management system.<br>The organization shall consider the results of analysis and evaluation and the outputs from management review to determine if there are needs or opportunities that shall be addressed as part of continual improvement. |
| 11-03 | Improvement opportunity approval request | Request | The generic considerations of the Generic Work Product category of 'Request' apply. |
| 11-04 | Nonconforming product corrective action request | Request | The organization shall retain documented information that describes the nonconformity;<br>The organization shall deal with nonconforming outputs through correction. |
| 11-05 | Nonconforming product corrective action request | Request | The generic considerations of the Generic Work Product category of 'Request' apply. |
| 11-06 | Nonconforming product quarantine request | Request | The organization shall ensure that outputs that do not conform to their requirements are [identified and] controlled to prevent their unintended use or delivery. |
| 11-07 | Process change request | Request | The organization shall control planned changes [and review] the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. |
| 11-08 | Product/service component change request | Request | The generic considerations of the Generic Work Product category of 'Request' apply. |
| 11-09 | Product/service design change request | Request | 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. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 11-10 | Product/service requirements change request | Request | 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.] |
| 12-01 | Communication process requirements | Specification | Communication with customers shall include:<br>a) providing information relating to products and services;<br>b) handling enquiries, contracts or orders, including changes;<br>c) obtaining customer feedback relating to products and services, including customer complaints;<br>d) handling or controlling customer property;<br>e) establishing specific requirements for contingency actions, when relevant. |
| 12-02 | Communication requirements | Specification | The organization shall determine the internal and external communications relevant to the quality management system, including:<br>a) on what it will communicate;<br>b) when to communicate;<br>c) with whom to communicate;<br>d) how to communicate;<br>e) who communicates. |
| 12-03 | Documentation management requirements | Specification | When creating and updating documented information, the organization shall ensure appropriate:<br>a) identification and description (e.g. a title, date, author, or reference number);<br>b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);<br>c) [review and approval] for suitability and adequacy.<br>c) review [and approval] for suitability and adequacy. |
| 12-04 | Improvement opportunity evaluation criteria | Specification | The generic considerations of the Generic Work Product category of 'Specification' apply. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 12-05 | Information management requirements | Specification | Documented information required by the quality management system and by this document shall be controlled [to ensure: a) it is available and suitable for use, where and when it is needed;]<br><br>Documented information required by the quality management system and by this document shall be controlled to ensure: a) it is available and suitable for use, where and when it is needed.<br><br>Documented information required by the quality management system and by this document shall be controlled to ensure: b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). |
| | | | For the control of documented information, the organization shall address, as applicable, retention and disposition.<br><br>Documented information retained as evidence of conformity shall be protected from unintended alterations.<br><br>For the control of documented information, the organization shall address the following activities, as applicable:<br><br>a) distribution, access, retrieval and use;<br><br>b) storage and preservation, including preservation of legibility. |
| 12-06 | Infrastructure requirements | Specification | The organization shall determine, [provide and maintain] the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. |
| 12-07 | Management system change evaluation criteria | Specification | The organization shall consider:<br><br>a) the purpose of the changes and their potential consequences;<br><br>b) the integrity of the quality management system;<br><br>c) the availability of resources;<br><br>d) the allocation or reallocation of responsibilities and authorities. |
| 12-08 | MS Relevant Interested parties MS expectations | Specification | 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 the requirements of these interested parties that are relevant to the quality management system. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 12-09 | MS Resource requirements | Specification | The organization shall determine [and provide] the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.<br>The organization shall consider:<br>a) the capabilities of, and constraints on, existing internal resources;<br>b) what needs to be obtained from external providers;<br>c) determine the resources needed for these processes and ensure their availability;<br>The organization shall .. by determining the resources needed to achieve conformity to the product and service requirements; |
| 12-10 | Organizational competence requirements | Specification | The organization shall determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system. |
| 12-11 | Organizational roles and responsibilities | Specification | Top management shall assign the responsibility and authority for:<br>a) ensuring that the quality management system conforms to the requirements of this document;<br>b) ensuring that the processes are delivering their intended outputs;<br>c) reporting on the performance of the quality management system and on opportunities for improvement (see ISO 9001:2015, 10.1), in particular to top management;<br>d) ensuring the promotion of customer focus throughout the organization;<br>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. |
| 12-12 | Process environment requirements | Specification | The organization shall determine, [provide and maintain] the environment necessary for the operation of its processes and to achieve conformity of products and services.<br>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. |
| 12-13 | Product review criteria | Specification | The generic considerations of the Generic Work Product category of 'Specification' apply. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 12-14 | Product/service acceptance criteria | Specification | The organization shall ensure that design and development outputs include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria |
| 12-15 | Product/service characteristics | Specification | Controlled conditions shall include, as applicable, the availability of [documented] information that defines:<br>a) the characteristics of the products to be produced, the services to be provided, or [the activities to be performed;<br>b) the results to be achieved.]<br>[Controlled conditions shall include, as applicable, the availability of] documented information [that defines:<br>a) the characteristics of the products to be produced, the services to be provided, or [the activities to be performed;<br>b) the results to be achieved.] |
| | | | Controlled conditions shall include, as applicable, [the availability of [documented] information that defines:<br>a) the characteristics of the products to be produced, the services to be provided,] or the activities to be performed;<br>b) the results to be achieved.<br>Controlled conditions shall include, as applicable, [the availability of] documented information [that defines:<br>a) the characteristics of the products to be produced, the services to be provided,] or the activities to be performed;<br>b) the results to be achieved; |
| 12-16 | Product/service component change evaluation criteria | Specification | The generic considerations of the Generic Work Product category of 'Specification' apply. |
| 12-17 | Product/service release criteria | Specification | The generic considerations of the Generic Work Product category of 'Specification' apply. |

**Table B.3** *(continued)*

| Reference | Name | Category | Characteristics |
|---|---|---|---|
| 12-18 | Product/service requirements | Specification | The organization shall .. by: determining the requirements for the products and services<br><br>When determining the requirements for the products and services to be offered to customers, the organization shall ensure that the requirements for the products and services are defined.<br><br>When determining the requirements for the products and services to be offered to customers, the organization shall ensure that [ the requirements for the products and services are defined, including] a) any applicable statutory and regulatory requirements; [b) those considered necessary by the organization.]<br><br>When determining the requirements for the products and services to be offered to customers, the organization shall ensure that the requirements for the products and services are defined, including [a) any applicable statutory and regulatory requirements;] b) those considered necessary by the organization.]<br><br>The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. |
| | | | The organization shall consider:<br><br>a) functional and performance requirements;<br><br>b) information derived from previous similar design and development activities;<br><br>c) statutory and regulatory requirements;<br><br>d) standards or codes of practice that the organization has committed to implement;<br><br>e) potential consequences of failure due to the nature of the products and services.<br><br>Inputs shall be adequate for design and development purposes, complete and unambiguous.<br><br>Conflicting design and development inputs shall be resolved.<br><br>The organization shall retain documented information on design and development inputs. |
| 12-19 | Product/service validation criteria | Specification | The generic considerations of the Generic Work Product category of 'Specification' apply. |
| 12-20 | Product/service verification criteria | Specification | The generic considerations of the Generic Work Product category of 'Specification' apply. |

# Annex C
(informative)

# Association between base practices and ISO 9001 requirements

## C.1 General

This document provides a Process Assessment Model for assessing the process capability of processes associated with a Quality Management (QMS). ISO 9001 provides requirements for the establishment of an QMS System. This annex identifies a Process Capability Profile (Level 1) that is implied by the requirements associated with a Management System conformant to ISO 9001.

## C.2 Associations of base practices with requirements

Table C.1 identifies each base practice with the associated singular requirements from ISO 9001, and the implied information item.

NOTE Not all the base practices identified in Clause 5 will correspond to an entry in Table C.1. Table C.3 identifies the base practices associated with outcomes that were added to the PRM in order to represent well-formed processes.

**Table C.1 — Association of base practices with singular requirements of ISO 9001**

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.01 Communication management | | | | |
| COM.01.BP.2 | **Identify parties to communicate to.** Identify parties to communicate with. | 07.4.3 | The organization shall determine the internal and external communications relevant to the quality management system, including with whom to communicate. | 12-02 Communication requirements |
| COM.01.BP.3 | **Identify party responsible for communication.** Identify the party responsible for the communication. | 07.4.5 | The organization shall determine the internal and external communications relevant to the quality management system, including who communicates. | 12-02 Communication requirements |
| COM.01.BP.4 | **Identify communication events.** Identify the events that require communication actions. | 07.4.2 | The organization shall determine the internal and external communications relevant to the quality management system, including when to communicate. | 12-02 Communication requirements |
| COM.01.BP.5 | **Select communication channel.** Select the channel for the communication. | 07.4.4 | The organization shall determine the internal and external communications relevant to the quality management system, including how to communicate. | 12-02 Communication requirements |
| COM.01.BP.6 | **Communicate information products.** Communicate information products to relevant interested parties. | 05.1.1.8 | Communicating the importance of effective quality management and of conforming to the quality management system requirements. | 08-53 QMS Communication records |
| COM.01.BP.6 | **Communicate information products.** Communicate information products to relevant interested parties. | 05.2.2.3 | The quality policy shall be communicated, understood and applied within the organization. | 08-53 QMS Communication records |
| COM.01.BP.6 | **Communicate information products.** Communicate information products to relevant interested parties. | 08.2.4.3 | [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. | 08-44 Product/service requirements communication record |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.01.BP.6 | **Communicate information products.** Communicate information products to relevant interested parties. | 08.4.3.2 | The organization shall communicate to external providers its requirements for:<br>a) the processes, products and services to be provided;<br>b) the approval of:<br>1) products and services;<br>2) methods, processes and equipment;<br>3) the release of products and services;<br>c) competence, including any required qualification of persons;<br>d) the external providers' interactions with the organization;<br>e) control and monitoring of the external providers' performance to be applied by the organization;<br>f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises. | 08-53 QMS Communication records |
| COM.01.BP.6 | **Communicate information products.** Communicate information products to relevant interested parties. | 08.7.1.7 | The organization shall deal with nonconforming outputs by informing the customer; | 08-25 Nonconforming product customer communication record |
| COM.01.BP.6 | **Communicate information products.** Communicate information products to relevant interested parties. | 09.2.2.8 | The organization shall ensure that the results of the audits are reported to relevant management | 08-03 Audit result communication record |
| COM.02 Documentation management | | | | |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 04.3.4 | The scope of the organization's quality management system shall be available [and be maintained] as [documented] information. | 03-04 Management system (MS) scope |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 05.2.2.1 | The quality policy shall: be available [and be maintained] as documented information. | 05-2 Quality policy |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 07.1.5.1.5 | The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources. | 08-21 Measurement resources effectiveness review result |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 07.2.5 | The organization shall retain appropriate documented information as evidence of competence. | 08-31 Personnel competency records |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.1.9 | The organization shall .. by determining and maintaining and retaining documented information to the extent necessary to have confidence that the processes have been carried out as planned. | 04-6 Product/service process lifecycle model |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.1.10 | The organization shall .. by determining and maintaining and retaining documented information to the extent necessary to demonstrate the conformity of products and services to their requirements. | 04-6 Product/service process lifecycle model |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.2.3.2.2 | [The organization shall retain] documented information, [as applicable on the results of the review.] | 08-45 Product/service requirements review record |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.2.3.2.4 | [The organization shall retain] documented information, [as applicable on any new requirements for the products and services.] | 08-45 Product/service requirements review record |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.3.2.10 | In determining the stages and controls for design and development, the organization shall consider the documented information needed to demonstrate that design and development requirements have been met. | 04-6 Product/service process lifecycle model |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.3.3.9 | The organization shall retain documented information on design and development inputs. | 12-18 Product/service requirements |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.3.5.5 | The organization shall retain documented information on design and development outputs. | 08-49 Product/service validation record |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.3.6.4 | The organization shall retain documented information on:<br>a) design and development changes;<br>b) the results of reviews;<br>[c) the authorization of the changes;<br>d) the actions taken to prevent adverse impacts.] | 08-35 Product/service design change log |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.3.6.5 | The organization shall retain documented information on:<br>[a) design and development changes;<br>b) the results of reviews;]<br>c) the authorization of the changes;<br>[d) the actions taken to prevent adverse impacts.] | 08-35 Product/service design change log |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.3.6.6 | The organization shall retain documented information on:<br>[a) design and development changes;<br>b) the results of reviews;<br>c) the authorization of the changes;]<br>d) the actions taken to prevent adverse impacts. | 08-35 Product/service design change log |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.4.1.7 | The organization shall retain [documented] information of these activities and any necessary actions arising from the evaluations. | 03-15 Management system strategy: outsourcing |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.4.1.8 | [The organization shall retain] documented information of these activities and any necessary actions arising from the evaluations.] | 03-15 Management system strategy: outsourcing |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.5.1.3 | Controlled conditions shall include, as applicable, [the availability of [documented] information that defines:<br>a) the characteristics of the products to be produced, the services to be provided,] or the activities to be performed;<br>b) the results to be achieved. | 12-15 Product/service characteristics |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.5.1.5 | [Controlled conditions shall include, as applicable, the availability of] documented [ information that defines:<br>a) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;<br>b) the results to be achieved.] | 12-15 Product/service characteristics |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.5.2.4 | [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. | 03-27 Product/service taxonomy |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.5.3.5 | [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. | 08-12 Product asset communication record |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.5.6.4 | [The organization shall retain] documented [information describing the results of the review of changes, the person(s) authorizing the change, and] any necessary actions arising from the review. | 02-7 Process change implementation log |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.5.6.6 | [The organization shall retain] documented [information describing the results of the review of changes], the person(s) authorizing the change, [and any necessary actions arising from the review]. | 08-32 Process change approval record |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.5.6.7 | The organization shall retain documented information describing the results of the review of changes, [the person(s) authorizing the change, and any necessary actions arising from the review.] | 08-34 Process change request review record |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.7.2.1 | The organization shall retain documented information that describes the nonconformity. | 11-04 Nonconforming product corrective action request |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.7.2.2 | The organization shall retain documented information that describes the actions taken. | 08-29 Non-conformity disposition record |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.7.2.3 | The organization shall retain documented information that describes any concessions obtained. | 08-25 Nonconforming product customer communication record |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08.7.2.4 | The organization shall retain documented information that identifies the authority deciding the action in respect of the nonconformity. | 08-27 Nonconforming product quarantine release authorization |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 09.1.1.6 | The organization shall retain appropriate documented information as evidence of the results. | 03-14 Management system strategy: measurement |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 09.1.1.7 | [The organization shall retain appropriate documented information as] evidence of the results. | 03-14 Management system strategy: measurement |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 09.2.2.10 | The organization shall retain documented information as evidence of the implementation of the audit programme [and the audit results.] | 08-22 MS Implementation log |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 09.2.2.11 | The organization shall retain documented information as evidence of the implementation of the [audit programme and] the audit results. | 08-22 MS Implementation log |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 09.3.3.3 | The organization shall retain documented information as evidence of the results of management reviews. | 08-20 Management review record |
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 10.2.2.1 | The organization shall retain documented information as evidence of the nature of the nonconformities and any subsequent actions taken. | 11-01 Corrective action request |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.02.BP.1 | **Identify documented information to be managed.** Identify documented information of internal and external origin necessary for the operation of the quality management system. | 10.2.2.2 | The organization shall retain documented information as evidence of the results of any corrective action. | 08-11 Corrective action record |
| COM.02.BP.2 | **Define the forms of documented information representation.** Identify the forms of information to be stored in the repository. For example, this may include documents, records, audio content, video content, image content. | 07.5.2.2 | When creating and updating documented information, the organization shall ensure appropriate format (e.g. language, software version, graphics) and media (e.g. paper, electronic). | 12-03 Documentation management requirements |
| COM.02.BP.2 | **Define the forms of documented information representation.** Identify the forms of information to be stored in the repository. For example, this may include documents, records, audio content, video content, image content. | 07.5.2.3 | When creating and updating documented information, the organization shall ensure appropriate review [and approval] for suitability and adequacy. | 12-03 Documentation management requirements |
| COM.02.BP.2 | **Define the forms of documented information representation.** Identify the forms of information to be stored in the repository. For example, this may include documents, records, audio content, video content, image content. | 07.5.3.2.5 | 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.] | 03-02 Information item identification |
| COM.02.BP.3 | **Determine the documented information content status.** The status of the documented information content refers to the timeliness of the information content. This includes the control of changes, for example, by using version control techniques. | 04.3.5 | The scope of the organization's quality management system shall be [available and be] maintained as documented information. | 03-04 Management system (MS) scope |
| COM.02.BP.3 | **Determine the documented information content status.** The status of the documented information content refers to the timeliness of the information content. This includes the control of changes, for example, by using version control techniques. | 06.2.1.8 | The quality objectives shall be updated as appropriate. | 03-34 Quality objectives |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.02.BP.3 | **Determine the documented information content status.** The status of the documented information content refers to the timeliness of the information content. This includes the control of changes, for example, by using version control techniques. | 08.2.4.2 | [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.] | 08-46 Product/service requirements status record |
| COM.02.BP.4 | **Determine whether the documented information is current, complete and valid.** The documented information contained in the repository is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). | 05.2.2.2 | The quality policy shall be [available and be] maintained as documented information. | 05-2 Quality policy |
| COM.02.BP.4 | **Determine whether the documented information is current, complete and valid.** The documented information contained in the repository is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). | 06.2.1.9 | The organization shall maintain documented information on the quality objectives. | 03-34 Quality objectives |
| COM.02.BP.4 | **Determine whether the documented information is current, complete and valid.** The documented information contained in the repository is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). | 07.1.6.2 | This knowledge shall be maintained [and be made available to the extent necessary.] | 03-12 Management system strategy: knowledge |
| COM.02.BP.4 | **Determine whether the documented information is current, complete and valid.** The documented information contained in the repository is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). | 07.5.3.1.1 | Documented information required by the quality management system and by this document shall be controlled [to ensure that it is available and suitable for use, where and when it is needed.] | 12-05 Information management requirements |
| COM.02.BP.4 | **Determine whether the documented information is current, complete and valid.** The documented information contained in the repository is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). | 07.5.3.1.3 | Documented information required by the quality management system and by this document shall be controlled to ensure that it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). | 12-05 Information management requirements |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.02.BP.4 | **Determine whether the documented information is current, complete and valid.** The documented information contained in the repository is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). | 07.5.3.2.2 | For the control of documented information, the organization shall address, as applicable, storage and preservation, including preservation of legibility. | 12-05 Information management requirements |
| COM.02.BP.4 | **Determine whether the documented information is current, complete and valid.** The documented information contained in the repository is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). | 07.5.3.2.7 | Documented information retained as evidence of conformity shall be protected from unintended alterations. | 12-05 Information management requirements |
| COM.02.BP.4 | **Determine whether the documented information is current, complete and valid.** The documented information contained in the repository is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). | 08.2.4.1 | 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.] | 11-10 Product/service requirements change request |
| COM.02.BP.5 | **Release documented information according to defined criteria.** The documented information release status refers to those situations typically where authorization is needed, such as in situations where:<br>a) agreements are in force;<br>b) policies and procedures are approved by management and their use in the organization is thereby obligatory. | 07.5.2.4 | When creating and updating documented information, the organization shall ensure appropriate [review and] approval for suitability and adequacy. | 08-17 Information item approval record |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.02.BP.5 | **Release documented information according to defined criteria.** The documented information release status refers to those situations typically where authorization is needed, such as in situations where:<br>a) agreements are in force;<br>b) policies and procedures are approved by management and their use in the organization is thereby obligatory. | 08.6.6 | The documented information shall include traceability to the person(s) authorizing the release. | 08-36 Product/service release approval record |
| COM.02.BP.6 | **Make documented information available to relevant interested parties.** Manage the distribution, access, retrieval and use of documented information towards interested parties. | 05.2.2.4 | The quality policy shall be available to relevant interested parties, as appropriate. | 05-2 Quality policy |
| COM.02.BP.6 | **Make documented information available to relevant interested parties.** Manage the distribution, access, retrieval and use of documented information towards interested parties. | 07.1.6.3 | This knowledge shall be [maintained and be] made available to the extent necessary. | 03-12 Management system strategy: knowledge |
| COM.02.BP.6 | **Make documented information available to relevant interested parties.** Manage the distribution, access, retrieval and use of documented information towards interested parties. | 07.5.3.1.2 | Documented information required by the quality management system and by this document shall be controlled to ensure that it is available and suitable for use, where and when it is needed; | 12-05 Information management requirements |
| COM.02.BP.6 | **Make documented information available to relevant interested parties.** Manage the distribution, access, retrieval and use of documented information towards interested parties. | 07.5.3.2.1 | For the control of documented information, the organization shall address, as applicable, distribution, access, retrieval and use. | 12-05 Information management requirements |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.02.BP.7 | **Archive, or dispose of documented information, as required**. Manage documented information, including records, through its lifecycle by addressing the following activities:<br>a) storage and preservation, including preservation of legibility;<br>b) retention and disposition.<br>Records should be protected in accordance with statutory, regulatory, contractual and business requirements. | 07.5.3.2.4 | For the control of documented information, the organization shall address, as applicable, retention and disposition. | 12-05 Information requirements |
| COM.03 Human resource management | | | | |
| COM.03.BP.1 | **Identify organizational competencies.** Identify the competencies required by the organization. | 07.2.1 | The organization shall determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system. | 12-10 Organizational competence requirements |
| COM.03.BP.2 | **Fill competency gaps.** Fill identified competency gaps through training or recruitment. | 07.2.2 | The organization shall ensure that these persons are competent on the basis of appropriate education, training, or experience. | 08-62 Training record |
| COM.03.BP.3 | **Demonstrate awareness of understanding of role.** Each individual demonstrates their understanding of their role and activities in achieving organizational objectives. | 07.3.1 | The organization shall ensure that persons doing work under the organization's control are aware of:<br>a) the quality policy;<br>b) relevant quality objectives;<br>c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;<br>d) the implications of not conforming with the quality management system requirements. | 08-61 Training effectiveness evaluation result |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.04 Improvement | | | | |
| COM.04.BP.1 | **Identify improvement opportunities.** These might arise from the following sources:<br>a) the decisions and actions arising from the outputs of the management reviews;<br>b) feedback arising from actions to meet customer requirements and assess customer satisfaction;<br>c) actions arising from:<br>1) improving products and services to meet requirements, as well as to address future needs and expectations;<br>2) correcting, preventing or reducing undesired effects;<br>3) improving the performance and effectiveness of the quality management system. | 09.3.3.2 | The outputs of the management review shall include decisions and actions related to opportunities for improvement. | 11-02 Improvement opportunity |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.04.BP.1 | **Identify improvement opportunities.** These might arise from the following sources:<br>a) the decisions and actions arising from the outputs of the management reviews;<br>b) feedback arising from actions to meet customer requirements and assess customer satisfaction;<br>c) actions arising from:<br>1) improving products and services to meet requirements, as well as to address future needs and expectations;<br>2) correcting, preventing or reducing undesired effects;<br>3) improving the performance and effectiveness of the quality management system. | 10.1.1 | The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction. | 11-02 Improvement opportunity |
| COM.04.BP.1 | **Identify improvement opportunities.** These might arise from the following sources:<br>a) The decisions and actions arising from the outputs of the management reviews;<br>b) feedback arising from actions to meet customer requirements and assess customer satisfaction;<br>c) actions arising from:<br>1) improving products and services to meet requirements as well as to address future needs and expectations;<br>2) correcting, preventing or reducing undesired effects;<br>3) improving the performance and effectiveness of the quality management system. | 10.1.2 | These shall include:<br>a) improving products and services to meet requirements, as well as to address future needs and expectations;<br>b) correcting, preventing or reducing undesired effects;<br>c) improving the performance and effectiveness of the quality management system. | 11-02 Improvement opportunity |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.04.BP.1 | **Identify improvement opportunities.** These might arise from the following sources:<br>a) the decisions and actions arising from the outputs of the management reviews;<br>b) feedback arising from actions to meet customer requirements and assess customer satisfaction;<br>c) actions arising from:<br>1) improving products and services to meet requirements, as well as to address future needs and expectations;<br>2) correcting, preventing or reducing undesired effects;<br>3) improving the performance and effectiveness of the quality management system. | 10.3.2 | The organization shall consider the results of analysis and evaluation, and the outputs from management review, to determine if there are needs or opportunities that shall be addressed as part of continual improvement. | 11-02 Improvement opportunity |
| COM.04.BP.2 | **Evaluate improvement opportunities.** Evaluate opportunities for improvement against defined criteria. The results of analysis are used to evaluate the need for improvements to the quality management system, and to the business processes. | 09.1.3.8 | The results of analysis shall be used to evaluate the need for improvements to the quality management system. | 09-02 Improvement opportunity evaluation report |
| COM.05 Internal audit | | | | |
| COM.05.BP.1 | **Define the criteria and scope of each audit.** Define the audit criteria and the scope of each audit. | 09.2.2.6 | The organization shall define the audit criteria and scope for each audit; | 04-2 Audit plan |
| COM.05.BP.2 | **Select auditors.** Select auditors to ensure objectivity and the impartiality of the audit process. | 09.2.2.7 | The organization shall select auditors and conduct audits to ensure objectivity and the impartiality of the audit process; | 08-05 Auditor list |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.05.BP.3 | **Conduct audits.** Conduct audits according to the defined criteria ensuring objectivity and the impartiality of the audit process. | 09.2.1.1 | The organization shall conduct internal audits [at planned intervals] to provide information on whether the quality management system:<br>a) conforms to:<br>1) the organization's own requirements for its quality management system;<br>2) the requirements of this document;;<br>b) is effectively implemented and maintained. | 08-01 Audit (MS) log |
| COM.05.BP.3 | **Conduct audits.** Conduct audits according to the defined criteria ensuring objectivity and the impartiality of the audit process. | 09.2.2.4 | The organization shall .. results of [previous] audits. | 08-04 Audit results |
| COM.05.BP.3 | **Conduct audits.** Conduct audits according to the defined criteria ensuring objectivity and the impartiality of the audit process. | 09.2.2.5 | The organization shall .. results of previous audits. | 08-04 Audit results |
| COM.06 Management review | | | | |
| COM.06.BP.1 | **Identify the objectives for management system review.** Objectives for management review include:<br>a) the status of actions from previous management reviews;<br>b) changes in external and internal issues that are relevant to the quality management system including its strategic direction;<br>c) information on the quality performance, including trends and indicators for: | 09.3.2.2 | The management review shall [be planned and carried out] taking into consideration:<br>a) the status of actions from previous management reviews;<br>b) changes in external and internal issues that are relevant to the quality management system;<br>c) information on the performance and effectiveness of the quality management system, including trends in:<br>1) customer satisfaction and feedback from relevant interested parties; | 03-03 Management review objectives |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| | 1) nonconformities and corrective actions;<br>2) monitoring and measurement results;<br>3) audit results;<br>4) customer satisfaction;<br>5) issues concerning external providers and other relevant interested parties;<br>6) adequacy of resources required for maintaining an effective quality management system;<br>7) process performance and conformity of products and services;<br>d) the effectiveness of actions taken to address risks and opportunities;<br>e) new potential opportunities for continual improvement. | | 2) the extent to which quality objectives have been met;<br>3) process performance and conformity of products and services;<br>4) nonconformities and corrective actions;<br>5) monitoring and measurement results;<br>6) audit results;<br>7) the performance of external providers;<br>d) the adequacy of resources;<br>e) the effectiveness of actions taken to address risks and opportunities (see 6.1);<br>f) opportunities for improvement. | |
| COM.06.BP.2 | **Assess status and performance of activities.** Top management conduct reviews of the organization's quality management system to ensure its continuing suitability, adequacy and effectiveness. | 09.3.1.1 | Top management shall review the organization's quality management system, [at planned intervals], to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization. | 08-20 Management review record |
| COM.06.BP.3 | **Identify risks, problems and opportunities for improvement.** Identify risks, problems, and opportunities related to improvement, and the need for changes to the quality management system. | 09.3.3.1 | The outputs of the management review shall include decisions and actions related to:<br>a) opportunities for improvement;<br>b) any need for changes to the quality management system;<br>c) resource needs. | 08-19 Management review action log |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.07 Non-conformity management | | | | |
| COM.07.BP.1 | **Identify non-conformities.** Non-conformities are identified. These might arise during development and/or production of the product/service, or from post-production activities, e.g. feedback from customers. | 07.1.5.2.6 | [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. | 08-30 Non-conformity record |
| COM.07.BP.1 | **Identify non-conformities.** Non-conformities are identified. These might arise during development and/or production of the product/service, or from post-production activities, e.g. feedback from customers. | 09.2.2.9 | The organization shall take appropriate correction and corrective actions without undue delay. | 08-02 Audit corrective action record |
| COM.07.BP.1 | **Identify non-conformities.** Non-conformities are identified. These might arise during development and/or production of the product/service, or from post-production activities, e.g. feedback from customers. | 10.2.1.1 | When a nonconformity occurs, [including any arising from complaints, the organization shall]: | 08-30 Non-conformity record |
| COM.07.BP.2 | **Resolve and close non-conformities.** Resolve and close non-conformities. When a nonconformity occurs, including any arising from complaints, the organization reacts to the nonconformity and, as applicable:<br>a) take action to control and correct it;<br>b) deal with the consequences. | 10.2.1.2 | When a nonconformity occurs, including any arising from complaints, the organization shall react to the nonconformity and, as applicable:<br>a) take action to control and correct it;<br>b) deal with the consequences. | 08-29 Non-conformity disposition record |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.07.BP.3 | **Determine cause of non-conformities.** Determine the cause of selected non-conformities. The organization evaluates the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:<br>a) reviewing and analysing the nonconformity;<br>b) determining the causes of the nonconformity;<br>c) determining if similar nonconformities exist, or could potentially occur. | 10.2.1.4 | [When a nonconformity occurs, including any arising from complaints, the organization shall evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:<br>a) reviewing and analysing the nonconformity];<br>b) determining the causes of the nonconformity;<br>c) determining if similar nonconformities exist, or could potentially occur. | 08-08 Corrective action cause analysis record |
| COM.07.BP.4 | **Determine the need for action.** Determine the need for action to eliminate the causes of non-conformities. Corrective actions are appropriate to the effects of the nonconformities encountered. | 10.2.1.9 | Corrective actions shall be appropriate to the effects of the nonconformities encountered. | 08-11 Corrective action record |
| COM.07.BP.5 | **Implement selected action proposals.** Implement a selected action proposal. The organization implements any action needed. If necessary, changes are made to the quality management system. | 10.2.1.3 | When a nonconformity occurs, including any arising from complaints, the organization shall evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:<br>[a) reviewing and analysing the nonconformity;<br>b) determining the causes of the nonconformity;<br>c) determining if similar nonconformities exist, or could potentially occur;] | 08-07 Correction action log |
| COM.07.BP.5 | **Implement selected action proposals.** Implement a selected action proposal. The organization implements any action needed. If necessary, changes are made to the quality management system. | 10.2.1.5 | When a nonconformity occurs, including any arising from complaints, the organization shall implement any action needed. | 08-09 Corrective action change proposal approval record |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.07.BP.5 | **Implement selected action proposals.** Implement a selected action proposal. The organization implements any action needed. If necessary, changes are made to the quality management system. | 10.2.1.8 | When a nonconformity occurs, including any arising from complaints, the organization shall make changes to the quality management system, if necessary. | 08-09 Corrective action change proposal approval record |
| COM.07.BP.6 | **Confirm change effectiveness.** Confirm the effectiveness of changes to eliminate the non-conformities. The organization reviews the effectiveness of any corrective action taken. | 10.2.1.6 | When a nonconformity occurs, including any arising from complaints, the organization shall review the effectiveness of any corrective action taken. | 08-10 Corrective action change proposal verification record |
| COM.08 Operational planning | | | | |
| COM.08.BP.1 | **Identify process requirements.** Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 05.2.1.4 | .. that: a) is appropriate to the purpose and context of the organization and supports its strategic direction; | 05-2 Quality policy |
| COM.08.BP.1 | **Identify process requirements.** Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 05.2.1.5 | .. that: b) provides a framework for setting quality objectives; | 05-2 Quality policy |
| COM.08.BP.1 | **Identify process requirements.** Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 05.2.1.6 | .. that: c) includes a commitment to satisfy applicable requirements; | 05-2 Quality policy |
| COM.08.BP.1 | **Identify process requirements.** Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 05.2.1.7 | .. that: d) includes a commitment to continual improvement of the quality management system. | 05-2 Quality policy |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.1 | **Identify process requirements.** Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 06.1.1.2 | [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:<br>a) give assurance that the quality management system can achieve its intended result(s);<br>b) enhance desirable effects;<br>c) prevent, or reduce, undesired effects;<br>d) achieve improvement. | 03-36 Risk and opportunity identification criteria |
| COM.08.BP.1 | **Identify process requirements.** Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 06.2.2.1 | When planning how to achieve its quality objectives, the organization shall determine what will be done. | 03-29 Product/service objectives |
| COM.08.BP.1 | **Identify process requirements.** Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 06.3.2 | The organization shall consider:<br>a) the purpose of the changes and their potential consequences;<br>b) the integrity of the quality management system;<br>c) the availability of resources;<br>d) the allocation or reallocation of responsibilities and authorities. | 12-07 Management system change evaluation criteria |
| COM.08.BP.1 | **Identify process requirements.** Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 07.1.3.1 | The organization shall determine, [provide and maintain] the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. | 12-06 Infrastructure requirements |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.1 | **Identify process requirements.** Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 07.1.4.1 | The organization shall determine, [provide and maintain] the environment necessary for the operation of its processes and to achieve conformity of products and services. | 12-12 Process environment requirements |
| COM.08.BP.1 | **Identify process requirements.** Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 07.1.5.1.1 | 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. | 12-12 Process environment requirements |
| COM.08.BP.1 | **Identify process requirements.** Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 07.5.2.1 | When creating and updating documented information, the organization shall ensure appropriate identification and description (e.g. a title, date, author, or reference number). | 12-03 Documentation management requirements |
| COM.08.BP.1 | **Identify process requirements.** Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 08.1.11 | The output of this planning shall be suitable for the organization's operations. | 04-6 Product/service process lifecycle model |
| COM.08.BP.1 | **Identify process requirements.** Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 08.2.1.1 | Communication with customers shall include:<br>a) providing information relating to products and services;<br>b) handling enquiries, contracts or orders, including changes;<br>c) obtaining customer feedback relating to products and services, including customer complaints;<br>d) handling or controlling customer property;<br>e) establishing specific requirements for contingency actions, when relevant. | 12-01 Communication process requirements |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.1 | **Identify process requirements.** Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 08.3.4.1 | The organization shall apply controls to the design and development process to ensure that the results to be achieved are defined. | 03-29 Product/service objectives |
| COM.08.BP.2 | **Determine process input and output products.** Determine process input and output products expected from these processes. | 04.4.1.3 | .. and shall determine the inputs required and the outputs expected from these processes. | 04-6 Product/service process lifecycle model |
| COM.08.BP.3 | **Determine the set of activities that transform the inputs into outputs.** Determine the set of activities that transform the inputs into outputs. Controlled conditions include, as applicable, the availability and use of suitable monitoring and measuring resources. | 08.5.1.6 | Controlled conditions shall include, as applicable, the availability and use of suitable monitoring and measuring resources; | 03-26 Product/service provision lifecycle model |
| COM.08.BP.4 | **Determine the sequence and interaction of the process with other processes.** Determine the sequence and interaction of the process with other processes, by establishing criteria for the acceptance of products and services, the need for 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, the implementation of actions to prevent human error, and the implementation of release, delivery and post-delivery activities. | 04.4.1.4 | .. and shall determine the sequence and interaction of these processes. | 04-6 Product/service process lifecycle model |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.4 | **Determine the sequence and interaction of the process with other processes.** Determine the sequence and interaction of the process with other processes, by establishing criteria for the acceptance of products and services, the need for 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, the implementation of actions to prevent human error, and the implementation of release, delivery and post-delivery activities. | 08.1.6 | The organization shall .. by establishing criteria for the acceptance of products and services. | 04-6 Product/service process lifecycle model |
| COM.08.BP.4 | **Determine the sequence and interaction of the process with other processes.** Determine the sequence and interaction of the process with other processes, by establishing criteria for the acceptance of products and services, the need for 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, the implementation of actions to prevent human error, and the implementation of release, delivery and post-delivery activities. | 08.5.1.10 | Controlled conditions shall include, as applicable, 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. | 03-26 Product/service provision lifecycle model |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.4 | **Determine the sequence and interaction of the process with other processes.** Determine the sequence and interaction of the process with other processes, by establishing criteria for the acceptance of products and services, the need for 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, the implementation of actions to prevent human error, and the implementation of release, delivery and post-delivery activities. | 08.5.1.11 | Controlled conditions shall include, as applicable, the implementation of actions to prevent human error. | 03-26 Product/service provision lifecycle model |
| COM.08.BP.4 | **Determine the sequence and interaction of the process with other processes.** Determine the sequence and interaction of the process with other processes, by establishing criteria for the acceptance of products and services, the need for 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, the implementation of actions to prevent human error, and the implementation of release, delivery and post-delivery activities. | 08.5.1.12 | Controlled conditions shall include, as applicable, the implementation of release, delivery and post-delivery activities. | 03-26 Product/service provision lifecycle model |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.5 | **Identify the required competencies and roles for performing the process.** Identify the required competencies and roles for performing the process. These include:<br>a) ensuring that the quality management system conforms to the management system requirements;<br>b) ensuring that the processes are delivering their intended outputs;<br>c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;<br>d) ensuring the promotion of customer focus throughout the organization;<br>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented;<br>f) who will be responsible for meeting quality system objectives;<br>g) the appointment of competent persons, including any required qualification. | 04.4.1.7 | .. and shall assign the responsibilities and authorities for these processes. | 03-20 Management system strategy: roles and responsibilities |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.5 | **Identify the required competencies and roles for performing the process**. Identify the required competencies and roles for performing the process. These include:<br>a) ensuring that the quality management system conforms to the management system requirements;<br>b) ensuring that the processes are delivering their intended outputs;<br>c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;<br>d) ensuring the promotion of customer focus throughout the organization;<br>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented;<br>f) who will be responsible for meeting quality system objectives;<br>g) the appointment of competent persons, including any required qualification. | 05.3.1 | Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, [communicated and understood within the organization.] | 03-20 Management system strategy: roles and responsibilities |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.5 | **Identify the required competencies and roles for performing the process.** Identify the required competencies and roles for performing the process. These include:<br>a) ensuring that the quality management system conforms to the management system requirements;<br>b) ensuring that the processes are delivering their intended outputs;<br>c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;<br>d) ensuring the promotion of customer focus throughout the organization;<br>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented;<br>f) who will be responsible for meeting quality system objectives;<br>g) the appointment of competent persons, including any required qualification. | 05.3.3 | Top management shall assign the responsibility and authority for ensuring that the quality management system conforms to the requirements of this document. | 12-11 Organizational roles and responsibilities |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.5 | **Identify the required competencies and roles for performing the process**. Identify the required competencies and roles for performing the process. These include:<br>a) ensuring that the quality management system conforms to the management system requirements;<br>b) ensuring that the processes are delivering their intended outputs;<br>c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;<br>d) ensuring the promotion of customer focus throughout the organization;<br>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented;<br>f) who will be responsible for meeting quality system objectives;<br>g) the appointment of competent persons, including any required qualification. | 05.3.4 | Top management shall assign the responsibility and authority for ensuring that the processes are delivering their intended outputs. | 12-11 Organizational roles and responsibilities |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.5 | **Identify the required competencies and roles for performing the process.** Identify the required competencies and roles for performing the process. These include:<br>a) ensuring that the quality management system conforms to the management system requirements;<br>b) ensuring that the processes are delivering their intended outputs;<br>c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;<br>d) ensuring the promotion of customer focus throughout the organization;<br>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented;<br>f) who will be responsible for meeting quality system objectives;<br>g) the appointment of competent persons, including any required qualification. | 05.3.5 | Top management shall assign the responsibility and authority for reporting on the performance of the quality management system and on opportunities for improvement (see ISO 9001:2015, 10.1), in particular to top management. | 12-11 Organizational roles and responsibilities |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.5 | **Identify the required competencies and roles for performing the process.** Identify the required competencies and roles for performing the process. These include:<br>a) ensuring that the quality management system conforms to the management system requirements;<br>b) ensuring that the processes are delivering their intended outputs;<br>c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;<br>d) ensuring the promotion of customer focus throughout the organization;<br>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented;<br>f) who will be responsible for meeting quality system objectives;<br>g) the appointment of competent persons, including any required qualification. | 05.3.6 | Top management shall assign the responsibility and authority for ensuring the promotion of customer focus throughout the organization. | 12-11 Organizational roles and responsibilities |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.5 | **Identify the required competencies and roles for performing the process.** Identify the required competencies and roles for performing the process. These include:<br>a) ensuring that the quality management system conforms to the management system requirements;<br>b) ensuring that the processes are delivering their intended outputs;<br>c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;<br>d) ensuring the promotion of customer focus throughout the organization;<br>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented;<br>f) who will be responsible for meeting quality system objectives;<br>g) the appointment of competent persons, including any required qualification. | 05.3.7 | Top management shall assign the responsibility and authority for ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. | 12-11 Organizational roles and responsibilities |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.5 | **Identify the required competencies and roles for performing the process.** Identify the required competencies and roles for performing the process. These include:<br>a) ensuring that the quality management system conforms to the management system requirements;<br>b) ensuring that the processes are delivering their intended outputs;<br>c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;<br>d) ensuring the promotion of customer focus throughout the organization;<br>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented;<br>f) who will be responsible for meeting quality system objectives;<br>g) the appointment of competent persons, including any required qualification. | 06.2.2.3 | When planning how to achieve its quality objectives, the organization shall determine who will be responsible. | 03-32 Project/service roles and responsibilities |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.5 | **Identify the required competencies and roles for performing the process.** Identify the required competencies and roles for performing the process. These include:<br>a) ensuring that the quality management system conforms to the management system requirements;<br>b) ensuring that the processes are delivering their intended outputs;<br>c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;<br>d) ensuring the promotion of customer focus throughout the organization;<br>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented;<br>f) who will be responsible for meeting quality system objectives;<br>g) the appointment of competent persons, including any required qualification. | 08.5.1.9 | Controlled conditions shall include, as applicable, the appointment of competent persons, including any required qualification. | 03-26 Product/service provision lifecycle model |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.6 | **Identify the required resources for performing the process.** Determine what resources will be required by the quality management system to achieve its quality objectives. This includes determining:<br>a) the resources needed for these processes;<br>b) the capabilities of, and constraints on, existing internal resources;<br>c) what needs to be obtained from external providers;<br>d) determining the resources needed to achieve conformity to the product and service requirements;<br>e) the use of suitable infrastructure and environment for the operation of processes. | 04.4.1.6 | .. and shall determine the resources needed for these processes and ensure their availability. | 12-09 MS Resource requirements |
| COM.08.BP.6 | **Identify the required resources for performing the process.** Determine what resources will be required by the quality management system to achieve its quality objectives. This includes determining:<br>a) the resources needed for these processes;<br>b) the capabilities of, and constraints on, existing internal resources;<br>c) what needs to be obtained from external providers;<br>d) determining the resources needed to achieve conformity to the product and service requirements;<br>e) the use of suitable infrastructure and environment for the operation of processes. | 06.2.2.2 | When planning how to achieve its quality objectives, the organization shall determine what resources will be required. | 03-31 Project/service resource needs |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.6 | **Identify the required resources for performing the process.** Determine what resources will be required by the quality management system to achieve its quality objectives. This includes determining:<br>a) the resources needed for these processes;<br>b) the capabilities of, and constraints on, existing internal resources;<br>c) what needs to be obtained from external providers;<br>d) determining the resources needed to achieve conformity to the product and service requirements;<br>e) the use of suitable infrastructure and environment for the operation of processes. | 07.1.1.1 | The organization shall determine [and provide] the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system. | 12-09 MS Resource requirements |
| COM.08.BP.6 | **Identify the required resources for performing the process.** Determine what resources will be required by the quality management system to achieve its quality objectives. This includes determining:<br>a) the resources needed for these processes;<br>b) the capabilities of, and constraints on, existing internal resources;<br>c) what needs to be obtained from external providers;<br>d) determining the resources needed to achieve conformity to the product and service requirements;<br>e) the use of suitable infrastructure and environment for the operation of processes. | 07.1.1.3 | The organization shall consider the capabilities of, and constraints on, existing internal resources. | 12-09 MS Resource requirements |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.6 | **Identify the required resources for performing the process.** Determine what resources will be required by the quality management system to achieve its quality objectives. This includes determining:<br>a) the resources needed for these processes;<br>b) the capabilities of, and constraints on, existing internal resources;<br>c) what needs to be obtained from external providers;<br>d) determining the resources needed to achieve conformity to the product and service requirements;<br>e) the use of suitable infrastructure and environment for the operation of processes. | 07.1.1.4 | The organization shall consider what needs to be obtained from external providers. | 12-09 MS Resource requirements |
| COM.08.BP.6 | **Identify the required resources for performing the process.** Determine what resources will be required by the quality management system to achieve its quality objectives. This includes determining:<br>a) the resources needed for these processes;<br>b) the capabilities of, and constraints on, existing internal resources;<br>c) what needs to be obtained from external providers;<br>d) determining the resources needed to achieve conformity to the product and service requirements;<br>e) the use of suitable infrastructure and environment for the operation of processes. | 08.1.7 | The organization shall .. by determining the resources needed to achieve conformity to the product and service requirements. | 12-09 MS Resource requirements |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.6 | **Identify the required resources for performing the process.** Determine what resources will be required by the quality management system to achieve its quality objectives. This includes determining:<br>a) the resources needed for these processes;<br>b) the capabilities of, and constraints on, existing internal resources;<br>c) what needs to be obtained from external providers;<br>d) determining the resources needed to achieve conformity to the product and service requirements;<br>e) the use of suitable infrastructure and environment for the operation of processes. | 08.5.1.8 | Controlled conditions shall include, as applicable, the use of suitable infrastructure and environment for the operation of processes. | 03-26 Product/service provision lifecycle model |
| COM.08.BP.7 | **Determine the methods for monitoring the effectiveness and suitability of the process**. Determine the methods for monitoring the effectiveness and suitability of the process. | 04.4.1.5 | .. and shall 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. | 03-24 MS Measurement methods |
| COM.08.BP.7 | **Determine the methods for monitoring the effectiveness and suitability of the process**. Determine the methods for monitoring the effectiveness and suitability of the process. | 04.4.1.9 | .. and shall evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results. | 04-6 Product/service process lifecycle model |
| COM.08.BP.7 | **Determine the methods for monitoring the effectiveness and suitability of the process.** Determine the methods for monitoring the effectiveness and suitability of the process. | 06.2.2.5 | When planning how to achieve its quality objectives, the organization shall determine how the results will be evaluated. | 03-30 Project/service measures |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.7 | **Determine the methods for monitoring the effectiveness and suitability of the process.** Determine the methods for monitoring the effectiveness and suitability of the process. | 08.5.1.7 | Controlled conditions shall include, as applicable, 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. | 03-26 Product/service provision lifecycle model |
| COM.08.BP.8 | **Plan the deployment of the process.** Plan that the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. | 06.1.1.1 | 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:<br>a) give assurance that the quality management system can achieve its intended result(s);<br>b) enhance desirable effects;<br>c) prevent, or reduce, undesired effects;<br>d) achieve improvement.] | 08-54 Risk and opportunity identification |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.8 | **Plan the deployment of the process.** Plan that the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. | 06.1.2.1 | The organization shall plan:<br>a) actions to address these risks and opportunities;<br>b) how to:<br>1) integrate and implement the actions into its quality management system processes (see 4.4);<br>2) evaluate the effectiveness of these actions. | 04-7 Risk management plan |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.8 | **Plan the deployment of the process.** Plan that the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. | 06.2.2.4 | When planning how to achieve its quality objectives, the organization shall determine when it will be completed. | 03-33 Project/service schedule |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.8 | **Plan the deployment of the process.** Plan that the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. | 08.3.2.1 | In determining the stages and controls for design and development, the organization shall consider the nature, duration and complexity of the design and development activities. | 04-6 Product/service process lifecycle model |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.8 | **Plan the deployment of the process.** Plan that the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. | 08.3.2.2 | In determining the stages and controls for design and development, the organization shall consider the required process stages, including applicable design and development reviews. | 04-6 Product/service process lifecycle model |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.8 | **Plan the deployment of the process**. Plan that the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;ix) the level of control expected for the design and development process by customers and other relevant interested parties. | 08.3.2.3 | In determining the stages and controls for design and development, the organization shall consider the required design and development verification and validation activities. | 04-6 Product/service process lifecycle model |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.8 | **Plan the deployment of the process.** Plan that the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. | 08.3.2.4 | In determining the stages and controls for design and development, the organization shall consider the responsibilities and authorities involved in the design and development process. | 04-6 Product/service process lifecycle model |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.8 | **Plan the deployment of the process**. Plan that the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. | 08.3.2.5 | In determining the stages and controls for design and development, the organization shall consider the internal and external resource needs for the design and development of products and services. | 04-6 Product/service process lifecycle model |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.8 | **Plan the deployment of the process.** Plan that the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. | 08.3.2.6 | In determining the stages and controls for design and development, the organization shall consider the need to control interfaces between persons involved in the design and development process. | 04-6 Product/service process lifecycle model |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.8 | **Plan the deployment of the process.** Plan that the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. | 08.3.2.7 | In determining the stages and controls for design and development, the organization shall consider the need for involvement of customers and users in the design and development process; | 04-6 Product/service process lifecycle model |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.8 | **Plan the deployment of the process.** Plan that the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. | 08.3.2.8 | In determining the stages and controls for design and development, the organization shall consider the requirements for subsequent provision of products and services. | 04-6 Product/service process lifecycle model |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.8 | **Plan the deployment of the process.** Plan that the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. | 08.3.2.9 | In determining the stages and controls for design and development, the organization shall consider the level of control expected for the design and development process by customers and other relevant interested parties. | 04-6 Product/service process lifecycle model |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.8 | **Plan the deployment of the process.** Plan that the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. | 09.1.1.3 | The organization shall determine when the monitoring and measuring shall be performed. | 03-22 MS Measurement information gathering events |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.8 | **Plan the deployment of the process.** Plan that the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. | 09.1.1.4 | The organization shall determine when the results from monitoring and measurement shall be analysed and evaluated. | 03-22 MS Measurement information gathering events |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.8 | **Plan the deployment of the process.** Plan that the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. | 09.2.1.2 | [The organization shall conduct internal audits] at planned intervals [to provide information on whether the quality management system:<br>a) conforms to:<br>1) the organization's own requirements for its quality management system;<br>2) the requirements of this document;<br>b) is effectively implemented and maintained.] | 04-1 Audit (MS) schedule |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.8 | **Plan the deployment of the process.** Plan that the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. | 09.2.2.1 | The organization shall plan, establish, [implement and maintain] an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits. | 04-3 Audit programme plan |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.8 | **Plan the deployment of the process.** Plan that the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. | 09.3.1.2 | [Top management shall review the organization's quality management system,] at planned intervals, [to ensure its continuing suitability, adequacy, effectiveness and alignment with the strategic direction of the organization.] | 04-5 Management review schedule |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.08.BP.8 | **Plan the deployment of the process.** Plan that the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. | 09.3.2.1 | The management review shall be planned [and carried out taking into consideration:] | 04-5 Management review schedule |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.09 Operational implementation and control | | | | |
| COM.09.BP.1 | **Allocate roles, responsibilities and authorities**. Allocate the required roles, responsibilities and authorities. Top management ensures that the responsibilities and authorities for relevant roles are communicated and understood within the organization. | 05.3.2 | Top management shall ensure that the responsibilities and authorities for relevant roles are [assigned], communicated and understood within the organization. | 08-57 Roles and responsibilities assignment record |
| COM.09.BP.2 | **Allocate resources.** Allocate and apply the required resources. The organization<br>a) provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system;<br>b) determines the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>c) provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>d) ensures that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken;<br>e) ensure that the resources provided are maintained to ensure their continuing fitness for their purpose. | 07.1.1.2 | The organization shall [determine and] provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system. | 08-24 MS Resources provision record |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.09.BP.2 | **Allocate resources.** Allocate and apply the required resources. The organization:<br>a) provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system;<br>b) determines the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>c) provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>d) ensures that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken;<br>e) ensure that the resources provided are maintained to ensure their continuing fitness for their purpose. | 07.1.2.1 | 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. | 08-24 MS Resources provision record |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.09.BP.2 | **Allocate resources.** Allocate and apply the required resources. The organization:<br>a) provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system;<br>b) determines the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>c) provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>d) ensures that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken;<br>e) ensure that the resources provided are maintained to ensure their continuing fitness for their purpose. | 07.1.2.2 | 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. | 08-24 MS Resources provision record |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.09.BP.2 | **Allocate resources.** Allocate and apply the required resources. The organization:<br>a) provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system;<br>b) determines the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>c) provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>d) ensures that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken;<br>e) ensure that the resources provided are maintained to ensure their continuing fitness for their purpose. | 07.1.5.1.3 | The organization shall ensure that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken. | 02-3 Measuring equipment asset list |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.09.BP.2 | **Allocate resources**. Allocate and apply the required resources. The organization:<br>a) provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system;<br>b) determines the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>c) provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>d) ensures that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken;<br>e) ensure that the resources provided are maintained to ensure their continuing fitness for their purpose. | 07.1.5.1.4 | The organization shall ensure that the resources provided are maintained to ensure their continuing fitness for their purpose. | 02-4 Measuring equipment maintenance log |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.09.BP.3 | **Perform process activities**. Perform process activities. The organization:<br>a) monitors and reviews information about these external and internal issues;<br>b) monitors and reviews information about interested parties and their relevant requirements;<br>c) evaluates the effectiveness of the actions taken;<br>d) ensures that contract or order requirements differing from those previously defined are resolved;<br>e) ensures the adequacy of requirements prior to their communication to the external provider;<br>f) maintains an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits. | 05.2.1.2 | Top management shall [establish], implement [and maintain] a quality policy that:.. | 08-22 MS Implementation log |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.09.BP.3 | **Perform process activities.** Perform process activities. The organization:<br>a) monitors and reviews information about these external and internal issues;<br>b) monitors and reviews information about interested parties and their relevant requirements;<br>c) evaluates the effectiveness of the actions taken;<br>d) ensures that contract or order requirements differing from those previously defined are resolved;<br>e) ensures the adequacy of requirements prior to their communication to the external provider;<br>f) maintains an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits. | 07.1.3.2 | The organization shall [determine], provide [and maintain] the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. | 08-22 MS Implementation log |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.09.BP.3 | **Perform process activities.** Perform process activities. The organization:<br>a) monitors and reviews information about these external and internal issues;<br>b) monitors and reviews information about interested parties and their relevant requirements;<br>c) evaluates the effectiveness of the actions taken;<br>d) ensures that contract or order requirements differing from those previously defined are resolved;<br>e) ensures the adequacy of requirements prior to their communication to the external provider;<br>f) maintains an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits. | 07.1.3.3 | The organization shall [determine, provide and] maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. | 08-23 MS Implementation review record |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.09.BP.3 | **Perform process activities.** Perform process activities. The organization:<br>a) monitors and reviews information about these external and internal issues;<br>b) monitors and reviews information about interested parties and their relevant requirements;<br>c) evaluates the effectiveness of the actions taken;<br>d) ensures that contract or order requirements differing from those previously defined are resolved;<br>e) ensures the adequacy of requirements prior to their communication to the external provider;<br>f) maintains an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits. | 07.1.4.2 | The organization shall [determine,] provide [and maintain] the environment necessary for the operation of its processes and to achieve conformity of products and services. | 08-22 MS Implementation log |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.09.BP.3 | **Perform process activities.** Perform process activities. The organization:<br>a) monitors and reviews information about these external and internal issues;<br>b) monitors and reviews information about interested parties and their relevant requirements;<br>c) evaluates the effectiveness of the actions taken;<br>d) ensures that contract or order requirements differing from those previously defined are resolved;<br>e) ensures the adequacy of requirements prior to their communication to the external provider;<br>f) maintains an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits. | 07.1.5.1.2 | 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. | 08-22 MS Implementation log |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.09.BP.3 | **Perform process activities.** Perform process activities. The organization:<br>a) monitors and reviews information about these external and internal issues;<br>b) monitors and reviews information about interested parties and their relevant requirements;<br>c) evaluates the effectiveness of the actions taken;<br>d) ensures that contract or order requirements differing from those previously defined are resolved;<br>e) ensures the adequacy of requirements prior to their communication to the external provider;<br>f) maintains an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits. | 08.1.2 | 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:.. | 03-09 Management system strategy: Establish the management system |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.09.BP.3 | **Perform process activities.** Perform process activities. The organization:<br>a) monitors and reviews information about these external and internal issues;<br>b) monitors and reviews information about interested parties and their relevant requirements;<br>c) evaluates the effectiveness of the actions taken;<br>d) ensures that contract or order requirements differing from those previously defined are resolved;<br>e) ensures the adequacy of requirements prior to their communication to the external provider;<br>f) maintains an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits. | 08.1.8 | The organization shall .. by implementing control of the processes in accordance with the criteria. | 08-23 MS Implementation review record |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.09.BP.3 | **Perform process activities.** Perform process activities. The organization:<br>a) monitors and reviews information about these external and internal issues;<br>b) monitors and reviews information about interested parties and their relevant requirements;<br>c) evaluates the effectiveness of the actions taken;<br>d) ensures that contract or order requirements differing from those previously defined are resolved;<br>e) ensures the adequacy of requirements prior to their communication to the external provider;vi) maintains an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits. | 08.5.1.7 | Controlled conditions shall include, as applicable, 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. | 02-5 MS Measurement information collection log |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.09.BP.3 | **Perform process activities**. Perform process activities. The organization:<br>a) monitors and reviews information about these external and internal issues;<br>b) monitors and reviews information about interested parties and their relevant requirements;<br>c) evaluates the effectiveness of the actions taken;<br>d) ensures that contract or order requirements differing from those previously defined are resolved;<br>e) ensures the adequacy of requirements prior to their communication to the external provider;<br>f) maintains an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits. | 09.2.2.2 | The organization shall [plan, establish], implement [and maintain] an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits. | 08-22 MS Implementation log |
| COM.09.BP.4 | **Review process activities**. Review process activities. | 04.1.2 | The organization shall monitor and review information about these external and internal issues. | 08-23 MS Implementation review record |
| COM.09.BP.4 | **Review process activities**. Review process activities. | 04.2.3 | The organization shall monitor and review information about these interested parties and their relevant requirements. | 08-23 MS Implementation review record |
| COM.09.BP.4 | **Review process activities**. Review process activities. | 05.2.1.3 | Top management shall [establish, implement and] maintain a quality policy that:.. | 08-23 MS Implementation review record |
| COM.09.BP.4 | **Review process activities**. Review process activities. | 07.1.4.3 | The organization shall [determine, provide and] maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. | 08-23 MS Implementation review record |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.09.BP.4 | **Review process activities**. Review process activities. | 07.2.3 | The organization shall where applicable, take actions to acquire the necessary competence, [and evaluate the effectiveness of the actions taken.] | 08-62 Training record |
| COM.09.BP.4 | **Review process activities**. Review process activities. | 07.2.4 | The organization shall where applicable, [take actions to acquire the necessary competence,] and evaluate the effectiveness of the actions taken. | 08-31 Personnel competency records |
| COM.09.BP.4 | **Review process activities**. Review process activities. | 08.1.3 | 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:.. | 03-09 Management system strategy: Establish the management system |
| COM.09.BP.4 | **Review process activities**. Review process activities. | 08.2.3.1.2 | The organization shall ensure that contract or order requirements differing from those previously defined are resolved. | 08-45 Product/service requirements review record |
| COM.09.BP.4 | **Review process activities**. Review process activities. | 08.4.3.1 | The organization shall ensure the adequacy of requirements prior to their communication to the external provider. | 08-45 Product/service requirements review record |
| COM.09.BP.4 | **Review process activities**. Review process activities. | 09.2.2.3 | The organization shall [plan, establish, implement and] maintain an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits; | 08-23 MS Implementation review record |
| COM.09.BP.5 | **Correct deviations**. Correct deviations from planned arrangements when targets are not achieved. | 08.1.12 | The organization shall control planned changes [and review the consequences of unintended changes], taking action to mitigate any adverse effects, as necessary. | 11-07 Process change request |
| COM.09.BP.5 | **Correct deviations**. Correct deviations from planned arrangements when targets are not achieved. | 08.1.13 | The organization shall [control planned changes and] review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary. | 08-33 Process change evaluation record |
| COM.09.BP.6 | **Collect and analyse data**. Collect and analyse data as a basis for understanding the behaviour of, and to demonstrate the suitability and effectiveness of the processes. | 09.1.3.1 | The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement. | 02-6 MS Performance measurement data |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.10 Performance evaluation | | | | |
| COM.10.BP.1 | **Determine what needs to be monitored**. Determine what needs to be monitored and measured. | 09.1.1.1 | The organization shall determine what needs to be monitored and measured. | 03-23 MS Measurement information needs |
| COM.10.BP.1 | **Determine what needs to be monitored**. Determine what needs to be monitored and measured. | 09.1.2.1 | The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. | 03-23 MS Measurement information needs |
| COM.10.BP.3 | **Determine the appropriate methods for monitoring, measurement, analysis and evaluation**. Determine the appropriate methods for monitoring, measurement, analysis and evaluation, as well as how the results will be evaluated. | 09.1.1.2 | The organization shall determine the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results. | 03-24 MS Measurement methods |
| COM.10.BP.3 | **Determine the appropriate methods for monitoring, measurement, analysis and evaluation**. Determine the appropriate methods for monitoring, measurement, analysis and evaluation, as well as how the results will be evaluated. | 09.1.2.2 | The organization shall determine the methods for obtaining, monitoring and reviewing this information. | 03-24 MS Measurement methods |
| COM.10.BP.4 | **Monitor and measure the quality management system performance**. Collect and verify data on the quality management system performance of the organization. | 09.1.1.7 | [The organization shall retain appropriate documented information as] evidence of the results. | 02-6 MS Performance measurement data |
| COM.10.BP.5 | **Analyse the collected data**. Analyse the collected data in order to evaluate the quality management system performance, the effectiveness of the quality management system as well as the effectiveness of any action taken within the scope of the quality management system. | 09.1.3.1 | The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement. | 02-6 MS Performance measurement data |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.10.BP.5 | **Analyse the collected data**. Analyse the collected data in order to evaluate the quality management system performance, the effectiveness of the quality management system as well as the effectiveness of any action taken within the scope of the quality management system. | 09.1.3.2 | The results of analysis shall be used to evaluate conformity of products and services. | 09-08 Product/service conformity evaluation report |
| COM.10.BP.5 | **Analyse the collected data**. Analyse the collected data in order to evaluate the quality management system performance, the effectiveness of the quality management system as well as the effectiveness of any action taken within the scope of the quality management system. | 09.1.3.3 | The results of analysis shall be used to evaluate the degree of customer satisfaction. | 09-01 Customer satisfaction evaluation report |
| COM.10.BP.5 | **Analyse the collected data**. Analyse the collected data in order to evaluate the quality management system performance, the effectiveness of the quality management system as well as the effectiveness of any action taken within the scope of the quality management system. | 09.1.3.4 | The results of analysis shall be used to evaluate the performance and effectiveness of the quality management system. | 09-03 Management system conformity evaluation report |
| COM.10.BP.5 | **Analyse the collected data**. Analyse the collected data in order to evaluate the quality management system performance, the effectiveness of the quality management system as well as the effectiveness of any action taken within the scope of the quality management system. | 09.1.3.5 | The results of analysis shall be used to evaluate if planning has been implemented effectively. | 09-04 Planning performance evaluation report |
| COM.10.BP.5 | **Analyse the collected data**. Analyse the collected data in order to evaluate the quality management system performance, the effectiveness of the quality management system as well as the effectiveness of any action taken within the scope of the quality management system. | 09.1.3.6 | The results of analysis shall be used to evaluate the effectiveness of actions taken to address risks and opportunities. | 09-05 Process capability assessment report |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.11 Risk management | | | | |
| COM.11.BP.1 | **Identify risks.** Identify risks and opportunities. The following may be considered for identifying such uncertainties:<br>— potential occurrence of set of circumstances and their consequences;<br>— set of circumstances and their consequences which may potentially not occur;<br>— potential consequences, which may affect objectives but where such consequences do not appear to be linked to specific risk source, type or sequence of events;<br>— changes in the internal or external environment leading to a state consisting of factors previously unknown to the organization. These are sometimes also referred to as "known unknowns";<br>— changes in the internal or external environment leading to a state where knowledge of the organization about its environment may become invalidated or irrelevant;<br>— gradual changes in the internal or external environment which individually may not have any effect on objectives but their repetitive occurrences overtime may result in significant changes to one or more factors resulting in a single or chain of events and consequences. | 10.2.1.7 | When a nonconformity occurs, including any arising from complaints, the organization shall update risks and opportunities determined during planning, if necessary. | 08-54 Risk and opportunity identification |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| COM.11.BP.5 | **Treat risks**. Treat selected risks. Risk treatment involves selecting one or more options for responding to risks and implementing those options. Risk treatment involves a cyclical process of:<br>— formulating and selecting risk treatment;<br>— implementing risk treatment;<br>— deciding whether residual risk levels are acceptable;<br>— if not acceptable, generating further risk treatment;<br>— assessing the effectiveness of that treatment;<br>— potential evolution over time. | 06.1.2.2 | Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services. | 08-56 Risk treatment action log |
| COM.11.BP.6 | **Identify opportunities**. One of the options for treating risk involve taking or increasing the risk in order to pursue an opportunity. | 06.1.2.2 | Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services. | 08-56 Risk treatment action log |
| ORG.01 Asset management | | | | |
| ORG.01.BP.1 | **Identify Items**. Identify Items requiring asset management. | 08.5.3.2 | The organization shall identify, [verify, protect and safeguard] customers' or external providers' property provided for use or incorporation into the products and services. | 07-1 Product asset |
| ORG.01.BP.2 | **Determine asset status**. Determine the status of the asset. | 08.5.3.4 | 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.] | 08-12 Product asset communication record |
| ORG.01.BP.4 | **Assure asset integrity**. Assure the integrity of assets. | 08.5.3.3 | The organization shall [identify,] verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services. | 07-1 Product asset |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| ORG.02 Measurement resource management | | | | |
| ORG.02.BP.3 | **Identify measurement resources**. Identify measurement resources. | 07.1.5.2.3 | 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 identified in order to determine their status. | 02-2 Measurement resource identification |
| ORG.02.BP.4 | **Confirm calibration status**. Confirm the calibration status of measurement resources, as applicable at appropriate intervals. | 07.1.5.2.1 | 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 calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. | 02-1 Measurement resource calibration log |
| ORG.02.BP.4 | **Confirm calibration status**. Confirm the calibration status of measurement resources, as applicable at appropriate intervals. | 07.1.5.2.2 | When no such standards exist, the basis used for calibration or verification shall be retained as documented information. | 02-1 Measurement resource calibration log |
| ORG.02.BP.4 | **Confirm calibration status**. Confirm the calibration status of measurement resources, as applicable at appropriate intervals. | 07.1.5.2.3 | 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 identified in order to determine their status. | 02-1 Measurement resource calibration log |
| ORG.02.BP.4 | **Confirm calibration status**. Confirm the calibration status of measurement resources, as applicable at appropriate intervals. | 07.1.5.2.4 | 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 safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results. | 02-1 Measurement resource calibration log |
| ORG.02.BP.6 | **Segregate malperforming measurement resources**. Segregate and control malperforming measurement resources in order to avoid unintended use. | 07.1.5.2.5 | 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.] | 02-1 Measurement resource calibration log |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| ORG.03 Supplier management | | | | |
| ORG.03.BP.6 | **Monitor supplier performance**. Monitor supplier performance against agreed criteria. | 09.1.3.7 | The results of analysis shall be used to evaluate the performance of external providers. | 09-11 Supplier performance evaluation report |
| TEC.01 Configuration management | | | | |
| TEC.01.BP.1 | **Identify configuration items**. Identify items requiring configuration management. | 08.5.2.1 | The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services. | 03-27 Product/service taxonomy |
| TEC.01.BP.1 | **Identify configuration items**. Identify items requiring configuration management. | 08.5.2.3 | 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.] | 03-27 Product/service taxonomy |
| TEC.01.BP.2 | **Identify configuration item status**. Identify the status of configuration items and modifications. | 08.5.2.2 | The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision. | 09-07 Product/service configuration status report |
| TEC.02 Process changes | | | | |
| TEC.02.BP.1 | **Classify process change requests**. Classify process change requests. The organization reviews changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. | 08.5.6.1 | The organization shall review [and control] changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. | 08-34 Process change request review record |
| TEC.02.BP.2 | **Assess process change requests**. Assess process change requests using defined criteria. | 08.5.6.2 | The organization shall [review and] control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements. | 08-33 Process change evaluation record |
| TEC.02.BP.2 | **Assess process change requests**. Assess process change requests using defined criteria. | 08.5.6.5 | The organization shall retain [documented] information describing [the results of the review of changes], the person(s) authorizing the change, [and any necessary actions arising from the review]. | 08-32 Process change approval record |
| TEC.02.BP.3 | **Implement process changes**. Implement process changes, as appropriate. | 08.5.6.3 | The organization shall retain [documented] information describing the [results of the review of changes, the person(s) authorizing the change, and] any necessary actions arising from the review. | 02-7 Process change implementation log |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| TEC.03 Product/service changes | | | | |
| TEC.03.BP.1 | **Identify product/service change requests**. Identify and classify product/service change requests. | 08.3.6.1 | 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. | 11-09 Product/service design change request |
| TEC.03.BP.2 | **Assess product/service change requests**. Assess product/service change requests using defined criteria. | 08.3.6.2 | 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. | 08-42 Product/service design change evaluation result |
| TEC.03.BP.3 | **Implement product/service changes**. Implement product/service changes, as appropriate. | 08.3.6.3 | 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. | 08-35 Product/service design change log |
| TEC.04 Product/service design | | | | |
| TEC.04.BP.1 | **Design each product/service component**. Develop the design for each product/service component in accordance with defined requirements. | 08.3.5.1 | The organization shall ensure that design and development outputs meet the input requirements. | 03-28 Product/service design |
| TEC.04.BP.2 | **Define external and internal interfaces**. Define the external and internal interfaces for each product/service component. | 08.3.5.2 | The organization shall ensure that design and development outputs are adequate for the subsequent processes for the provision of products and services. | 03-28 Product/service design |
| TEC.05 Product/service planning | | | | |
| TEC.05.BP.6 | **Develop plans**. Develop plans for the development of the product/service. | 08.3.4.2 | The organization shall apply controls to the design and development process to ensure that reviews are conducted to evaluate the ability of the results of design and development to meet requirements. | 02-8 Product/service review schedule |
| TEC.06 Product/service quarantine | | | | |
| TEC.06.BP.1 | **Identify non-conforming product/services**. Identify product/service that does not conform to requirements. | 08.7.1.1 | The organization shall ensure that outputs that do not conform to their requirements are identified [and controlled] to prevent their unintended use or delivery. | 08-30 Non-conformity record |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| TEC.06.BP.2 | **Quarantine nonconforming product/services**. Place under quarantine nonconforming product/services. | 08.7.1.2 | The organization shall ensure that outputs that do not conform to their requirements are [identified and] controlled to prevent their unintended use or delivery. | 11-06 Nonconforming product quarantine request |
| TEC.06.BP.3 | **Identify alternative approaches**. Identify alternative approaches regarding disposition of the nonconforming product/service. | 08.7.1.6 | The organization shall deal with nonconforming outputs in one or more of the following ways segregation, containment, return or suspension of provision of products and services. | 08-29 Non-conformity disposition record |
| TEC.06.BP.4 | **Take agreed actions**. Take agreed actions regarding disposition of nonconforming product/service. | 08.7.1.3 | The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. | 08-26 Nonconforming product disposition evaluation result |
| TEC.06.BP.4 | **Take agreed actions**. Take agreed actions regarding disposition of nonconforming product/service. | 08.7.1.4 | This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services. | 08-26 Nonconforming product disposition evaluation result |
| TEC.06.BP.4 | **Take agreed actions**. Take agreed actions regarding disposition of nonconforming product/service. | 08.7.1.5 | The organization shall deal with nonconforming outputs by correction. | 11-04 Nonconforming product corrective action request |
| TEC.06.BP.5 | **Re-verify corrected product/service**. Re-verify product/service that has been corrected to demonstrate conformity to requirements. | 08.7.1.9 | Conformity to the requirements shall be verified when nonconforming outputs are corrected. | 08-28 Nonconforming product re-verification record |
| TEC.06.BP.7 | **Release product/service from quarantine**. Release product/service from quarantine when authorized. | 08.7.1.8 | The organization shall deal with nonconforming outputs through obtaining authorization for acceptance under concession. | 08-27 Nonconforming product quarantine release authorization |
| TEC.07 Product/service requirements | | | | |
| TEC.07.BP.1 | **Identify product/service characteristics**. Identify the required characteristics and context of use of products/services. | 08.3.3.1 | The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. | 12-18 Product/service requirements |
| TEC.07.BP.2 | **Identify solution constraints**. Identify the constraints for a product/service solution. | 08.3.3.4 | The organization shall consider statutory and regulatory requirements. | 12-18 Product/service requirements |
| TEC.07.BP.2 | **Identify solution constraints**. Identify the constraints for a product/service solution. | 08.3.3.5 | The organization shall consider standards or codes of practice that the organization has committed to implement. | 12-18 Product/service requirements |
| TEC.07.BP.2 | **Identify solution constraints**. Identify the constraints for a product/service solution. | 08.3.3.6 | The organization shall consider potential consequences of failure due to the nature of the products and services. | 12-18 Product/service requirements |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| TEC.07.BP.3 | **Define requirements**. Define the requirements for the product/service. | 08.1.4 | The organization shall .. by determining the requirements for the products and services. | 12-18 Product/service requirements |
| TEC.07.BP.3 | **Define requirements**. Define the requirements for the product/service. | 08.2.2.1 | When determining the requirements for the products and services to be offered to customers, the organization shall ensure that the requirements for the products and services are defined. | 12-18 Product/service requirements |
| TEC.07.BP.3 | **Define requirements**. Define the requirements for the product/service. | 08.2.2.2 | When determining the requirements for the products and services to be offered to customers, the organization shall ensure that the requirements for the products and services are defined, including:<br>[a) any applicable statutory and regulatory requirements;]<br>b) those considered necessary by the organization. | 12-18 Product/service requirements |
| TEC.07.BP.3 | **Define requirements**. Define the requirements for the product/service. | 08.2.2.3 | When determining the requirements for the products and services to be offered to customers, the organization shall ensure that [the requirements for the products and services are defined], including:]<br>a) any applicable statutory and regulatory requirements;<br>[b) those considered necessary by the organization.] | 12-18 Product/service requirements |
| TEC.07.BP.3 | **Define requirements**. Define the requirements for the product/service. | 08.2.3.2.3 | The organization shall retain [documented] information, as applicable, on any new requirements for the products and services. | 08-45 Product/service requirements review record |
| TEC.07.BP.3 | **Define requirements**. Define the requirements for the product/service. | 08.3.3.2 | The organization shall consider functional and performance requirements. | 12-18 Product/service requirements |
| TEC.07.BP.3 | **Define requirements**. Define the requirements for the product/service. | 08.3.3.3 | The organization shall consider information derived from previous similar design and development activities. | 12-18 Product/service requirements |
| TEC.07.BP.3 | **Define requirements.** Define the requirements for the product/service. | 08.3.3.7 | Inputs shall be adequate for design and development purposes, complete and unambiguous. | 12-18 Product/service requirements |
| TEC.07.BP.3 | **Define requirements**. Define the requirements for the product/service. | 08.3.3.8 | Conflicting design and development inputs shall be resolved. | 12-18 Product/service requirements |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| TEC.08 Product/service review | | | | |
| TEC.08.BP.3 | **Perform reviews**. Perform the required review activities. | 08.3.4.2 | The organization shall apply controls to the design and development process to ensure that reviews are conducted to evaluate the ability of the results of design and development to meet requirements. | 08-45 Product/service requirements review record |
| TEC.08.BP.4 | **Identify action items**. Identify action items. | 08.3.4.5 | The organization shall apply controls to the design and development process to ensure that any necessary actions are taken on problems determined during the reviews, or verification and validation activities. | 08-45 Product/service requirements review record |
| TEC.09 Product/ service supply | | | | |
| TEC.09.BP.2 | **Evaluate product/service request(s)**. Evaluate product/service request(s) in terms of mandated product/ service delivery criteria. | 08.2.2.4 | When determining the requirements for the products and services to be offered to customers, the organization shall ensure that the organization can meet the claims for the products and services it offers. | 03-21 Management system strategy: supplier capability |
| TEC.09.BP.2 | **Evaluate product/service request(s)**. Evaluate product/service request(s) in terms of mandated product/ service delivery criteria. | 08.2.3.1.1 | The organization shall conduct a review before committing to supply products and services to a customer, to include:<br>a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;<br>b) requirements not stated by the customer, but necessary for the specified or intended use, when known;<br>c) requirements specified by the organization;<br>d) statutory and regulatory requirements applicable to the products and services;<br>e) contract or order requirements differing from those previously expressed. | 08-45 Product/service requirements review record |
| TEC.09.BP.2 | **Evaluate product/service request(s)**. Evaluate product/service request(s) in terms of mandated product/ service delivery criteria. | 08.2.3.2.1 | The organization shall retain [documented] information, as applicable, on the results of the review. | 08-45 Product/service requirements review record |
| TEC.09.BP.3 | **Produce a response to a request**. Produce a response to a customer's product/service request. | 08.2.3.1.3 | The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements. | 08-44 Product/service requirements communication record |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| TEC.09.BP.4 | **Establish an agreement**. Establish an agreement between the customer and the supplier for providing the product/service. | 08.3.5.3 | The organization shall ensure that design and development outputs include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria; | 12-14 Product/service acceptance criteria |
| TEC.09.BP.5 | **Provide product/service**. Provide the product/service to the customer in accordance with the agreed requirements. | 08.6.2 | The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed, [unless otherwise approved by a relevant authority and, as applicable, by the customer.] | 08-36 Product/service release approval record |
| TEC.09.BP.5 | **Provide product/service**. Provide the product/service to the customer in accordance with the agreed requirements. | 08.6.3 | [The release of products and services to the customer shall not proceed until the planned arrangements have been satisfactorily completed,] unless otherwise approved by a relevant authority and, as applicable, by the customer. | 08-36 Product/service release approval record |
| TEC.09.BP.6 | **Verify conformity to requirements**. Verify conformity to applicable stated and implied customer and supplier requirements by internal processes and/or product provided. | 08.3.5.4 | The organization shall ensure that design and development outputs specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision. | 08-49 Product/service validation record |
| TEC.09.BP.6 | **Verify conformity to requirements**. Verify conformity to applicable stated and implied customer and supplier requirements by internal processes and/or product provided. | 08.6.4 | The organization shall retain documented information on the release of products and services. | 08-49 Product/service validation record |
| TEC.09.BP.6 | **Verify conformity to requirements**. Verify conformity to applicable stated and implied customer and supplier requirements by internal processes and/or product provided. | 08.6.5 | The documented information shall include evidence of conformity with the acceptance criteria. | 08-36 Product/service release approval record |
| TEC.10 Product/service validation | | | | |
| TEC.10.BP.3 | **Perform validation activities**. Perform required validation activities. | 08.3.4.4 | The organization shall apply controls to the design and development process to ensure that validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use. | 08-49 Product/service validation record |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| TEC.11 Product/service verification | | | | |
| TEC.11.BP.3 | **Perform verification**. Perform required verification activities. | 08.3.4.3 | The organization shall apply controls to the design and development process to ensure that verification activities are conducted to ensure that the design and development outputs meet the input requirements. | 08-51 Product/service verification record |
| TEC.11.BP.3 | **Perform verification**. Perform required verification activities. | 08.6.1 | The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met. | 08-51 Product/service verification record |
| TOP.01 Leadership | | | | |
| TOP.01.BP.1 | **Determine external and internal issues that are relevant to the organization and analyse their impacts**. Determine external and internal issues that are relevant to the purpose of the assessed organization and that affect its ability to achieve the intended outcome(s) of its quality management system. | 04.1.1 | 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. | 03-10 Management system strategy: external and internal issues |
| TOP.01.BP.2 | **Determine relevant the interested parties and analyse their requirements**. Determine the relevant interested parties that are relevant to the quality management system and establish appropriate contacts with them. | 04.2.1 | 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 the interested parties that are relevant to the quality management system. | 03-25 MS Relevant Interested parties |
| TOP.01.BP.2 | **Determine relevant the interested parties and analyse their requirements**. Determine the relevant interested parties that are relevant to the quality management system and establish appropriate contacts with them. | 04.2.2 | 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 the requirements of these interested parties that are relevant to the quality management system. | 12-08 MS Relevant Interested parties MS expectations |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| TOP.01.BP.3 | **Determine the scope of the quality management system**. Determine the boundaries and applicability of the quality management system, taking into consideration the context of the organization, the requirements of relevant interested parties and the interfaces and dependencies between activities performed by the organization, and those that are performed by other organization. | 04.3.1 | The organization shall determine the boundaries and applicability of the quality management system to establish its scope. | 03-04 Management system (MS) scope |
| TOP.01.BP.3 | **Determine the scope of the quality management system**. Determine the boundaries and applicability of the quality management system, taking into consideration the context of the organization, the requirements of relevant interested parties and the interfaces and dependencies between activities performed by the organization, and those that are performed by other organization. | 04.3.2 | When determining this scope, the organization shall consider:<br>a) the external and internal issues referred to in 4.1;<br>b) the requirements of relevant interested parties referred to in 4.2;<br>c) the products and services of the organization. | 03-04 Management system (MS) scope |
| TOP.01.BP.3 | **Determine the scope of the quality management system**. Determine the boundaries and applicability of the quality management system, taking into consideration the context of the organization, the requirements of relevant interested parties and the interfaces and dependencies between activities performed by the organization, and those that are performed by other organization. | 04.3.3 | The organization shall apply all the requirements of this document if they are applicable within the determined scope of its quality management system. | 03-04 Management system (MS) scope |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| TOP.01.BP.3 | **Determine the scope of the quality management system**. Determine the boundaries and applicability of the quality management system, taking into consideration the context of the organization, the requirements of relevant interested parties and the interfaces and dependencies between activities performed by the organization, and those that are performed by other organization. | 04.3.6 | The scope shall state the types of products and services covered, and provide justification for any requirement of this document that the organization determines is not applicable to the scope of its quality management system. | 03-04 Management system (MS) scope |
| TOP.01.BP.3 | **Determine the scope of the quality management system**. Determine the boundaries and applicability of the quality management system, taking into consideration the context of the organization, the requirements of relevant interested parties and the interfaces and dependencies between activities performed by the organization, and those that are performed by other organization. | 04.3.7 | Conformity to this document 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. | 03-04 Management system (MS) scope |
| TOP.01.BP.4 | **Define a quality policy**. Define a quality policy that is appropriate to the purpose of the organization. | 05.1.1.3 | ..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; | 03-13 Management system strategy: management commitment |
| TOP.01.BP.4 | **Define a quality policy**. Define a quality policy that is appropriate to the purpose of the organization. | 05.1.1.4 | ..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; | 03-13 Management system strategy: management commitment |
| TOP.01.BP.4 | **Define a quality policy**. Define a quality policy that is appropriate to the purpose of the organization. | 05.2.1.1 | Top management shall establish, [implement and maintain] a quality policy that:.. | 05-2 Quality policy |
| TOP.01.BP.5 | **Define quality objectives**. Define quality objectives at relevant functions and levels, which are measurable, consistent with the quality policy. | 06.2.1.1 | The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system. | 03-34 Quality objectives |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| TOP.01.BP.5 | **Define quality objectives**. Define quality objectives at relevant functions and levels, which are measurable, consistent with the quality policy. | 06.2.1.2 | The quality objectives shall be consistent with the quality policy. | 03-34 Quality objectives |
| TOP.01.BP.5 | **Define quality objectives**. Define quality objectives at relevant functions and levels, which are measurable, consistent with the quality policy. | 06.2.1.3 | The quality objectives shall be measurable. | 03-34 Quality objectives |
| TOP.01.BP.5 | **Define quality objectives**. Define quality objectives at relevant functions and levels, which are measurable, consistent with the quality policy. | 06.2.1.4 | The quality objectives shall take into account applicable requirements. | 03-34 Quality objectives |
| TOP.01.BP.5 | **Define quality objectives**. Define quality objectives at relevant functions and levels, which are measurable, consistent with the quality policy. | 06.2.1.5 | The quality objectives shall be relevant to conformity of products and services and to enhancement of customer satisfaction. | 03-34 Quality objectives |
| TOP.01.BP.5 | **Define quality objectives**. Define quality objectives at relevant functions and levels, which are measurable, consistent with the quality policy. | 06.2.1.6 | The quality objectives shall be monitored. | 03-34 Quality objectives |
| TOP.01.BP.5 | **Define quality objectives**. Define quality objectives at relevant functions and levels, which are measurable, consistent with the quality policy. | 06.2.1.7 | The quality objectives shall be communicated. | 03-34 Quality objectives |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 04.4.1.1 | 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 document. | 03-09 Management system strategy: Establish the management system |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 04.4.1.2 | The organization shall determine the processes needed for the quality management system and their application throughout the organization. | 03-09 Management system strategy: Establish the management system |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 04.4.1.8 | .. and shall address the risks and opportunities as determined in accordance with the requirements of 6.1. | 03-09 Management system strategy: Establish the management system |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 04.4.1.10 | .. and shall improve the processes and the quality management system. | 03-11 Management system strategy: improvement |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 04.4.2.1 | To the extent necessary, the organization shall maintain documented information to support the operation of its processes. | 03-09 Management system strategy: Establish the management system |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 04.4.2.2 | To the extent necessary, the organization shall retain documented information to have confidence that the processes are being carried out as planned. | 03-09 Management system strategy: Establish the management system |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 07.1.6.1 | The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. | 03-12 Management system strategy: knowledge |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 07.1.6.4 | 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. | 03-12 Management system strategy: knowledge |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 07.5.1.1 | The organization's quality management system shall include documented information required by this International Standard; | 03-08 Management system strategy: documentation |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 07.5.1.2 | The organization's quality management system shall include documented information determined by the organization as being necessary for the effectiveness of the quality management system. | 03-08 Management system strategy: documentation |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 07.5.3.2.3 | For the control of documented information, the organization shall address, as applicable, the control of changes (e.g. version control). | 08-18 Information status record |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 07.5.3.2.6 | 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. | 08-18 Information status record |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.1.1 | 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. | 03-09 Management system strategy: Establish the management system |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.1.14 | The organization shall ensure that outsourced processes are controlled (see ISO 9001:2015, 8.4). | 03-05 Management system strategy: change management |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.3.1.1 | The organization shall establish [implement and maintain] a design and development process that is appropriate to ensure the subsequent provision of products and services. | 03-17 Management system strategy: process environment |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.3.1.2 | The organization shall [establish] implement [and maintain] a design and development process that is appropriate to ensure the subsequent provision of products and services. | 03-17 Management system strategy: process environment |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.3.1.3 | The organization shall [establish, implement and] maintain a design and development process that is appropriate to ensure the subsequent provision of products and services. | 03-17 Management system strategy: process environment |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.4.1.1 | The organization shall ensure that externally provided processes, products and services conform to requirements. | 03-17 Management system strategy: process environment |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.4.1.2 | The organization shall determine the controls to be applied to externally provided processes, products and services when products and services from external providers are intended for incorporation into the organization's own products and services. | 03-15 Management system strategy: outsourcing |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.4.1.3 | The organization shall determine the controls to be applied to externally provided processes, products and services when products and services are provided directly to the customer(s) by external providers on behalf of the organization. | 03-15 Management system strategy: outsourcing |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.4.1.4 | The organization shall determine the controls to be applied to externally provided processes, products and services when a process, or part of a process, is provided by an external provider as a result of a decision by the organization. | 03-15 Management system strategy: outsourcing |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.4.1.5 | 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. | 03-15 Management system strategy: outsourcing |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.4.1.6 | 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. | 03-15 Management system strategy: outsourcing |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.4.2.1 | 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. | 03-17 Management system strategy: process environment |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.4.2.2 | The organization shall ensure that externally provided processes remain within the control of its quality management system. | 03-17 Management system strategy: process environment |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.4.2.3 | The organization shall define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output. | 03-17 Management system strategy: process environment |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.4.2.4 | The organization shall take into consideration 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. | 03-15 Management system strategy: outsourcing |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.4.2.5 | The organization shall take into consideration the effectiveness of the controls applied by the external provider. | 03-15 Management system strategy: outsourcing |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.4.2.6 | The organization shall determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements. | 03-17 Management system strategy: process environment |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.5.1.1 | The organization shall implement production and service provision under controlled conditions. | 03-17 Management system strategy: process environment |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.5.1.2 | Controlled conditions shall include, as applicable the availability of [documented] information that defines:<br>a) the characteristics of the products to be produced, the services to be provided, [or the activities to be performed;<br>b) the results to be achieved;] | 12-15 Product/service characteristics |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.5.1.4 | Controlled conditions shall include, as applicable, the availability of [documented] information that defines:<br>[a) the characteristics of the products to be produced, the services to be provided, or] the activities to be performed;<br>b) the results to be achieved; | 12-15 Product/service characteristics |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.5.3.1 | 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. | 03-07 Management system strategy: customer property |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.5.4.1 | The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements. | 03-18 Management system strategy: product preservation |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 08.5.5.1 | The organization shall meet requirements for post-delivery activities associated with the products and services. | 03-09 Management system strategy: Establish the management system |
| TOP.01.BP.6 | **Determine process strategy.** Determine the management system and operational process strategy. | 08.5.5.2 | In determining the extent of post-delivery activities that are required, the organization shall consider:<br>a) statutory and regulatory requirements;<br>b) the potential undesired consequences associated with its products and services;<br>c) the nature, use and intended lifetime of its products and services;<br>d) customer requirements;<br>e) customer feedback. | 03-09 Management system strategy: Establish the management system |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 09.1.1.5 | The organization shall evaluate the performance and the effectiveness of the quality management system. | 03-14 Management system strategy: measurement |
| TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 10.3.1 | The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system. | 03-11 Management system strategy: improvement |
| TOP.01.BP.7 | **Integrate the quality management system requirements into the business processes of the organization**. Ensure the integration of the quality management system requirements into the business processes of the organization. | 05.1.1.1 | Top management shall demonstrate leadership and commitment with respect to the quality management system [by:] | 03-13 Management system strategy: management commitment |
| TOP.01.BP.7 | **Integrate the quality management system requirements into the business processes of the organization.** Ensure the integration of the quality management system requirements into the business processes of the organization. | 05.1.1.2 | ..by taking accountability for the effectiveness of the quality management system. | 03-13 Management system strategy: management commitment |
| TOP.01.BP.7 | **Integrate the quality management system requirements into the business processes of the organization.** Ensure the integration of the quality management system requirements into the business processes of the organization. | 05.1.1.5 | ..by ensuring the integration of the quality management system requirements into the organization's business processes. | 03-13 Management system strategy: management commitment |
| TOP.01.BP.7 | **Integrate the quality management system requirements into the business processes of the organization.** Ensure the integration of the quality management system requirements into the business processes of the organization. | 05.1.1.6 | ..by promoting the use of the process approach and risk-based thinking. | 03-13 Management system strategy: management commitment |
| TOP.01.BP.7 | **Integrate the quality management system requirements into the business processes of the organization.** Ensure the integration of the quality management system requirements into the business processes of the organization. | 05.1.1.7 | ..by ensuring that the resources needed for the quality management system are available. | 03-13 Management system strategy: management commitment |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| TOP.01.BP.7 | **Integrate the quality management system requirements into the business processes of the organization.** Ensure the integration of the quality management system requirements into the business processes of the organization. | 05.1.1.10 | ..by engaging, directing and supporting persons to contribute to the effectiveness of the quality management system. | 03-13 Management system strategy: management commitment |
| TOP.01.BP.7 | **Integrate the quality management system requirements into the business processes of the organization.** Ensure the integration of the quality management system requirements into the business processes of the organization. | 05.1.1.11 | ..by promoting improvement. | 03-13 Management system strategy: management commitment |

**Table C.1** *(continued)*

| Base practice reference | Base practice description | ISO 9001 Requirement reference | Associated singular requirement | Information item |
|---|---|---|---|---|
| TOP.01.BP.7 | **Integrate the quality management system requirements into the business processes of the organization.** Ensure the integration of the quality management system requirements into the business processes of the organization. | 05.1.2.1 | Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:<br>a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;<br>b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;<br>c) the focus on enhancing customer satisfaction is maintained. | 03-06 Management system strategy: customer focus |
| TOP.01.BP.8 | **Demonstrate leadership by enabling contributions to organizational effectiveness.** Direct and support persons to contribute to the effectiveness of the quality management system and support other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. | 05.1.1.9 | ..by ensuring that the quality management system achieves its intended results. | 03-13 Management system strategy: management commitment |
| TOP.01.BP.8 | **Demonstrate leadership by enabling contributions to organizational effectiveness.** Direct and support persons to contribute to the effectiveness of the quality management system and support other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. | 05.1.1.12 | ..by supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. | 03-13 Management system strategy: management commitment |

## C.3 Associations of requirements with base practices

Table C.2 identifies subclauses and singular requirements, associated base practices and implied information items.

**Table C.2 — Association of ISO 9001 requirements with capability levels and base practices**

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 04 Context of the organization | | | | |
| 04.1 Understanding the organization and its context | | | | |
| 1 | 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. | TOP.01.BP.1 | **Determine external and internal issues that are relevant to the organization and analyse their impacts.** Determine external and internal issues that are relevant to the purpose of the assessed organization and that affect its ability to achieve the intended outcome(s) of its quality management system. | 03-10 Management system strategy: external and internal issues |
| 2 | The organization shall monitor and review information about these external and internal issues. | COM.09.BP.4 | **Review process activities.** Review process activities. | 08-23 MS Implementation review record |
| 04.2 Understanding the needs and expectations of interested parties | | | | |
| 1 | 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 the interested parties that are relevant to the quality management system. | TOP.01.BP.2 | **Determine relevant the interested parties and analyse their requirements.** Determine the relevant interested parties that are relevant to the quality management system and establish appropriate contacts with them. | 03-25 MS Relevant Interested parties |
| 2 | 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 the requirements of these interested parties that are relevant to the quality management system. | TOP.01.BP.2 | **Determine relevant the interested parties and analyse their requirements.** Determine the relevant interested parties that are relevant to the quality management system and establish appropriate contacts with them. | 12-08 MS Relevant Interested parties MS expectations |
| 3 | The organization shall monitor and review information about these interested parties and their relevant requirements. | COM.09.BP.4 | **Review process activities.** Review process activities. | 08-23 MS Implementation review record |
| 04.3 Determining the scope of the quality management system | | | | |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 1 | The organization shall determine the boundaries and applicability of the quality management system to establish its scope. | TOP.01.BP.3 | **Determine the scope of the quality management system.** Determine the boundaries and applicability of the quality management system, taking into consideration the context of the organization, the requirements of relevant interested parties and the interfaces and dependencies between activities performed by the organization, and those that are performed by other organization. | 03-04 Management system (MS) scope |
| 2 | When determining this scope, the organization shall consider:<br>a) the external and internal issues referred to in 4.1;<br>b) the requirements of relevant interested parties referred to in 4.2;<br>c) the products and services of the organization. | TOP.01.BP.3 | **Determine the scope of the quality management system.** Determine the boundaries and applicability of the quality management system, taking into consideration the context of the organization, the requirements of relevant interested parties and the interfaces and dependencies between activities performed by the organization, and those that are performed by other organization. | 03-04 Management system (MS) scope |
| 3 | The organization shall apply all the requirements of this document if they are applicable within the determined scope of its quality management system. | TOP.01.BP.3 | **Determine the scope of the quality management system**. Determine the boundaries and applicability of the quality management system, taking into consideration the context of the organization, the requirements of relevant interested parties and the interfaces and dependencies between activities performed by the organization, and those that are performed by other organization. | 03-04 Management system (MS) scope |
| 4 | The scope of the organization's quality management system shall be available [and be maintained] as [documented] information. | COM.02.BP.1 | **Identify documented information to be managed**. Identify documented information of internal and external origin necessary for the operation of the quality management system. | 03-04 Management system (MS) scope |
| 5 | The scope of the organization's quality management system shall be [available and be] maintained as documented information. | COM.02.BP.3 | **Determine the documented information content status**. The status of the documented information content refers to the timeliness of the information content. This includes the control of changes, for example, by using version control techniques. | 03-04 Management system (MS) scope |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 6 | The scope shall state the types of products and services covered, and provide justification for any requirement of this document that the organization determines is not applicable to the scope of its quality management system. | TOP.01.BP.3 | **Determine the scope of the quality management system.** Determine the boundaries and applicability of the quality management system, taking into consideration the context of the organization, the requirements of relevant interested parties and the interfaces and dependencies between activities performed by the organization, and those that are performed by other organization. | 03-04 Management system (MS) scope |
| 7 | Conformity to this document 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. | TOP.01.BP.3 | **Determine the scope of the quality management system.** Determine the boundaries and applicability of the quality management system, taking into consideration the context of the organization, the requirements of relevant interested parties and the interfaces and dependencies between activities performed by the organization, and those that are performed by other organization. | 03-04 Management system (MS) scope |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 04.4 Quality management system and its processes | | | | |
| 04.4.1 | | | | |
| 1 | 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 document. | TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 03-09 Management system strategy: Establish the management system |
| 2 | The organization shall determine the processes needed for the quality management system and their application throughout the organization, | TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 03-09 Management system strategy: Establish the management system |
| 3 | .. and shall determine the inputs required and the outputs expected from these processes; | COM.08.BP.2 | **Determine process input and output products**. Determine process input and output products expected from these processes. | 04-6 Product/service process lifecycle model |
| 4 | .. and shall determine the sequence and interaction of these processes; | COM.08.BP.4 | **Determine the sequence and interaction of the process with other processes**. Determine the sequence and interaction of the process with other processes, by establishing criteria for the acceptance of products and services, the need for 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, the implementation of actions to prevent human error, and the implementation of release, delivery and post-delivery activities. | 04-6 Product/service process lifecycle model |
| 5 | .. and shall 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; | COM.08.BP.7 | **Determine the methods for monitoring the effectiveness and suitability of the process**. Determine the methods for monitoring the effectiveness and suitability of the process. | 03-24 MS Measurement methods |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 6 | .. and shall determine the resources needed for these processes and ensure their availability; | COM.08.BP.6 | **Identify the required resources for performing the process**. Determine what resources will be required by the quality management system to achieve its quality objectives. This includes determining:<br>a) the resources needed for these processes;<br>b) the capabilities of, and constraints on, existing internal resources;<br>c) what needs to be obtained from external providers;<br>d) determining the resources needed to achieve conformity to the product and service requirements;<br>e) the use of suitable infrastructure and environment for the operation of processes. | 12-09 MS Resource requirements |
| 7 | .. and shall assign the responsibilities and authorities for these processes; | COM.08.BP.5 | **Identify the required competencies and roles for performing the process**. Identify the required competencies and roles for performing the process. These include:<br>a) ensuring that the quality management system conforms to the management system requirements;<br>b) ensuring that the processes are delivering their intended outputs;<br>c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;<br>d) ensuring the promotion of customer focus throughout the organization;<br>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented;<br>f) who will be responsible for meeting quality system objectives;<br>g) the appointment of competent persons, including any required qualification. | 03-20 Management system strategy: roles and responsibilities |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 8 | .. and shall address the risks and opportunities as determined in accordance with the requirements of 6.1; | TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 03-09 Management system strategy: Establish the management system |
| 9 | .. and shall evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results; | COM.08.BP.7 | **Determine the methods for monitoring the effectiveness and suitability of the process**. Determine the methods for monitoring the effectiveness and suitability of the process. | 04-6 Product/service process lifecycle model |
| 10 | .. and shall improve the processes and the quality management system. | TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 03-11 Management system strategy: improvement |
| 04.4.2 | | | | |
| 1 | To the extent necessary, the organization shall maintain documented information to support the operation of its processes. | TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 03-09 Management system strategy: Establish the management system |
| 2 | To the extent necessary, the organization shall retain documented information to have confidence that the processes are being carried out as planned. | TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 03-09 Management system strategy: Establish the management system |
| 05 Leadership | | | | |
| 05.1 Leadership and commitment | | | | |
| 05.1.1 General | | | | |
| 1 | Top management shall demonstrate leadership and commitment with respect to the quality management system [by:] | TOP.01.BP.7 | **Integrate the quality management system requirements into the business processes of the organization.** Ensure the integration of the quality management system requirements into the business processes of the organization. | 03-13 Management system strategy: management commitment |
| 2 | a) taking accountability for the effectiveness of the quality management system; | TOP.01.BP.7 | **Integrate the quality management system requirements into the business processes of the organization**. Ensure the integration of the quality management system requirements into the business processes of the organization. | 03-13 Management system strategy: management commitment |
| 3 | 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; | TOP.01.BP.4 | **Define a quality policy.** Define a quality policy that is appropriate to the purpose of the organization. | 03-13 Management system strategy: management commitment |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 4 | 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; | TOP.01.BP.4 | **Define a quality policy**. Define a quality policy that is appropriate to the purpose of the organization. | 03-13 Management system strategy: management commitment |
| 5 | c) ensuring the integration of the quality management system requirements into the organization's business processes; | TOP.01.BP.7 | **Integrate the quality management system requirements into the business processes of the organization**. Ensure the integration of the quality management system requirements into the business processes of the organization. | 03-13 Management system strategy: management commitment |
| 6 | d) promoting the use of the process approach and risk-based thinking; | TOP.01.BP.7 | **Integrate the quality management system requirements into the business processes of the organization**. Ensure the integration of the quality management system requirements into the business processes of the organization. | 03-13 Management system strategy: management commitment |
| 7 | e) ensuring that the resources needed for the quality management system are available; | TOP.01.BP.7 | **Integrate the quality management system requirements into the business processes of the organization**. Ensure the integration of the quality management system requirements into the business processes of the organization. | 03-13 Management system strategy: management commitment |
| 8 | f) communicating the importance of effective quality management and of conforming to the quality management system requirements; | COM.01.BP.6 | **Communicate information products**. Communicate information products to relevant interested parties. | 08-53 QMS Communication records |
| 9 | g) ensuring that the quality management system achieves its intended results; | TOP.01.BP.8 | **Demonstrate leadership by enabling contributions to organizational effectiveness**. Direct and support persons to contribute to the effectiveness of the quality management system and support other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. | 03-13 Management system strategy: management commitment |
| 10 | h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system; | TOP.01.BP.7 | **Integrate the quality management system requirements into the business processes of the organization**. Ensure the integration of the quality management system requirements into the business processes of the organization. | 03-13 Management system strategy: management commitment |
| 11 | i) promoting improvement; | TOP.01.BP.7 | **Integrate the quality management system requirements into the business processes of the organization**. Ensure the integration of the quality management system requirements into the business processes of the organization. | 03-13 Management system strategy: management commitment |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 12 | j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. | TOP.01.BP.8 | **Demonstrate leadership by enabling contributions to organizational effectiveness**. Direct and support persons to contribute to the effectiveness of the quality management system and support other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility. | 03-13 Management system strategy: management commitment |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 05.1.2 Customer focus | | | | |
| 1 | Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:<br>a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;<br>b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;<br>c) the focus on enhancing customer satisfaction is maintained. | TOP.01.BP.7 | **Integrate the quality management system requirements into the business processes of the organization**. Ensure the integration of the quality management system requirements into the business processes of the organization. | 03-06 Management system strategy: customer focus |
| 05.2 Policy | | | | |
| 05.2.1 Establishing the quality policy | | | | |
| 1 | Top management shall establish, [implement and maintain] a quality policy that:.. | TOP.01.BP.4 | **Define a quality policy**. Define a quality policy that is appropriate to the purpose of the organization. | 05-2 Quality policy |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 2 | Top management shall [establish], implement [and maintain] a quality policy that:.. | COM.09.BP.3 | **Perform process activities**. Perform process activities. The organization:<br>a) monitors and reviews information about these external and internal issues;<br>b) monitors and reviews information about interested parties and their relevant requirements;<br>c) evaluates the effectiveness of the actions taken;<br>d) ensures that contract or order requirements differing from those previously defined are resolved;<br>e) ensures the adequacy of requirements prior to their communication to the external provider;<br>f) maintains an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits. | 08-22 MS Implementation log |
| 3 | Top management shall [establish, implement and] maintain a quality policy that:.. | COM.09.BP.4 | **Review process activities**. Review process activities. | 08-23 MS Implementation review record |
| 4 | a) is appropriate to the purpose and context of the organization and supports its strategic direction; | COM.08.BP.1 | **Identify process requirements**. Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 05-2 Quality policy |
| 5 | b) provides a framework for setting quality objectives; | COM.08.BP.1 | **Identify process requirements**. Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 05-2 Quality policy |
| 6 | c) includes a commitment to satisfy applicable requirements; | COM.08.BP.1 | **Identify process requirements**. Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 05-2 Quality policy |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 7 | d) includes a commitment to continual improvement of the quality management system. | COM.08.BP.1 | **Identify process requirements**. Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 05-2 Quality policy |
| 05.2.2 Communicating the quality policy | | | | |
| 1 | The quality policy shall be available [and be maintained] as documented information. | COM.02.BP.1 | **Identify documented information to be managed**. Identify documented information of internal and external origin necessary for the operation of the quality management system. | 05-2 Quality policy |
| 2 | The quality policy shall be [available and be] maintained as documented information. | COM.02.BP.4 | **Determine whether the documented information is current, complete and valid**. The documented information contained in the repository is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). | 05-2 Quality policy |
| 3 | The quality policy shall be communicated, understood and applied within the organization. | COM.01.BP.6 | **Communicate information products**. Communicate information products to relevant interested parties. | 08-53 QMS Communication records |
| 4 | The quality policy shall be available to relevant interested parties, as appropriate. | COM.02.BP.6 | **Make documented information available to relevant interested parties**. Manage the distribution, access, retrieval and use of documented information towards interested parties. | 05-2 Quality policy |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 05.3 Organizational roles, responsibilities and authorities | | | | |
| 1 | Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, [communicated and understood within the organization.] | COM.08.BP.5 | **Identify the required competencies and roles for performing the process**. Identify the required competencies and roles for performing the process. These include:<br>a) ensuring that the quality management system conforms to the management system requirements;<br>b) ensuring that the processes are delivering their intended outputs;<br>c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;<br>d) ensuring the promotion of customer focus throughout the organization;<br>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented;<br>f) who will be responsible for meeting quality system objectives;<br>g) the appointment of competent persons, including any required qualification. | 03-20 Management system strategy: roles and responsibilities |
| 2 | Top management shall ensure that the responsibilities and authorities for relevant roles are [assigned], communicated and understood within the organization. | COM.09.BP.1 | **Allocate roles, responsibilities and authorities**. Allocate the required roles, responsibilities and authorities. Top management ensures that the responsibilities and authorities for relevant roles are communicated and understood within the organization. | 08-57 Roles and responsibilities assignment record |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 3 | Top management shall assign the responsibility and authority for ensuring that the quality management system conforms to the requirements of this document. | COM.08.BP.5 | **Identify the required competencies and roles for performing the process**. Identify the required competencies and roles for performing the process. These include:<br>a) ensuring that the quality management system conforms to the management system requirements;<br>b) ensuring that the processes are delivering their intended outputs;<br>c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;<br>d) ensuring the promotion of customer focus throughout the organization;<br>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented;<br>f) who will be responsible for meeting quality system objectives;<br>g) the appointment of competent persons, including any required qualification. | 12-11 Organizational roles and responsibilities |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 4 | Top management shall assign the responsibility and authority for ensuring that the processes are delivering their intended outputs. | COM.08.BP.5 | **Identify the required competencies and roles for performing the process**. Identify the required competencies and roles for performing the process. These include:<br>a) ensuring that the quality management system conforms to the management system requirements;<br>b) ensuring that the processes are delivering their intended outputs;<br>c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;<br>d) ensuring the promotion of customer focus throughout the organization;<br>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented;<br>f) who will be responsible for meeting quality system objectives;<br>g) the appointment of competent persons, including any required qualification. | 12-11 Organizational roles and responsibilities |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 5 | Top management shall assign the responsibility and authority for reporting on the performance of the quality management system and on opportunities for improvement (see ISO 9001:2015, 10.1), in particular to top management. | COM.08.BP.5 | **Identify the required competencies and roles for performing the process.** Identify the required competencies and roles for performing the process. These include:<br>a) ensuring that the quality management system conforms to the management system requirements;<br>b) ensuring that the processes are delivering their intended outputs;<br>c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;<br>d) ensuring the promotion of customer focus throughout the organization;<br>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented;<br>f) who will be responsible for meeting quality system objectives;<br>g) the appointment of competent persons, including any required qualification. | 12-11 Organizational roles and responsibilities |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 6 | Top management shall assign the responsibility and authority for ensuring the promotion of customer focus throughout the organization. | COM.08.BP.5 | **Identify the required competencies and roles for performing the process.** Identify the required competencies and roles for performing the process. These include:<br>a) ensuring that the quality management system conforms to the management system requirements;<br>b) ensuring that the processes are delivering their intended outputs;<br>c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;<br>d) ensuring the promotion of customer focus throughout the organization;<br>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented;<br>f) who will be responsible for meeting quality system objectives;<br>g) the appointment of competent persons, including any required qualification. | 12-11 Organizational roles and responsibilities |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 7 | Top management shall assign the responsibility and authority for ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented. | COM.08.BP.5 | **Identify the required competencies and roles for performing the process.** Identify the required competencies and roles for performing the process. These include:<br>a) ensuring that the quality management system conforms to the management system requirements;<br>b) ensuring that the processes are delivering their intended outputs;<br>c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;<br>d) ensuring the promotion of customer focus throughout the organization;<br>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented;<br>f) who will be responsible for meeting quality system objectives;<br>g) the appointment of competent persons, including any required qualification. | 12-11 Organizational roles and responsibilities |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 06 Planning | | | | |
| 06.1 Actions to address risks and opportunities | | | | |
| 06.1.1 | | | | |
| 1 | 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:<br>a) give assurance that the quality management system can achieve its intended result(s);<br>b) enhance desirable effects;<br>c) prevent, or reduce, undesired effects;<br>d) achieve improvement.] | COM.08.BP.8 | **Plan the deployment of the process**. Plan the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. | 08-54 Risk and opportunity identification |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 2 | [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:<br>a) give assurance that the quality management system can achieve its intended result(s);<br>b) enhance desirable effects;<br>c) prevent, or reduce, undesired effects;<br>d) achieve improvement. | COM.08.BP.1 | **Identify process requirements**. Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 03-36 Risk and opportunity identification criteria |
| 06.1.2 | | | | |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 1 | The organization shall plan:<br>a) actions to address these risks and opportunities;<br>b) how to:<br>1) integrate and implement the actions into its quality management system processes (see 4.4);<br>2) evaluate the effectiveness of these actions. | COM.08.BP.8 | **Plan the deployment of the process**. Plan the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. | 04-7 Risk management plan |
| 2 | Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services. | COM.11.BP.5 | **Treat risks**. Treat selected risks. Risk treatment involves selecting one or more options for responding to risks, and implementing those options. Risk treatment involves a cyclical process of:<br>— formulating and selecting risk treatment;<br>— implementing risk treatment;<br>— deciding whether residual risk levels are acceptable;<br>— if not acceptable, generating further risk treatment;<br>— assessing the effectiveness of that treatment;<br>— potential evolution over time. | 08-56 Risk treatment action log |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 2 | Actions taken to address risks and opportunities shall be proportionate to the potential impact on the conformity of products and services. | COM.11.BP.6 | **Identify opportunities**. One of the options for treating risk involve taking or increasing the risk in order to pursue an opportunity. | 08-56 Risk treatment action log |
| 06.2 Quality objectives and planning to achieve them | | | | |
| 06.2.1 | | | | |
| 1 | The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system. | TOP.01.BP.5 | **Define quality objectives.** Define quality objectives at relevant functions and levels, which are measurable, consistent with the quality policy. | 03-34 Quality objectives |
| 2 | The quality objectives shall:<br>a) be consistent with the quality policy; | TOP.01.BP.5 | **Define quality objectives**. Define quality objectives at relevant functions and levels, which are measurable, consistent with the quality policy. | 03-34 Quality objectives |
| 3 | b) be measurable; | TOP.01.BP.5 | **Define quality objectives**. Define quality objectives at relevant functions and levels, which are measurable, consistent with the quality policy. | 03-34 Quality objectives |
| 4 | c) take into account applicable requirements; | TOP.01.BP.5 | **Define quality objectives**. Define quality objectives at relevant functions and levels, which are measurable, consistent with the quality policy. | 03-34 Quality objectives |
| 5 | d) be relevant to conformity of products and services and to enhancement of customer satisfaction; | TOP.01.BP.5 | **Define quality objectives**. Define quality objectives at relevant functions and levels, which are measurable, consistent with the quality policy. | 03-34 Quality objectives |
| 6 | e) be monitored; | TOP.01.BP.5 | **Define quality objectives**. Define quality objectives at relevant functions and levels, which are measurable, consistent with the quality policy. | 03-34 Quality objectives |
| 7 | f) be communicated; | TOP.01.BP.5 | **Define quality objectives**. Define quality objectives at relevant functions and levels, which are measurable, consistent with the quality policy. | 03-34 Quality objectives |
| 8 | g) be updated as appropriate. | COM.02.BP.3 | **Determine the documented information content status**. The status of the documented information content refers to the timeliness of the information content. This includes the control of changes, for example, by using version control techniques. | 03-34 Quality objectives |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 9 | The organization shall maintain documented information on the quality objectives. | COM.02.BP.4 | **Determine whether the documented information is current, complete and valid**. The documented information contained in the repository is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). | 03-34 Quality objectives |
| 06.2.2 | | | | |
| 1 | When planning how to achieve its quality objectives, the organization shall determine what will be done. | COM.08.BP.1 | **Identify process requirements**. Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 03-29 Product/service objectives |
| 2 | When planning how to achieve its quality objectives, the organization shall determine what resources will be required. | COM.08.BP.6 | **Identify the required resources for performing the process**. Determine what resources will be required by the quality management system to achieve its quality objectives. This includes determining:<br>a) the resources needed for these processes;<br>b) the capabilities of, and constraints on, existing internal resources;<br>c) what needs to be obtained from external providers;<br>d) determining the resources needed to achieve conformity to the product and service requirements;<br>e) the use of suitable infrastructure and environment for the operation of processes. | 03-31 Project/service resource needs |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 3 | When planning how to achieve its quality objectives, the organization shall determine who will be responsible. | COM.08.BP.5 | **Identify the required competencies and roles for performing the process**. Identify the required competencies and roles for performing the process. These include:<br>a) ensuring that the quality management system conforms to the management system requirements;<br>b) ensuring that the processes are delivering their intended outputs;<br>c) reporting on the performance of the quality management system and on opportunities for improvement, in particular to top management;<br>d) ensuring the promotion of customer focus throughout the organization;<br>e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented;<br>f) who will be responsible for meeting quality system objectives;<br>g) the appointment of competent persons, including any required qualification. | 03-32 Project/service roles and responsibilities |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 4 | When planning how to achieve its quality objectives, the organization shall determine when it will be completed. | COM.08.BP.8 | **Plan the deployment of the process.** Plan the processes will be deployed in order to achieve the quality objectives. Planning includes, but is not limited to:<br>a) the nature, duration and complexity of the design and development activities;<br>b) the required process stages, including applicable design and development reviews;<br>c) the required design and development verification and validation activities;<br>d) the responsibilities and authorities involved in the design and development process;<br>e) the internal and external resource needs for the design and development of products and services;<br>f) the need to control interfaces between persons involved in the design and development process;<br>g) the need for involvement of customers and users in the design and development process;<br>h) the requirements for subsequent provision of products and services;<br>i) the level of control expected for the design and development process by customers and other relevant interested parties. | 03-33 Project/service schedule |
| 5 | When planning how to achieve its quality objectives, the organization shall determine how the results will be evaluated. | COM.08.BP.7 | **Determine the methods for monitoring the effectiveness and suitability of the process**. Determine the methods for monitoring the effectiveness and suitability of the process. | 03-30 Project/service measures |
| 06.3 Planning of changes | | | | |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 2 | The organization shall consider:<br>a) the purpose of the changes and their potential consequences;<br>b) the integrity of the quality management system;<br>c) the availability of resources;<br>d) the allocation or reallocation of responsibilities and authorities. | COM.08.BP.1 | **Identify process requirements**. Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 12-07 Management system change evaluation criteria |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 07 Support | | | | |
| 07.1 Resources | | | | |
| 07.1.1 General | | | | |
| 1 | The organization shall determine [and provide] the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system. | COM.08.BP.6 | **Identify the required resources for performing the process**. Determine what resources will be required by the quality management system to achieve its quality objectives. This includes determining:<br>a) the resources needed for these processes;<br>b) the capabilities of, and constraints on, existing internal resources;<br>c) what needs to be obtained from external providers;<br>d) determining the resources needed to achieve conformity to the product and service requirements;<br>e) the use of suitable infrastructure and environment for the operation of processes. | 12-09 MS Resource requirements |
| 2 | The organization shall [determine and] provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system. | COM.09.BP.2 | **Allocate resources**. Allocate and apply the required resources. The organization<br>a) provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system;<br>b) determines the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>c) provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>d) ensures that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken;<br>e) ensures that the resources provided are maintained to ensure their continuing fitness for their purpose. | 08-24 MS Resources provision record |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 3 | The organization shall consider the capabilities of, and constraints on, existing internal resources. | COM.08.BP.6 | **Identify the required resources for performing the process**. Determine what resources will be required by the quality management system to achieve its quality objectives. This includes determining:<br>a) the resources needed for these processes;<br>b) the capabilities of, and constraints on, existing internal resources;<br>c) what needs to be obtained from external providers;<br>d) determining the resources needed to achieve conformity to the product and service requirements;<br>e) the use of suitable infrastructure and environment for the operation of processes. | 12-09 MS Resource requirements |
| 4 | The organization shall consider what needs to be obtained from external providers. | COM.08.BP.6 | **Identify the required resources for performing the process**. Determine what resources will be required by the quality management system to achieve its quality objectives. This includes determining:<br>a) the resources needed for these processes;<br>b) the capabilities of, and constraints on, existing internal resources;<br>c) what needs to be obtained from external providers;<br>d) determining the resources needed to achieve conformity to the product and service requirements;<br>e) the use of suitable infrastructure and environment for the operation of processes. | 12-09 MS Resource requirements |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 07.1.2 People | | | | |
| 1 | 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. | COM.09.BP.2 | **Allocate resources**. Allocate and apply the required resources. The organization:<br>a) provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system;<br>b) determines the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>c) provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>d) ensures that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken;<br>e) ensure that the resources provided are maintained to ensure their continuing fitness for their purpose. | 08-24 MS Resources provision record |
| 2 | 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. | COM.09.BP.2 | **Allocate resources**. Allocate and apply the required resources. The organization:<br>a) provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system;<br>b) determines the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>c) provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>d) ensures that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken;<br>e) ensure that the resources provided are maintained to ensure their continuing fitness for their purpose. | 08-24 MS Resources provision record |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 07.1.3 Infrastructure | | | | |
| 1 | The organization shall determine, [provide and maintain] the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. | COM.08.BP.1 | **Identify process requirements**. Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 12-06 Infrastructure requirements |
| 2 | The organization shall [determine], provide [and maintain] the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. | COM.09.BP.3 | **Perform process activities**. Perform process activities. The organization:<br>a) monitors and reviews information about these external and internal issues;<br>b) monitors and reviews information about interested parties and their relevant requirements;<br>c) evaluates the effectiveness of the actions taken;<br>d) ensures that contract or order requirements differing from those previously defined are resolved;<br>e) ensures the adequacy of requirements prior to their communication to the external provider;<br>f) maintains an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits. | 08-22 MS Implementation log |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 3 | The organization shall [determine, provide and] maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services. | COM.09.BP.3 | **Perform process activities.** Perform process activities. The organization:<br>a) monitors and reviews information about these external and internal issues;<br>b) monitors and reviews information about interested parties and their relevant requirements;<br>c) evaluates the effectiveness of the actions taken;<br>d) ensures that contract or order requirements differing from those previously defined are resolved;<br>e) ensures the adequacy of requirements prior to their communication to the external provider;<br>f) maintains an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits. | 08-23 MS Implementation review record |
| 07.1.4 Environment for the operation of processes | | | | |
| 1 | The organization shall determine, [provide and maintain] the environment necessary for the operation of its processes and to achieve conformity of products and services. | COM.08.BP.1 | **Identify process requirements.** Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 12-12 Process environment requirements |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 2 | The organization shall [determine,] provide [and maintain] the environment necessary for the operation of its processes and to achieve conformity of products and services. | COM.09.BP.3 | **Perform process activities.** Perform process activities. The organization:<br>a) monitors and reviews information about these external and internal issues;<br>b) monitors and reviews information about interested parties and their relevant requirements;<br>c) evaluates the effectiveness of the actions taken;<br>d) ensures that contract or order requirements differing from those previously defined are resolved;<br>e) ensures the adequacy of requirements prior to their communication to the external provider;<br>f) maintains an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits. | 08-22 MS Implementation log |
| 3 | The organization shall [determine, provide and] maintain the environment necessary for the operation of its processes and to achieve conformity of products and services. | COM.09.BP.4 | **Review process activities**. Review process activities. | 08-23 MS Implementation review record |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 07.1.5 Monitoring and measuring resources | | | | |
| 07.1.5.1 General | | | | |
| 1 | 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. | COM.08.BP.1 | **Identify process requirements**. Identify process requirements. These might arise from requirements associated with the quality management system, from realizing the quality objectives, the operational and/or product/service requirements. | 12-12 Process environment requirements |
| 2 | 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. | COM.09.BP.3 | **Perform process activities**. Perform process activities. The organization:<br>a) monitors and reviews information about these external and internal issues;<br>b) monitors and reviews information about interested parties and their relevant requirements;<br>c) evaluates the effectiveness of the actions taken;<br>d) ensures that contract or order requirements differing from those previously defined are resolved;<br>e) ensures the adequacy of requirements prior to their communication to the external provider;<br>f) maintains an audit programme(s) including the frequency, methods, responsibilities, planning requirements and reporting, which shall take into consideration the importance of the processes concerned, changes affecting the organization, and the results of previous audits. | 08-22 MS Implementation log |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 3 | The organization shall ensure that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken. | COM.09.BP.2 | **Allocate resources.** Allocate and apply the required resources. The organization:<br>a) provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system;<br>b) determines the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>c) provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>d) ensures that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken;<br>e) ensure that the resources provided are maintained to ensure their continuing fitness for their purpose. | 02-3 Measuring equipment asset list |
| 4 | The organization shall ensure that the resources provided are maintained to ensure their continuing fitness for their purpose. | COM.09.BP.2 | **Allocate resources**. Allocate and apply the required resources. The organization:<br>a) provides the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system;<br>b) determines the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>c) provides the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes;<br>d) ensures that the resources provided are suitable for the specific type of monitoring and measurement activities being undertaken;<br>e) ensure that the resources provided are maintained to ensure their continuing fitness for their purpose. | 02-4 Measuring equipment maintenance log |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 5 | The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources. | COM.02.BP.1 | **Identify documented information to be managed**. Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08-21 Measurement resources effectiveness review result |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 07.1.5.2 Measurement traceability | | | | |
| 1 | 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 calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards. | ORG.02.BP.4 | **Confirm calibration status**. Confirm the calibration status of measurement resources, as applicable at appropriate intervals. | 02-1 Measurement resource calibration log |
| 2 | When no such standards exist, the basis used for calibration or verification shall be retained as documented information. | ORG.02.BP.4 | **Confirm calibration status**. Confirm the calibration status of measurement resources, as applicable at appropriate intervals. | 02-1 Measurement resource calibration log |
| 3 | 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 identified in order to determine their status. | ORG.02.BP.3 | **Identify measurement resources**. Identify measurement resources. | 02-2 Measurement resource identification |
| 3 | 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 identified in order to determine their status. | ORG.02.BP.4 | **Confirm calibration status**. Confirm the calibration status of measurement resources, as applicable at appropriate intervals. | 02-1 Measurement resource calibration log |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 4 | 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 safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results. | ORG.02.BP.4 | **Confirm calibration status**. Confirm the calibration status of measurement resources, as applicable at appropriate intervals. | 02-1 Measurement resource calibration log |
| 5 | 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.] | ORG.02.BP.6 | **Segregate mal-performing measurement resources**. Segregate and control mal-performing measurement resources in order to avoid unintended use. | 02-1 Measurement resource calibration log |
| 6 | [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. | COM.07.BP.1 | **Identify non-conformities**. Non-conformities are identified. These might arise during development and/or production of the product/service, or from post-production activities e.g. feedback from customers. | 08-30 Non-conformity record |
| 07.1.6 Organizational knowledge | | | | |
| 1 | The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. | TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 03-12 Management system strategy: knowledge |
| 2 | This knowledge shall be maintained [and be made available to the extent necessary.] | COM.02.BP.4 | **Determine whether the documented information is current, complete and valid**. The documented information contained in the repository is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity). | 03-12 Management system strategy: knowledge |
| 3 | This knowledge shall be [maintained and be] made available to the extent necessary. | COM.02.BP.6 | **Make documented information available to relevant interested parties**. Manage the distribution, access, retrieval and use of documented information towards interested parties. | 03-12 Management system strategy: knowledge |

**Table C.2** *(continued)*

| Reference number | Singular requirement | BP reference | Base practice | Information item implied |
|---|---|---|---|---|
| 4 | 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. | TOP.01.BP.6 | **Determine process strategy**. Determine the management system and operational process strategy. | 03-12 Management system strategy: knowledge |
| 07.2 Competence | | | | |
| 1 | The organization shall determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system. | COM.03.BP.1 | **Identify organizational competencies**. Identify the competencies required by the organization. | 12-10 Organizational competence requirements |
| 2 | The organization shall ensure that these persons are competent on the basis of appropriate education, training, or experience. | COM.03.BP.2 | **Fill competency gaps**. Fill identified competency gaps through training or recruitment. | 08-62 Training record |
| 3 | The organization shall, where applicable, take actions to acquire the necessary competence, [and evaluate the effectiveness of the actions taken.] | COM.09.BP.4 | **Review process activities**. Review process activities. | 08-62 Training record |
| 4 | The organization shall, where applicable, [take actions to acquire the necessary competence,] and evaluate the effectiveness of the actions taken. | COM.09.BP.4 | **Review process activities.** Review process activities. | 08-31 Personnel competency records |
| 5 | The organization shall retain appropriate documented information as evidence of competence. | COM.02.BP.1 | **Identify documented information to be managed**. Identify documented information of internal and external origin necessary for the operation of the quality management system. | 08-31 Personnel competency records |
| 07.3 Awareness | | | | |