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GUIDANCE FOR ORGANISATIONS SEEKING BINDT QUALITY MANAGEMENT SYSTEMS CERTIFICATION

ASSOCIATED DOCUMENTS

QS2	PROCEDURE FOR PCN ASSESSMENT AND CERTIFICATION
CP14	QUALITY MANAGEMENT SYSTEM ASSESSMENT INSTRUCTIONS AND CHECKLIST
QS4	APPLICATION FOR ASSESSMENT AND REGISTRATION
PSL/35	CHARGES FOR PCN CERTIFICATION SERVICES

Those organisations that are currently implementing an ISO 9001:2008 QMS certified by BINDT, or certified by a CB recognised by BINDT are advised that they have until 1st September 2018 to complete the transition to ISO 9001:2015.

This transition cannot be accomplished during a surveillance visit, and to demonstrate implementation and conformity and of the QMS with the 2015 edition of the international standard, organisations will undergo recertification – effectively the equivalent of an initial assessment (stages 1 and 2).

It is the responsibility of the BINDT Approved, Authorised or Certified Organisation to advise BINDT Certification Services Division (CSD) when they are ready for a full recertification assessment for conformance to ISO 9001:2015. It must be borne in mind that the complete process of recertification needs to be concluded before 1st September 2018 and that the recertification audit shall be completed by 31st May 2018.



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Foreword

General

The 2008 (4th) edition of ISO 9001 extended the requirements of its earlier 3rd edition to “enhance customer satisfaction”. The single most obvious change in the 2008 edition of the standard is the requirement to “identify the processes and determine their sequence and interaction as well as monitoring, measuring and analysing them.”

The 5th edition of ISO 9001: 2015 (which supersedes the 4th edition), embodies the following principal changes:

- ✓ An explicit requirement for risk-based thinking to support and improve the understanding and application of the process approach
- ✓ Fewer prescribed requirements
- ✓ Less emphasis on documents
- ✓ Improved applicability for services
- ✓ A requirement to define the boundaries of the QMS
- ✓ Increased emphasis on organizational context
- ✓ Increased leadership requirements
- ✓ Greater emphasis on achieving desired outcomes to improve customer satisfaction

References

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

BS EN ISO/IEC 17021: Conformity assessment - Requirements for bodies providing audit and certification of quality management systems,

BS EN ISO 9001: Quality management systems requirement

BS EN ISO 9004: Managing for the sustained success of an organization — A quality management approach, this standard provides guidance for organizations that choose to progress beyond the requirements of ISO 9001.

Introduction

The adoption of a quality management system is a strategic decision for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives.

The potential benefits to an organization of implementing a quality management system based on the International Standard are:

- a) the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;
- b) facilitating opportunities to enhance customer satisfaction;
- c) addressing risks and opportunities associated with its context and objectives;
- d) the ability to demonstrate conformity to specified quality management system requirements.

The quality management system requirements specified in the International Standard are complementary to requirements for products and services.

The International Standard employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking. The process approach enables an organization to plan its processes and their interactions. The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are determined and acted on.

PDCA is a tool that can be used to manage processes and systems. PDCA stands for:

- P** Plan: set the objectives of the system and processes to deliver results (“What to do” and “how to do it”)
- D** Do: implement and control what was planned
- C** Check: monitor and measure processes and results against policies, objectives and requirements and report results
- A** Act: take actions to improve the performance of processes

PDCA operates as a cycle of continual improvement, with risk-based thinking at each stage.

Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise (see Clause A.4).

Risk-based thinking is used throughout the process approach to:

- Decide how risk (positive or negative) is addressed in establishing the processes to improve process outputs and prevent undesirable results
- Define the extent of process planning and controls needed (based on risk)
- improve the effectiveness of the quality management system
- maintain and manage a system that inherently addresses risk and meets objectives

What are the possible benefits?

- A focus on the more important (“high-risk”) processes and their outputs
- improved understanding, definition and integration of interdependent processes
- systematic management of planning, implementation, checks and improvement of processes and the management system as a whole.
- better use of resources and increased accountability
- more consistent achievement of the policies and objectives, intended results and overall performance
- process approach can facilitate the implementation of any management system
- enhanced customer satisfaction by meeting customer requirements
- enhanced confidence in the organization.

Requirements for BINDT QMS Certification

This document provides guidance for organisations seeking BINDT management systems certification within the current scope of BINDT's UKAS accreditation.

Preparing to implement a QMS

For organizations that are in the process of implementing a QMS, and wish to meet the requirements of ISO 9001:2015, the following comments may be useful.

- For organizations that are in the process of implementing or have yet to implement a QMS, ISO 9001:2015 emphasizes a process approach. This includes:
 - determining the processes necessary for the effective implementation of the quality management system
 - determining the interactions between these processes.
 - *documenting* the processes to the extent necessary to assure their effective operation and control. (It may be appropriate to document the processes using process mapping tools. It is emphasized, however, that documented process mapping tools are *not* a requirement of ISO 9001:2015).

Analysis of the processes should be the driving force for defining the amount of documented information needed for the quality management system, taking into account the requirements of ISO 9001:2015. It should *not* be the documented information that drives the processes.

Adapting an existing QMS

For organizations that currently have a QMS the following comments are intended to assist in understanding the changes to documented information that may be required or facilitated by the transition to ISO 9001:2015:

- An organization with an existing QMS should not need to rewrite all of its documented information in order to meet the requirements of ISO 9001:2015. This is particularly true if an organization has structured its QMS based on the way it effectively operates, using a process approach.
- An organization may be able to carry out some simplification and/or consolidation of existing documented information in order to simplify its QMS.

Demonstrating conformity with the standard

For organizations wishing to demonstrate conformity with the requirements of ISO 9001:2015, for the purposes of certification/registration, contractual, or other reasons, it is important to remember the need to provide evidence of the effective implementation of the QMS.

- Organizations may be able to demonstrate conformity without the need for extensive documented information
- To claim conformity with ISO 9001:2015, the organization has to be able to provide objective evidence of the *effectiveness* of its processes and its quality management system. Clause 3.8.3 of ISO 9000:2015 defines “objective evidence” as “*data supporting the existence or verity of something*” and notes that “*objective evidence may be obtained through observation, measurement, test, or other means.*”
- Objective evidence does not necessarily depend on the existence of documented information, except where specifically mentioned in ISO 9001:2015. In some cases, (for example, in clause 8.1 (e) *Operational planning and control*, it is up to the organization to determine what documented information is necessary in order to provide this objective evidence.
- Where the organization has no specific documented information for a particular activity, and this is not required by the standard, it is acceptable for this activity to be conducted using as a basis the relevant clause of ISO 9001:2015. In these situations, both internal and external audits may use the text of ISO 9001:2015 for conformity assessment

purposes.

Impartiality

BINDT's top management has made public its commitment to impartiality, and how it manages conflict of interest and ensures the objectivity of its management system certification activities.

The PCN Certification Management Committee (CMC), which is widely representative of industry and of the stakeholders in the various PCN Schemes, requires that decisions taken and implemented at all levels, including management and committees, are free from commercial or other pressures that may prevent the objective provision of certification services. In order to ensure that the desired impartiality is provided, the CMC maintains an overview of the implementation of its policies to ensure impartiality, which includes (at least) an annual internal audit to confirm that impartiality is maintained.

Neither BINDT, its Certification Services Division, nor any sub-contractors will not offer or provide internal audits to its certified clients. BINDT will not certify a management system on which it has provided internal audits or any form of management system consultancy within the two years following the end of the internal audits or consultancy.

To ensure that there is no conflict of interests, personnel who have provided management system consultancy, including those acting in a managerial capacity, shall not be used by BINDT to take part in an audit or other certification activities if they have been involved in management system consultancy towards the client in question within two years following the end of the consultancy.

Outsourcing

BINDT will

- Take full responsibility for all activities outsourced to another body,
- ensure that the body that provides outsourced services, and the individuals that it uses, conform to requirements of BINDT and also to the applicable provisions of the International Standard ISO/IEC 17021, including competence, impartiality and confidentiality.
- ensure that the body that provides outsourced services, and the individuals that it uses, is not involved, either directly or through any other employer, with an organization to be audited, in such a way that impartiality could be compromised.

BINDT will not outsource audits to a management system consultancy organization, as this poses an unacceptable threat to impartiality (this does not apply to individuals contracted as auditors). Neither will BINDT certification be marketed or offered as linked with the activities of an organization that provides management system consultancy.

Quality management systems — Requirements

Important note:

This document provides guidance only where it is considered helpful to do so. Where no guidance is offered, it is because the ISO 9001: 2015 criterion is considered clear and unambiguous.

The requirements of the standard are replicated in part, but may be truncated, and users of this guide must refer to the official international standard in order to read the unexpurgated requirements.

4 Context of the organization

4.1 Understanding the organization and its context

The organization shall determine external and internal issues that are relevant to its purpose and its strategic direction and that affect its ability to achieve the intended result(s) of its quality management system.

This is the combination of those internal and external factors that affect an organization's approach to the way in which it provides products and services that are delivered to its customer.

External factors can include, for example, cultural, social, political, legal, regulatory, financial, technological, economic, and competitive environment, at the international, national, regional or local level.

Internal factors typically include the organization's corporate culture, governance, organizational structure, technologies, information systems, and decision-making processes (both formal and informal).

4.2 Understanding the needs and expectations of interested parties

The organization shall determine:

- a) the interested parties that are relevant to the quality management system;
- b) the requirements of these interested parties that are relevant to the quality management system.

The organization shall monitor and review information about these interested parties and their relevant requirements.

As stated in the scope, the International Standard is applicable where an organization needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and aims to enhance customer satisfaction.

The organization will therefore need to determine the interested parties that are relevant to the quality management system and the requirements of those interested parties, as outlined in clause 4.2.

4.3 Determining the scope of the quality management system

The organization shall determine the boundaries and applicability of the quality management system to establish its scope.

ISO 9001:2015 no longer refers to "exclusions" in relation to the applicability of its requirements to the organization's quality management system. However, an organization can determine the applicability of requirements. All requirements in the new standard are intended to apply. The organization can only decide that a requirement is not applicable if its decision will not affect its ability or responsibility to ensure the conformity of products and services and the enhancement of customer satisfaction.

When determining this scope, the organization shall consider:

- a) the external and internal issues referred to in 4.1;
- b) the requirements of relevant interested parties referred to in 4.2;
- c) the products and services of the organization.

The organization shall apply all the requirements of this International Standard 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. The scope shall state the types of products and services covered, and provide justification for any requirement of this International Standard that the organization determines is not applicable to the scope of its quality management system.

Conformity to this International Standard may only be claimed if the requirements determined as not being applicable do not affect the organization's ability or responsibility to ensure the conformity of its products and services and the enhancement of customer satisfaction.

4.4 Quality management system and its processes

4.4.1 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 International Standard.

A quality manual is no longer specifically required. The standard requires the organization to maintain documented information necessary for the effectiveness of the quality management system (QMS). There are many ways to do this and a quality manual is just one. If it is convenient and appropriate for an organization to continue to describe its quality management system in a quality manual then that is perfectly acceptable

The organization shall determine the processes needed for the quality management system and their application throughout the organization, and shall:

A process is defined as interrelated or interacting activities that use inputs to deliver an intended result.

- a) determine the inputs required and the outputs expected from these processes;

Inputs and outputs may be tangible (e.g. materials, components or equipment) or intangible (e.g. data, information or knowledge).

- b) determine the sequence and interaction of these processes;
- c) determine and apply the criteria and methods (including monitoring, measurements and related performance indicators) needed to ensure the effective operation and control of these processes;
- d) determine the resources needed for these processes and ensure their availability;
- e) assign the responsibilities and authorities for these processes;
- f) address the risks and opportunities as determined in accordance with the requirements of 6.1;
- g) evaluate these processes and implement any changes needed to ensure that these processes achieve their intended results;
- h) improve the processes and the quality management system.

The process approach includes establishing the organization's processes to operate as an integrated and complete system.

- *The management system integrates processes and measures to meet objectives*
 - *Processes define interrelated activities and checks, to deliver intended outputs*

• *Detailed planning and controls can be defined and documented as needed, depending on the organization's context.*

4.4.2 To the extent necessary, the organization shall:

- a) maintain documented information to support the operation of its processes;
- b) retain documented information to have confidence that the processes are being carried out as planned.

5 Leadership

5.1 Leadership and commitment

5.1.1 General

Top management shall demonstrate leadership and commitment with respect to the quality management system by:

- a) taking accountability for the effectiveness of the quality management system;
- b) ensuring that the quality policy and quality objectives are established for the quality management system and are compatible with the context and strategic direction of the organization;
- c) ensuring the integration of the quality management system requirements into the organization's business processes;

NOTE Reference to "business" in this International Standard can be interpreted broadly to mean those activities that are core to the purposes of the organization's existence, whether the organization is public, private, for profit or not for profit.

- d) promoting the use of the process approach and risk-based thinking;
- e) ensuring that the resources needed for the quality management system are available;
- f) communicating the importance of effective quality management and of conforming to the quality management system requirements;
- g) ensuring that the quality management system achieves its intended results;
- h) engaging, directing and supporting persons to contribute to the effectiveness of the quality management system;

Although the prescriptive title of a management representative has been deleted, it is up to top management to ensure that the roles and responsibilities are assigned for reporting on the performance of the QMS. Some organizations might find it convenient to maintain their current structure, with a single person carrying out this role. Others might take advantage of the additional flexibility to consider other structures depending on their organizational context.

- i) promoting improvement;
- j) supporting other relevant management roles to demonstrate their leadership as it applies to their areas of responsibility.

5.1.2 Customer focus

Top management shall demonstrate leadership and commitment with respect to customer focus by ensuring that:

- a) customer and applicable statutory and regulatory requirements are determined, understood and consistently met;
- b) the risks and opportunities that can affect conformity of products and services and the ability to enhance customer satisfaction are determined and addressed;
- c) the focus on enhancing customer satisfaction is maintained.

5.2 Policy

5.2.1 Establishing the quality policy

Top management shall establish, implement and maintain a quality policy that:

- a) is appropriate to the purpose and context of the organization and supports its strategic direction;
- b) provides a framework for setting quality objectives;
- c) includes a commitment to satisfy applicable requirements;
- d) includes a commitment to continual improvement of the quality management system.

5.2.2 Communicating the quality policy

The quality policy shall:

- a) be available and be maintained as documented information;
- b) be communicated, understood and applied within the organization;
- c) be available to relevant interested parties, as appropriate.

5.3 Organizational roles, responsibilities and authorities

Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood within the organization.

Top management shall assign the responsibility and authority for:

- a) ensuring that the quality management system conforms to the requirements of this International Standard;
- b) ensuring that the processes are delivering their intended outputs;
- c) reporting on the performance of the quality management system and on opportunities for improvement (see [10.1](#)), in particular to top management;
- d) ensuring the promotion of customer focus throughout the organization;
- e) ensuring that the integrity of the quality management system is maintained when changes to the quality management system are planned and implemented.

6 Planning

6.1 Actions to address risks and opportunities

6.1.1 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:

- a) give assurance that the quality management system can achieve its intended result(s);
- b) enhance desirable effects;
- c) prevent, or reduce, undesired effects;
- d) achieve improvement.

6.1.2 The organization shall plan:

- a) actions to address these risks and opportunities;
- b) how to:
 - 1) integrate and implement the actions into its quality management system processes (see [4.4](#));
 - 2) evaluate the effectiveness of these actions.

Actions taken to address risks and opportunities shall be proportionate to the potential

impact on the conformity of products and services.

NOTE 1 Options to address risks can include avoiding risk, taking risk in order to pursue an opportunity, eliminating the risk source, changing the likelihood or consequences, sharing the risk, or retaining risk by informed decision.

NOTE 2 Opportunities can lead to the adoption of new practices, launching new products, opening new markets, addressing new clients, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

6.2 Quality objectives and planning to achieve them

6.2.1 The organization shall establish quality objectives at relevant functions, levels and processes needed for the quality management system.

The quality objectives shall:

- a) be consistent with the quality policy;
- b) be measurable;
- c) take into account applicable requirements;
- d) be relevant to conformity of products and services and to enhancement of customer satisfaction;
- e) be monitored;
- f) be communicated;
- g) be updated as appropriate.

The organization shall maintain documented information on the quality objectives.

6.2.2 When planning how to achieve its quality objectives, the organization shall determine:

- a) what will be done;
- b) what resources will be required;
- c) who will be responsible;
- d) when it will be completed;
- e) how the results will be evaluated.

6.3 Planning of changes

When the organization determines the need for changes to the quality management system, the changes shall be carried out in a planned manner (see 4.4).

The organization shall consider:

- a) the purpose of the changes and their potential consequences;
- b) the integrity of the quality management system;
- c) the availability of resources;
- d) the allocation or reallocation of responsibilities and authorities.

Typical steps to Implement change

- *Define the specifics of what is to be changed*
- *Have a plan (tasks, timeline, responsibilities, authorities, budget, resources, needed information, others)*
- *Engage other people as appropriate in the change process*
- *Develop a communication plan (appropriate people within the organization, customers, suppliers, interested parties, etc. may need to be informed)*

- *Use a cross functional team review the plan to provide feedback related to the plan and associated risks*
- *Train people*
- *Measure the effectiveness*

7 Support

7.1 Resources

7.1.1 General

The organization shall determine and provide the resources needed for the establishment, implementation, maintenance and continual improvement of the quality management system.

The organization shall consider:

- a) the capabilities of, and constraints on, existing internal resources;
- b) what needs to be obtained from external providers.

7.1.2 People

The organization shall determine and provide the persons necessary for the effective implementation of its quality management system and for the operation and control of its processes.

7.1.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes and to achieve conformity of products and services.

NOTE Infrastructure can include:

- a) buildings and associated utilities;
- b) equipment, including hardware and software;
- c) transportation resources;
- d) information and communication technology.

7.1.4 Environment for the operation of processes

The organization shall determine, provide and maintain the environment necessary for the operation of its processes and to achieve conformity of products and services.

NOTE A suitable environment can be a combination of human and physical factors, such as:

- a) social (e.g. non-discriminatory, calm, non-confrontational);
- b) psychological (e.g. stress-reducing, burnout prevention, emotionally protective);
- c) physical (e.g. temperature, heat, humidity, light, airflow, hygiene, noise).

These factors can differ substantially depending on the products and services provided.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

The organization shall determine and provide the resources needed to ensure valid and reliable results when monitoring or measuring is used to verify the conformity of products and services to requirements.

The organization shall ensure that the resources provided:

- a) are suitable for the specific type of monitoring and measurement activities being undertaken;
- b) are maintained to ensure their continuing fitness for their purpose.

The organization shall retain appropriate documented information as evidence of fitness for purpose of the monitoring and measurement resources.

7.1.5.2 Measurement traceability

When measurement traceability is a requirement, or is considered by the organization to be an essential part of providing confidence in the validity of measurement results, measuring equipment shall be:

- a) calibrated or verified, or both, at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; when no such standards exist, the basis used for calibration or verification shall be retained as documented information;
- b) identified in order to determine their status;
- c) safeguarded from adjustments, damage or deterioration that would invalidate the calibration status and subsequent measurement results.

The organization shall determine if the validity of previous measurement results has been adversely affected when measuring equipment is found to be unfit for its intended purpose, and shall take appropriate action as necessary.

7.1.6 Organizational knowledge

The organization shall determine the knowledge necessary for the operation of its processes and to achieve conformity of products and services. This knowledge shall be maintained and be made available to the extent necessary.

Requirements regarding organizational knowledge were introduced for the purpose of safeguarding the organization from loss of knowledge and encouraging the organization to acquire new knowledge as its business context changes.

NOTE 1 Organizational knowledge is knowledge specific to the organization; it is gained by experience. It is information that is used and shared to achieve the organization's objectives.

NOTE 2 Organizational knowledge can be based on:

- a) internal sources (e.g. intellectual property; knowledge gained from experience; lessons learned from failures and successful projects; capturing and sharing undocumented knowledge and experience; the results of improvements in processes, products and services);*
- b) external sources (e.g. standards; academia; conferences; gathering knowledge from customers or external providers).*

7.2 Competence

The organization shall:

- a) determine the necessary competence of person(s) doing work under its control that affects the performance and effectiveness of the quality management system;
- b) ensure that these persons are competent on the basis of appropriate education, training, or experience;
- c) where applicable, take actions to acquire the necessary competence, and evaluate the effectiveness of the actions taken;
- d) retain appropriate documented information as evidence of competence.

NOTE Applicable actions can include, for example, the provision of training to, the mentoring of, or the re-assignment of currently employed persons; or the hiring or contracting of competent persons.

7.3 Awareness

The organization shall ensure that persons doing work under the organization's control are aware of:

- a) the quality policy;
- b) relevant quality objectives;
- c) their contribution to the effectiveness of the quality management system, including the benefits of improved performance;
- d) the implications of not conforming with the quality management system requirements.

7.4 Communication

The organization shall determine the internal and external communications relevant to the quality management system, including:

- a) on what it will communicate;
- b) when to communicate;
- c) with whom to communicate;
- d) how to communicate;
- e) who communicates.

7.5 Documented information

7.5.1 General

The organization's quality management system shall include:

- a) documented information required by this International Standard;
- b) documented information determined by the organization as being necessary for the effectiveness of the quality management system.

NOTE The extent of documented information for a quality management system can differ from one organization to another due to:

- *the size of organization and its type of activities, processes, products and services;*
- *the complexity of processes and their interactions;*
- *the competence of persons.*

All the documented information that forms part of the QMS has to be controlled in accordance with ISO 9001: 2015 clause 7.5 (Documented information). Documented information can refer to documented information needed to be maintained by the organization for the purposes of establishing a QMS (high level transversal documents).

These include:

- *The scope of the quality management system (clause 4.3).*
- *Documented information necessary to support the operation of processes (clause 4.4).*
- *The quality policy (clause 5.).*
- *The quality objectives (clause 6.2).*
- *Documented information maintained by the organization for the purpose of communicating the information necessary for the organization to operate (low level, specific documents).*

7.5.2 Creating and updating

When creating and updating documented information, the organization shall ensure appropriate:

- a) identification and description (e.g. a title, date, author, or reference number);

- b) format (e.g. language, software version, graphics) and media (e.g. paper, electronic);
- c) review and approval for suitability and adequacy.

Although ISO 9001:2015 does not specifically require any of them, examples of documents that can add value to a QMS may include:

- *Organization charts*
- *Process maps, process flow charts and/or process descriptions*
- *Procedures*
- *Work and/or test instructions*
- *Specifications*
- *Documents containing internal communications*
- *Production schedules*
- *Approved supplier lists*
- *Test and inspection plans*
- *Quality plans*
- *Quality manuals*
- *Strategic plans*
- *Forms*

7.5.3 Control of documented information

7.5.3.1 Documented information required by the quality management system and by this International Standard shall be controlled to ensure:

- a) it is available and suitable for use, where and when it is needed;
- b) it is adequately protected (e.g. from loss of confidentiality, improper use, or loss of integrity).

Documented information needed to be retained by the organization for the purpose of providing evidence of result achieved (records). These include (with ISO 9001: 2015 references):

- *Documented information to the extent necessary to have confidence that the processes are being carried out as planned (clause 4.4).*
- *Evidence of fitness for purpose of monitoring and measuring resources (clause 7.1.5.1).*
- *Evidence of the basis used for calibration of the monitoring and measurement resources (when no international or national standards exist) (clause 7.1.5.2).*
- *Evidence of competence of person(s) doing work under the control of the organization that affects the performance and effectiveness of the QMS (clause 7.2).*
- *Results of the review and new requirements for the products and services (clause 8.2.3).*
- *Records needed to demonstrate that design and development requirements have been met (clause 8.3.2)*
- *Records on design and development inputs (clause 8.3.3).*
- *Records of the activities of design and development controls (clause 8.3.4).*
- *Records of design and development outputs (clause 8.3.5).*
- *Design and development changes, including the results of the review and the authorization of the changes and necessary actions (clause 8.3.6).*
- *Records of the evaluation, selection, monitoring of performance and re-evaluation of external providers and any and actions arising from these activities (clause 8.4.1)*
- *Evidence of the unique identification of the outputs when traceability is a requirement (clause 8.5.2).*
- *Records of property of the customer or external provider that is lost, damaged or otherwise found to be unsuitable for use and of its communication to the owner (clause 8.5.3).*

- *Results of the review of changes for production or service provision, the persons authorizing the change, and necessary actions taken (clause 8.5.6).*
- *Records of the authorized release of products and services for delivery to the customer including acceptance criteria and traceability to the authorizing person(s) (clause 8.6).*
- *Records of nonconformities, the actions taken, concessions obtained and the identification of the authority deciding the action in respect of the nonconformity (clause 8.7).*
- *Results of the evaluation of the performance and the effectiveness of the QMS (clause 9.1.1)*
- *Evidence of the implementation of the audit programme and the audit results (clause 9.2.2).*
- *Evidence of the results of management reviews (clause 9.3.3).*
- *Evidence of the nature of the nonconformities and any subsequent actions taken (clause*

7.5.3.2 For the control of documented information, the organization shall address the following activities, as applicable:

- a) distribution, access, retrieval and use;
- b) storage and preservation, including preservation of legibility;
- c) control of changes (e.g. version control);
- d) retention and disposition.

NOTE Access can imply a decision regarding the permission to view the documented information only, or the permission and authority to view and change the documented information.

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.

Documented information retained as evidence of conformity shall be protected from unintended alterations.

Documents may be in any form or type of medium, and the definition of “document” in ISO 9000:2015 clause 3.8.5 gives the following examples:

- *paper*
- *magnetic*
- *electronic or optical computer disc*
- *photograph*
- *master sample*

8 Operation

8.1 Operational planning and control

The organization shall plan, implement and control the processes (see [4.4](#)) needed to meet the requirements for the provision of products and services, and to implement the actions determined in [Clause 6](#), by:

- a) determining the requirements for the products and services;
- b) establishing criteria for:
 - 1) the processes;
 - 2) the acceptance of products and services;
- c) determining the resources needed to achieve conformity to the product and service requirements;
- d) implementing control of the processes in accordance with the criteria;
- e) determining and keeping documented information to the extent necessary;

- 1) to have confidence that the processes have been carried out as planned;
- 2) to demonstrate the conformity of products and services to their requirements.

The output of this planning shall be suitable for the organization's operations.

The organization shall control planned changes and review the consequences of unintended changes, taking action to mitigate any adverse effects, as necessary.

The organization shall ensure that outsourced processes are controlled (see 8.4).

8.2 Requirements for products and services

8.2.1 Customer communication

Communication with customers shall include:

- a) providing information relating to products and services;
- b) handling enquiries, contracts or orders, including changes;
- c) obtaining customer feedback relating to products and services, including customer complaints;
- d) handling or controlling customer property;
- e) establishing specific requirements for contingency actions, when relevant.

8.2.2 Determining the requirements for products and services

When determining the requirements for the products and services to be offered to customers, the organization shall ensure that:

- a) the requirements for the products and services are defined, including:
 - 1) any applicable statutory and regulatory requirements;
 - 2) those considered necessary by the organization;
- b) the organization can meet the claims for the products and services it offers.

8.2.3 Review of requirements for products and services

8.2.3.1 The organization shall ensure that it has the ability to meet the requirements for products and services to be offered to customers. The organization shall conduct a review before committing to supply products and services to a customer, to include:

- a) requirements specified by the customer, including the requirements for delivery and post-delivery activities;
- b) requirements not stated by the customer, but necessary for the specified or intended use, when known;
- c) requirements specified by the organization;
- d) statutory and regulatory requirements applicable to the products and services;
- e) contract or order requirements differing from those previously expressed.

The organization shall ensure that contract or order requirements differing from those previously defined are resolved.

The customer's requirements shall be confirmed by the organization before acceptance, when the customer does not provide a documented statement of their requirements.

NOTE In some situations, such as internet sales, a formal review is impractical for each order. Instead, the review can cover relevant product information, such as catalogues or advertising material.

8.2.3.2 The organization shall retain documented information, as applicable:

- a) on the results of the review;

- b) on any new requirements for the products and services.

8.2.4 Changes to requirements for products and services

The organization shall ensure that relevant documented information is amended, and that relevant persons are made aware of the changed requirements, when the requirements for products and services are changed.

8.3 Design and development of products and services

8.3.1 General

The organization shall establish, implement and maintain a design and development process that is appropriate to ensure the subsequent provision of products and services.

8.3.2 Design and development planning

In determining the stages and controls for design and development, the organization shall consider:

- a) the nature, duration and complexity of the design and development activities;
- b) the required process stages, including applicable design and development reviews;
- c) the required design and development verification and validation activities;
- d) the responsibilities and authorities involved in the design and development process;
- e) the internal and external resource needs for the design and development of products and services;
- 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;
- h) the requirements for subsequent provision of products and services;
- i) the level of control expected for the design and development process by customers and other relevant interested parties;
- j) the documented information needed to demonstrate that design and development requirements have been met.

8.3.3 Design and development inputs

The organization shall determine the requirements essential for the specific types of products and services to be designed and developed. The organization shall consider:

- a) functional and performance requirements;
- b) information derived from previous similar design and development activities;
- c) statutory and regulatory requirements;
- d) standards or codes of practice that the organization has committed to implement;
- e) potential consequences of failure due to the nature of the products and services.

Inputs shall be adequate for design and development purposes, complete and unambiguous.

Conflicting design and development inputs shall be resolved.

The organization shall retain documented information on design and development inputs.

8.3.4 Design and development controls

The organization shall apply controls to the design and development process to ensure that:

- a) the results to be achieved are defined;
- b) reviews are conducted to evaluate the ability of the results of design and

- development to meet requirements;
- c) verification activities are conducted to ensure that the design and development outputs meet the input requirements;
 - d) validation activities are conducted to ensure that the resulting products and services meet the requirements for the specified application or intended use;
 - e) any necessary actions are taken on problems determined during the reviews, or verification and validation activities;
 - f) documented information of these activities is retained.

NOTE Design and development reviews, verification and validation have distinct purposes. They can be conducted separately or in any combination, as is suitable for the products and services of the organization.

8.3.5 Design and development outputs

The organization shall ensure that design and development outputs:

- a) meet the input requirements;
- b) are adequate for the subsequent processes for the provision of products and services;
- c) include or reference monitoring and measuring requirements, as appropriate, and acceptance criteria;
- d) specify the characteristics of the products and services that are essential for their intended purpose and their safe and proper provision.

The organization shall retain documented information on design and development outputs.

8.3.6 Design and development changes

The organization shall identify, review and control changes made during, or subsequent to, the design and development of products and services, to the extent necessary to ensure that there is no adverse impact on conformity to requirements.

The organization shall retain documented information on:

- a) design and development changes;
- b) the results of reviews;
- c) the authorization of the changes;
- d) the actions taken to prevent adverse impacts.

8.4 Control of externally provided processes, products and services

8.4.1 General

The organization shall ensure that externally provided processes, products and services conform to requirements.

The organization shall determine the controls to be applied to externally provided processes, products and services when:

- a) products and services from external providers are intended for incorporation into the organization's own products and services;
- b) products and services are provided directly to the customer(s) by external providers on behalf of the organization;
- c) a process, or part of a process, is provided by an external provider as a result of a decision by the organization.

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. The organization

shall retain documented information of these activities and any necessary actions arising from the evaluations.

8.4.2 Type and extent of control

The organization shall ensure that externally provided processes, products and services do not adversely affect the organization's ability to consistently deliver conforming products and services to its customers.

The organization shall:

- a) ensure that externally provided processes remain within the control of its quality management system;
- b) define both the controls that it intends to apply to an external provider and those it intends to apply to the resulting output;
- c) take into consideration:
 - 1) the potential impact of the externally provided processes, products and services on the organization's ability to consistently meet customer and applicable statutory and regulatory requirements;
 - 2) the effectiveness of the controls applied by the external provider;
- d) determine the verification, or other activities, necessary to ensure that the externally provided processes, products and services meet requirements.

8.4.3 Information for external providers

The organization shall ensure the adequacy of requirements prior to their communication to the external provider.

The organization shall communicate to external providers its requirements for:

- a) the processes, products and services to be provided;
- b) the approval of:
 - 1) products and services;
 - 2) methods, processes and equipment;
 - 3) the release of products and services;
- c) competence, including any required qualification of persons;
- d) the external providers' interactions with the organization;
- e) control and monitoring of the external providers' performance to be applied by the organization;
- f) verification or validation activities that the organization, or its customer, intends to perform at the external providers' premises.

8.5 Production and service provision

8.5.1 Control of production and service provision

The organization shall implement production and service provision under controlled conditions.

Controlled conditions shall include, as applicable:

- a) the availability of documented information that defines:
 - 1) the characteristics of the products to be produced, the services to be provided, or the activities to be performed;
 - 2) the results to be achieved;
- b) the availability and use of suitable monitoring and measuring resources;
- c) the implementation of monitoring and measurement activities at appropriate stages

to verify that criteria for control of processes or outputs, and acceptance criteria for products and services, have been met;

- d) the use of suitable infrastructure and environment for the operation of processes;
- e) the appointment of competent persons, including any required qualification;
- f) the validation, and periodic revalidation, of the ability to achieve planned results of the processes for production and service provision, where the resulting output cannot be verified by subsequent monitoring or measurement;
- g) the implementation of actions to prevent human error;
- h) the implementation of release, delivery and post-delivery activities.

8.5.2 Identification and traceability

The organization shall use suitable means to identify outputs when it is necessary to ensure the conformity of products and services.

The organization shall identify the status of outputs with respect to monitoring and measurement requirements throughout production and service provision.

The organization shall control the unique identification of the outputs when traceability is a requirement, and shall retain the documented information necessary to enable traceability.

8.5.3 Property belonging to customers or external providers

The organization shall exercise care with property belonging to customers or external providers while it is under the organization's control or being used by the organization.

The organization shall identify, verify, protect and safeguard customers' or external providers' property provided for use or incorporation into the products and services.

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.

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

8.5.4 Preservation

The organization shall preserve the outputs during production and service provision, to the extent necessary to ensure conformity to requirements.

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

8.5.5 Post-delivery activities

The organization shall meet requirements for post-delivery activities associated with the products and services.

In determining the extent of post-delivery activities that are required, the organization shall consider:

- a) statutory and regulatory requirements;
- b) the potential undesired consequences associated with its products and services;
- c) the nature, use and intended lifetime of its products and services;
- d) customer requirements;
- e) customer feedback.

NOTE Post-delivery activities can include actions under warranty provisions, contractual obligations such as maintenance services, and supplementary services such as recycling or final disposal.

8.5.6 Control of changes

The organization shall review and control changes for production or service provision, to the extent necessary to ensure continuing conformity with requirements.

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.

8.6 Release of products and services

The organization shall implement planned arrangements, at appropriate stages, to verify that the product and service requirements have been met.

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.

The organization shall retain documented information on the release of products and services. The documented information shall include:

- a) evidence of conformity with the acceptance criteria;
- b) traceability to the person(s) authorizing the release.

8.7 Control of nonconforming outputs

8.7.1 The organization shall ensure that outputs that do not conform to their requirements are identified and controlled to prevent their unintended use or delivery.

The organization shall take appropriate action based on the nature of the nonconformity and its effect on the conformity of products and services. This shall also apply to nonconforming products and services detected after delivery of products, during or after the provision of services.

The organization shall deal with nonconforming outputs in one or more of the following ways:

- a) correction;
- b) segregation, containment, return or suspension of provision of products and services;
- c) informing the customer;
- d) obtaining authorization for acceptance under concession.

Conformity to the requirements shall be verified when nonconforming outputs are corrected.

8.7.2 The organization shall retain documented information that:

- a) describes the nonconformity;
- b) describes the actions taken;
- c) describes any concessions obtained;
- d) identifies the authority deciding the action in respect of the nonconformity.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

The organization shall determine:

- a) what needs to be monitored and measured;
- b) the methods for monitoring, measurement, analysis and evaluation needed to ensure valid results;
- c) when the monitoring and measuring shall be performed;
- d) when the results from monitoring and measurement shall be analysed and

evaluated.

The organization shall evaluate the performance and the effectiveness of the quality management system.

The organization shall retain appropriate documented information as evidence of the results.

9.1.2 Customer satisfaction

The organization shall monitor customers' perceptions of the degree to which their needs and expectations have been fulfilled. The organization shall determine the methods for obtaining, monitoring and reviewing this information.

NOTE Examples of monitoring customer perceptions can include customer surveys, customer feedback on delivered products and services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.

9.1.3 Analysis and evaluation

The organization shall analyse and evaluate appropriate data and information arising from monitoring and measurement.

The results of analysis shall be used to evaluate:

- a) conformity of products and services;
- b) the degree of customer satisfaction;
- c) the performance and effectiveness of the quality management system;
- d) if planning has been implemented effectively;
- e) the effectiveness of actions taken to address risks and opportunities;
- f) the performance of external providers;
- g) the need for improvements to the quality management system.

NOTE Methods to analyse data can include statistical techniques.

9.2 Internal audit

9.2.1 The organization shall conduct internal audits at planned intervals to provide information on whether the quality management system:

- a) conforms to:
 - 1) the organization's own requirements for its quality management system;
 - 2) the requirements of this International Standard;
- b) is effectively implemented and maintained.

9.2.2 The organization shall:

- 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;
- b) define the audit criteria and scope for each audit;
- c) select auditors and conduct audits to ensure objectivity and the impartiality of the audit process;
- d) ensure that the results of the audits are reported to relevant management;
- e) take appropriate correction and corrective actions without undue delay;
- f) retain documented information as evidence of the implementation of the audit programme and the audit results.

NOTE See ISO 19011 for guidance.

9.3 Management review

9.3.1 General

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.

9.3.2 Management review inputs

The management review shall be planned and carried out taking into consideration:

- a) the status of actions from previous management reviews;
- b) changes in external and internal issues that are relevant to the quality management system;
- c) information on the performance and effectiveness of the quality management system, including trends in:
 - 1) customer satisfaction and feedback from relevant interested parties;
 - 2) the extent to which quality objectives have been met;
 - 3) process performance and conformity of products and services;
 - 4) nonconformities and corrective actions;
 - 5) monitoring and measurement results;
 - 6) audit results;
 - 7) the performance of external providers;
- d) the adequacy of resources;
- e) the effectiveness of actions taken to address risks and opportunities (see [6.1](#));
- f) opportunities for improvement.

9.3.3 Management review outputs

The outputs of the management review shall include decisions and actions related to:

- a) opportunities for improvement;
- b) any need for changes to the quality management system;
- c) resource needs.

The organization shall retain documented information as evidence of the results of management reviews.

10 Improvement

ISO 9001:2008 used the term continual improvement to emphasize the fact that this is an ongoing activity. However, it is important to recognize that there are a number of ways in which an organization may improve. Small step continual improvement is only one of these. Others may include breakthrough improvements, re-engineering initiatives or innovation. ISO 9001:2015 therefore uses the more general term improvement, of which continual improvement is one component, but not the only one.

10.1 General

The organization shall determine and select opportunities for improvement and implement any necessary actions to meet customer requirements and enhance customer satisfaction.

These shall include:

- a) improving products and services to meet requirements as well as to address future needs and expectations;

- b) correcting, preventing or reducing undesired effects;
- c) improving the performance and effectiveness of the quality management system.

NOTE Examples of improvement can include correction, corrective action, continual improvement, breakthrough change, innovation and re-organization.

10.2 Nonconformity and corrective action

10.2.1 When a nonconformity occurs, including any arising from complaints, the organization shall:

- a) react to the nonconformity and, as applicable:
 - 1) take action to control and correct it;
 - 2) deal with the consequences;
- b) evaluate the need for action to eliminate the cause(s) of the nonconformity, in order that it does not recur or occur elsewhere, by:
 - 1) reviewing and analysing the nonconformity;
 - 2) determining the causes of the nonconformity;
 - 3) determining if similar nonconformities exist, or could potentially occur;
- c) implement any action needed;
- d) review the effectiveness of any corrective action taken;
- e) update risks and opportunities determined during planning, if necessary;
- f) make changes to the quality management system, if necessary.

Corrective actions shall be appropriate to the effects of the nonconformities encountered.

10.2.2 The organization shall retain documented information as evidence of:

- a) the nature of the nonconformities and any subsequent actions taken;
- b) the results of any corrective action.

10.3 Continual improvement

The organization shall continually improve the suitability, adequacy and effectiveness of the quality management system.

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.
