INTERNATIONAL STANDARD

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Quality management systems — Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS)

Systèmes de management de la qualité — Exigences spécifiques pour l'application de l'ISO 9001:2015 par les organisations de la chaîne d'approvisionnement du secteur de l'énergie nucléaire fournissant des produits ou services importants pour la sûreté nucléaire (IPNS)

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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Foreword

ISO (the International Organization for Standardization) is a worldwide federation of national standards bodies (ISO member bodies). The work of preparing International Standards is normally carried out through ISO technical committees. Each member body interested in a subject for which a technical committee has been established has the right to be represented on that committee. International organizations, governmental and non-governmental, in liaison with ISO, also take part in the work. ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular the different approval criteria needed for the different types of ISO documents should be noted. This document was drafted in accordance with the editorial rules of the ISO/IEC Directives, Part 2 (see www.iso.org/directives).

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. ISO shall not be held responsible for identifying any or all such patent rights. Details of any patent rights identified during the development of the document will be in the Introduction and/or on the ISO list of patent declarations received (see www.iso.org/patents).

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

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

This document was prepared by Technical Committee ISO/TC 85, *Nuclear energy, nuclear technologies, and radiological protection*.

Introduction

ISO collaborates closely with the International Atomic Energy Agency (IAEA). The IAEA establishes standards for safety for use by its member states in the framework of national regulations. ISO standards in the field of nuclear safety are complementary technical documents.

In this document, the text reproduced from ISO 9001:2015 is placed in boxes, in order to distinguish it from the sector-specific requirements for nuclear safety given for each clause. It is understood that the requirements of each clause include requirements for nuclear safety. Whenever the ISO 9001:2015 text refers to "this International Standard", this applies to this document, including the text outside the boxes.

Informative annexes referenced in ISO 9001:2015 are not included in this document.

0.1 General

ISO 9001:2015, Quality management systems — Requirements

0.1 General

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 this 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.

This International Standard can be used by internal and external parties.

It is not the intent of this International Standard to imply the need for:

— uniformity in the structure of different quality management systems;

— alignment of documentation to the clause structure of this International Standard;

— the use of the specific terminology of this International Standard within the organization.

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

This 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 identified and acted on.

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).

Consistently meeting requirements and addressing future needs and expectations poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation and re-organization.

In this International Standard, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.

Information marked as "NOTE" is for guidance in understanding or clarifying the associated requirement.

0.2 Quality management principles

ISO 9001:2015, Quality management systems — Requirements

0.2 Quality management principles

This International Standard is based on the quality management principles described in ISO 9000. The descriptions include a statement of each principle, a rationale of why the principle is important for the organization, some examples of benefits associated with the principle and examples of typical actions to improve the organization's performance when applying the principle.

The quality management principles are:

— customer focus;

— leadership;

— engagement of people;

— process approach;

— improvement;

— evidence-based decision making;

— relationship management.

The following also apply:

— nuclear safety culture;

— determination of ITNS items and activites;

— graded approach to the application of quality requirements.

0.3 Process approach

0.3.1 General

ISO 9001:2015, Quality management systems — Requirements

0.3 Process approach

0.3.1 General

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. Specific requirements considered essential to the adoption of a process approach are included in 4.4.

Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle (see 0.3.2) with an overall focus on risk-based thinking (see 0.3.3) aimed at taking advantage of opportunities and preventing undesirable results.

The application of the process approach in a quality management system enables:

a) understanding and consistency in meeting requirements;

b) the consideration of processes in terms of added value;

c) the achievement of effective process performance;

d) improvement of processes based on evaluation of data and information.

Figure 1 gives a schematic representation of any process and shows the interaction of its elements. The monitoring and measuring checkpoints, which are necessary for control, are specific to each process and will vary depending on the related risks.

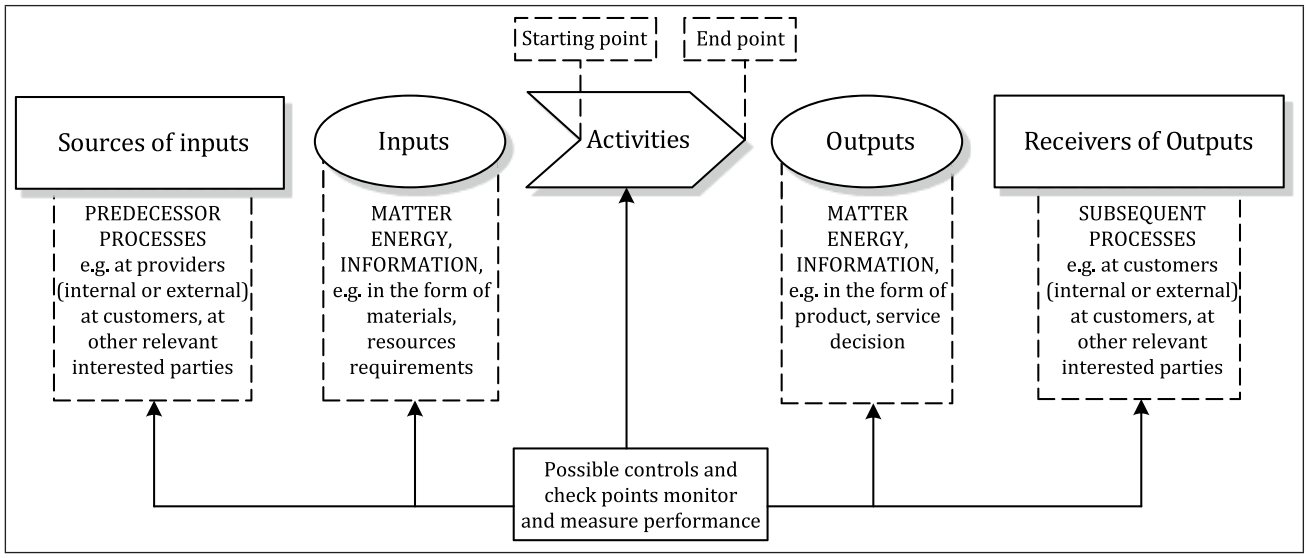


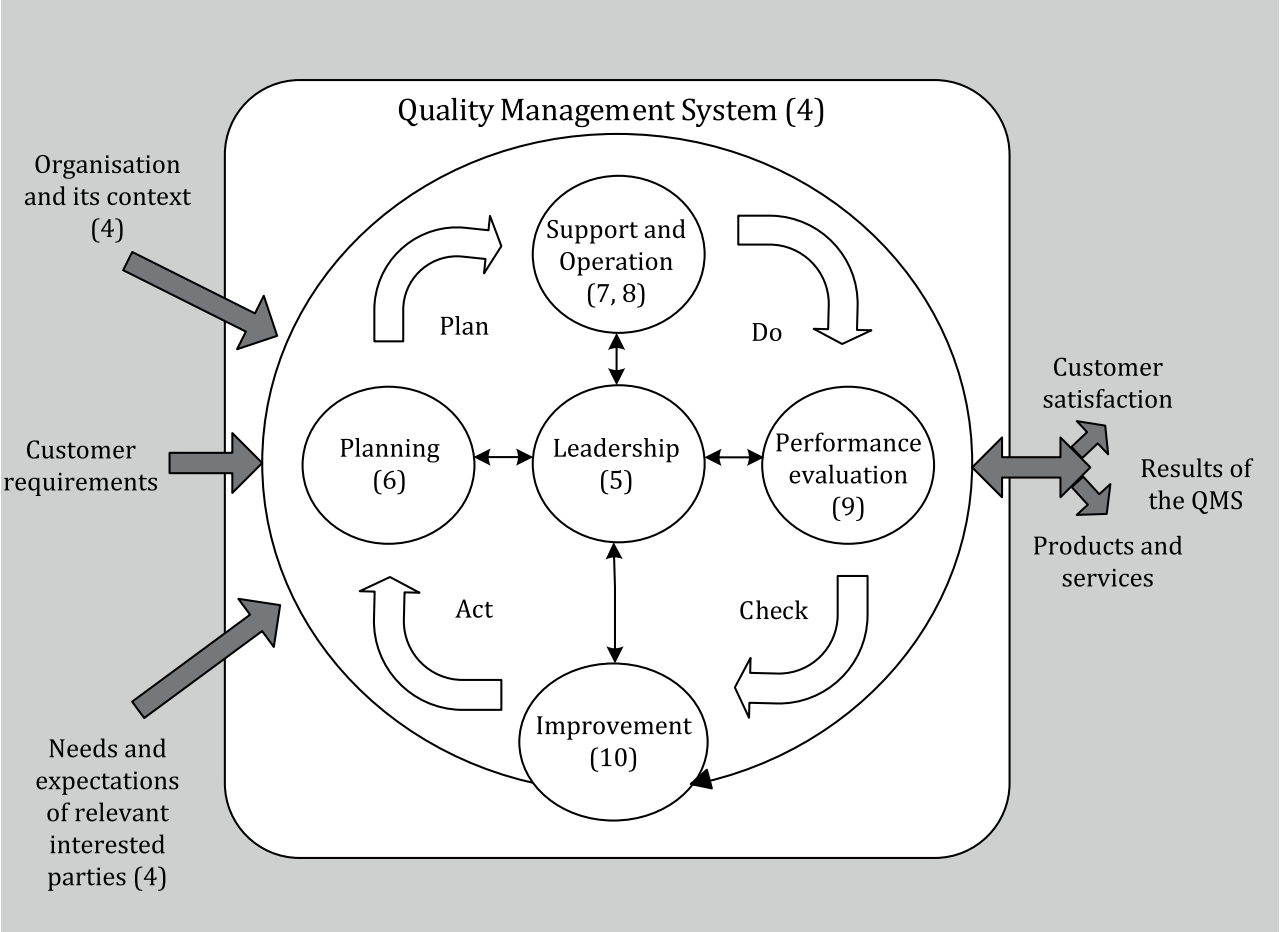
Figure 1 — Schematic representation of the elements of a single process

0.3.2 Plan-Do-Check-Act cycle

ISO 9001:2015, Quality management systems — Requirements

0.3.2 Plan-Do-Check-Act cycle

The PDCA cycle can be applied to all processes and to the quality management system as a whole. Figure 2 illustrates how Clauses 4 to 10 can be grouped in relation to the PDCA cycle.



NOTE Numbers in brackets refer to the clauses in this International Standard.

Figure 2 — Representation of the structure of this International Standard in the PDCA cycle

The PDCA cycle can be briefly described as follows:

— **Plan**: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies, and identify and address risks and opportunities;

— **Do**: implement what was planned;

— **Check**: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results;

— **Act**: take actions to improve performance, as necessary.

0.3.3 Risk-based thinking

ISO 9001:2015, Quality management systems — Requirements

0.3.3 Risk-based thinking

Risk-based thinking (see Clause A.4) is essential for achieving an effective quality management system. The concept of risk-based thinking has been implicit in previous editions of this International Standard including, for example, carrying out preventive action to eliminate potential nonconformities, analysing any nonconformity that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity.

To conform to the requirements of this International Standard, an organization needs to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results and preventing negative effects.

Opportunities can arise as a result of a situation favourable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers, develop new products and services, reduce waste or improve productivity. Actions to address opportunities can also include consideration of associated risks. Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

0.4 Relationship with other management system standards

ISO 9001:2015, Quality management systems — Requirements

0.4 Relationship with other management system standards

This International Standard applies the framework developed by ISO to improve alignment among its International Standards for management systems (see Clause A.1).

This International Standard enables an organization to use the process approach, coupled with the PDCA cycle and risk-based thinking, to align or integrate its quality management system with the requirements of other management system standards.

This International Standard relates to ISO 9000 and ISO 9004 as follows:

— ISO 9000, *Quality management systems — Fundamentals and vocabulary* provides essential background for the proper understanding and implementation of this International Standard;

— ISO 9004, *Managing for the sustained success of an organization — A quality management approach* provides guidance for organizations that choose to progress beyond the requirements of this International Standard.

Annex B provides details of other International Standards on quality management and quality management systems that have been developed by ISO/TC 176.

This International Standard does not include requirements specific to other management systems, such as those for environmental management, occupational health and safety management, security management, nuclear accounting and control or financial management.

Sector-specific quality management system standards based on the requirements of this International Standard have been developed for a number of sectors. Some of these standards specify additional quality management system requirements, while others are limited to providing guidance to the application of this International Standard within the particular sector.

A matrix showing the correlation between the clauses of this edition of this International Standard and the previous edition (ISO 9001:2008) can be found on the ISO/TC 176/SC 2 open access web site at: www.iso.org/tc176/sc02/public.

Management system requirements specific to security management, and nuclear material accounting and control are not addressed in this International Standard.

Quality management systems — Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS)

1 Scope

ISO 9001:2015, Quality management systems — Requirements

1 Scope

This International Standard specifies requirements for a quality management system when an organization:

a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All the requirements of this International Standard are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

NOTE 1 In this International Standard, the terms "product" or "service" only apply to products and services intended for, or required by, a customer.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

This International Standard applies to organizations supplying ITNS products or services.

Application of this standard to organizations performing activities on a licensed nuclear site is subject to prior agreement by the Licensee.

Requirements specified in this International Standard are complementary (not alternative) to customer and applicable statutory and regulatory requirements.

2 Normative references

ISO 9001:2015, Quality management systems — Requirements

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

ISO 9001:2015, Quality management systems — Requirements

3 Terms and definitions

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

3.1
activity
task which contributes to the realization of the products or services

3.2
commercial grade item or activity
item (see 3.6) or activity (see 3.1) that affects nuclear safety and that was not designed, manufactured or performed in accordance with specific nuclear requirements

Note 1 to entry: Commercial-grade items do not include items where the design and manufacturing process require in-process inspection and verification to ensure that defects or failures to comply are identified and corrected (i.e. where one or more critical characteristics of the item cannot be verified). Critical characteristics are important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Note 2 to entry: The determination of the critical characteristics, the means for verification and acceptance for intended safety functions are the responsibility of the customer.

3.3 Counterfeit/fraudulent/suspect (CFS) item

3.3.1
counterfeit items
items that are intentionally manufactured, refurbished or altered to imitate original products without authorization in order to pass themselves off as genuine

[SOURCE: IAEA NP-T-3.21]

3.3.2
fraudulent items
items that are intentionally misrepresented with intent to deceive

Note 1 to entry: Fraudulent items include items provided with incorrect identification, falsified or inaccurate certification. They may also include items sold by entities that have acquired the legal right to manufacture a specified quantity of an item but produce a larger quantity than authorized and sell the excess as legitimate inventory.

[SOURCE: IAEA NP-T-3.21]

3.3.3
suspect items
items where there is an indication or suspicion that it may not be genuine

[SOURCE: IAEA NP-T-3.21]

3.4
graded approach
process or method employed to ensure that the application of the requirements related to quality management, documentation, monitoring and measurement is commensurate, with nuclear safety significance

3.5
important to nuclear safety
ITNS
characteristic of a product, service, item or activity, whose failure could result in undue radiation exposure of people or the environment

3.6
item
all-inclusive term used in place of any of the following: assembly, component, equipment, material, module, part, software, structure, sub-assembly, sub-system, system or unit

Note 1 to entry: This definition replaces the ISO 9000 definition.

3.7
licensee
holder of a current authorization granted by the nuclear regulator to an organization that has the responsibility for the siting, design, construction, commissioning, operation or decommissioning of a nuclear installation

3.8
nuclear safety
achievement of proper operating conditions, prevention of accidents and mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation risks

[SOURCE: IAEA Safety glossary]

Note 1 to entry: The implementation of a quality management system is essential to ensure nuclear safety.

4 Context of the organization

4.1 Understanding the organization and its context

ISO 9001:2015, Quality management systems — Requirements

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.

The organization shall monitor and review information about these external and internal issues.

NOTE 1 Issues can include positive and negative factors or conditions for consideration.

NOTE 2 Understanding the external context can be facilitated by considering issues arising from legal, technological, competitive, market, cultural, social and economic environments, whether international, national, regional or local.

NOTE 3 Understanding the internal context can be facilitated by considering issues related to values, culture, knowledge and performance of the organization.

External and internal issues shall include nuclear safety considerations.

4.2 Understanding the needs and expectations of interested parties

ISO 9001:2015, Quality management systems — Requirements

4.2 Understanding the needs and expectations of interested parties

Due to their effect or potential effect on the organization's ability to consistently provide products and services that meet customer, applicable statutory and regulatory requirements, 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.

4.3 Determining the scope of the quality management system

ISO 9001:2015, Quality management systems — Requirements

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.

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

ISO 9001:2015, Quality management systems — Requirements

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.

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

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

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.

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.

4.4.3 The organization shall maintain documented information that includes a description of how the requirements of this International Standard are met (e.g. quality manual or quality plan).

5 Leadership

5.1 Leadership and commitment

5.1.1 General

ISO 9001:2015, Quality management systems — Requirements

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;

d) promoting the use of the process approach and risk-based thinking;

e) ensuring that the resources needed for the quality management system are available;

f) communicating the importance of effective quality management and of conforming to the quality management system requirements;

g) ensuring that the quality management system achieves its intended results;

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

i) promoting improvement;

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

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.

Demonstrating the above leadership and commitment, top management shall ensure that nuclear safety is taken into account in decision making and is not compromised by any decisions taken.

5.1.2 Customer focus

ISO 9001:2015, Quality management systems — Requirements

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.

5.1.3 Nuclear safety culture

The organization shall ensure an appropriate nuclear safety culture by consideration of

a) leadership and commitment of top and line management to nuclear safety, ensuring awareness by all personnel of nuclear safety and encouraging a questioning attitude (see 5.1 and 7.3),

b) a balanced, rigorous and prudent approach to decision making with respect to quality, cost and schedule such that nuclear safety is not compromised (see 5.1),

c) transparency in communication (see 7.4),

d) the use of suitable documented information (see 7.5),

e) reporting of human, technical and organizational issues (see 9.3 and 10.2),

f) lessons learned (see 10.1), and

g) challenging unsafe acts, behaviours and conditions (see 10.2 and 10.3).

5.2 Policy

5.2.1 Establishing the quality policy

ISO 9001:2015, Quality management systems — Requirements

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.

e) includes appropriate nuclear safety considerations;

f) includes a commitment to ensure that nuclear safety is not compromised by other priorities.

5.2.2 Communicating the quality policy

ISO 9001:2015, Quality management systems — Requirements

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

ISO 9001:2015, Quality management systems — Requirements

5.3 Organizational roles, responsibilities and authorities

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

Top management shall appoint a member of the organization's management who has

a) the organizational independence and authority to manage nuclear safety and quality issues, and

b) unrestricted access to top management.

6 Planning

6.1 Actions to address risks and opportunities

ISO 9001:2015, Quality management systems — Requirements

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 customers, building partnerships, using new technology and other desirable and viable possibilities to address the organization's or its customers' needs.

The organization shall maintain and retain related documented information.

6.1.3 Determination of ITNS items and activities

The organization shall

a) break down ITNS products and services into items and activities, and

b) determine the items and activities, i.e those whose potential failure or malfunction may jeopardize the products and/or services safety function(s) specified by the customer in line with Licensee's safety classification of Systems, Structures and Components.

The organization shall maintain and retain related documented information.

6.1.4 Graded approach to the application of quality requirements

For items and activities, the organization shall grade the application of requirements related to quality management, documentation, monitoring and measurement taking account of the

a) requirements for ITNS products or services as specified by the customer,

b) complexity of each item or activity, and

c) organizational aspects.

The organisation shall maintain and retain related documented information.

6.2 Quality objectives and planning to achieve them

ISO 9001:2015, Quality management systems — Requirements

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.

Note to a): in accordance with 5.2 e), quality objectives should address nuclear safety.

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

ISO 9001:2015, Quality management systems — Requirements

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.

e) the communication of changes (see 7.4).

Changes to the quality management system shall be managed to ensure nuclear safety is not compromised.

7 Support

7.1 Resources

7.1.1 General

ISO 9001:2015, Quality management systems — Requirements

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.

Determination and provisions of resources shall ensure that nuclear safety is not compromised.

7.1.2 People

ISO 9001:2015, Quality management systems — Requirements

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

ISO 9001:2015, Quality management systems — Requirements

7.1.3 Infrastructure

The organization shall determine, provide and maintain the infrastructure necessary for the operation of its processes 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

ISO 9001:2015, Quality management systems — Requirements

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, non-blaming);

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.

For b), examples of psychological factors include non-blaming.

For c), examples of physical factors include cleanliness.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

ISO 9001:2015, Quality management systems — Requirements

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.

Considering the specified tolerance(s) for the products and/or services, the suitability of the monitoring and measurement resources used shall take into account the measuring range and measurement accuracy.

7.1.5.2 Measurement traceability

ISO 9001:2015, Quality management systems — Requirements

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.

The organisation shall retain as documented information the outputs of the above determination and the actions taken.

7.1.6 Organizational knowledge

ISO 9001:2015, Quality management systems — Requirements

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.

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.

NOTE 1 Organizational knowledge is knowledge specific to the organization; it is generally 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

ISO 9001:2015, Quality management systems — Requirements

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.

Competence shall also address qualification of person(s) when necessary.

Competence and qualification shall be maintained.

7.3 Awareness

ISO 9001:2015, Quality management systems — Requirements

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.

Persons involved in the realization of ITNS products or services shall be trained on the importance of their tasks, including the potential nuclear safety consequences of errors in their activities.

7.4 Communication

ISO 9001:2015, Quality management systems — 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.

NOTE External parties can be licensee/operator, regulatory bodies, national authorities, etc.

7.5 Documented information

7.5.1 General

ISO 9001:2015, Quality management systems — Requirements

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.

7.5.2 Creating and updating

ISO 9001:2015, Quality management systems — Requirements

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, version 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.

Where translation is required, the completeness and accuracy of the translation shall be ensured.

Review and approval shall be performed by competent and authorized individual(s). The organization shall determine when the review shall be performed by individual(s) different from the author(s).

7.5.3 Control of documented information

ISO 9001:2015, Quality management systems — Requirements

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).

c) it is adequately traceable and authenticated.

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.

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.

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.

Personnel shall be made aware of changes to documented information.

The organization shall prevent the unintended use of obsolete documented information.

8 Operation

8.1 Operational planning and control

ISO 9001:2015, Quality management systems — Requirements

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, maintaining and retaining 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).

Operational planning and control shall consider project and configuration management aspects.

In considering the above requirements, schedule and interface management shall be taken into account.

8.1.1 Provisions for counterfeit, fraudulent or suspect (CFS) items

The organization shall prevent CFS items at all levels of operations including

a) selection of external providers (see 8.4.1),

b) specific information to external providers (see 8.4.3), including requirements for control of their sub tier providers,

c) control of externally provided processes, products and services (see 8.4.2), and

d) monitoring and measurement activities (see 8.5.1.2).

When CFS items are detected, they shall be managed as nonconformities (see 10.2) and relevant parties, including the customer, shall be informed without delay.

8.2 Requirements for products and services

8.2.1 Customer communication

ISO 9001:2015, Quality management systems — Requirements

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.

f) managing the interfaces with external parties.

8.2.2 Determination of requirements related for products and services

ISO 9001:2015, Quality management systems — Requirements

8.2.2 Determining the requirements related to 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 the requirements for products and services

ISO 9001:2015, Quality management systems — Requirements

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.

The review shall involve all relevant functional groups associated with the supply of the products or services (e.g. design, procurement, manufacture, quality, inspection and test).

ISO 9001:2015, Quality management systems — Requirements

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.

c) on the actions taken as the results of the review in a).

8.2.4 Changes to requirements for products and services

ISO 9001:2015, Quality management systems — Requirements

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 requirements for products and services are changed.

Changes to requirements for products and services shall be properly managed (see 8.2.2 and 8.2.3).

8.3 Design and development of products and services

8.3.1 General

ISO 9001:2015, Quality management systems — Requirements

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.

The design and development process shall identify the internal and external design interfaces and associated controls.

The design and development activities shall be documented and detailed enough to avoid ambiguity or misunderstanding and to demonstrate that the products or services meet the requirements for their specific intended use or application.

Where design tools (e.g. computation codes or computerized models) are used, the organization shall demonstrate that these are fit for purpose.

8.3.2 Design and development planning

ISO 9001:2015, Quality management systems — Requirements

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.

For b), the required process stages shall identify those stages requiring authorization before progressing to the next stage.

8.3.3 Design and development inputs

ISO 9001:2015, Quality management systems — Requirements

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

ISO 9001:2015, Quality management systems — Requirements

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.

For b), when relevant [see 8.3.2 b)], reviews shall include authorization to progress to the next stage.

Verification and validation of design and development shall be performed by competent person(s) or group(s) different from those having performed the design.

Documented information for design and development controls shall be maintained.

8.3.4.1 Design and development verification and validation testing

Where tests are necessary for verification and/or validation of the design, these tests shall be planned, performed, controlled, reviewed and documented to ensure:

a) test plans and/or specifications identify the products and/or services being tested and the resources being used;

b) test plans and/or specifications define test objectives and conditions (including most adverse conditions), parameters to be recorded and relevant acceptance criteria;

c) test procedures describe the method of operation, the performance of the test and the recording of the results;

d) correct configuration of the products and/or services is submitted for the test;

e) requirements of the test plan and test procedures are met;

f) acceptance criteria are met.

8.3.5 Design and development outputs

ISO 9001:2015, Quality management systems — Requirements

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.

The organization shall ensure that design and development outputs specify the conditions under which commercial grade items or activities can be used as ITNS items or activities.

8.3.6 Design and development changes

ISO 9001:2015, Quality management systems — Requirements

8.3.6 Design and development changes

The organization shall identify, substantiate, 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 including substantiation;

b) the results of reviews;

c) the authorization of the changes;

d) the actions taken to prevent adverse impacts.

Documented information shall include substantiation of design and development changes.

The personnel involved in the design and development changes shall be designated, competent in the specific design area and have knowledge of the requirements and the intent of the original design.

8.4 Control of externally provided processes, products and services

8.4.1 General

ISO 9001:2015, Quality management systems — Requirements

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.

Controls to be applied to externally provided processes, products and services shall consider any level of the supply chain and take into account the graded approach outputs (see 6.1.4).

NOTE Compliance with this document can be considered as a criterion for external provider qualification which can also consider other criteria like the occupational safety, security, technical capability and capacity, environment, socio-economic aspects.

The organization shall be responsible for demonstrating equivalence of provisions taken when an external provider, responsible for an ITNS items or activities, cannot demonstrate that its quality management system meets the requirements of this document.

The result of evaluation of external providers shall be valid for a limited period of time and a stated scope.

The organization shall maintain and retain documented information related to control of external providers.

8.4.2 Type and extent of control

ISO 9001:2015, Quality management systems — Requirements

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.

The organization shall define and implement the responsibilities and authorities for control of externally provided processes, products and/or services.

For c) 2), controls applied by the external provider shall include appropriate control of its supply chain.

For d), the verification shall consider the critical characteristics of commercial grade items or activities.

The organization shall be responsible for the conformity of all externally provided processes, products and/or services.

8.4.3 Information for external providers

ISO 9001:2015, Quality management systems — 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 provider's interactions with the organization;

e) control and monitoring of the external provider's performance to be applied by the organization;

f) verification or validation activities that the organization, or its customer, intends to perform at the external provider's premises.

For a), the requirements for the processes, products and services to be provided [see 8.4.3 a)] shall include

1) associated quality management system requirements,

2) technical specifications (including instructions and acceptance criteria for the products and services),

3) list of applicable documentation such as drawings, codes, standards, regulations, with their reference, revision and, if appropriate, status,

4) identification of the documentation that the external provider must submit, and

5) identification of spare parts and the related data required for ordering these spare parts,

For b) 1), the requirements for approval of products and services shall include approval of associated documentation.

For d), the requirements for the external provider's interactions with the organization shall include the need for the external provider to

1) notify the organization of nonconforming products and services including CFS items,

2) obtain the organization's approval for nonconforming products and services disposition,

3) notify the organization of changes in products and services, changes of sub external providers, changes of manufacturing facility location and, where required, to obtain the organization's approval, and

4) provide access to the organization, its customers, third party organizations, regulatory bodies, and/or their respective representatives, to the relevant areas of all facilities, at any level of the supply chain, involved in the order and to all relevant information,

The organization shall communicate to external providers its requirements for passing down relevant requirements to all levels of its supply chain.

The organization shall review its requirements for adequacy prior to communication to external provider, ensuring cascading of relevant customer requirements.

Procurement changes affecting the requirements shall be subject to the same process and control as used in the production of the original requirements.

The organization shall retain relevant documented information.

8.5 Production and service provision

8.5.1 Control of production and service provision

ISO 9001:2015, Quality management systems — Requirements

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.

i) customer and applicable statutory and regulatory requirements related to monitoring and measurement activities (see 8.5.1.2);

j) evidence that all production and monitoring and measurement activities have been completed as planned [see 8.1 e)], or as otherwise authorized and documented;

k) top management involvement to ensure that product conformity and on-time delivery performance are measured and that appropriate action is taken, if planned results are not, or will not be, achieved, while, at the same time, ensuring that nuclear safety is not compromised.

Controlled conditions shall take into account the graded approach outputs (see 6.1.4).

8.5.1.1 Control of production equipment

Computer controlled aided production equipment shall be validated as required prior to release for production and shall be maintained.

Storage requirements, including periodic preservation/condition monitoring, shall be defined for production equipment or tooling in storage.

8.5.1.2 Monitoring and measurement activities

The provisions and methods used for these monitoring and measurement activities shall take into account the graded approach outputs (see 6.1.4).

For ITNS items and activities, monitoring and measurement intended for product acceptance shall be performed by competent persons different from those who performed the work.

Documented information shall be retained, identifying, as a minimum, the following:

a) item inspected;

b) monitoring or measurement performed;

c) date of performance;

d) identification of personnel who performed;

e) reference of the documented information used;

f) acceptance criteria;

g) acceptability;

h) if necessary, follow up actions including information on actions taken in connection with nonconformities.

8.5.2 Identification and traceability

ISO 9001:2015, Quality management systems — Requirements

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.

When identification marks or labels are used, the organisation shall ensure that these do not prejudice product conformity.

Where media are used for identification of persons (e.g. stamps, electronic signatures), the organization shall establish appropriate controls for their usage, including clear identification of the user.

8.5.3 Property belonging to customers or external providers

ISO 9001:2015, Quality management systems — Requirements

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

ISO 9001:2015, Quality management systems — Requirements

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.

For the prevention of ITNS products deterioration which may compromise their intended use, preservation shall consider

a) access limitation to avoid undue intervention,

b) cleaning,

c) prevention, detection and removal of foreign objects,

d) special handling for sensitive products or hazardous materials, and

e) identification and labelling, including safety warnings.

8.5.5 Post-delivery activities

ISO 9001:2015, Quality management systems — Requirements

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.

The following also applies:

f) actions to be taken, including investigation and reporting, when problems are detected after delivery.

8.5.6 Control of changes

ISO 9001:2015, Quality management systems — Requirements

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 and assessment of changes, the persons authorizing the change, and any necessary actions arising from the review.

8.6 Release of products and services

ISO 9001:2015, Quality management systems — Requirements

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.

c) statement of conformity.

The organization shall ensure that all required documented information is present at delivery.

8.7 Control of nonconforming outputs

ISO 9001:2015, Quality management systems — Requirements

8.7 Control of nonconforming outputs

8.7.1 The organization shall ensure that outputs that do not conform to their requirements are timely 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.

The following also applies:

e) taking actions necessary to contain the effect of the non-conformity on other processes or products;

f) scrap.

For c), information to the customer shall include those non-conformances to be reported.

For d), where applicable, a “use-as-is” or repair justification shall be approved by the customer.

For ITNS items or activities, at least b), c), e) shall be developped for nonconforming outputs.

NOTE The disposition of a nonconforming item can be delayed pending the results of a root cause analysis.

Documented information for the control of nonconforming outputs shall be maintained.

ISO 9001:2015, Quality management systems — Requirements

8.7 Control of nonconforming outputs

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.

For b) and c), the description shall include justifications.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

ISO 9001:2015, Quality management systems — Requirements

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.

In determining the above, the organization shall consider demonstration of conformity to products and/or services requirements and the ability of the processes to achieve planned results.

9.1.2 Customer satisfaction

ISO 9001:2015, Quality management systems — Requirements

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 or services, meetings with customers, market-share analysis, compliments, warranty claims and dealer reports.

9.1.3 Analysis and evaluation

ISO 9001:2015, Quality management systems — Requirements

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.

The following also applies:

h) nuclear safety culture aspects.

9.2 Internal audit

ISO 9001:2015, Quality management systems — Requirements

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.

For a), the following also applies:

3) customer requirements.

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.

Auditors shall be qualified [see 7.2 a)] and shall not audit the work that they have undertaken or had direct responsibility for.

9.3 Management review

9.3.1 General

ISO 9001:2015, Quality management systems — Requirements

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.

Nuclear safety shall receive the attention warranted by its significance.

9.3.2 Management review inputs

ISO 9001:2015, Quality management systems — Requirements

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 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.

For f) opportunities shall include lessons learned from nuclear experience.

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

10.1 General

ISO 9001:2015, Quality management systems — Requirements

10 Improvement

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.

The following also applies:

d) lessons learned from experience;

e) risk mitigation;

The following can also apply:

f) technical advances and research and development;

g) methods for identifying good practices.

The organization shall provide adequate resources for improvement plans.

The organization shall share with its customer and disseminate to its supply chain organizations relevant learning from experience.

10.2 Nonconformity and corrective action

ISO 9001:2015, Quality management systems — Requirements

10.2 Nonconformity and corrective action

10.2.1 When 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

The organization shall ensure that nonconformities and corrective actions are managed and reported without undue delay to the relevant level of management and, as appropriate, to the customer.

For b) 1), the analysis shall include the impact assessment of the nonconformity.

For b) 2), root cause analysis shall be undertaken as applicable.

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

ISO 9001:2015, Quality management systems — Requirements

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.

Continual improvement shall encompass nuclear safety culture.

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