FILIANCE
Filière de confiance

GUIDELINES FOR IMPLEMENTATION OF ISO 19443

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English version

Contents

Abstract

This guideline published by Filiance, gives several keys to reading ISO 19443, a management standard for quality and nuclear safety systems intended for nuclear suppliers. The main themes introduced by the standard, the expectations, and the good practices are explained. The keys to reading the standard are detailed in 13 guide sheets.

The document has been updated (Rev.1) in Novembre 2023 in order to introduce the feedback after 2 years of implementation of the ISO 19443 Certification.

Note: The reference document remains the French version.

Foreword

ISO 19443 is a standard for quality management systems that is applicable to companies operating in the nuclear energy sector. It provides the nuclear supply chain with an organizational structure based on the management of quality and nuclear safety. It aims to reaffirm the place of nuclear safety as the central focus of all nuclear industry suppliers that adopt it: "*It's a vade mecum that answers all their questions*."

In some workshops, nuclear safety may seem remote: nuclear risk awareness is different for those working on or near a nuclear reactor, and those operating a range of machine tools. However, nuclear safety is likewise dependent on the work practices of all the stakeholders in the nuclear equipment supply sector, who are key intermediaries. ISO 19443 sets out how the quality and nuclear safety cultures shall structure and strengthen the values of the company and underline each individual's actions. All stakeholders shall understand the principle – and shall incorporate it in their daily practices – that the safety of the nuclear facilities in which they work, or which will receive their product or service, is equally dependent on them.

ISO 19443, strictly implemented in all relevant company departments and requiring the involvement of all, guarantees the practical application of the fundamental values of nuclear safety culture, and its thorough and lasting adoption.

ISO 19443 certification, issued by accredited bodies (themselves subject to strict specifications: ISO/TS 23406), provides all the actors in the supply chain who have obtained it an objective and factual guarantee of the implementation of a quality and nuclear safety management system. And by so doing, it renews the contract of trust that binds them to the licensees, who are themselves responsible for the nuclear safety of their installations.

The members of the French Nuclear Industry Association GIFEN are determined to meet the major challenge of reasserting a set of values that confirm the place of nuclear safety as the uppermost priority of the actors in the supply chain. And, of course, they seek to foster its practical deployment in a manner that is adapted to their daily practices and evolves in light of the safety challenges faced by all.

The purpose of this guide is to help both suppliers and auditors understand the operational expectations associated with the requirements of nuclear sector standards. It supplements, but does not replace, the guide to ISO/TR 4450.

The editorial position of this guideline is:

- To present (Part 1) the key themes introduced by ISO 19443,
- To set out (Part 2) the expectations and good practices relating to the chapters of ISO 19443.

Guideline sheets are given for some of the requirements in the standard, in order to:

- Clarify the phrasing of certain points in one (or several) standards and facilitate understanding,
- Standardise the auditors' evaluation practices,
- Highlight some possible good practices that could be implemented.

These guidelines are intended to provide a concrete and practical response to the issues raised by the implementation of the standard. Accredited bodies can consult them for clarification on certain points. They are designed to preclude any conflicting interpretations.
Any potential difficulties in either applying them or using them shall be reported to FILIANCE to ensure that they are addressed and bring about a revision of the existing document.

The guide sheets in Part 2 of this document provide companion notes for the particular requirements of ISO 19443 that represent additions to ISO 9001. The requirements under ISO 9001, incorporated in ISO 19443, are not set out in detail, beyond a clarification of their framework of application. Related definitions can be found in ISO 9000.

All the requirements defined in ISO 19443 remain applicable in the context of an audit; it is well understood that the audit findings shall make exclusive reference to the requirements of the standard and shall in no case make reference to this guideline.

At the end of the document, definitions, acronyms and abbreviations are clarified in the glossary and all the references are listed in the bibliography.

1 Part 1. The key themes of the standard

Among the key themes or enhanced themes (in relation to ISO 9001) introduced by the ISO 19443 standard, along with definitions, we have selected six themes that will be explained in Part 1 of this guide:

1. Nuclear safety and nuclear safety culture requirements for organizations supplying nuclear products and services
2. Counterfeit, fraudulent or suspect (CFS) items
3. Breakdown of ITNS/non-ITNS and graded approach
4. Control of the supply chain
5. Traceability
6. Skills.

1.1 Nuclear safety and nuclear safety culture in organizations in the supply chain of the nuclear energy sector, supplying products and services important to nuclear safety (ITNS)

1.1.1 Foreword – Nuclear safety and nuclear safety culture in ISO 19443

ISO 19443 makes a total of 14 references to “nuclear safety” and 4 references to “nuclear safety culture” in the requirements set out in §4 to §10 of the standard.

Nuclear safety is defined in the standard (§3.8 of ISO 19443 – Source IAEA) as “The achievement of proper operating conditions, prevention of accidents or mitigation of accident consequences, resulting in protection of workers, the public and the environment from undue radiation risks.”

The International Atomic Energy Agency (IAEA) defines safety culture as “The assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance”. One of its key components relates to the general practice of thinking in terms of nuclear safety, which implies a questioning attitude, a refusal to be satisfied with present achievements, a constant regard for quality, and a commitment to accountability and collective self-discipline in relation to nuclear safety.

These definitions apply to all nuclear sector stakeholders: licensees, manufacturers, inspection bodies, etc.

These definitions are applied in practice, on a daily basis, by all those working in a nuclear facility or in the immediate vicinity of such an installation. Additional examples of their practical application may be required for organizations whose activities may lead directly to an accident with radiological consequences for people or the environment, including in particular the majority of suppliers of products and services falling under the requirements of ISO 19443 but “nowhere near a nuclear risk”.

Bearing this in mind, the themes governing “nuclear safety” and “nuclear safety culture” are developed and clarified below, with a particular focus on these organizations that are “nowhere near a nuclear risk”.

1.1.2 Nuclear safety – Practical implementation

In a bid to help with the practical implementation of the requirements set out in the standard, this guide provides a more comprehensive understanding of the concept of nuclear safety for organizations in the supply chain of the nuclear sector, supplying products and services important to nuclear safety (ITNS), based on the definition proposed in France, in the Environment Code (article L. 591-1): “Nuclear safety encompasses all the technical provisions and organizational measures relative to the design, construction, operation, shutdown and decommissioning of basic nuclear installations, and to the transport of radioactive materials, that are taken with a view to preventing accidents or mitigating their consequences.”

The licensee or the client ordering a product or service defines the requirements in order to ultimately meet the operating requirements and the safety case requirements of the nuclear facility.

The technical characteristics of the product or service provided by the supplier shall therefore comply with the necessary technical requirements, and the demonstration of conformity is used by the licensee in the nuclear facility safety case detailed the safety report.

The supplier’s product or service and its associated technical file (demonstrating conformity with technical requirements) have a direct impact on nuclear safety. Therefore, the technical provisions (as defined in the French Environment Code) that have a direct impact on nuclear safety are those that - during production of the product or service - may influence the technical characteristics and cause them to deviate from the required values.

These technical provisions can vary from supplier to supplier, or can be specific to their sector and to their place in the value chain of the nuclear industry. Clear identification of these provisions is recommended.

The most important and most common of these are the following:

- Conformity with the technical requirements (regulatory and client requirements) by means of work procedures and instructions (which shall provide an operational interpretation of the contractual requirements) that shall then be strictly followed, and their rigorous implementation by the suppliers.
- A culture of demonstration of conformity (the ability to provide solid evidence of claims made) and of traceability (the ability to trace operations), in particular for those characteristics that cannot be verified once the product has been manufactured, in order to ensure an exhaustive, robust and reliable finished product or service file.
- A clear understanding of the nuclear safety challenges that the product or service presents for the nuclear facility, in other words, an appreciation of how the characteristics of the delivered product or service are used in the nuclear facility safety case.

For a supplier, nuclear safety is taken into account by way of an organization, production processes and behaviours that ensure the conformity of deliverable products and services with the technical requirements (through relevant documented information) and enable full control of all the (technical, human and organizational) factors that - during production of the product or service - may influence the technical characteristics and cause them to deviate from the required values.

1.1.3 Nuclear safety culture

ISO 19443 makes 4 references to "nuclear safety culture", for which it defines a set of minimum characteristics in §5.1.3:

"*The organization shall ensure an appropriate safety culture by consideration of:*

a. *Leadership and commitment to nuclear safety of top and line management, 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. *Use of suitable, documented information (see §7.5);*
e. *Reporting of human, technical and organizational issues (see §9.3 and §10.2);*
f. *Operating experience (see §10.1);*
g. *Challenging unsafe acts, behaviours and conditions (see §10.2 and §10.3).*"

In addition, Guide Sheet #1 in this document provides details of points a) and b) of §5.1.3 to help compliance.

1.1.4 Safety culture good practices for nuclear product or service providers

During their evaluations, the auditors are invited to seek good practices that can be effectively implemented in the nuclear energy supply chain organizations providing products and services that are important to nuclear safety (ITNS), both in terms of nuclear safety – through control, in particular, of the technical provisions that influence nuclear safety – and the deployment of a safety culture, as detailed in the licensee standards drafted by WANO, INPO and the IAEA.

The auditors may focus on certain technical, human and organizational measures implemented by the suppliers of nuclear products and services, that impact nuclear safety, such as:

- Conformity with the technical requirements (regulatory and client requirements), with any exemptions approved by the client,
- A culture of demonstration of conformity (the ability to provide solid evidence of claims made) and of traceability (the ability to trace operations),
- A clear understanding of the nuclear safety challenges of the product or service for the nuclear facility.

And they may also focus on the organizational and human traits that are in common with nuclear operators:

- Personal commitment, where every person has a sense of personal accountability for nuclear safety, applies a questioning attitude, and promotes a culture of challenge, discussion and transparent communication,
- The commitment of management, whose behaviour and decision-making bear witness to their determination to ensure that nuclear safety has overriding priority, through leadership by example, a trusting environment and the stated objective of prohibiting or eradicating all "fraud or concealment",
- A management system that fosters a culture of learning (ISO 19443 §10.1), the reporting of issues and use of lessons learned, problem resolution, successful work execution on the strength of good preparation and planning, and appropriate documentation.

During audits, these traits of safety culture will clearly be identified as good practices - when they are not requirements directly cited in the standard - and will be highlighted at the end of the audit.

1.2 Counterfeit, fraudulent or suspect (CFS) items (CFSI)

There is growing concern worldwide over the infiltration of counterfeit, fraudulent and suspect items across all industrial sectors. These items can be defined as follows [definitions given in §3.3 of the ISO 19443 standard):

- *"Counterfeit items":* items that are intentionally manufactured, refurbished or altered to imitate original products, without authorisation, in order to pass them off as genuine [Source: IAEA NP-T-3.21].
- *"Fraudulent items":* items that are intentionally misrepresented with the intent to deceive [Source: IAEA NP-T-3.21].
- *"Suspect items":* items for which there is an indication or suspicion that they may not be genuine [Source: IAEA NP-T-3.21].

<table>
<tr><td colspan="2">Genuine item</td><td colspan="2">Non-genuine item</td></tr>
<tr><td>Conforming item</td><td>Non-conforming item</td><td>Counterfeit item</td><td>Fraudulent item</td></tr>
<tr><td colspan="4">Suspect item</td></tr>
</table>

These items include, for example, base materials, consumables, components, or equipment as a whole. To illustrate, this may include:

- falsifying documents (deliberate alteration of the contents of reports or conformity certificates, actions seemingly but not in reality carried out, the use of data for purposes other than those for which it was intended, etc.),
- selling counterfeit components that are visually identical but do not have the same technical characteristics as the original.

Note: Lack of traceability (including in the evidence of conformity) leads to an increased risk of counterfeit, suspect or fraudulent products.

When this relates to ITNS products and services, it represents a potential threat to the nuclear facility.

Thus organization shall be fully aware of the issue and consequently implement measures to identify and prevent the onset, introduction and even use of these items and activities in:

- the supply of products,
- the services entrusted to external providers,
- their own activities.

The risk of CSFI shall therefore be addressed to stop them occurring or, failing that, for purposes of detection at the earliest opportunity when they do, across all levels of activity (from procurement to supply).

1.3 ITNS/non-ITNS breakdown, and graded approach

These two concepts were introduced into the ISO 19443 standard to enable the use of a graded approach in the application of the quality requirements to the different constituent items and activities of a ITNS product or service.

In practice, the graded approach as described in the standard is based on a breakdown of the products and services into two categories:

- ITNS items and activities;
- Non-ITNS items and activities.

Note 1 : the degree of detailed breakdown of the product or service factors in the complexity of the product or service, which can be clarified during development. It is for the organization to determine the appropriate degree of breakdown.

Note 2 : The guide to ISO/TR 4450 sets out a valid methodology for identifying within a ITNS product the items or activities that are ITNS and the items or activities that are not ITNS (see §6.1.4 and appendices E and F, along with Guide Sheet #3 in this document).

The ISO 19443 standard has specified three areas requiring a graded approach:

- The quality management requirements that are applicable to external providers,
- The content and depth of analysis of the documentation associated with the product or service,
- The level of monitoring and quality measurement that is applied to the product or service.

The guide to ISO/TR 4450 sets out the methodology to be applied (see §6.1.3 and appendices C and D, along with Guide Sheet #3 in this document).

It should be noted that the ISO 19443 requirement to apply a graded approach does not come with any criteria allowing the licensee or regulator to determine the acceptability of the chosen graded approach. So, for example, grading the application of the technical requirements, and thus facilitating their implementation, should be done based on industry-accepted professional standards that offer a graded approach.

1.4 Control of the supply chain

In a nuclear context, due consideration shall be given to control of the supply chain, across all levels:

- The providers of ITNS products and services, across all tiers, shall be identified and periodically evaluated on the following:
  - Technical performance: capacity to supply a product or service that demonstrates first-time-right conformity, including qualification requirements, such as compliance with codes and standards, and schedule adherence,
  - Quality and nuclear safety culture: quality management system compliance with the applicable requirements specified, lessons learned from previous purchase orders, number of complaints raised by the organization, completeness of the quality management documentation provided for past deliveries, follow-up of outputs, qualification of technical personnel, and the resilience (financial health, integrity, etc.) of the instructing party.

Other aspects such as responsiveness, cost and so on can be considered in addition to the contractual provisions.

- The providers of ITNS products and services, across all tiers, receive and draw up necessary and sufficient specifications, in written form if so required, identifying the ITNS classification of the outsourced supplies and/or services, the extent of control required, the skills needed to deliver the product or service, the expected outputs, and the degree of associated traceability.
- Communication and information channels are established with the instructing party or client, in order to share and decide on possible changes, exemptions, nonconformities, suspected or established fraud, and chosen measures.

Implementing ISO 19443 is a progressive process, and many tier 2 and 3 suppliers (and beyond), have not initiated the certification process. In such a case, it might be difficult to fulfil requirement §8.4.1 which stipulates that "*The organization shall be responsible for demonstrating equivalence of provisions taken when an external provider, responsible for ITNS items or activities, cannot demonstrate that its quality management system meets the requirements of this international standard."* Among the provisions taken to justify this equivalence, special attention is to be paid to all the measures designed to guarantee the fulfilment of client technical requirements, quality of design, production and inspection of the product, and the authenticity of the documents demonstrating the technical characteristics of the product. The organization will supplement these actions through a surveillance activity.

1.5 Traceability

The traceability of the information that forms the basis of the demonstration of compliance with the requirements that underpin conformity and nuclear safety is paramount.

In France, this is a regulatory requirement (the decree governing nuclear facilities). In the absence of supporting evidence, the product or service may be rejected.
For example, in the safety case for a piece of equipment that only fulfils a function in accident conditions, and where its specifications shall therefore withstand the loads placed on it (seismic resistance, radiation resistance, resilience to the design basis thermohydraulic accident, etc.), normal plant operation gives no indication of its performance in accident conditions: it is the technical file drawn up during its manufacture that provides the constituents of the safety case. All supporting evidence of a technical feature that is valuable to the safety case shall be recorded for subsequent retrieval if necessary.

The implementation of certain manufacturing processes is subject to prior qualification demonstrating that strict compliance with an operating procedure guarantees that the component has attained the desired characteristics (mechanical strength, homogeneity, weld quality, etc.). The traceability of compliance with the operating procedure used is essential for a long-term guarantee of the component's characteristics.

To illustrate, traceability could take into account the following:

- Materials: different materials and consumables used,
- Environment: location, date and conditions of production,
- Methods: procedures used, calculations, operational qualification,
- Equipment: equipment, machinery and tools used
- Workforce: human resources, and associated skills and/or qualifications.

For more information: refer to §1.3 and to Guide Sheets #3, #4 and #7 in this document.

1.6 Skills

Skills play a key part in determining the acceptability of a result. This is the case, for example, for the implementation of processes/methods that can only be verified through destructive testing or that may alter the product (so-called special processes such as welding, calculations, thermal treatment, etc.).
Aside from contributing to the demonstration of the acceptability of a result, the skills of the operatives producing a service or a product can significantly affect the quality of the end result.
These types of skills are referred to as key skills. They shall be identified in the company and managed.
Managing skills requires first an understanding of what they are based on, a definition of levels of proficiency (the ability to apply knowledge), periodic evaluations by subject-matter specialists, and conditions for maintaining these skills and, failing that, changing them.
The definition and management of skills shall ensure that the required skills are assigned to the completion of each task.
Skills also encompass understanding and controlling the environment, and thus an awareness of safety culture, of fraud prevention, and of the consequences of an error in work execution, in terms of quality and nuclear safety.

1.7 Conclusions on the key themes of the standard and their use in this guide

FILIANCE is of the view that the standard's key themes highlighted in this guide are those that most contribute to quality and nuclear safety in ISO 19443 certification.

Suppliers beginning the process of certification can use these companion notes to move towards a quality management system that offers greater control, an improved company performance in relation to CFSI, the graded approach, the determination of ITNS items, the management of requirements and their impact on the supply chain, traceability and, most of all, improved performance in regard to a safety culture that is adapted to its environment.

As a result, these companion notes are intended to guide the auditor in highlighting good practices, and identifying areas for improvement and watch-points related to these key themes.

2 Part 2. The requirements of ISO 19443

2.1 General information on the guide sheets

The guide sheets are ordered in accordance with the main chapters of the standard, with the following breakdown:

- Chapter 5 [Leadership]: 2 sheets.
- Chapter 6 [Planning]: 1 sheet.
- Chapter 7 [Support]: 2 sheets.
- Chapter 8 [Operation]: 6 sheets.
- Chapter 9 [Performance evaluation]: 1 sheet.
- Chapter 10 [Improvement]: 1 sheet.

Each guide sheet singles out specific ISO 19443 requirements in the relevant chapter. Not all the requirements are adressed. The shortlist is an editorial choice made by FILIANCE on the basis in particular of available lessons learned on difficulties in understanding and/or applying a requirement.

Each guide sheet sets out, for each shortlisted requirement:

- Guidance to understanding the requirement,
- The expectation relating to the requirement,
- Good practices deemed to fulfil the requirement that the auditor can possibly point out
- Associated requirements in other chapters of the ISO 19443 standard, or other requirements, as specified.
- “Find out more”, with suggestions for further reading on the requirement.

2.2 Guide sheets for ISO 19443 requirements

2.2.1 Guide Sheet #1 Leadership and commitment (Part 1)

Topic	**LEADERSHIP AND COMMITMENT: NUCLEAR SAFETY CULTURE**	**Requirements: §5.1.1, §5.1.3, §5.2**
Overview	Chapter 5.1 "Leadership and commitment" in ISO 9001 contains two sections: • §5.1.1 "General" • §5.1.2 "Customer focus" ISO 19443 adds a nuclear safety aspect to requirement §5.1.1 and a new sub-chapter: • §5.1.3 "Nuclear safety culture" ISO 19443 supplements requirement 5.2 "Establishing the quality policy" with an obligation for the organization to commit to nuclear safety. Lastly, §5.3 of ISO 19443 requires that top management select a member of the organization's management who has the organizational independence and authority to manage nuclear safety and quality issues. These individuals have unrestricted access to senior management, and the necessary independence and authority (see Guide Sheet #2).	
Expectations	The new additions of § 5.1.1 and 5.1.3 concentrate on the concept of nuclear safety. The first calls for top management to guarantee that its decision-making process takes into account nuclear safety and potential related impacts. The second introduces the concept of nuclear safety culture. The senior management of a nuclear product or service provider are committed to nuclear safety: • The decisions taken with respect to quality, cost and schedule shall not compromise either the fulfilment of the technical requirements (regulatory and client requirements) governing the product or service, or the quality of the product or service delivered (completeness, robustness, reliability), or human and organizational factors. • The development and endorsement of the quality policy shall include a commitment to the adoption of the concepts of safety culture. More specifically, the commitment of senior management shall encompass the dissemination and the acceptance by all of the principles of nuclear safety culture. This acceptance is one of the fundamentals that is applicable to the organizations in the nuclear supply chain, providers of products and services that are important to nuclear safety, in particular, the nuclear safety culture requirements detailed in §1.2 of this document, and reiterated in §5.1.3 in subparagraphs a) to g). §5.1.3 on nuclear safety culture requires in-depth investigation by the auditor, on the basis of the nuclear safety culture requirements. To this end, the auditor shall first and foremost ensure that for each requirement [subparagraphs a to g)] there is sufficient evidence of the following:	

	• Nuclear safety is indeed included in the formal statement and undertaking signed and communicated by senior management, aimed at both personnel and other internal and external stakeholders (see the sheet on the requirements under chapter 5.2 Policy); • The top management and line management are committed to safety culture (deployment, internalisation, etc.); • Messages, policies and objectives have been effectively cascaded down to all personnel; • §7.3: all company personnel involved in any operational or functional activities with a nuclear safety impact have been made aware of nuclear safety. Awareness includes the concept of a questioning attitude, and is encouraging all personnel to apply a questioning attitude during work execution and during the implementation of all processes, whether operational or functional. With regard to this subparagraph and chapter 7.3 on awareness, the auditor ensures that "personnel involved in the production of ITNS products and services have been trained on the importance of their tasks, and understand the potential nuclear safety consequences of errors in their activities." Note: this approach assumes that the risks to nuclear safety presented by worker tasks have – with the operator's assistance – undergone prior analysis to identify the potential consequences of errors on nuclear safety by clients. This point concerning the risk assessment of tasks shall be examined by the auditor. • The practice of a rigorous and prudent approach to decision-making is demonstrated, and in particular that resources needs have been identified, safety significant processes (for example, design, manufacture, etc.) have been correctly resourced in terms of numbers and quality, and that this is documented (for example, in senior management review meeting reports, etc.). The auditor asks specifically for concrete evidence from the areas of activity of the different reporting lines (for example from the managers of the finance, human resources, quality, and purchasing departments). • §7.4 and §8.4: the auditor checks that the company (through its purchasing department, for example) ensures that the nuclear safety requirements are properly communicated to suppliers and to the entire supply chain; • §7.5: the company has a system in place to ensure that only the appropriate versions of documents are used (for example through an electronic document management system) and prevent the use of obsolete documents. At §9.1.3 and §9.3.2, the gathering of information derived from lessons learned and their analysis are available , and the auditor verifies on the basis of concrete facts that the company makes effective use of lessons these learned process (internal procedures, identification of sources of internal and external lessons learned , senior management review reports, changes stemming from one or more events reports, continuous improvement measures associated with relevant lessons learned , etc.).

Good practices	**Examples of good practices** (what could be seen as a strength?) A good practice for an organization is the ability to showcase: • Technical provisions that are unique to them (specific to the company or industrial sector in question) and contribute to nuclear safety. • The internal procedures for communicating these provisions to all personnel involved in these activities. • The planned provisions include: • Compliance with the technical requirements (regulatory and client requirements) and their strict implementation by suppliers. • A culture of demonstration of conformity (the ability to provide solid evidence of claims made) and traceability (the ability to trace operations). • Encouragement of all personnel involved in these activities to apply a questioning attitude, and the establishment of a system for logging the questions raised. Top management and line management are committed to: • Highlighting the safety challenges associated with the product/service provided, • Maintaining dialogue that reinforces trust and understanding among all interested parties, • Creating a climate of professionalism and trust, that fosters and values a questioning attitude among the personnel. The arrangements for processing operating experience are organised and described in a detailed process. Teams are regularly made aware of the impact of their activities on nuclear safety. Safety Culture maturity is checked periodically There are regular checks to measure the maturity of the safety culture. For this purpose, suitable questionnaires, such as those produced by GIFEN or the IAEA, are used to evaluate improvements in the quality of the safety culture, at intervals set in accordance with its maturity within the organization.
Associated requirements	• §7.3 - §7.4
Find out more	• Guide to ISO/TR 4450, Appendix I • IAEA Harmonized Safety Culture Model (May 2020), describing the 10 traits of a strong safety culture: - Personal accountability - Questioning attitude - Communication - Leadership accountability / Decision-making process - Work environment - Continuous learning - Problem identification & resolution - Environment for raising concerns - Work processes • IAEA: INSAG 4; IAEA safety culture self-assessment • WANO: Traits of a healthy safety culture (WANO-PL-2013-1-Pocketbook-French.pdf.aspx) • GIFEN safety culture survey.

2.2.2 Guide Sheet #2 - Leadership and commitment (Part 2)

Topic	§5.3: ORGANIZATIONAL ROLES, RESPONSIBILITIES AND AUTHORITIES WITHIN THE ORGANIZATION	Requirement: § 5.3
Overview	Under the ISO 9001 standard, "Top management shall ensure that the responsibilities and authorities for relevant roles are assigned, communicated and understood throughout the organization." ISO/TS 9002 makes clear that responsibilities and authorities can be "assigned to one or more persons […] to be able to make decisions and effect change to the area and/or processes to which they have been assigned. […] Overall responsibility for the quality management system remains with top management." Relevant roles under ISO 19443 are those that are directly linked to ITNS products or services, in terms of operational activities (production, design, project, etc.), as well as monitoring activities (inspections, test verifications, document approval, etc.) and functional or support processes (human resources, training, environment, etc.). Senior management is therefore responsible for identifying the relevant roles, and for assigning and communicating their responsibilities and authorities. The task of these players is to serve as links to the senior managers they report to, for example through management reviews (see §9.3) or regular reports, via a system for managing events or improvement measures, etc. In addition to the requirements of ISO 9001, the ISO 19443 standard stipulates the following: "top management shall appoint a member of the organization's management who has: • the organizational independence and authority to manage nuclear safety and quality issues"; • unrestricted access to the organization's top management."	
Expectations	The responsibility for management of matters relating to quality and nuclear safety lies with one or more members of the organization's management. If responsibilities are held by several people, it will be important to provide evidence of good communication between them. This requirement is met once: • The respective responsibilities and authorities are clearly defined (role description sheet, organization chart, etc.), • The scope of these responsibilities is clearly identified, • The skills and knowledge prescribed for the role are clearly demonstrated (see §7.2), • Relevant topics are addressed, with complete impartiality, and senior management are kept informed, • The organization is clearly communicated to and understood by all. The role description of this or these member(s) of the organization's management shall clearly indicate their status of "organizational independence" in relation to other processes, and to operational and functional activities in particular.	

	To illustrate, this may be an organization with: • One or more operational and/or functional reporting lines; • A reporting line that is independent of others, led by the member of the organization's management tasked with managing matters relating to nuclear safety and quality. The direct reporting line to senior management demonstrates unrestricted access to the organization's top management.
Good practices	**Examples of good practices** (what could be seen as a strength?) A senior lead for nuclear safety and quality, who meets the requirement for independence and authority, and is a suitably qualified person, reports directly to top management. A formal appointment letter (with a nuclear safety brief) is approved by senior management. Nuclear safety and quality representatives are designated to work together with each of the company's sub-divisions to reinforce nuclear safety, oversee and monitor the application of the safety and quality requirements, and provide technical support to the teams. A team that is independent of the production units is in charge of checking that the provisions for nuclear safety (monitoring programme) and quality (management system) are correctly implemented. It supports the senior management strategy, fulfils an early warning role, and provides training and support to the teams.
Associated requirements	• §5.1 - §7.2 - §7.3
Find out more	WANO PO&C 2019-1, chapter CO.4 pertaining to "Corporate independent oversight" sets out in particular the following overall performance objective: "Independent oversight provides the chief nuclear officer (or equivalent) and corporate senior management - up to the Board of Directors - with a continuous evaluation of performance at the nuclear facilities and at company level, in comparison with industry performance, with a particular focus on nuclear safety, plant reliability and emergency response." As an example, the document published on the British regulator's website (the Office for Nuclear Regulation), NS-TAST-GD-080, Revision 4 (2018), "Challenge Culture, Independent Challenge Capability (including an Internal Regulation function), and the provision of Nuclear Safety Advice", and more specifically the 4 items below, are an illustration of these good practices: • A challenge culture, whereby receiving advice and challenge are an expected and accepted part of routine business. • An independent challenge capability, with adequate independent challenge to, and oversight of, nuclear safety leadership, management and decision-making at all levels of the organization, and the establishment of an independent internal regulatory function or suitable alternative. • Provision of nuclear safety advice which supports effective, proportionate nuclear safety leadership, management and decision-making at all levels of the organization. • Appropriate organizational capability for nuclear safety advice and independent challenge: appropriate organization, staffing and management of the nuclear safety advice and independent challenge questioning capabilities.

2.2.3 Guide Sheet #3 – Planning

Topic	§6: PLANNING – DETERMINATION OF ITNS ITEMS AND ACTIVITIES – GRADED APPROACH	Requirement: § 6.1.4
Overview	ISO 9001 stipulates that the organization shall plan the actions to be implemented to address the risks and opportunities that have to be taken into account in relation to the identified challenges. ISO 19443 sets out requirements to determine ITNS items and activities, and to apply a graded approach for the implementation of the requirements related to quality management, documentation, monitoring and measurement. Changes to the quality management system shall not compromise nuclear safety.	
Expectations	The ITNS breakdown of products or services delivered is based on input data provided by the client. On the basis of this data, the organization shall carry out a detailed analysis of its products and services to determine which of them, identified as ITNS items or activities, will have an impact on nuclear safety. Once it has performed this breakdown of items and activities, the organization applies a graded approach. Under the standard, it shall "grade the application of requirements related to quality management, documentation, monitoring and measurement" (§6.1.4). Changes made to the quality management system shall not compromise the technical, organizational and human provisions that are specific to the organization and contribute to nuclear safety.	
Good practices	**Examples of good practices** (what could be seen as a strength?) A proper classification of items and activities is essential. This is the main reason why communication channels between client and its supplier are so important. As far as practicable, this communication shall include information on the functions that lead to an ITNS rating for the product or service being supplied. The organization carries a detailed analysis, perhaps even a functional analysis, of the product or service identified as ITNS, by applying the ITNS characteristics in accordance with the complexity and criticality of the items and services to be provided. The ITNS features are assessed on the basis of a contract review, design input data, inspections and purchases - and in particular the application of the client's nuclear safety requirements to suppliers -, production, and the process from release to delivery of the products and services. During the audit, a guidance document is presented to show relevant identification of ITNS items and services based on the client's documented information.	
Associated requirements	• §5.2 - § 6.1.3 - §6.1.4	
Find out more	• Appendices C and D of ISO/TR 4450 offer examples of ITNS determination.	

2.2.4 Guide Sheet #4 – Support (Part 1)

Topic	**SKILLS AND MONITORING OF INFORMATION**	**Requirements: §7.2, §7.3, §8.4.3, §8.5.1**
Overview	**§7.2**: The requirements in ISO 9001 and ISO 19443 are identical in regard to the arrangements for identifying the required skills of personnel whose work affects the performance and effectiveness of the quality management system. Evidence of these skills and of any actions taken to acquire the necessary skills shall be documented (initial training, professional development, experience, etc.). ISO 19443 requires the inclusion of : • The provisions for qualification • The provisions for maintaining skills and the arrangements for continued qualification. **§7.3:** ISO 9001 stipulates that the organization shall ensure that personnel are aware of the quality management system in place. This awareness shall include: the quality policy, relevant quality objectives, their contribution to the effectiveness of the quality management system, its positive impacts, and the potential implications of noncompliance with the requirements. ISO 19443 adds requirement of training personnel involved in the production of ITNS products or services on the importance of their tasks, including the potential nuclear safety consequences of errors in their activities. Awareness by all personnel of the nuclear safety importance of their individual activities is considered to be essential (see §5.1.3).	
Expectations	**§7.2:** Clear provisions shall be defined for initial as well as continued qualification. They shall set out the arrangements for: • Ensuring that the required skills are acquired and maintained by all personnel whose work affects the performance and effectiveness of the quality management system, • Retaining appropriate documented information as evidence of these skills, • The qualification of personnel, if applicable. In this context, it is important to specify the skills required by the auditors tasked with performing internal audits under ISO 19443 (§9.2.2), and the associated qualification process. **§7.3:** The purpose is to ensure that personnel are aware of the relationship between their own activity and the nuclear safety level of the installation. In order to incorporate nuclear safety aspects into the awareness-raising actions aimed at personnel involved in the production of ITNS products and services, the auditor is asked to refer to the characteristics of this culture, as described in the document published by the IAEA on 5 May 2020 entitled "*Harmonized Safety Culture Model*" and the document published by WANO in May 2013 entitled "*Traits of a healthy nuclear safety culture*". **Requirement 8.4.3 – subparagraph c)** stipulates that the organization shall also communicate to external providers its requirements for skills and qualification, in order to ensure alignment of skills and qualifications. It is worth pointing out that the decision to outsource or not can also be one of the items analysed as part of the graded approach.	

	Requirement 8.5.1. – subparagraph e) implies that, where relevant, the necessary qualification requirements for "competent" persons features among the requirements applicable to the conditions that demonstrate control of production and service provision (for example, by defining the skills needed to carry out a document verification task at the design stage or at the production stage).
Good practices	**Examples of good practices** (what could be seen as a strength?) **§7.2:** The principle of a graded approach is applied in determining the required skills. A matrix maps out qualifications and skills, and thus ensures appropriate staffing. This approach is applied to all employees (starting with the operational line as a priority), including temporary staff. A specific training plan and qualification route are established for completion of a qualification (and continued qualification) and are documented. Arrangements can also be made for shadow training and mentoring. If need be, some qualifications can be obtained by way of an internal decision of the organization. In that case, it is recommended that each individual training path should be documented, including in particular the nuclear safety components of the training (§7.3). **§7.3:** The involvement of operational personnel in the implementation of FMECA enables their awareness of the impact of their activities on nuclear safety. Welcome booklets covering nuclear safety and the key aspects of the project are shared with new personnel. In addition to the training given on health and safety hazards, enhanced training and awareness-raising actions on nuclear safety culture and CSFI are delivered to field team leaders. A presentation on nuclear safety culture and CSFI is available and is given to anyone involved in an activity (even if only occasionally, such as sub-tier providers, temporary workers, etc.). Visual communication is used to convey information on the nuclear safety aspects of the activity (including indicators, etc.). **§8.5.1 (point e)**: A matrix setting out qualifications and required skills can be used (see Good Practice §7.2 above). The documentation for each ITNS product or service includes evidence of personnel qualification and is available if needed.
Associated requirements	• §7.2: §7.3- §8.4.3 - §8.5.1 - §9.2 • §7.3: §5.1.3 - §6.1.3
Find out more	• §7.2: Appendix H of the Guide to ISO/TR 4450 for implementation of ISO 19443 • §7.3: Appendix I of the Guide to ISO/TR 4450 for implementation of ISO 19443

2.2.5 Guide Sheet #5 – Support (Part 2)

Topic	MANAGEMENT OF COMMUNICATION AND DOCUMENTED INFORMATION	Requirements: §7.4, §7.5
Overview	**§7.4:** The requirements of ISO 9001 and ISO 19443 are identical in regard to the provisions for identifying the requirements for communication with internal and external stakeholders. Thought should be given to the communication arrangements for different events: thus, the organization shall define who should communicate, how (information/training, working group, test, etc.), with whom (internal/external parties, client, regulatory bodies, etc.) and when. A note in ISO 19443 specifies who may be external stakeholders. Other paragraphs in ISO 19443 introduce additional requirements for the topics of this communication, namely: • Safety culture (§5.1.3), • Planning of changes (§6.3), • Client communication (§8.2.1), • Information for external suppliers (§8.4.3), • Improvement driven by relevant lessons learned to share with organizations belonging to the supply chain (§10.1). Internal, provisions shall be defined to deliver l communication on nuclear safety and thus foster awareness of nuclear safety among all personnel (see §7.3). **§7.5:** ISO 9001 requires the organization to document in its quality management system the information needed for: • Demonstrating compliance with the requirements set out in the standard, • Monitoring the effectiveness of the quality management system. The creation and update of this information shall be recorded, and access to it and its protection shall be guaranteed at all stages (distribution, storage and preservation, changes, retention, and disposition). ISO 19443 also stipulates that: • Measures should be taken to ensure the quality of translations (in terms of completeness and accuracy), which should be reviewed and approved by competent and authorised persons other than the authors, in accordance with established procedures (§7.5.2), • Documented information should be adequately traceable and authenticated (§7.5.3.1), • Personnel should be made aware of changes to documented information, and measures taken to prevent the unintended use of obsolete documented information (§7.5.3.2).	
Expectation	**§7.4:** The standard does not define here any requirement for the topic of Communication. A “note”, which is not a requirement, lists examples of external parties. It is suggested that suppliers draw up a detailed list of these external parties and establish clear communication channels with all.	

	§7.5: It is useful to refer to the additional information provided in the chapter "Control of documented information" in the Guide to ISO/TR 4450 as regards the implementation of ISO 19443. This additional material specifies in particular that: • Traceability and authentication have been included in relation to the requirements in §7.5.2, • Personnel are made aware of any changes to documented information, • Obsolete documents are identified, and if possible withdrawn from use or archived to prevent inadvertent use. Note: temporary documented information may be required to oversee an activity for a limited period of time, pending its formal update. The provisions for the review and approval of documented information are dependent on the breakdown of products and services into ITNS items and activities (§6.1.3 and §6.1.4). The determination of "competent and authorised" persons for the translation of documented information, and for its review and approval, is checked by the auditor. It should be noted that the term "authorised persons" refers here to a provider who have demonstrated their ability to deliver accurate output, in accordance with predetermined criteria, and who have undergone a formal review in keeping with the organization's quality management system.
Good practices	**Examples of good practices** (what could be seen as a strength?) **§5.1.3 subparagraph c) (see Guide Sheet No. 1, Nuclear Safety Culture):** among the traits of a nuclear safety culture, emphasis is given to transparency in communication. This covers primarily the need to convey appropriate information internally within the organization, externally with clients and at all levels of the supply chain. The use of document management software provides for automation of information on updates. **§7.4:** the IAEA document "Harmonized Safety Culture Model", 2020 edition, stresses formal and informal communication, and effective dialogue between managers and personnel. This harmonised model enhances the "Communication" section of the evaluation, in particular in relation to the 5 following traits: • Free flow of internal information, both up and down the organization, • Transparency during audits, and in interactions with regulatory bodies, • Leaders communicate the reasons for technical and administrative decisions to the appropriate individuals, • Leaders communicate the expectation that safety is the overriding priority, • Communication about health and safety is included in all work activities so that personnel have the required information to work safely and effectively. Suitable topics of communication could be connected to policy, to objectives, to the importance of the tasks linked to ITNS products and services, to the occurrence of an event, or to operating experience. Communication can include presenting the results on the objectives (and displaying them), and client feedback. An annual communication strategy could be drawn up to define the methods for communication all through the year, and the topics chosen.

	Communication methods and rules could be defined to foster transparency and the development of nuclear safety culture (no-blame communication, reinforcement of certain behaviours, certain values, etc.). Other measures could include: • A permanent communication system based on posters and other media, conveying information on objectives, safety/quality deficiencies, causal analyses and corrective actions taken, results, client feedback, etc. • Live communications (talks, workshop training sessions, etc.), • A process for managing events that includes provisions for communication, particularly for events linked to nuclear safety or counterfeit, fraudulent and suspect items (see §8.1.1). **§7.5:** Particular attention should be paid to data protection: • What key characteristics of the product or service are connected with nuclear safety issues? • What protection measures ensure that these characteristics are not subject to irregularities, either within the organization's activities or within those of the sub-tier providers who also have to comply with the particular criteria for these characteristics? • If any "unprotected areas" are brought to light for key characteristics, what are the countermeasures deployed to check, if only by spot-checks, that they are not subject to irregularities? A careful analysis of data integrity can also be carried out, particularly in regard to the integrity of data deemed to be important for the safety case, namely: • The data is logged as close as possible to execution time (e.g., for mechanical tests); • Access to the data for purposes of modification is secure (authorised persons only, a limited number of people, password identification). Control and tracking systems clearly identify which sections of documents, including electronic documents, have been modified.
Associated requirements	• §5.1.3 – subparagraph c) • §6.3 – subparagraph e) • §7.3 - §7.4 - §7.5 - §8.1.1 - §8.2.1 - §8.4.3 - §10.1.
Find out more	For further information, and details of how to use the guides for record management systems, it is worth referring to the ISO 30300 series, which sets out standards for information management and for the creation and control of documented information: • ISO 30301 – Fundamentals & vocabulary • ISO 30302 – Requirements • ISO 30303 – Guidelines for implementation.

2.2.6 Guide Sheet #6 – Operation (Part 1)

Topic	**OPERATION** **Operational planning and control** **Requirements for products and services** Note: §8.1.1 (CFSI) is addressed separately in Guide Sheet #6b.	**Requirements: § 8.1 and §8.2**
Overview	ISO 9001 stipulates the following: • Five measures that allow the organization to meet the requirements for the provision of products and services (§8.1); • Clear lines of communication for information relating to products and services, provisions for communication with clients regarding contracts and possible changes to contracts, and contingency actions (§7.4 and §8.2.1); • Five measures for reviewing client needs in order to ensure that the organization has the ability to meet these needs. There is no indication of who should perform this assessment (§8.2.3); • Should changes be made to the requirements governing products and services, the associated documented information shall be amended, and relevant personnel shall be informed of the revised requirements (§8.2.4). ISO 19443 also sets out: • Further details on these measures, in particular the requirement to consider project management, interface and schedule management, as well as configuration management aspects (§8.1); • Provisions for CSF items (§8.1.1, covered in Guide Sheet #6b); • The obligation to communicate with the client regarding the management of interfaces with external parties (§7.4); • That relevant information should flow to all supply chain stakeholders, and in particular to the sub-tier providers and suppliers associated with ITNS products and services (§8.2.1); • That all functional groups associated with the supply of products or services shall be involved in the review of requirements (§8.2.3.1) and in the retention of documented information on the actions taken as a result of the review (§8.2.3.2); • That changes to the requirements for ITNS products and services shall be properly managed, in compliance with preceding requirements §8.2.2 and §8.2.3 (§8.2.4).	

Expectations	The organization is expected to establish a process or a series of processes ensuring that the products or services – including products incorporated into end-products, and externally provided services – fulfil the stated requirements (§ 8.4). This process or these processes will cover all phases of a project, from launch to closure, including the gathering and use of lessons learned. These processes shall be established in accordance with the significance of the activities impacting the supply chain, and in keeping with the principle of a graded approach. The conformity of the products and services shall be determined on the basis of criteria that are clear enough to avoid ambiguity. Similarly, corresponding records shall provide evidence of this conformity with requirements (§8.1). The auditor also reviews the ways in which the organization communicates with clients. There can be several forms of communication: computer files, emails, responses to complaints, information on contingency actions, etc. (§8.2.1). In regard to bid and contract reviews, and the involvement of relevant support units (§8.2.3), the auditor can check: • Which departments were involved, out of all those associated with the deliverables for the client (manufacturing, design, R&D, procurement, quality, inspection, etc.)? • When did these reviews take place? • What actions were defined and taken following these reviews? It should be noted that this involvement shall not be limited to the members of the organization who have direct contact with the client (sales department, or equivalent) but shall also include project related personnel (manufacturing, design, R&D, inspection, quality, etc.) (§8.2.3). If changes are made to the requirements for products and services (client and regulatory requirements), the review shall be updated (§8.2.3) and documented (§8.2.4).
Good practices	**Examples of good practices** (what could be seen as a strength?) **§8.1:** • Planning includes determining the quality and quantity of resources. • Sufficient resources in terms of quality and quantity are provided and monitored. • Project management encompasses all the phases of the project, from launch and product or service definition and delivery, to closure and analysing lessons learned. • The established project organization provides a clear definition of the stakeholders and internal or external interfaces. • Configuration management includes a robust modification management process covering all the production processes (in other words, providing an answer to the question: how is a modification implemented and documented through these processes?). • The specifications are analysed, and then approved using a checklist that is applied throughout, from bid to delivery of products or services, recording compliance with the requirements. **§8.2.1:** • The client's technical and quality specifications, the general terms and conditions of purchase, the general terms and conditions of sales, etc., all provide details of applicable requirements. • The interfaces with external parties define the type of expected information (product testing, root cause analysis, remedial measures, impact assessment,

	corrective action plan, etc.), as well as the information/documents to be provided to contact persons (client or others). **§8.2.3:** • All the requirements that a product or service shall fulfil are taken into consideration, and all inputs (requirements specified by the client, statutory and regulatory requirements, requirements for the specified or intended use, etc.) are reviewed for completeness using a suitable tool such as a conformity matrix. The documents establishing compliance with the requirements that have to be met are all recorded and retained. • All the organizations designate personnel in every relevant department (engineering, procurement, quality, etc.) in order to enable a review of all these requirements and a verification of their exhaustiveness. **§8.2.4:** The organization has a process for managing changes to requirements, which sets out: • Provisions for determining new applicable requirements (§8.2.2), • The organization and responsibilities for managing changes to requirements, • The arrangements for carrying out an impact analysis of changes to requirements (including requirements for pending deliveries) (§8.2.3), and the measures ensuring that relevant personnel are made aware of the changed requirements (§8.2.3).
Associated requirements	• §8.1: §4.4 - §6.1 - §6.2 - §6.3 - §8.4 • §8.2: §7.4 - §8.4.3
Find out more	• IAEA document NT-G-1.6, Project Management. • The IAEA's consistency model, based on the three elements of configuration management, as described in Chapter 5 of GS-G-3.5 (see §5.141 to 5), The Management System for Nuclear Installations.

2.2.7 Guide Sheet #6bis – Operation (Part 2)

Topic	**OPERATION** **Provisions for counterfeit, fraudulent or suspect (CFS) items**	**Requirement: § 8.1.1**
Overview	ISO 19443 introduces the topic of CFSI, stipulating that the organization shall control this risk in all operational activities, including both internal and external activities. To this end, the organization shall eliminate CFS items at all levels of operations, and implement 4 provisions designed to prevent the introduction of CFS items: • Selection of external providers, • Specific information for external providers (§8.4.3), and for their control of sub-tier providers (§8.4.3), • Control of all outsourcing (§8.4.2) and • Monitoring and measurement activities (§8.5.1.2). It should be noted that when CFS items are identified, they shall be managed as nonconformities (§10.2) and reported to the relevant parties, including the client. This requirement also applies to external providers (see §8.4.3).	
Expectation	In regard to operational activities, the auditor checks that the organization controls the risk of CFS items, both internally and externally, in other words, that: • The organization has analysed and documented its risk-points in relation to CFSI. • The organization has set up risk prevention measures. In particular, it has defined relevant provisions in documents (in a procedure, for example). • The provisions shall be communicated to, and known by, all relevant parties. • These provisions apply to the supply chain (communication of requirements, obligation of the provider to notify the organization, and the organization's verification of the level control). • If CFS items are identified, arrangements are in place for communication (without delay) and response/management (for example a taskforce). • The auditor will assess the degree of ownership of the subject (degree of maturity), by ensuring that the organization does not tolerate, foster, or fail to identify individual or collective CFSI practices. The auditor will focus for example on the content of the awareness-raising/training actions relating to the risk of CFS.	

Good practices (§8.1.1)	**Examples of good practices** (what could be seen as a strength?) Note: The topic of CFSI is often addressed alongside nuclear safety culture (and features in nuclear safety policy/objectives and training) *Nuclear safety culture acts as a safeguard against CFSI risk.* The measures against CFS items and activities shall be practical, and could include document cross-checks, unannounced inspections, requests for original copies, re-tests, internal reporting processes, self-assessments, and so on. When drawing up its provisions, the organization may consider the following focal points (non-exhaustive list): • Has the organization already dealt with internal cases of CFSI? • Has the organization already dealt with cases of CFSI among its clients/providers? • Does the organization have a monitoring system? • Does the organization have a policy defining the attention given to this issue by top management and line management? • Have CFSI-prevention objectives been set? • How is the subject addressed within the organization? How is it addressed by the organization's suppliers? • Has the organization performed a risk assessment of this issue? • How are new product and/or service providers selected, and does the process consider CFS items? • Does the organization have a list of risk-significant procurement? • Does the organization pay a particular attention to commercial grade items? • Is there a programme for raising awareness of the internal threat of fraud, document falsification, or even collusion with clients or interested parties? Is it appropriate? • Is there a programme for raising awareness of the external threat of fraud and document falsification? Is it appropriate? • What are the training actions on this topic? Who are they aimed at? Engineering, procurement, quality, management, store/logistics personnel, etc.? • Do new personnel have to sign up to a code of ethics? How is it disseminated? Is it known to all employees, and how is this verified (a signature, etc.)? • Do storekeepers have catalogues with photos of original components or products, to help them perform visual checks if needed? • Are there practical and operational measures in place for each process (for example, checks of materials files, etc.)? • Are there detection mechanisms in place? With regard to document falsification, a good practice is to manage data (beyond the documentation, which is only a support) by putting in place measures to ensure its continuity and integrity.
Associated requirements	• §8.4, §8.4.3

2.2.8 Guide Sheet #7 – Operation (Part 3)

Topic	**OPERATION** **Design and development of products and services**	**Requirement: § 8.3**
Overview	ISO 9001 stipulates that the organization: • Establishes and implements an appropriate design and development process, and keeps it up to date (§8.3.1), • Fulfils ten requirements in its design and development planning (§8.3.2), • Meets five requirements relating to data inputs (§8.3.3) • Fulfils six requirements governing the control of design and development (§8.3.4), • Complies with four requirements for the verification of design and development outputs (§8.3.5). ISO 19443 also sets out: • The obligation to identify interfaces, to document activities, and to use appropriate tools (§8.3.1), • The obligation to determine the process stages requiring authorisation before progress to the following stage (§8.3.2), • Three requirements linked to design reviews (§8.3.2), to the resources needed for verification and validation activities, and to the update of documented information (§8.3.4), • Requirement §8.4.3.1, “Design and development verification and validation testing”, stipulating that, where tests are necessary, these tests are planned, performed, checked, reviewed and documented, • The obligation to specify the conditions under which commercial grade items or activities can be used as ITNS items or activities (§8.3.5), • The designation of competent and relevant personnel for the task of design and development changes (§8.3.6).	
Expectation	**§8.3.1:** The auditor will check: • The existing organization, process and documentation, and in particular the level of detail of documentation, including design activity records, • That design interfaces have been defined and associated controls are in place, and that design tools, including digital tools, have been demonstrated to be fit for purpose. **§8.3.2:** The auditor will verify which stages of the design process require authorisation, and will review the criteria, roles and responsibilities involved in authorising the design and development process to proceed, and associated records. **§8.3.4**: The auditor ensures that: • The process includes reviews, with milestones authorising the transition to the following stage, • Roles and responsibilities, and associated records, are defined for each of these stages, • Design verification and validation is carried out by competent personnel, different from those responsible for the design, • Documented information on these activities is retained.	

	§8.3.4.1: The auditor ensures that the following provisions are in place when tests are necessary for design verification and/or validation: • Test plans (including the allocation of resources and testing equipment) • The documentation required for test execution • Test execution and test verification • Acceptance criteria. **§8.3.5:** The auditor checks and evaluates the conditions under which commercial grade items or activities can be used as ITNS items or activities (for example, the conditions of use for software, information technology, catalogue equipment and products, etc.). The auditor shall specifically examine the appraisal of the conditions under which commercial grade items or activities can be used as ITNS items or activities. **§8.3.6:** The auditor checks that personnel involved in design modifications are competent and have knowledge of the requirements and intent of the original design.
Good practices	**Examples of good practices** (what could be seen as a strength?) **§8.3.1:** The organization has documents (for example a quality plan or a development plan) setting out the following information: • The general organization in terms of resources, • Roles and responsibilities, and internal interfaces • The management of product and service design and development (definition of design stages, reviews, and associated milestones), • External interfaces, • Input data, • Validation criteria. Where design tools are used (computation codes, for example), the organization ensures that: • It has created a list of the tools that are used and qualified for use, with details of the versions of these tools, • It has defined and presented a process that helps demonstrate the qualification of ITNS product or service design study tools, • It has checked the adequacy of the scope of qualification for each tool in relation to its actual use, be it generic or specific, • Kept evidence (records) of the qualification of these tools. **§8.3.2 and §8.3.4**: The decision-making element is brought to the fore: criteria are established and validated by competent persons, authorised to decide on the transition to the following design stage. **§8.3.4:** A design-task allocation matrix comprising skills (see §8.3.1) is used to meet this requirement. When tests, or verification and acceptance tests, are planned, in accordance with §8.3.4.1, a document is used, which incorporates the client's requirements, the test specifications and the client file.

	§8.3.5: The conditions under which commercial grade items or activities can be used as ITNS items or activities are formally defined and traceable.
Associated requirements	• §8.1
Find out more	• Appendix K of the Guide to ISO/TR 4450

2.2.9 Guide Sheet #8 – Operation (Part 4)

Topic	**OPERATION** **Control of externally provided processes, products and services**	**Requirement: §8.4.**
Overview	ISO 9001 stipulates that the organization shall ensure compliance with the requirements: • When the processes, products and services from external providers are intended for incorporation into the products and services supplied by the organization itself; • When the products and services are provided directly on behalf of the organization, or when a process, or part of a process, is undertaken by an external provider; • The criteria for the selection and monitoring of external providers shall be based on their ability to carry out processes or provide services that meet the requirements; • Associated documented information shall be retained (§8.4.1). Furthermore, the organization shall also: • Define its control of external providers and of the products and services supplied; • Verify that processes, products and services meet requirements, and ensure the effectiveness of the controls applied by the external provider (§8.4.2), • Ensure the adequacy of its requirements for external providers, before communicating them. The requirements that shall be communicated cover the processes, products or services to be provided, the various approvals required, skills and qualifications, the interactions between parties, the organization's monitoring of the provider's performance, and the types of checks that it intends to perform at the external provider's premises (§8.4.3). ISO 19443 also sets out the following requirements: • The controls applied to externally provided products and services apply to all levels of the supply chain, but shall be in line with the outputs of the graded approach; • If a provider responsible for ITNS items or activities is not ISO 19443 certified, the organization shall demonstrate the equivalence of the provisions taken; • The evaluation of external providers is valid for a limited period of time and within a stated scope. • Documented information on the organization's control of external providers shall be kept up to date and retained (§8.4.1); • The organization shall define, assign and deploy the responsibilities and authorities for control of externally provided processes, products and services; • The organization is responsible for the conformity of all the processes, products and/or services supplied by external providers. In light of this, the following is required in addition to the ISO 9000 standard: - The external provider shall demonstrate control of its supply chain, - The organization's verification of the compliance of products and services shall consider the critical characteristics of commercial grade items or activities (§8.4.2). Regarding the requirements that shall be communicated to the external provider, ISO 19443 stipulates that they should include: • The QMS requirements, the technical specifications, the list of applicable documents and their status, details of the documentation to be submitted by the external provider and of spare parts and related data required for ordering them; • Approval of the documentation associated with the provision of the product or service;	

	• The obligation to report nonconformities (including CSFI items and activities); • The obligation to obtain the organization's approval for the measures taken to address nonconformities, and to inform it of significant changes (to the products and services, to the location of manufacturing facilities, to external providers, etc.); • The obligation to ensure that representatives of the organization, its clients, third parties and regulatory bodies all have access to the relevant facilities, at all levels of the supply chain, and to all relevant information. • Provisions for cascading relevant requirements down through all levels of the supply chain. • The obligation to check that the requirements are aligned with those of the client, prior to communicating them. In the event of changes to the requirements for procurement, these changes are subject to the same processes and controls as those used in establishing the original requirements. • Associated documented information shall be retained (§8.4.3).
Expectations	In regard to the chapter on control of externally provided processes, products and services, the auditor shall be aware of the number and range of requirements under the ISO 19443 standard. It is essential for the auditor to be able to check that the organization is aware that it bears full responsibility for externally provided processes, products and/or services, and that it is complying with all applicable requirements to demonstrate control. The auditor focuses on: • The defined process and the organization (including interfaces) for consideration and control of processes and externally provided products or services; • The accuracy and completeness of procurement data, ensuring in particular that the requirements of the client and other requirements – technical, documentation, quality, safety requirements, etc. – are properly passed on; • The organization's procedure for demonstrating equivalence of the provisions made when a provider responsible for ITNS items or activities cannot demonstrate that its QMS meets the requirements of the ISO 19443 standard; • Consideration of the outputs of the graded approach in relation to requirements, controls of products and services, and the supply chain; • The updated and preservation of all documented information on the organization's control of external providers and their supply chain; • The organization's ability to ensure that the externally provided processes, products and services do not compromise its own ability to meet client requirements as well as statutory and regulatory requirements; • The thorough verification to apply to the critical characteristics of commercial grade items and activities, as defined at the design stage, including the traceability of monitoring actions; • The method employed for the verification and monitoring of critical characteristics, and its traceability; • Compliance with all the requirements set out in §8.4.3.

Good practices	**Examples of good practices** (what could be seen as a strength?) It is advisable to refer to §8.4 of the Guide to ISO/TR 4450 for implementation of the ISO 19443 standard in regard to: • The TQRDC criteria recommended for the evaluation (detailed below), selection and monitoring of external providers, • The commercial grade items and activities and their critical characteristics, including monitoring measures and traceability. Note: With respect to the TQRDC criteria, the factors taken into account in the evaluation, selection and monitoring of external providers are as follows: • Technology: the ability to deliver a defect-free product, with the expected qualification. Measures are taken, for example, to ensure that the supplier has full control of its core activities, based in particular on its experience and technical references. • Quality and nuclear safety culture: alignment with its integrated management system, quality of documentation, personnel skills and qualifications, evidence of awareness of safety culture and of the essentials of nuclear safety culture, etc. As an example, this means ensuring specifically that the provider has an integrated management system in which there is continuous improvement of its most critical processes, and where the improvements lead to actual change, particularly in the follow-up of deficiencies of all types (workplace accident, client complaint, loss of another certification, etc.). • Responsiveness: the ability to adjust to client needs while maintaining the expected quality. As an example, this means ensuring specifically that the provider gives a proper response, not only to requests for bids but also to requests for audits of its processes and/or visits to its manufacturing facilities. • Delivery: the ability to deliver the products and associated documentation within the agreed period. As an example, this means reviewing specifically how the provider proceeds when releasing its products or services, including documentation. It may prove useful to consult the potential provider's existing clients. • Cost: the cost of what is provided is based on all the elements demonstrating the expected conformity and quality. As an example, this means verifying specifically the quality-price ratio on completion of the above investigations, after a visit to the manufacturing facilities in particular. Other good practices are mentioned below. Thus, reference can also be made expressly to: • Appendix L of the Guide to ISO/TR 4450, covering the contents of the documentation giving proof of the provisions made for monitoring activities; • Appendix K of the Guide to ISO/TR 4450, concerning the determination of the critical characteristics of commercial grade items and activities. The following good practices can be mentioned relating to the monitoring of the processes implemented by external providers, in particular when the provider is responsible for an ITNS item or service but is not ISO 19443 certified: - The setting up of regular meetings with the external provider or any other interested party, particularly to explain clearly the nuclear safety role of the items or services on order; - Document reviews of information submitted by the provider (quality control plans, inspection and testing plans, etc.);

	- Supervision of the external provider by means of independent evaluations, site visits to facilities, hold points, progress meetings, and/or audits; - Evidence of control of the nuclear-quality critical factors derived from the procurement specifications or technical specifications. Any subsequent deviation from the specifications shall be subject to a review by the higher-tier contracting party (to update the bid review, for example with the use of a grade of metal slightly different from the specifications); - Checks to ensure that controls of ITNS activities are indeed carried out by different persons from those who performed the work. - Verification of the completeness, robustness and reliability of the files governing items or services delivered.
Associated requirements	• §6.1.4
Find out more	Aside from the Guide to ISO/TR 4450 - § 8.4 and Appendix L, it may also prove useful to refer to the following documents: • Regarding equivalent standards for commercial grade items and activities: - Regulatory Guide 1.164, Dedication of Commercial-Grade Items for Use in Nuclear Power Plants - 2017. - US DOE - Office of Environmental Safety and Quality: Commercial Grade Dedication Guidance – September 2011. - IAEA NR-T-3.31, Challenges and Approaches for Selecting, Assessing and Qualifying Commercial Industrial Digital Instrumentation and Control Equipment for Use in Nuclear Power Plant Applications – 2020. - IAEA NP-T-3.21, Procurement Engineering and Supply Chain Guidelines in Support of Operation and Maintenance of Nuclear Facilities – 2016. Note: According to Chapter 1 Part 21 of 10 CFR, critical characteristics are defined as “those 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.” • In regard to the management of supplier: - IAEA-TECDOC-1910, Quality Assurance and Quality Control in Nuclear Facilities and Activities - Good Practices and Lessons Learned.

2.2.10 Guide Sheet #9 – Operation (Part 5)

Topic	**OPERATION** **Production and service provision**	**Requirements: §8.5.1, §8.5.1.1, §8.5.1.2**
Overview	**§8.5.1:** Control of production and service production Under ISO 9001, the organization shall implement production and service provision under controlled conditions. These shall include eight criteria, as applicable: • Documented information on the products to be produced, the activities to be performed, or the services to provided, • Resources, • The monitoring and measurement activities, at appropriate stages, • Suitable infrastructure, • The appointment of competent persons for these activities, • Validation of the processes to be implemented, • Human error prevention measures, • Release, delivery and post-delivery activities. ISO 19443 adds the following controlled conditions, including §8.5.1.1 and §8.5.1.2: • Client requirements, and statutory and regulatory requirements, related to monitoring and measurement activities. • Evidence that all production, monitoring and measurement activities have been completed as planned [§8.1 subparagraph e)], or as authorised and documented (production-line product tracking document or manufacturing procedure, compliance report for manufacturing or service controls, including compliance with hold points and/or progress meetings, documents published by the quality department or the client representative who visited the given supplier's manufacturing facilities, etc.). • The involvement of top management, to ensure that product conformity and on-time delivery are measured, and that appropriate measures are taken if planned results are not or will not be achieved, all the while ensuring that nuclear safety is never compromised. It should be noted that the controlled conditions shall take into account the outputs of the graded approach (§6.1.4). **§8.5.1.1:** Control of production equipment – verifications cover: • The validation of computer-aided manufacturing equipment prior to production use; • Its maintenance; • The definition of the requirements for the storage and periodic preservation/condition monitoring of this equipment (or of tooling in storage). **§8.5.1.2:** Monitoring and measurement activities. The provisions and methods used for these activities shall take into account the outputs of the graded approach (§6.1.4). As regards ITNS items and activities, monitoring and measurement for product acceptance shall be carried out by competent persons different from those who performed the work. Documented information shall be retained, and shall encompass a minimum eight constituent parts, such as the item inspected, the monitoring or measurement performed, the date, details of personnel assigned to the task, the acceptance criteria, and any follow-up actions, including those taken in response to nonconformities.	

Expectation	**§8.5.1:** The auditor checks that the organization implements production and service preparation in compliance with the requirements of §8.5.1. Regarding the specific requirements of ISO 19443: • For subparagraph i), full compliance with client and applicable statutory and regulatory requirements; • For subparagraph j), evidence that all production, monitoring and measurement activities have been completed as planned; • For subparagraph k), - How top management is involved in ensuring that product conformity and on-time delivery performance are measured and appropriate action is taken, without compromising nuclear safety, if planned results are not or will not be achieved; - How the organization guarantees compliance with client and applicable statutory and regulatory requirements; - How the organization establishes and retains the documented information providing evidence of compliance with client and applicable statutory and regulatory requirements. **§8.5.1.1:** The auditor checks: • The methods used to validate equipment prior to release for production use. This may be, for example, by initiating a short production series if feasible or, if only one product is to be produced, verifying the equipment's internal parameters. • When maintenance was carried out in relation to the production cycle, and the reference of the procedure used. • How the equipment and tooling are stored and preserved, along with the reference of the associated procedure. • Priority will be given to equipment whose validation requires: - A conformity certificate following validation; - Specific checks before the start of so-called special processes such as welding, thermal treatment, non-destructive testing, etc.; - Compliance with the requirements stipulated by the contract, a standard, or regulations. **§8.5.1.2:** The auditor reviews: • How the monitoring and measurement activities are implemented, and how they reflect the graded approach: scope of these activities, frequency of monitoring measures, frequency of calibration and calibration checks, and responses to loss of calibration between two intervals; • For ITNS items and activities, the skills of competent persons other than those who carried out the work, who are responsible for the acceptance of products subject to monitoring and/or measurement. • If the eight applicable criteria for the identification and retention of relevant documented information are systematically fulfilled.

Good practices	**Examples of good practices** (what could be seen as a strength?) **§8.5.1**: • Subparagraph j): the creation of a compliance framework to keep track of compliance with client, statutory and regulatory requirements, and ensure the completeness of the information documented in the product or service file. • Subparagraph k): - The ability to demonstrate top management involvement in addressing client complaints and both positive and negative feedback from interested parties; - The official inclusion of this type of subject in the agenda for senior management team meetings. **§ 8.5.1.1:** • Validation of the programming of machining operations if computer-assisted, by working from a representative part; • Regular visual checks of the equipment and production tooling; • Operator knowledge of the equipment validation protocol prior to release for production; • Good cleanliness and safety provisions in workshops and production lines; • A clean working environment (and clean work clothes); • The condition of storage areas in relation to the identified risks, for example, segregated storage (stainless steels/ferritic steels), humidity levels, etc. **§8.5.1.2:** The monitoring and measurement activities are appropriately and effectively tailored to the graded approach, on the basis of objective criteria. **§8.5.2**: The extensive use of digital tools to identify good and persons, such as: • The use of barcodes to enhance the traceability of manufacturing operations, their progress, and possibly their conformity status; • The use of electronic signatures in documentation.
Associated requirements	• §5.3 - §6.1.4 -§8.5 - §10.2
Find out more	

2.2.11 Guide Sheet #10 – Operation (Part 6)

Topic	**OPERATION** **Design and development of products and services** **Control of nonconforming outputs**	**Requirement: §8.7**
Overview	**§8.7.1**: ISO 9001 specifies that the organization shall ensure that outputs that do not conform to the applicable criteria are identified in a timely manner so as to prevent their release or possible use. Depending on the type of nonconformity and its impact, the ISO 9001 sets out four ways in which the organization can take action. The implementation of one or more of these measures will ensure control of nonconforming outputs. These measures also apply to nonconformities identified after delivery, and to nonconformities detected during or after the provision of services. ISO 19443 sets out additional measures: • Actions to minimise the impact of nonconformities on other processes; • Scraping of material; • Client notification of the nonconformities that affect them; • A use-as-is or repair justification in the event of a nonconformity, approved by the client; • Measures to update and maintain documented information for the control of nonconforming outputs. Note : As regards ITNS items or activities, the auditor shall establish whether the requirements set out in subparagraphs b), c) and e) of § 8.7.1 are mandatory. **§8.7.2**: ISO 9001 stipulates that the organization shall retain the documented information detailing the nonconformity, the measures taken, any concessions obtained, and the authority that ruled on the measures and concessions. ISO 19443 adds the obligation to include the justifications in the descriptions of referenced measures and concessions.	

Expectation	**§8.7.1**: The objective is to limit and control the risk impact of a perceived nonconformity on the organization's activities but also on interested external parties. The focus here is on minimising the nuclear safety impact of the nonconformity (§7.3). The requirement of the standard is: • To undertake immediate and appropriate measures, • To be transparent in all communications with the client (§5.1.3), • To control the impact of the nonconformity on other processes and products. The management of the issue, decision-making and communication system will have to be established in light of the critical nature of the nonconformity and its impact on client requirements. The organization shall ensure that nonconformities and corrective actions are promptly managed and reported to relevant line management, and to the client when required. Products that are declared to be nonconforming or are earmarked for disposal shall clearly be identified as such (with visible and permanent markings, for example) and their management shall be fully controlled (for example by means of segregation, containment or return to sender) until they have, if necessary, been rendered physically unusable. The organization's nonconformity control process shall be supported by up-to-date documented information identifying the authority that ruled on the actions taken to deal with the nonconformity, and detailing: • The nonconformity, and the measures taken to prevent its use, while the nonconformity status remains unchanged, • An analysis of the reported nonconformity's impact on the process or product flagged up as deficient (demonstrating the lack of impact on other processes or products, if need be), • The measures implemented, with justifications, • All the concessions obtained, with justifications. **§8.7.2**: The objective is to assess the organization's determination and/or ability to improve the failed process(es) that gave rise to this nonconformity. The root-cause analysis of the nonconformity leads to an assessment of its potential impact on other ITNS or non-ITSN processes, and on other ITNS equipment or services.
Good practices	**Examples of good practices** (what could be seen as a strength?) In regard to the routine management of nonconformities, Steps 1 and 2 below apply: • Step 1: Response – if a nonconformity is identified, the priority is to protect integrity: segregate the nonconforming products, evaluate the scope of the issue, and determine the initial root causes so as to control secondary risks; • Step 2: Management of the issue – the nonconformity is addressed in the following sequence: - Continue the root cause analysis (see below), - Define actions (corrective and preventive), including the timelines for their implementation, - Categorise each nonconformity according to its description (critical/non-critical, major/minor, etc.), thereby enabling a gradual approach to its management,

	- Identify any impact on the product's main technical characteristics and thus potentially on nuclear safety. If an impact is determined, or if in doubt, the nonconformity should systematically be reported to the authority responsible for nuclear safety within the company, - Identification of a nuclear safety impact: if an impact is determined, or if in doubt, the nonconformity should systematically be reported to the authority responsible for nuclear safety within the company, - Identify any potential impact on ITNS products or services, - Establish corrective and preventive actions, - Define criteria for determining the effectiveness of the measures taken, - Deploy the actions and communicate with relevant parties. There are more and more process flow systems and database systems for managing nonconformities, with automatic reminders. A periodic multidisciplinary review of the progress status of additional measures remains necessary to ensure that deadlines are met. **Root-cause analysis and its inclusion in the management system** A good practice during the root-cause analysis of nonconformities entails the use of a rigorous method (Pareto analysis, 5M management model, etc.) to clearly identify: • Technical aspects, • Organizational aspects, • Human factor and nuclear safety culture aspects. The findings of the root-cause analysis should be correlated with the risks identified in the processes. The aim is to: • Validate the proportionate (or graded) approach for the processes involved; • Review the risk assessment, if necessary, so as to factor in any operating experience (the addition of new risks or changes to the measures designed to control or minimise these risks); • Increase the efficiency of the Quality Management System.
Associated requirements	• §7.3 - §8.4.3 - §9.1.1 - §10.1 - §10.2
Find out more	• §8.7.1: Appendix M of ISO/TR 4450 provides an example of a framework for information on nonconformity, and requests for approval, throughout the supply chain. • §8.7.2: ISO/TR 4450 cross-references ISO/TS 9002 to explain requirement §8.7.2, setting out examples of documented information. The following documents may be of use: - ISO 30301, ISO 30302, - The IAEA's Harmonized Safety Culture Model.

2.2.12 Guide Sheet #11 – Performance evaluation

Topic	**PERFORMANCE EVALUATION** **Performance in line with the nuclear safety requirements**	**Requirements: §9.1 - §9.2 - §9.3**
Overview	**§9.1 Monitoring, measurement, analysis and evaluation** **§9.1.1. General information** Under ISO 9001, the organization shall make four provisions for monitoring and measuring the effectiveness of its quality management system. It shall also retain relevant documented information as evidence of its results. ISO 19443 supplements the above criteria with a requirement: • To demonstrate compliance with the requirements that apply to the products and services • To ensure that the processes are capable of delivering the expected results. **§9.1.3 Analysis and evaluation** ISO 9001 requires the organization to analyse the data and information arising from the monitoring and measurement of its processes in order to assess the quality of seven key performance indicators, including in particular the conformity of products and services, the effectiveness of its quality management system, the performance of external providers, improvement needs, etc. ISO 19443 adds a further indicator to this list, relating to nuclear safety culture aspects. This evaluation of nuclear safety culture shall allow for the early identification of underlying organizational and human issues that may have a positive or negative impact on operations and on the results of organizations. **§9.2 Internal audit** **§9.2.1:** Under ISO 9001, the organization shall plan and conduct internal audits to measure the effectiveness of the quality management system, and keep it updated with regard to: • its own requirements, • those of the ISO 9001 standard. ISO 19443 supplements these first two criteria with the obligation for the organization to ensure that the quality management system meets client requirements. **§9.2.2:** ISO 9001 stipulates the requirement to plan, establish, implement and maintain one or more audit programmes, in accordance with provisions that are broken down into six criteria. ISO 19443 stipulates that auditors shall be qualified and shall not audit their own work. **§9.3 Management review** **§9.3.1 General information** Under ISO 9001, top management shall review its quality management system so as to ensure its continuing effectiveness and alignment with the company's strategic guidelines. In ISO 19443, the above requirement applicable to the management review is supplemented by the obligation that nuclear safety will receive the attention warranted by its significance.	

	§9.3.2 Management review inputs Under ISO 9001, the management review shall be planned and carried out in accordance with six general criteria. The criterion for information on the effectiveness of the management system is based on seven sub-criteria. ISO 19443 supplements the last criterion by specifying that the opportunities for improvement shall include lessons learned from the nuclear energy sector.
Expectation	The auditor focuses on: • The manner in which the organization evaluates the performance of the various constituent parts of its management system, including nuclear safety culture aspects. • The demonstration that the requirements applicable to the products and services have been fulfilled (for example, using a table showing all the requirements to be met, and systematically including the organization's response, in sufficient detail for compliance with all these requirements to be demonstrated). • The type of documented information that is used as evidence of results and shall be retained. The auditor checks in particular the skills and the appropriate formal qualifications of internal auditors. Furthermore, the auditor pays particular attention to the way in which nuclear safety related issues are addressed as part of the management review. This evaluation can be based on several reports. In regard to improvement opportunities, the auditor should check the sources used for the incorporation of operating experience within the organization.

Good practices	**Examples of good practices** (what could be seen as a strength?) One common method is the use of a conformity matrix from the bid stage onwards. In accordance with the provisions of §4.4.3, the organization shall have documented information (performance reviews, process reviews, management reviews) that demonstrate the conformity of the following items: • The 6 criteria of ISO 19443 (including 4 from ISO 9001) defined in §9.1.1; • The 8 criteria in §9.1.3 of ISO 19443, including the nuclear safety culture criterion (see Guide Sheet No. 3); • The 3 criteria under §9.2.1 of ISO 19443; • Evidence demonstrating that the internal auditors of the organization undergoing the ISO 19443 audit are suitably qualified; • The 6 criteria and 7 sub-criteria applicable to the management review inputs, including the use of nuclear sector operating experience for opportunities for improvement. The management review outputs are conclusive on the effectiveness of the system and/or give rise to a list of improvement measures. For complex organizations, the reviews are very often broken down by entity or discipline, and participants have appropriate authority / decision-making capacity. Regarding the qualification of internal auditors, the qualification criteria are drawn from the provisions of ISO 19011.
Associated requirements	• §5.1 - §5.1.3 - §8.4.3
Find out more	• §9.1.2 of ISO 9001 requires organizations to monitor clients' perceptions. • ISO 19011, Guidelines for Auditing Management Systems, and more specifically, §7.2.3.3 of these guidelines stipulates that internal auditors shall possess discipline-specific and sector-specific knowledge, and be able to provide evidence of their qualification for this type of audit. • The IAEA's Harmonized Safety Culture Model – May 2020. • IAEA GSR Part 2, Leadership and Management for Safety • Definition of nuclear safety: reference should be made to a wider definition that goes beyond the operators of nuclear installations, and most importantly, that specifies that it encompasses technical, organizational and human provisions throughout the life stages of such an installation.

2.2.13 Guide Sheet #12 – Improvement

Topic	IMPROVEMENT	Requirements: §10.1, §10.2, §10.3
Overview	**§10.1: General information** ISO 9001 sets out three mandatory inputs for determining and selecting opportunities for improvement: • Improving products and services in order to meet requirements and address future needs and expectations; • Correcting, preventing, or minimising unwanted effects; • Improving the performance and effectiveness of the quality management system. ISO 19443 adds an obligation to factor in operating experience and risk reduction. In practical terms, technical advances, research and development, and methods for identifying good practices can all be taken into consideration. ISO 19443 also adds two further specific requirements for the organization: • To provide the resources needed to carry out improvements, • To share relevant operating experience with clients, and pass it down to its supply chain organizations. **§10.2 Nonconformity and corrective actions** **§10.2.1:** ISO 9001 specifies that, in the event of nonconformities, the organization is required to meet six direct criteria and five sub-criteria, so as to: • Remove the causes of the nonconformities, • Prevent their recurrence through appropriate corrective actions, • Adapt its quality management system if necessary. ISO 19443 supplements the above with requirements to: • Manage the nonconformities and corrective actions, and report without undue delay to line management and, as appropriate, to the client, • Broaden the scope of the analysis of the nonconformity in order to assess its impact, by determining the root causes if applicable. **§10.3 Continuous improvement** ISO9001 stipulates: • Continuous improvement of the features of the quality management system (adequacy, effectiveness, etc.); • The identification of improvement needs is to be considered on the basis of the evaluation of the quality management system and the conclusions of the management review. ISO 19443 supplements these two requirements by specifying that the continuous improvement process should encompass nuclear safety culture.	
Expectation	The auditor focuses on: • The lessons learned from the root-cause analysis of nonconformities and of their unwanted impacts on the effectiveness of the management system and the adequacy of the processes used by the audited organization, as well as the link with the risks identified;	

	• The drivers of improvement, which were evaluated in particular during the management reviews; • The resources provided to ensure these improvements are carried out within a reasonable timeframe; • The management of nonconformities and resulting improvements; • Specific improvement measures related to nuclear safety, and measures to reduce risks stemming from technical, organizational and human factors; • The relevance of the operating experience, its distribution, and whether it is sufficiently broadly based.
Good practices	**Examples of good practices** (what could be seen as a strength?) The objective of improvement as a part of the management system means identifying and selecting opportunities for improvement, and carrying out all the measures needed to meet client requirements and enhance client satisfaction. This impetus includes the measures taken to address nonconformities (see Guide Sheet 10). For action to be effective, the following points can be considered: • An overall survey of nonconformities and of the root-cause analyses carried out; • A review of the effectiveness of the corrective actions, possibly incorporated in the management review, to initiate cross-cutting measures; • The identification of similar processes and/or products that may be subject to the identified risk factors; • Top management stewardship of the deployment of actions, and their effectiveness, in a drive for continuous improvement in quality and nuclear safety culture; • The output of lessons learned, including good practices, is clearly written up, and the corresponding improvement plans are invariably rolled out; • The sharing and communication of relevant operating experience with clients and supply chain organizations is clear, transparent and recorded. • The organization has an indicator for the processing time.
Associated requirements	• §5.1.3 - §8.2.1 - §9.3.2 f)
Find out more	• Standard NF-EN IEC 31010, Risk Management – Risk assessment techniques, regarding the risk assessment of processes.

3 Conclusion :

This guide is a work in progress, with room for improvement. **Share your comments.**

With this in mind, Filiance has set up a dedicated email address.

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4 Glossary

CEA	:	Atomic Energy and Alternative Energies Commission
CFSI	:	Counterfeit, Fraudulent and Suspect Items
FMECA	:	Failure Mode and Effect Critical Analysis
GIFEN	:	French Nuclear Industry Association. GIFEN is a trade association created in 2018, gathering over 300 member companies, encompassing all types of industrial activities and all aspects of nuclear generation.
IAEA	:	International Atomic Energy Agency
INPO	:	Institute of Nuclear Power Operations. INPO is an organisation created in the United States, which establishes performance criteria, rules and guidelines for the use of nuclear installations.
INSAG	:	International Nuclear Safety Group (INSAG). An IAEA group of experts in the field of safety.
ISO	:	International Organisation for Standardisation
ITNS	:	(products or services) Important To Nuclear Safety
ONR	:	Office for Nuclear Regulation
Organization:		"Person or group of people that has its own functions with responsibilities, authorities and relationships to achieve its objectives", 3.2.1, ISO 9000:2015
TQRDC	:	Technology, Quality, Responsiveness, Delivery, Cost
WANO	:	World Association of Nuclear Operators. WANO is an international group of nuclear power plant operators, dedicated to nuclear safety.