TECHNICAL REPORT

ISO/TR 4450

First edition

Quality management systems — Guidance for the application of ISO 19443:2018

Systèmes de management de la qualité — Lignes directrices pour l'application de l'ISO 19443:2018

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Foreword

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ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The relationship of ISO standards to the IAEA safety standards (http://www-ns.iaea.org/standards/) needs to be understood to avoid confusions.

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

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

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

This document was prepared by the Technical Committee ISO/TC 85, *Nuclear energy, nuclear technologies, and radiological protection* WG 4, *Management systems and conformity assessment.*

Any feedback or questions on this document should be directed to the user's national standards body. A complete listing of these bodies can be found at www .iso .org/members .html.

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Introduction

As general consideration, this guideline document:

— has been developed to assist users to apply the quality management system requirements of ISO 19443:2018 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS)[1],

— does not add to, subtract from, or in any way modify those requirements,

— does not prescribe mandatory approaches to implementation, or provide any preferred method of interpretation of ISO 19443:2018 requirements supplementing those of ISO 9001:2015[2], but only provide examples of possible solutions an organization can implement to meet the requirements,

— proposes also good practices for some clauses of ISO 9001 when applied to ISO 19443.

Where there is no supplementary text to ISO 9001[2] (refer also to Annex A which gives a global picture of additional requirements of ISO 19443:2018 versus ISO 9001:2015), the sentence "*No ISO 19443 additional requirement to ISO 9001*" has been included. In this case, for guidance on the initial text of ISO 9001, refer to:

- ISO 9001:2015[2], Annex A,
- ISO/TS 9002[3], and
- ISO/IAF Auditing Practices Group[4].

Where it is considered that the added text is self-explanatory and thus no guidance has been added, the sentence "*No supplementary guidance provided* " has been included.

This guidance follows the layout of ISO 19443 and thus, users need to clearly understand the vocabulary of ISO 9000 and ISO 9001, which underlie it, before addressing the added text in ISO 19443.

The delivery of all products or services will involve tiers (See Figure 1) to which the Licensee requirements will be cascaded through Contractor(s) using technical specifications, procedures, management system (including Quality Assurance and Quality Control) requirements, and other contractual documents.

At each level, the external provider (called hereby "contractor", "supplier" or "sub-supplier") will be potentially in position to be "the organization" considered by ISO 19443.

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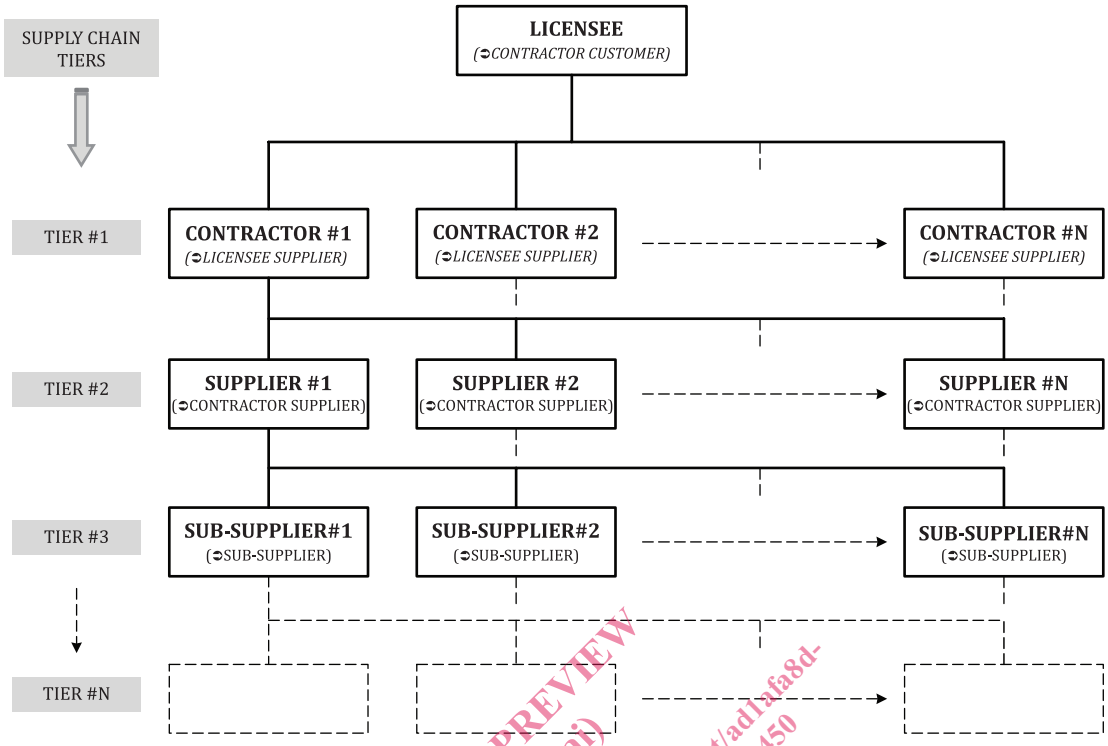

Figure 1 — Schematic breakdown of tiers.

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0.1 General

No ISO 19443 additional requirement to ISO 9001.

0.2 Quality management principles

No supplementary guidance provided.

0/3 Process approach

No ISO 19443 additional requirement to ISO 9001.

0.4 Relationship with other management system standards

No supplementary guidance provided.

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Quality management systems — Guidance for the application of ISO 19443:2018

1 Scope

This document provides guidance on the implementation of the ISO 19443 requirements, with examples of possible steps an organization can take to meet the requirements.

It does not add to, subtract from, or in any way modify those requirements.

This document does not prescribe mandatory approaches to implementation, or provide any preferred method of interpretation.

2 Normative references

There are no normative references in this document.

No ISO 19443 additional requirement to ISO 9001.

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3 Terms and definitions

No terms and definitions are listed in this document.

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

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

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

4 Context of the organization

4.1 Understanding the organization and its context

As part of risk-based thinking of ISO 19443:2018, 0.3.3, the organization should consider any risks and the nuclear safety implications to its activities.

Refer also to Annex B.

4.2 Understanding the needs and expectations of interested parties

No ISO 19443 additional requirement to ISO 9001.

4.3 Determining the scope of the quality management system

No ISO 19443 additional requirement to ISO 9001.

4.4 Quality management system and its processes

4.4.1 *No ISO 19443 additional requirement to ISO 9001.*

4.4.2 *No ISO 19443 additional requirement to ISO 9001.*

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4.4.3 Refer to ISO 9000:2015[5] for definition of quality manual or quality plan and to following standards referenced in ISO 9001:2015, Annex B:

— ISO 10005, *Quality management systems — Guidelines for quality plans*[6]. This document provides guidance on establishing and using quality plans as a means of relating requirements of the process, product, project or contract, to work methods and practices that support product realization. Benefits of establishing a quality plan are increased confidence that requirements will be met, that processes are in control and the motivation that this can give to those involved.

— ISO 10006, *Quality management systems — Guidelines for quality management in projects*[7]. This document is applicable to projects from the small to large, from simple to complex, from an individual project to being part of a portfolio of projects. ISO 10006 is to be used by personnel managing projects and who need to ensure that their organization is applying the practices contained in the ISO quality management

The intent of this subclause is for the organization to demonstrate compliance with ISO 19443 requirements, whatever the form, format or media. Quality manual and/or quality plan are examples of typical ways to comply with this clause, but any other means (e.g. matrix, correspondence table, etc.) can be used.

5 Leadership

Material can be found as guidelines for whole chapter 5 in the following documents.

— IAEA, Safety Series No.75-INSAG-4, 1991 – Safety Culture[21]

— INPO – "Principles for a Strong Nuclear Safety Culture"[22]

— WANO – Principles PL | 2013-1 - Traits of a Healthy Nuclear Safety Culture[23]

— IAEA, No.INSAG-10, 1996 – Defence in Depth in Nuclear Safety[24]

— AIEA, No.INSAG-13, 1999 – Management of Operational Safety in Nuclear Power Plants[25]

— IAEA, No.INSAG-15, 2002 – Key Practical Issues in Strengthening Safety Culture[26]

— IAEA Bulletin 50-1 – September 2008 – The mind-set of nuclear safety[27]

— IAEA General Safety Requirements - GSR Part 2:2016 - Leadership and Management for Safety[28]

— IAEA Safety Guide No. GS-G-3.1:2006 - Application of the Management System for Facilities and Activities[29]

— IAEA Safety Reports Series No 83:2016 - Performing Safety Culture Self-assessments[30]

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5.1 Leadership and commitment

5.1.1 General

No supplementary guidance provided.

5.1.2 Customer focus

No ISO 19443 additional requirement to ISO 9001.

5.1.3 Nuclear safety culture

Definition of IAEA Safety glossary[8]:

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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.

Section 5.1.3 of the standard addresses the principles of nuclear safety culture as a contribution to nuclear safety, see Figure 2:

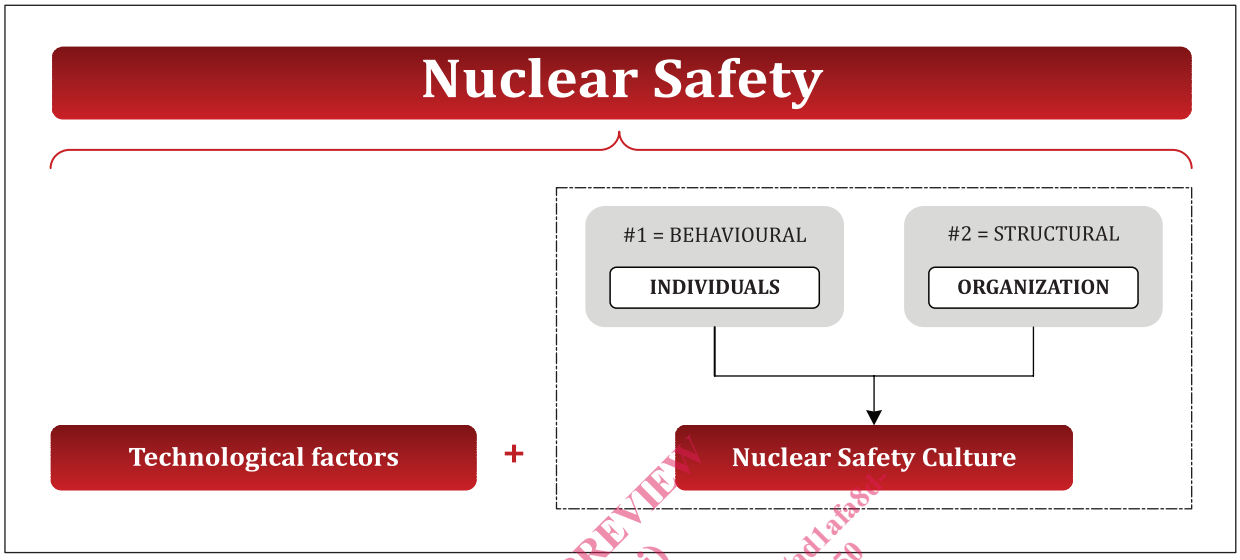

Figure 2 — Nuclear safety and nuclear safety culture

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5.2 Policy

5.2.1 Establishing the quality policy

Appropriate nuclear safety considerations of 5.2.1 e) should take into account nuclear safety culture aspects.

It's up to the organization to develop separated policies for quality and safety or an integrated one.

5.2.2 Communicating the quality policy

No ISO 19443 additional requirement to ISO 9001.

5.3 Organizational roles, responsibilities and authorities

No supplementary guidance provided.

6 Planning

6.1 Actions to address risks and opportunities

No supplementary guidance provided.

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6.1.1 The only ISO 19443 additional requirement to ISO 9001 is the requirement to maintain and retain documented information issued to identify actions to address risks and opportunities. As reminder of the state of the art, the following can be considered as a good practice for both 6.1.1 and 6.1.2.

The organization should develop a documented risk management method, related to the achievement of applicable requirements. This includes, as appropriate to the organization and the product:

a) assignment of responsibilities for risk management;

b) definition of risk criteria (e.g., likelihood, consequences, risk acceptance), which could require use of probabilistic model;

c) identification, assessment and communication of risks throughout product realization including supply chain;

d) identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria;

e) tolerability of risks remaining after implementation of mitigating actions.

See Annex B for proposed practical solution.

6.1.2 See above 6.1.1.

6.1.3 Determination of ITNS items and activities

Depending on the context of the product or service, the determination of ITNS items and activities can generally be performed by the following technical analysis performed in two consecutive steps as shown in Figure 3.

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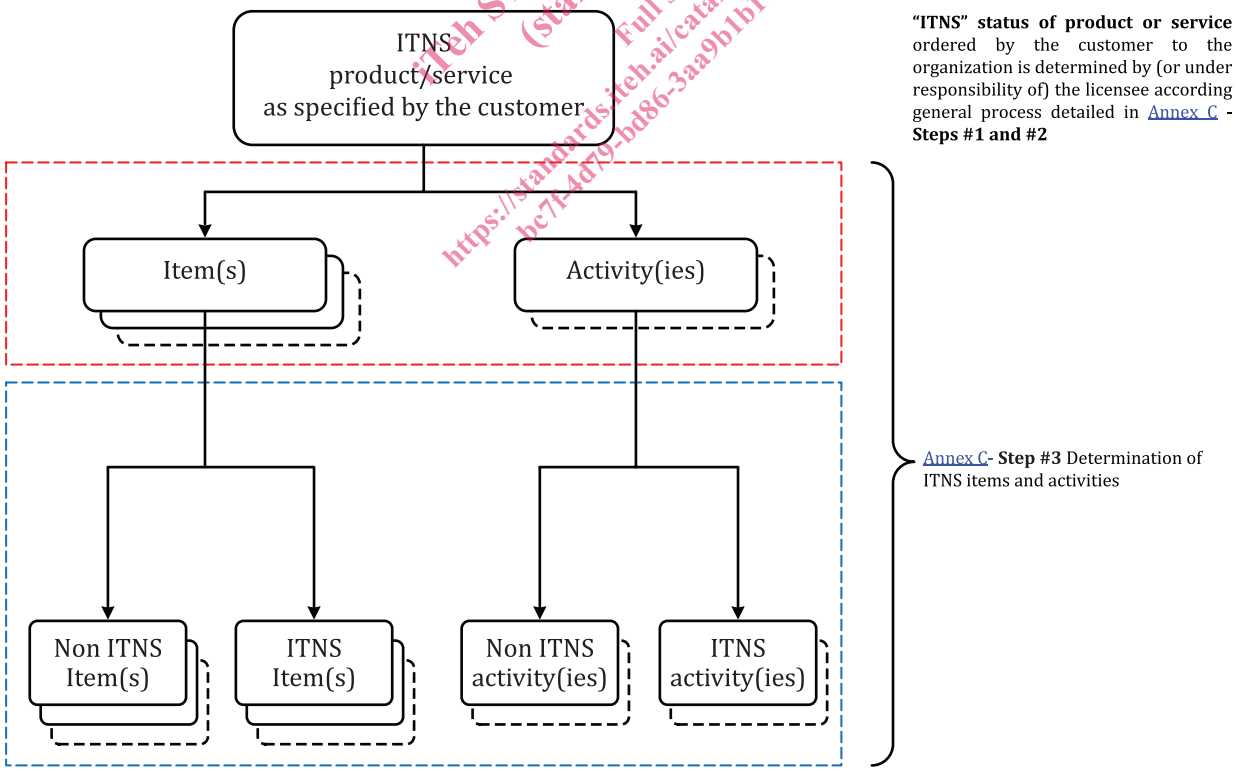

Figure 3 — Determination of ITNS items and activities (see practical example In Annex D)

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Annex D - Step #3 is performed in two steps.

— **Step #3-1**: The product or service would normally be broken down in different items or activities [see ISO 19443:2018, 6.1.3 a)]. When relevant and depending on the complexity of product and service, following analysis methods can be used: F.A.S.T. (Functional Analysis System Technique), Value engineering, etc.

— **Step #3-2**: Identification of the impact of the potential failure or malfunction of each item or activity on the product or service function(s) specified by the customer as related to nuclear safety [see ISO 19443:2018, 6.1.3 b)]:

  — a risk analysis, performed for each item or activity, would support this identification, considering that the conclusion should be formulated in a binary sense (ITNS or non-ITNS);

  — it is recommended to refer to one of the different type of risk analysis methods as listed in IEC/ISO 31010[9], e.g. Failure modes and effects analysis (FMEA).

  NOTE When appropriate, design/construction codes or standards can be used for identification of the impact of the potential failure or malfunction of each item or activity on the above function(s) related to nuclear safety.

For a practical example (electromechanical pump) of ITNS determination, refer to Annex D.

6.1.4 Graded approach to the application of quality requirements

The intent of the ISO 19443 is to define the graded approach as it should be applied by the organization to the items constituting and/or activities resulting in the ITNS product or service ordered by the customer. A practical understanding of the requirement would be:

Items and/or activities supplied by the organization itself:

— **Quality management**. Set of requirements are those of ISO 19443 since the product or service supplied by the organization to its customer is ITNS. However, the organization can grade, for each item or activity, the conditions in which the implementation of all ISO 19443 requirements is performed, to the extent authorized by ISO 19443 provisions, with a particular focus on:

  — **Documentation** requirements. As an example, grading provisions could address number and extent (complexity, level of detail, …) of documented information (from a single certificate of compliance to a full set of lifetime records, procedures, plans, specifications, drawings, reports, …) the organization maintains and retains for the item or activity, having regard to the appropriate level of assurance to be established, based on the level of risk (i.e. ITNS or not),

  — **Monitoring and measurement** requirements. Grading examples could be, but not limited to:

    — Conditions for review and/or approval of documented information.

    — Internal assessment and oversight of processes (internal audit, inspection, document review …). It's recommended that the oversight particularly takes into consideration the processes "the result of which the specified quality cannot be readily determined by inspection of test of the product".

    — Design and development : number and type of reviews (e.g. peer reviews), methods of verification, means of validation (e.g. testing, alternative calculations, mock-ups, …).

    — Production control: sampling procedures, witness/hold points on ITP, resources, gate reviews …

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