PD CEN ISO/TR 4450:2022
Incorporating corrigendum December 2022

BSI Standards Publication

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

Documents
Document Sharing Hub

Full document details: PD CEN ISO/TR 4450:2022

National foreword

This Published Document is the UK implementation of CEN ISO/TR 4450:2022. It is identical to ISO/TR 4450:2020.

The UK participation in its preparation was entrusted to Technical Committee NCE/2, Radiation protection and measurement.

A list of organizations represented on this committee can be obtained on request to its committee manager.

Contractual and legal considerations

This publication has been prepared in good faith, however no representation, warranty, assurance or undertaking (express or implied) is or will be made, and no responsibility or liability is or will be accepted by BSI in relation to the adequacy, accuracy, completeness or reasonableness of this publication. All and any such responsibility and liability is expressly disclaimed to the full extent permitted by the law.

This publication is provided as is, and is to be used at the recipient's own risk.

The recipient is advised to consider seeking professional guidance with respect to its use of this publication.

This publication is not intended to constitute a contract. Users are responsible for its correct application.

© The British Standards Institution 2022
Published by BSI Standards Limited 2022

ISBN 978 0 539 22959 2

ICS 03.100.70; 03.120.10; 27.120.01

Compliance with a British Standard cannot confer immunity from legal obligations.

This Published Document was published under the authority of the Standards Policy and Strategy Committee on 30 September 2020.

Amendments/corrigenda issued since publication

Date	Text affected
31 December 2022	This corrigendum renumbers PD ISO/TR 4450:2020 as PD CEN ISO/TR 4450:2022

Documents
Document Sharing Hub

Full document details: PD CEN ISO/TR 4450:2022

TECHNICAL REPORT

RAPPORT TECHNIQUE

TECHNISCHER REPORT

CEN ISO/TR 4450

October 2022

ICS 03.120.10; 27.120.01; 03.100.70

English Version

Quality management systems - Guidance for the application of ISO 19443:2018 (ISO/TR 4450:2020)

Systèmes de management de la qualité - Lignes directrices pour l'application de l'ISO 19443:2018 (ISO/TR 4450:2020)

This Technical Report was approved by CEN on 23 October 2022. It has been drawn up by the Technical Committee CEN/TC 430.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

© 2022 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. CEN ISO/TR 4450:2022 E

Documents
Document Sharing Hub

Full document details: PD CEN ISO/TR 4450:2022

European foreword

The text of ISO/TR 4450:2020 has been prepared by Technical Committee ISO/TC 85 "Nuclear energy, nuclear technologies, and radiological protection" of the International Organization for Standardization (ISO) and has been taken over as CEN ISO/TR 4450:2022 by Technical Committee CEN/TC 430 "Nuclear energy, nuclear technologies, and radiological protection" the secretariat of which is held by AFNOR.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

Endorsement notice

The text of ISO/TR 4450:2020 has been approved by CEN as CEN ISO/TR 4450:2022 without any modification.

Documents
Document Sharing Hub

Full document details: PD CEN ISO/TR 4450:2022

Contents

Page

Foreword ..... **v**
Introduction ..... **vi**
1 Scope **1**
2 Normative references **1**
3 Terms and definitions **1**
4 Context of the organization **1**
4.1 Understanding the organization and its context 1
4.2 Understanding the needs and expectations of interested parties 1
4.3 Determining the scope of the quality management system 1
4.4 Quality management system and its processes 1
5 Leadership **2**
5.1 Leadership and commitment 2
5.1.1 General 2
5.1.2 Customer focus 2
5.1.3 Nuclear safety culture 2
5.2 Policy 3
5.2.1 Establishing the quality policy 3
5.2.2 Communicating the quality policy 3
5.3 Organizational roles, responsibilities and authorities 3
6 Planning **3**
6.1 Actions to address risks and opportunities 3
6.2 Quality objectives and planning to achieve them 6
6.3 Planning of changes 6
7 Support **6**
7.1 Resources 6
7.1.1 General 6
7.1.2 People 7
7.1.3 Infrastructure 7
7.1.4 Environment for the operation of processes 7
7.1.5 Monitoring and measuring resources 7
7.1.6 Organizational knowledge 8
7.2 Competence 8
7.3 Awareness 8
7.4 Communication 8
7.5 Documented information 8
7.5.1 General 9
7.5.2 Creating and updating 9
7.5.3 Control of documented information 9
8 Operation **10**
8.1 Operational planning and control 10
8.1.1 Provisions for Counterfeit, Fraudulent or Suspect (CFS) items 10
8.2 Requirements for products and services 10
8.2.1 Customer communication 10
8.2.2 Determination of requirements related for products and services 10
8.2.3 Review of requirements related for products and services 10
8.2.4 Changes to requirements for products and services 10
8.3 Design and development of products and services 10
8.4 Control of externally provided processes, products and services 10
8.4.1 General 10
8.4.2 Type and extent of control 11
8.4.3 Information for external providers 12

AVA Documents
Document Sharing Hub

© ISO 2020 – All rights reserved

Full document details: PD CEN ISO/TR 4450:2022

8.5 Production and service provision 12
8.5.1 Control of production and service provision 12
8.5.2 Identification and traceability 12
8.5.3 Property belonging to customers or external providers 12
8.5.4 Preservation 12
8.5.5 Post-delivery activities 12
8.5.6 Control of changes 13
8.6 Release of products and services 13
8.7 Control of nonconforming outputs 13

9 Performance evaluation 13
9.1 Monitoring, measurement, analysis and evaluation 13
9.1.1 General 13
9.1.2 Customer satisfaction 13
9.1.3 Analysis and evaluation 13
9.2 Internal audit 13
9.3 Management review 13
9.3.1 General 13
9.3.2 Management review inputs 13
9.3.3 Management review outputs 13

10 Improvement 14
10.1 General 14
10.2 Nonconformity and corrective action 14
10.3 Continual improvement 14

Annex A (informative) **Additional requirements of ISO 19443:2018 versus ISO 9001:2015 15**

Annex B (informative) **How to perform a risk analysis for the project? 18**

Annex C (informative) **Determination of ITNS items and activities 22**

Annex D (informative) **Practical example of determination of ITNS items and activities 24**

Annex E (informative) **Typical (general) example for graded approach 27**

Annex F (informative) **Practical example of graded approach 29**

Annex G (informative) **Metrological guidelines 32**

Annex H (informative) **Competence and qualification 35**

Annex I (informative) **Awareness training for personnel 38**

Annex J (informative) **List of ISO 19443 additional requirements related to documented information 42**

Annex K (informative) **Good practices for 8.3 45**

Annex L (informative) **Demonstration of the evidence of provisions for monitoring activities 50**

Annex M (informative) **Example of scheme for non-conformance information and request for approval along supply chain 53**

Bibliography 54

© ISO 2020 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD CEN ISO/TR 4450:2022

Foreword

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

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

The 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).

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

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.

© ISO 2020 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD CEN ISO/TR 4450:2022

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.

© ISO 2020 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD CEN ISO/TR 4450:2022

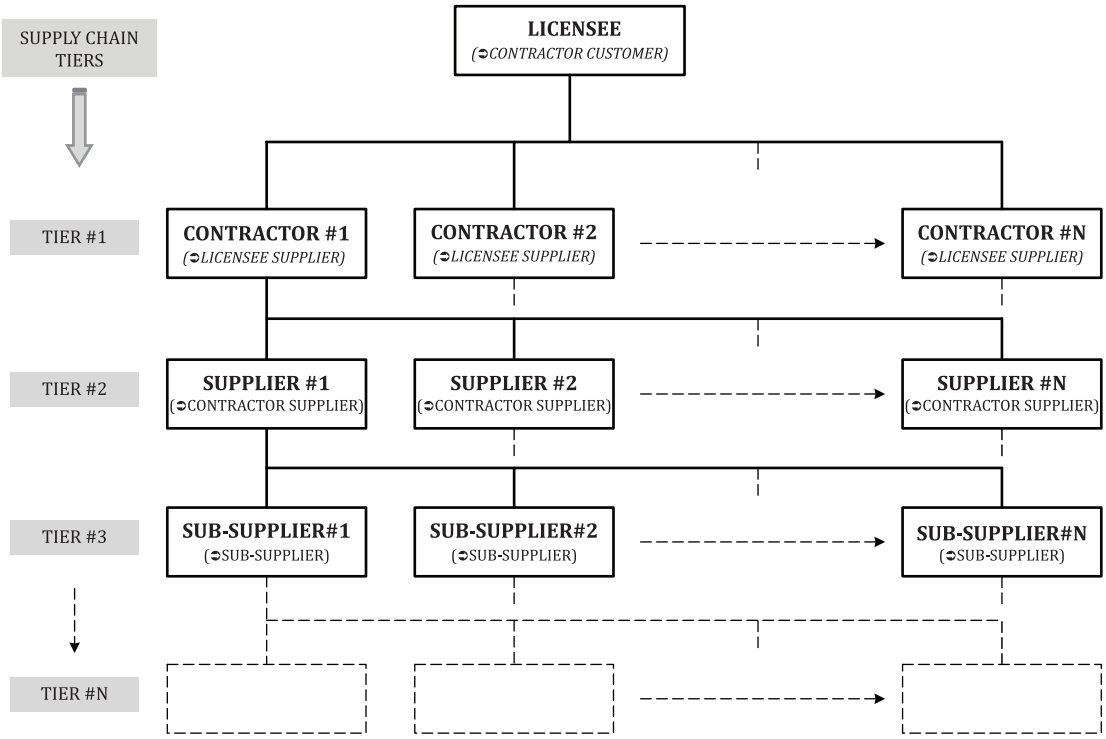

Figure 1 — Schematic breakdown of tiers.

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.

© ISO 2020 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD CEN ISO/TR 4450:2022

Documents
Document Sharing Hub

Full document details: PD CEN ISO/TR 4450:2022

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.

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.*

© ISO 2020 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD CEN ISO/TR 4450:2022

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]

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]:

© ISO 2020 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD CEN ISO/TR 4450:2022

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:

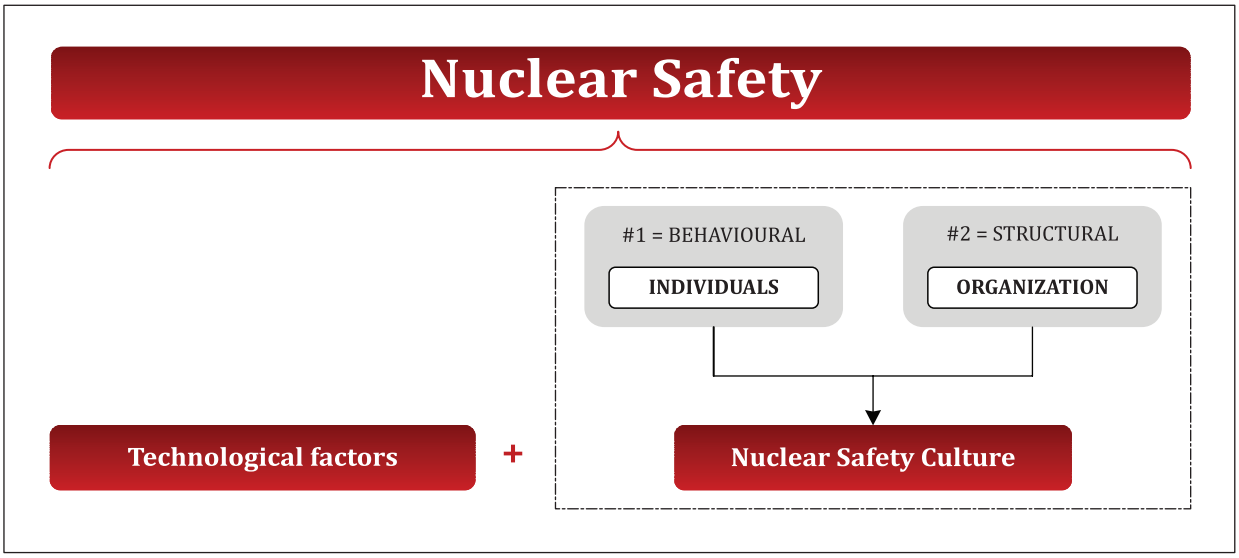

Figure 2 — Nuclear safety and nuclear safety culture

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.

© ISO 2020 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD CEN ISO/TR 4450:2022

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.

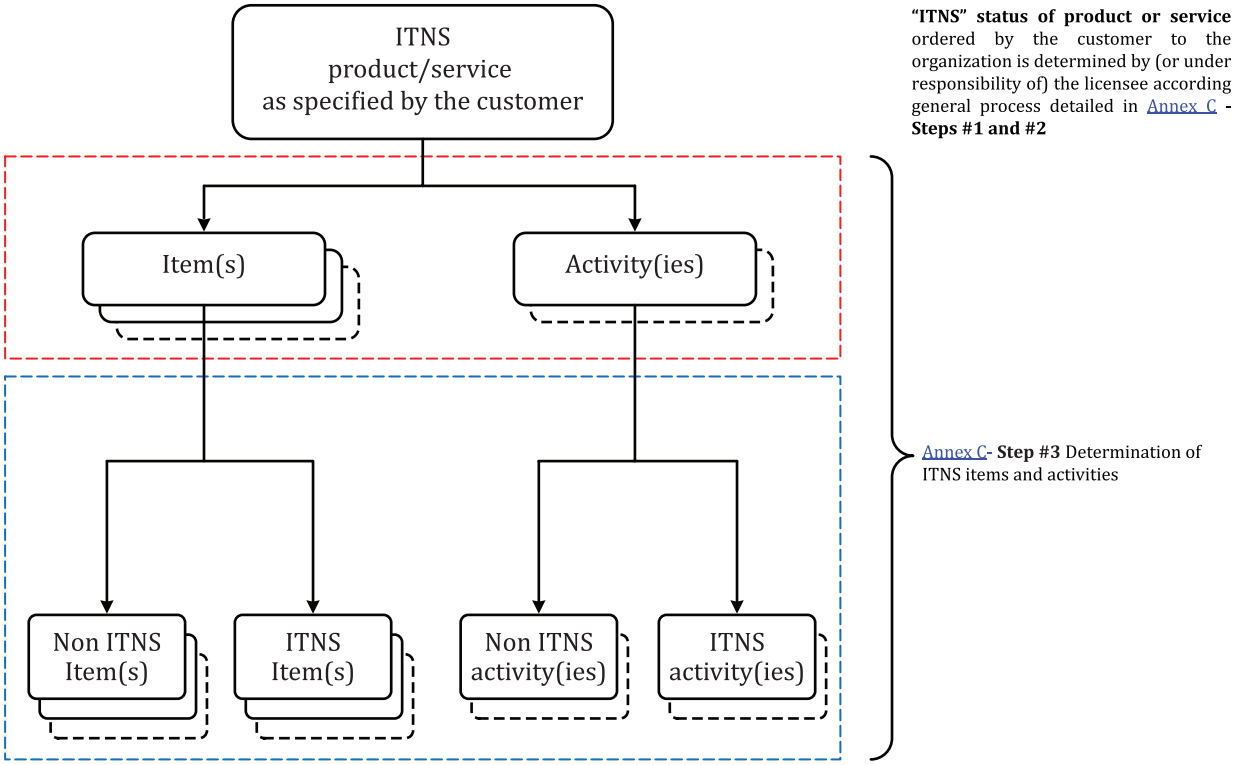

Figure 3 — Determination of ITNS items and activities (see practical example In Annex D)

© ISO 2020 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD CEN ISO/TR 4450:2022

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 …

© ISO 2020 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD CEN ISO/TR 4450:2022

Items and/or activities supplied by an external provider:

— **Quality management**. The set of requirements determined as applicable for the external provider could be, but not limited to:

  — for externally provided "ITNS items and activities": ISO 19443,

  — for externally provided "non ITNS items and activities", one of the following given as examples: ISO 9001, specific quality management requirements, industrial good practices, no particular ones.

— **Documentation requirements**. As an example, grading provisions could address number and extent (complexity, level of detail, …) of documented information, defined having regard to the appropriate level of assurance to be established, based on the level of risk (i.e. ITNS or not):

  — the organization should issue for control of externally provided item and activities,

  — the external provider should maintain and retain for the item or activity (from a single certificate of compliance to a full set of lifetime records, procedures, plans, specifications, drawings, reports, …),

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

  — Conditions for review and/or approval by the organization of documented information issued by the external provider,

  — External provider assessment and processes oversight (audit, inspection, document review, design and development reviews, …) through sampling rules, witness/hold points, gate reviews … 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".

Refer to Annex E for typical general example of grading and to Annex F for a practical simplified example (electromechanical pump) of grading.

For more general information, refer to:

— IAEA-TECDOC-1740[10];

— IAEA-Technical Report-328[11].

6.2 Quality objectives and planning to achieve them

6.2.1 *No supplementary guidance provided.*

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

6.3 Planning of changes

No supplementary guidance provided.

7 Support

7.1 Resources

7.1.1 General

No supplementary guidance provided.

© ISO 2020 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD CEN ISO/TR 4450:2022

7.1.2 People

No ISO 19443 additional requirement to ISO 9001.

7.1.3 Infrastructure

No ISO 19443 additional requirement to ISO 9001.

7.1.4 Environment for the operation of processes

b) *Psychological*

Nuclear safety culture studies have identified that it is important that the workforce can be open with reporting when they have made mistakes. Experience has shown that this requires management to have a ***non-blaming*** approach, though still considering the root-causes of mistakes may require changes in activities, retraining or ultimately removal from ITNS work.

c) *Physical*

Cleanliness is a significant matter in the manufacture, assembly and construction of Structures Systems and Components (SSCs) that will be subject to ionising radiation.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

Nuclear SSCs frequently require fine tolerances and thus, it is necessary to put the emphasis on measuring resources requirements within nuclear context compared to current industrial practices. Therefore, particular attention is drawn to situations (See Figure G.1) where:

— the measuring interval of the measuring equipment is much higher than the measurand (e.g. when use of a ruler of 0,3 m rather than a micrometer 0 mm to 25 mm for the acceptance of a measurand of 0,5 mm),

— the measured value is close to the specified limits (boundaries of specification zone) and therefore, due to measurement uncertainty, the real value may be outside the specification zone,

— the measurement uncertainty is much lower than the tolerance given in the specification.

To avoid or minimize incorrect judgement of conformity to requirements, it is suggested, as a good practice, to select measuring equipment which has:

— a measuring interval close to the measurand (e.g. manometer range 0 bar to 100 bar for a measured value of 80 bar),

— a measurement accuracy with a minimum coverage factor of 8 compared with the value of the tolerance (e.g. use of a calliper with a measurement accuracy of $1/100^{th}$ mm when the tolerance is $1/10^{th}$ mm).

As a good practice, the organization should also:

— maintain a monitoring and measuring equipment register, and define the process employed for their calibration/verification including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria,

— ensure that environmental conditions are suitable for the calibration, inspection, measurement and testing being carried out.

© ISO 2020 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD CEN ISO/TR 4450:2022

7.1.5.2 Measurement traceability

The monitoring and measuring equipment (e.g. measuring instrument, software, measurement standard or auxiliary apparatus or combination thereof) necessary to perform a measurement process needs a metrological confirmation by verification and/or calibration when it is used to certify the conformity of the product.

This metrological confirmation ensures that measuring equipment conforms to the requirements for its intended use, taking into account calibration or verification, as referred to in Annex G.

7.1.6 Organizational knowledge

No ISO 19443 additional requirement to ISO 9001.

7.2 Competence

For definition of **Competence** refer to ISO 9000 and, for **Qualification**, interpretation is provided in ISO 9000 and examples given in Annex H.

Examples for knowledge and skills which can be taken into account for competence are given in Annex H.

Examples for demonstration of ability to pronounce qualification are given in Annex H.

7.3 Awareness

This awareness training for persons involved (including workers and managers) in ITNS products and services realization should consider nuclear safety culture topics [see ISO 19443:2018, 5.1.3 a)] such as:

— What nuclear safety is;

— What an ITNS product, service, item or activity is;

— Importance and impact of individual's role in achieving nuclear safety;

— How individuals know they are working on ITNS;

— What my role is in preventing CFS Items being brought into the organization;

— Management: leadership, decision-making and creating a respectful work environment;

— Expected behavior : questioning attitude, adherence to procedures, transparency in reporting issues, events and NCR; …

Refer to Annex I for more detailed material.

7.4 Communication

No supplementary guidance provided.

7.5 Documented information

To confirm that the specified requirements have been met, the documentation is of great importance in the nuclear industry ("culture of the proof") by demonstrating

— effective performance of an action (traceability), and

— conformance with applicable requirements.

This is why ISO 19443 as added to ISO 9001 additional requirements for documented information. Those additional requirements are identified in the table of Annex J.

© ISO 2020 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD CEN ISO/TR 4450:2022

7.5.1 General

No ISO 19443 additional requirements to ISO 9001.

For supplementary guidance, see good practices proposed by ISO 9001:2015, A.6 and ISO/TS 9002.

7.5.2 Creating and updating

Comprehensive identification of documented information is necessary especially for products and services that will need to be replicated during the life of a nuclear facility.

Translation of documented information is not just a question of languages (Refer also to Annex H for competence) but could also include measurement systems considerations and information (e.g. metric/imperial, US/British liquid volumes) and date conventions (e.g. DD/MM/YYYY vs MM/DD/YYYY). It is useful to indicate where translations have been made, when and by whom.

Consideration should be given to making a clear statement at the outset as to the systems to be applied and abbreviations used, e.g. SI units as defined in ISO 80000 series[12].

The degree of review and approval of documented information will generally depend on the safety determination of the product and services addressed. For lower grades, a suitably qualified and experienced person from within the work unit may be acceptable but as the importance is raised the need to move towards persons from either other work units or even different organizations may be called for. The management of the organization need to decide the approaches to be taken and authorize people to undertake the reviews and approvals. In principal, no one should review their own work.

7.5.3 Control of documented information

Traceability and ***authentication*** have been included, linked to the requirements added into 7.5.2.

It is important that management draw workers attention to changed documentation information that is appropriate to their activities. Revision marking systems should be used to identify discrete elements of text that have been altered.

Obsolete documented information should at least be marked as such, but if possible should be withdrawn/archived so that it cannot be inadvertently used.

For electronic documented information revision marking modes are one means of identifying changes.

Under certain circumstances, a temporary/interim documented information may be required to control an activity for a limited period, waiting their formal update. A practical example could be a work instruction modified by hand with a mark-up. This should clearly (e.g. in coloured inks) identify what the change is, who has made the modification (only authorized personnel should modify the documented information) and, if possible, relate to a document control note which sets out the history and justification for the change. Any correction method which would make the change illegible, such as the use of correcting fluid or tape, should not be permitted.

Maintenance of the documented information is a typical mean to ensure that the requirements of 7.5.3 are met.

For additional information and guidelines on management systems for records, refer to ISO 30300 series[13] which constitutes a reference point for information management and for the creation and control of documented information.

7.5.3.1 *See above 7.5.3 guidelines.*

7.5.3.2 *See above 7.5.3 guidelines.*

© ISO 2020 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD CEN ISO/TR 4450:2022

8 Operation

8.1 Operational planning and control

For project management, further guidance is given in ISO 10006[7] and ISO 21500[14].

For configuration management, further guidance is given in ISO 10007[15], IEEE 828[16] and IEEE 1042[17].

8.1.1 Provisions for Counterfeit, Fraudulent or Suspect (CFS) items

The wording "at all levels of operations" includes the organization itself.

For more information, refer to:

— IAEA Nuclear Energy Series No. NP-T-3.21:2016[18],

— IAEA Tecdoc 1169:2000[19],

— IAEA Technical Report No. NP-T-3.26:2019[20].

8.2 Requirements for products and services

8.2.1 Customer communication

No supplementary guidance provided.

8.2.2 Determination of requirements related for products and services

No ISO 19443 additional requirement to ISO 9001.

8.2.3 Review of requirements related for products and services

8.2.3.1 *No supplementary guidance provided.*

8.2.3.2 *No supplementary guidance provided.*

8.2.4 Changes to requirements for products and services

No supplementary guidance provided.

8.3 Design and development of products and services

For supplementary guidance and good practices proposed for the whole of 8.3, refer to Annex K.

8.4 Control of externally provided processes, products and services

8.4.1 General

Criteria for the external providers evaluation and selection should consider topics such as:

© ISO 2020 – All rights reserved
Documents
Document Sharing Hub
Full document details: PD CEN ISO/TR 4450:2022

— **T**echnical: Ability to provide a product or service compliant right first time including qualification requirements e.g. compliance with codes and standards as applicable,

— **Q**uality and nuclear safety culture: Compliance of Quality Management System with the applicable specified requirements, lessons learnt from previous orders: number of complaints raised by the organization, completeness of quality documentation provided for previous deliveries, monitoring results, qualification of personnel…

— **R**esponsiveness: Ability to answer rapidly to organization (needs, Complaint Resolution Time etc.),

— **D**elivery: Respect of schedule, on time in full,

— **C**ost: Value for money.

Typical documented information on external provider assessment could be assessment files, approved external providers lists, etc.

When demonstrating equivalence of provisions taken when an external provider, responsible for an ITNS items or activities, cannot demonstrate that its quality management system meets the requirements of ISO 19443, a good practice could be to for the organization to issue a document (e.g. a quality plan) identifying those of the requirements:

— fulfilled by the external supplier's quality management system, and

— covered by the organization's specific provisions taken for the requirements for which the quality management system of the external provider doesn't offer adequate or sufficient provisions.

8.4.2 Type and extent of control

Commercial grade items

Commercial-grade items may be specified, procured and installed into ITNS products and can be defined as items that:

a) are generally utilised in non-nuclear applications and are therefore not designed or manufactured to nuclear specific requirements,

b) can be ordered by an organization based on the specification and characteristics defined in a manufacturer or supplier catalogue. This type of item is often referred to as "commercial off the shelf",

c) have not been subject to any modifications from their original design, specification, service application or operating parameters defined in above catalogue.

The following are examples of services that could be determined as ITNS activities:

— repair services;

— testing services;

— fabrication/machining/cleaning/manufacturing services;

— engineering/technical services;

— calibration services;

— computer software services.

Monitoring of commercial grade items

© ISO 2020 – All rights reserved

Documents
Document Sharing Hub
Full document details: PD CEN ISO/TR 4450:2022