

<b>STN P</b>	<b>Jadrové odvetvie Požiadavky na orgány poskytujúce audit a certifikáciu systémov manažérstva kvality organizácií dodávajúcich výrobky a služby dôležité pre jadrovú bezpečnosť (ISO/TS 23406: 2024, opravená verzia 2025-07)</b>	<b>STN P CEN ISO/TS 23406</b>  01 0331
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Nuclear sector - Requirements for bodies providing audit and certification of quality management systems for organizations supplying products and services important to nuclear safety (ITNS) (ISO/TS 23406:2024, Corrected version 2025-07)

Táto norma obsahuje anglickú verziu európskej normy.  
This standard includes the English version of the European Standard.

Táto norma bola oznámená vo Vestníku ÚNMS SR č. 01/26

Táto predbežná slovenská technická norma je určená na overenie. Prípadné pripomienky pošlite do septembra 2027 Úradu pre normalizáciu, metrológiu a skúšobníctvo Slovenskej republiky.

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Oznámením tejto normy sa ruší  
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Slovenská technická norma a technická normalizačná informácia je chránená zákonom č. 60/2018 Z. z. o technickej normalizácii v znení neskorších predpisov.

TECHNICAL SPECIFICATION

CEN ISO/TS 23406

SPÉCIFICATION TECHNIQUE

TECHNISCHE SPEZIFIKATION

April 2024

ICS 03.120.20; 27.120.01

Supersedes CEN ISO/TS 23406:2021

English Version

**Nuclear sector - Requirements for bodies providing audit and certification of quality management systems for organizations supplying products and services important to nuclear safety (ITNS) (ISO/TS 23406:2024, Corrected version 2025-07)**

Secteur nucléaire - Exigences pour les organismes procédant à l'audit et à la certification des systèmes de management de la qualité d'organisations fournissant des produits et services importants pour la sûreté nucléaire (IPSN) (ISO/TS 23406:2024, Version corrigée 2025-07)

Nuklearsektor - Anforderungen an Stellen, die Qualitätsmanagementsysteme für Organisationen prüfen und zertifizieren, die für die nukleare Sicherheit wichtige Produkte und Dienstleistungen (ITNS) liefern (ISO/TS 23406:2023, korrigierte Fassung 2025-07)

This Technical Specification (CEN/TS) was approved by CEN on 5 April 2024 for provisional application.

This European Standard was corrected and reissued by the CEN-CENELEC Management Centre on 03 September 2025.

The period of validity of this CEN/TS is limited initially to three years. After two years the members of CEN will be requested to submit their comments, particularly on the question whether the CEN/TS can be converted into a European Standard.

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COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

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**CEN ISO/TS 23406:2024 (E)**

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## **European foreword**

This document (CEN ISO/TS 23406:2024) has been prepared by Technical Committee ISO/TC 85 "Nuclear energy, nuclear technologies, and radiological protection" in collaboration with 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.

This document supersedes CEN ISO/TS 23406:2021.

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

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to announce this Technical Specification: 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 the United Kingdom.

## **Endorsement notice**

The text of ISO/TS 23406:2024, Corrected version 2025-07 has been approved by CEN as CEN ISO/TS 23406:2024 without any modification.



# Technical Specification

**ISO/TS 23406**

## **Nuclear sector — Requirements for bodies providing audit and certification of quality management systems for organizations supplying products and services important to nuclear safety (ITNS)**

*Secteur nucléaire — Exigences pour les organismes procédant  
à l'audit et à la certification des systèmes de management de  
la qualité d'organisations fournissant des produits et services  
importants pour la sûreté nucléaire (IPSN)*

**Second edition  
2024-03**

**Corrected version  
2025-07**

## ISO/TS 23406:2024(en)



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**ISO/TS 23406:2024(en)****Foreword**

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

The procedures used to develop this document and those intended for its further maintenance are described in the ISO/IEC Directives, Part 1. In particular, the different approval criteria needed for the different types of ISO document 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](http://www.iso.org/directives)).

ISO draws attention to the possibility that the implementation of this document may involve the use of (a) patent(s). ISO takes no position concerning the evidence, validity or applicability of any claimed patent rights in respect thereof. As of the date of publication of this document, ISO had not received notice of (a) patent(s) which may be required to implement this document. However, implementers are cautioned that this may not represent the latest information, which may be obtained from the patent database available at [www.iso.org/patents](http://www.iso.org/patents). ISO shall not be held responsible for identifying any or all such patent rights.

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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](http://www.iso.org/iso/foreword.html).

This document was prepared by Technical Committee ISO/TC 85, *Nuclear energy, nuclear technologies and radiological protection*, in collaboration with ISO Committee on Conformity Assessment (CASCO), and in collaboration with the European Committee for Standardization (CEN) Technical Committee CEN/TC 430, *Nuclear energy, nuclear technologies, and radiological protection*, in accordance with the Agreement on technical cooperation between ISO and CEN (Vienna Agreement).

This second edition cancels and replaces the first edition (ISO/TS 23406:2020), which has been technically revised.

The main changes are as follows:

- clarification on the multiple site organization audit duration.

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](http://www.iso.org/members.html).

This corrected version of ISO/TS 23406:2020 incorporates the following corrections:

- in [9.1.4](#), the paragraph numbering 9.1.4.1 was deleted at the beginning of the first paragraph;
- in [9.6](#), in the first paragraph after the list, the sentence was replaced by the following one: "The requirements of ISO/IEC 17021-1:2015, 9.6.4 are complemented as follow with an added subclause 9.6.4.3."

**ISO/TS 23406:2024(en)****Introduction**

Certification of the quality management system (QMS) of an organization supplying products and services important to nuclear safety (ITNS) is one means of providing assurance that the organization has implemented a system for the management of quality in line with its policy.

Supplementing ISO/IEC 17021-1 requirements, this document has been developed for the nuclear sector to assist in the conformity assessment and certification according to ISO 19443.

# Nuclear sector — Requirements for bodies providing audit and certification of quality management systems for organizations supplying products and services important to nuclear safety (ITNS)

## 1 Scope

This document complements the existing requirements of ISO/IEC 17021-1 for bodies providing audit and certification of quality management systems against ISO 19443.

NOTE This document can be used as a criteria document for accreditation, peer assessment or other audit processes.

## 2 Normative references

The following documents are referred to in the text in such a way that some or all of their content constitutes requirements of this document. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

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

ISO/IEC 17000, *Conformity assessment — Vocabulary and general principles*

ISO/IEC 17021-1:2015, *Conformity assessment — Requirements for bodies providing audit and certification of management systems — Part 1: Requirements*

ISO 19443, *Quality management systems — Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS)*

## 3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000, ISO/IEC 17000, ISO/IEC 17021-1 and ISO 19443 apply.

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

- ISO Online browsing platform: available at <https://www.iso.org/obp>
- IEC Electropedia: available at <https://www.electropedia.org/>

## 4 Principles

The principles of ISO/IEC 17021-1:2015, Clause 4, apply.

## 5 General requirements

### 5.1 Legal and contractual matters

The requirements of ISO/IEC 17021-1:2015, 5.1, apply and 5.1.2 is complemented as follows.

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The certification agreement shall include provision that the certification body is informed by the client of any starting, interruption or resumption of all activities on ITNS products or services.

### 5.2 Management of impartiality

The requirements of ISO/IEC 17021-1:2015, 5.2, apply.

### 5.3 Liability and financing

The requirements of ISO/IEC 17021-1:2015, 5.3, apply.

## 6 Structural requirements

### 6.1 Organizational structure and top management

The requirements of ISO/IEC 17021-1:2015, 6.1, apply.

### 6.2 Operational control

The requirements of ISO/IEC 17021-1:2015, 6.2 apply and 6.2.2 is complemented as follows.

The certification body shall identify a single office location and appoint an employee of this office that has overall responsibility and authority for the implementation of this document by all its relevant locations.

## 7 Resource requirements

### 7.1 Competence of personnel

#### 7.1.1 General considerations

The requirements of ISO/IEC 17021-1:2015, 7.1.1, apply.

#### 7.1.2 Determination of competence criteria

The requirements of ISO/IEC 17021-1:2015, 7.1.2, apply, and ISO/IEC 17021-1:2015, Annex A, is complemented by [Annex A](#) of this document.

#### 7.1.3 Evaluation processes

The requirements of ISO/IEC 17021-1:2015, 7.1.3, apply and are complemented as follows.

- Satisfactory evaluation of auditor competence shall result in a documented auditor qualification.
- The initial qualification shall be based on requirements given in [Annex A](#) and is valid for 3 years.

Qualification renewal for a 3-year period shall be based on demonstration of:

- performance of at least 6 ISO 19443 certification, recertification or surveillance audits in 3 years with a minimum of 20 days of audit,
- maintenance of professional knowledge related to codes, standards, procedures, instructions, and other documents related to quality management systems in nuclear industry,
- participation in mandatory trainings,
- satisfactory supervision of the auditor performed during an ISO 19443 audit,
- absence of significant or recurrent complaint related to his auditing activities.

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At any time, the certification body shall consider taking appropriate action, such as: training, withdrawing or suspending auditor qualification, in case of:

- no auditing activity during more than one year,
- after a non-satisfactory supervised audit and/or examination of an audit report (e.g. by the certification body or by an accreditation body),
- following a client's significant complaint concerning the auditing activity,
- on request of the auditor's management.

### 7.1.4 Other considerations

The requirements of ISO/IEC 17021-1:2015, 7.1.4, apply.

## 7.2 Personnel involved in the certification activities

The requirements of ISO/IEC 17021-1:2015, 7.2, apply and 7.2.8 is complemented as follow.

The certification body shall have at least one person with nuclear industry knowledge involved in the certification decisions.

The minimum nuclear industry knowledge required for this role shall encompass: ISO/IEC 17021-1, ISO 19443 and sufficient nuclear industry experience to understand the sector specificities and assess the contents of the certification audit report and the relevance of its conclusions.

## 7.3 Use of individual external auditors and external technical experts

The requirements of ISO/IEC 17021-1:2015, 7.3, apply.

## 7.4 Personnel records

The requirements of ISO/IEC 17021-1:2015, 7.4, apply.

These requirements shall also apply to individual external auditors and external technical experts.

## 7.5 Outsourcing

The requirements of ISO/IEC 17021-1:2015, 7.5 apply and are complemented as follows.

The certification body shall maintain the responsibility for all functions in [Table A.1](#) and shall not transfer the responsibility to any other organization.

This doesn't preclude the certification body's use of an organization or individuals which operate according to the certification body's own procedures and under its control.

# 8 Information requirements

## 8.1 Public information

The requirements of ISO/IEC 17021-1:2015, 8.1, apply and are complemented as follows.

The certification body shall make publicly available and accessible:

- a) the list of certifications issued;
- b) list of data related to certification as listed in ISO/IEC17021-1:2015, 8.2.2.

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**NOTE** A good practice is to share the list of public data related to certification with a non-profit association representing the sector. For example, for the nuclear sector the NQSA association (Nuclear Quality Standard Association) is collecting the list of public data related to certification.

### 8.2 Certification documents

The requirements of ISO/IEC 17021-1:2015, 8.2 apply and are complemented as follow.

The certification body shall mention on the certificate “for ITNS activities” before the scope of the certified activities.

### 8.3 Reference to certification and marks

The requirements of ISO/IEC 17021-1:2015, 8.3, apply.

### 8.4 Confidentiality

The requirements of ISO/IEC 17021-1:2015, 8.4 apply and are complemented as follows.

The certification body shall ensure that the client agrees to make public the certification information as listed in ISO/IEC 17021-1:2015, 8.2.2.

**NOTE** A good practice is to transmit the certification information to a non-profit association representing the sector. For information, for the nuclear sector the NQSA association (Nuclear Quality Standard Association) is collecting the list of public data related to certification.

### 8.5 Information exchange between a certification body and its client

The requirements of ISO/IEC 17021-1:2015, 8.5 apply and are complemented as follows.

The certification body shall consider provisions (e.g. authorized auditor, security clearance) for access to specific sensitive information or material as relevant to the certification scope.

The certification body shall provide information and update clients on the data it has transmitted when drawing up the lists of certifications issued.

## 9 Process requirements

### 9.1 Pre-certification activities

#### 9.1.1 Application

The requirements of ISO/IEC 17021-1:2015, 9.1.1 apply.

#### 9.1.2 Application review

The requirements of ISO/IEC 17021-1:2015, 9.1.2 apply.

#### 9.1.3 Audit programme

The requirements of ISO/IEC 17021-1:2015, 9.1.3 apply.

#### 9.1.4 Determining audit time

The requirements of ISO/IEC 17021-1:2015, 9.1.4 apply and 9.1.4.2 is complemented as follows.

[Table 1](#) below is intended to be used when the entire management system of an organization is undergoing an ISO 19443 audit, without being already ISO 9001<sup>[1]</sup> certified. The minimum audit duration for initial,

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surveillance, and recertification audits are shown in [Table 1](#). In this configuration, no reductions are allowed but increases to the minimum required audit duration are expected for areas with identified risk, complexity or increased scope.

NOTE The definition of audit duration can be found in ISO/IEC TS 17023:2013, 3.7.

If the management system to be certified according to ISO 19443 is only part of a broader integrated management system, the certification body shall consider the number of employees involved in the nuclear specific activities and shall increase the time specified by [Table 1](#) to take into account the quality management system support functions.

In all cases, the number of employees dedicated to ITNS activities shall be taken into account for the audit duration calculation and the number of people cannot be reduced.

If the certification body is already performing the ISO 9001<sup>[1]</sup> certification of the management system, the certification body has to apply without reduction the “recertification” duration given in [Table 1](#) in order to transition to ISO 19443 certification. The requirements of [9.1.4](#) apply in the event of audit being performed as combined or integrated audits with other management system(s).

**Table 1 — Minimum audit duration requirements (audit days)**

Number of employees	ISO 19443			ISO 19443:2018, 8.3 w/o design and development		
	Initial	Annual surveillance	Recertification	Initial	Annual surveillance	Recertification
1 to 5	2,0	1,0	2,0	2,0	1,0	1,5
6 to 10	2,5	1,0	2,0	2,5	1,0	1,5
11 to 15	3,0	1,5	2,5	2,5	1,0	2,0
16 to 25	3,5	1,5	3,0	3,0	1,5	2,5
26 to 45	5,0	2,0	4,0	4,5	2,0	3,5
46 to 65	6,0	2,5	4,5	5,0	2,0	4,0
66 to 85	7,0	3,0	5,5	6,0	2,5	4,5
86 to 100	8,0	3,0	6,0	7,0	3,0	5,0
101 to 125	8,5	3,5	6,5	7,5	3,0	5,5
126 to 175	9,5	4,0	7,0	8,0	3,5	6,0
176 to 275	10,5	4,0	8,0	9,0	3,5	6,5
276 to 425	12,0	5,0	9,0	10,0	4,5	7,5
426 to 625	13,0	5,5	9,5	11,0	4,5	8,0
626 to 875	14,0	5,5	10,5	12,0	5,0	8,5
876 to 1 000	15,0	6,0	11,0	12,5	5,0	9,0
1 001 to 1 175	16,0	6,5	12,0	13,5	5,5	10,0
1 176 to 1 550	17,0	7,0	12,5	14,5	6,0	11,0
1 551 to 2 025	18,0	7,0	13,5	15,0	6,0	11,5
2 026 to 2 675	19,0	7,5	14,0	16,0	6,5	12,0
2 676 to 3 450	20,0	8,0	14,5	17,0	7,0	12,5
3 451 to 4 350	21,0	8,0	15,5	17,5	7,0	13,0
4 351 to 5 450	22,0	8,5	16,0	18,5	7,5	13,5
5 451 to 6 800	23,0	9,0	16,5	19,0	7,5	14,0
6 801 to 8 500	24,0	9,0	17,5	20,0	8,0	14,5
8 501 to 10 700	25,0	9,5	18,0	21,0	8,0	15,0
10 701 to 14 564	26,0	10,0	18,5	21,5	8,5	15,5
14 565 to 19 630	27,0	10,0	19,5	22,5	8,5	16,0

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Table 1 (continued)

Number of employees	ISO 19443			ISO 19443:2018, 8.3 w/o design and development		
	Initial	Annual surveillance	Recertification	Initial	Annual surveillance	Recertification
19 631 to 24 695	28,0	10,5	20,0	23,0	9,0	16,5
24 696 to 33 571	29,0	11,0	20,5	24,0	9,0	17,0
33 572 to 45 031	30,0	11,0	21,5	25,0	9,5	17,5
45 032 to 59 258	31,0	11,5	22,0	25,5	9,5	18,5
59 259 to 79 784	32,0	12,0	22,5	26,5	10,0	19,0
79 785 to 101 635	33,0	12,0	23,5	27,0	10,0	19,5

NOTE These durations are intended to cover all the quality management system requirements, including those originating from ISO 9001.

Time for preparation of the audit and for audit report writing is not included and shall be added.

### 9.1.5 Multi-site sampling

The requirements of ISO/IEC 17021-1:2015, 9.1.5 apply and 9.1.5 is complemented as follows.

Application of reduced surveillance by sampling, as described in [Table 2](#) is applicable for certification of a multi-site organization.

Table 2 — Multi-site site organization audit frequency and duration

Category	Organization scope	Audit frequency	Audit duration
1	Meet the eligibility requirements for sampling given in <a href="#">Annex C</a> .	<p>Annual surveillance (frequency for year 1 and year 2).</p> <ul style="list-style-type: none"> <li>— Year 1: Central function and approximately 50 % of sites (rounded up to the next integer),</li> <li>— Year 2: Central function and remaining sites not audited in Year 1</li> </ul> <p><u>Recertification</u> (Frequency for Year 3)</p> <ul style="list-style-type: none"> <li>— Central function and all sites.</li> </ul>	<p>Audit duration shall be performed according to <a href="#">9.1.4</a> provision for annual surveillance or recertification.</p> <p>The audit duration of each audited site shall be established by using the number of employees of the site.</p> <p>A total duration shall be determined from the sum of each site unit duration calculated from <a href="#">Table 1</a>. A reduction factor shall be applied to the total duration as follows:</p> <ul style="list-style-type: none"> <li>— 2 to 7 sites: yearly reduction factor = 20 %</li> <li>— 8 to 15 sites: yearly reduction factor = 30 %</li> <li>— &gt;15 sites: yearly reduction factor = 40 %</li> </ul> <p>The total number of sites shall be considered for the reduction factor.</p> <p>The total duration thus reduced shall be rounded up to the next integer and allocated by the certification body to the sites concerned, taking into account the activities actually performed at each site.</p>
2	Does not meet the eligibility requirements for sampling given in <a href="#">Annex C</a>	Each site shall be treated individually, and certification processed accordingly.	According to <a href="#">9.1.4</a> provisions.

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If temporary sites are identified in the certification document, they shall be included in the three years' audit programme.

### 9.1.6 Multiple management systems standards

The requirements of ISO/IEC 17021-1:2015, 9.1.6 apply and are complemented as follow.

The audit duration for the ISO 19443 part of the multiple management system standards audit (see [Table 1](#)) shall not be reduced.

### 9.1.7 Organization that does not supply ITNS products and services at the time of the initial certification audit

The certification body shall consider an application for initial certification of an organization that does not already supply ITNS products or services provided the organization has a management system in place (e.g. a quality management system that fulfils ISO 9001) within the considered technical sector (see [Table A.2](#)), and its management system complies with the requirements of ISO 19443.

## 9.2 Planning audits

The requirements of ISO/IEC 17021-1:2015, 9.2 apply and 9.2.2.1.2 is complemented as follow.

The same audit team leader shall be limited to a maximum of two consecutive certification cycles at the same client (organization).

NOTE 1 To avoid over-familiarity, supporting auditors can be rotated after each certification cycle.

NOTE 2 For continuity, the audit team leader can be nominated from the members of the previous audit team.

## 9.3 Initial certification

The requirements of ISO/IEC 17021-1:2015, 9.3 apply.

## 9.4 Conducting audits

The requirements of ISO/IEC 17021-1:2015, 9.4 apply and are complemented with the following clauses.

The requirements of ISO/IEC 17021-1:2015, 9.4.5.3 are complemented as follow.

Nonconformity shall be recorded even if closed during the audit.

The requirements of ISO/IEC 17021-1:2015, 9.4.8 are complemented as follow.

Audit report shall contain evidence regarding conformity and any nonconformity to all clauses of ISO 19443, which are assessed during the audit. For each clause which is assessed, relevant documented information shall be recorded.

The requirements of ISO/IEC 17021-1:2015, 9.4.8.3 are complemented as follow.

d) [Annex B](#) (ISO 23406:2023) provides a typical summary sheet.

The requirements of ISO/IEC 17021-1:2015, 9.4.9 are complemented as follow.

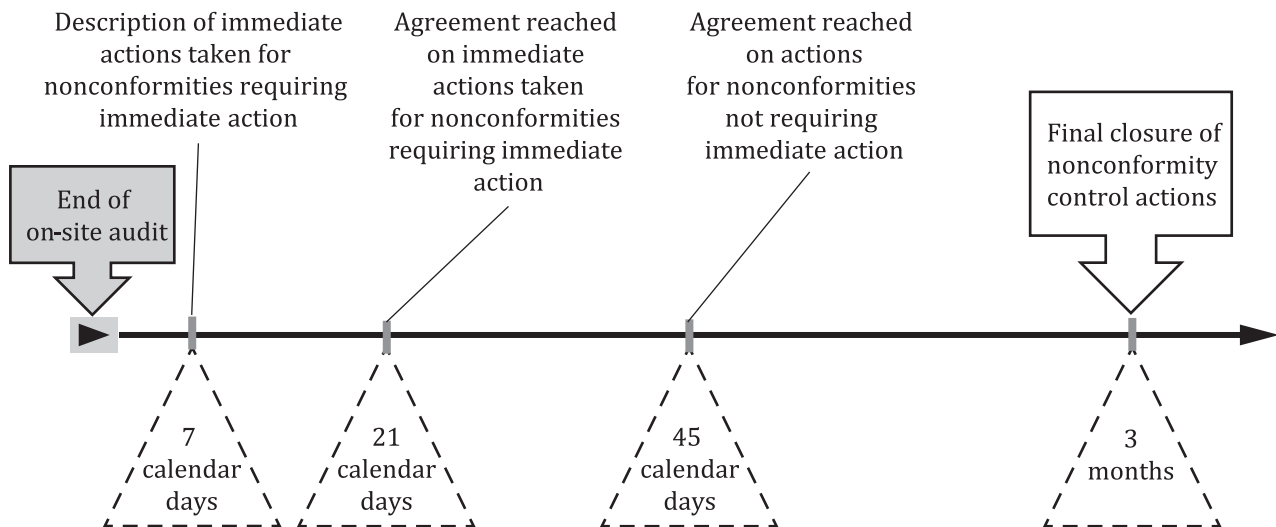
The defined time shall be no more than 45 calendar days from the end of the on-site audit.

When the nature of the nonconformity needs immediate action(s) to contain the nonconformity, the audit team leader shall require the organization to:

- describe the immediate actions ('fix now' actions) taken to contain the nonconforming situation/conditions and to control any identified nonconforming products. Correction shall always be recorded; and

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- report within 7 calendar days, after the audit, these immediate action(s) to contain the nonconformity specific containment actions, including correction, and reach agreement on those actions with the audit team leader within 21 calendar days.



**Figure 1 — Time for the nonconformities' treatment**

NOTE Containment action and correction can be reviewed during the audit.

The requirements of ISO/IEC 17021-1:2015, 9.4.10 are complemented as follow.

The audit team leader shall verify the effective closure of nonconformities as defined by the certification body's procedures, but no later than 3 months after the end of the audit.

If the certification body has not been able to close the nonconformity within 3 months, the certification scope shall be reduced or certification shall not be granted, shall be suspended or withdrawn.

## 9.5 Certification decision

The requirements of ISO/IEC 17021-1:2015, 9.5 apply.

## 9.6 Maintaining certification

The requirements of ISO/IEC 17021-1:2015, 9.6 apply and are complemented as follow.

The requirements of ISO/IEC 17021-1:2015, 9.6.2.2 are complemented as follow.

- i) systematic re-assessment of the following ISO 19443 clauses:
  - classification (6.1.3),
  - graded approach (6.1.4),
  - leadership (5.1) and safety culture (5.1.3),
  - provisions for Counterfeit, Fraudulent or Suspect (CFS) items (8.1.1),
  - design and development control (8.3.4),
  - control of externally provided processes, products and services (8.4),
  - surveillance and control activities (8.5.1),
  - nonconformity and corrective action (10.2).

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The requirements of ISO/IEC 17021-1:2015, 9.6.4 are complemented as follow with an added subclause 9.6.4.3.

9.6.4.3 Surveillance and recertification audits of an organization that does not have ITNS activities up until the time of the audit

When the organization had no activity on ITNS products or services since the last audit, the certification body shall assess the continued ability of the organization to meet the requirements of ISO 19443 standard.

If the certification body concludes that the client's certified management system continues to fulfil ISO 19443 requirements, the certification shall be maintained until the next audit, subject to the formal commitment of the organization to inform the certification body of the restart of the ITNS activities within the scope of ISO 19443 certification (see. [5.1](#)).

Further to the restart of ITNS activities, the certification body shall consider planning an additional audit, whose duration and program are determined based on the information provided by the organization.

Surveillance audit or recertification audit of an organization that does not have ITNS activities at the time of the audit may be performed two consecutive times. The certification body shall withdraw certification when the organization has not had any ITNS activities up until the time of the third consecutive audit.

NOTE During the additional audit the certification body can consider the following:

- a) Management's involvement in nuclear safety and organization's level of safety culture are maintained.
- b) Resources (e.g. design and development, production or service, human, monitoring and measurements) are maintained to an appropriate level (e.g. number, competences, calibration).
- c) Provisions implemented during previous ITNS activities are either:
  - reviewed and/or maintained (e.g. have been, when relevant, subject to an evolution to integrate the lessons learned during these previous activities);
  - demonstrated on a dedicated test case,
  - fully or partly implemented on all or part of the organization's non-ITNS activities.

### 9.7 Appeals

The requirements of ISO/IEC 17021-1:2015, 9.7 apply.

### 9.8 Complaints

The requirements of ISO/IEC 17021-1:2015, 9.8 apply.

### 9.9 Client records

The requirements of ISO/IEC 17021-1:2015, 9.9 apply.

## 10 Management system requirements for certification bodies

The requirements of ISO/IEC 17021-1:2015, 10 apply.

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## Annex A (normative)

### Required knowledge and skills to determine competence

The requirements of ISO/IEC 17021-1:2015, Annex A apply, and Annex A is complemented as follows.

#### A.1 General

[Table A.1](#) specifies the knowledge and skills that a certification body shall define for specific certification functions. “X” indicates that the certification body shall define the criteria and depth of knowledge and skills according to the different certification functions. The knowledge and skill requirements specified in [Table A.1](#) are explained in more detail in the text following the table and are referenced by the number in parentheses.

**Table A.1 — Knowledge and skills**

Knowledge and skills	Certification functions		
	Conducting the application review to determine audit team competence required, to select the audit team members, and to determine the audit time	Reviewing audit reports and making certification decisions	Auditing and leading the audit team
Knowledge of business management practices			X (see ISO/IEC 17021-1:2015, A.3.4)
Knowledge of audit principles, practices and techniques		X (see ISO/IEC 17021-1:2015, A.3.1)	X (see ISO/IEC 17021-1:2015, A.2.2)
Knowledge of certification body's processes	X (see ISO/IEC 17021-1:2015, A.4.2)	X (see ISO/IEC 17021-1:2015, A.3.3)	X (see ISO/IEC 17021-1:2015, A.2.4)
Knowledge of client's technological sector i.e. client products, processes and organization	X (see ISO/IEC 17021-1:2015, A.4.3)		X (see <a href="#">A.2</a> )
Understanding of the nuclear industry and familiar with nuclear safety culture	X (see ISO/IEC 17021-1:2015, A.4.3)	X (see ISO/IEC 17021-1:2015, A.3.4)	X (see <a href="#">A.2</a> )
Knowledge of ISO 19443	X (see ISO/IEC 17021-1:2015, A.4.1)	X (see ISO/IEC 17021-1:2015, A.3)	X (see <a href="#">A.3</a> )

NOTE Risk and complexity are other considerations when deciding the level of expertise needed for any of these functions.

**ISO/TS 23406:2024(en)****Table A.1 (continued)**

Knowledge and skills	Certification functions		
	Conducting the application review to determine audit team competence required, to select the audit team members, and to determine the audit time	Reviewing audit reports and making certification decisions	Auditing and leading the audit team
General professional competences	X (see ISO/IEC 17021-1:2015, A.4.4)		X (see <a href="#">A.4</a> )
Language skills appropriate to all levels within the client organization			X (see ISO/IEC 17021-1:2015, A.2.7)
Note-taking and report-writing skills			X (see ISO/IEC 17021-1:2015, A.2.8)
Presentation skills			X (see ISO/IEC 17021-1:2015, A.2.9)
Interviewing skills			X (see ISO/IEC 17021-1:2015, A.2.10)
Audit-management skills			X (see ISO/IEC 17021-1:2015, A.2.11)
NOTE Risk and complexity are other considerations when deciding the level of expertise needed for any of these functions.			

**A.2 Understanding of the nuclear industry and familiar with nuclear safety culture and knowledge of client's technological sector**

The auditor shall have sufficient experience to understand the nuclear industry which means to be in a position to assess properly the followings topics related to the client's technology:

- Nuclear safety including nuclear safety culture;
- Risks assessment techniques;
- Graded approach principles;
- Definition and graded approach of nuclear requirements (in consistency with the regulatory and code requirements);
- Supply chain management;
- Counterfeit, fraudulent, suspect items awareness;
- Conformity demonstration (qualification, testing, traceability, documented information management...).

The auditor shall have knowledge of the client's technological sector(s) relevant to the scope of certification.

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The auditor(s) technical knowledge shall be assessed.

NOTE [Table A.2](#) can be used as guidance.

The assessment shall be performed under the responsibility of the certification body by internal or external competent personnel, based on review of records (education, experience based on Curriculum Vitae (CV) other external or internal technical qualification ...) and/or interviews.

Documented information of assessment shall be retained.

**Table A.2 — Typical technological sector(s)**

<b>Technological sector(s) — Typical</b>	
1)	Manufacturing of wrought metal works (e.g. foundry, forging)
2)	Manufacturing/assembling of mechanical structures, mechanical component, pressure equipment and piping
3)	Manufacturing of industrial machinery (e.g. handling equipment)
4)	Manufacturing of electrical equipment
5)	HVAC (Heating Ventilation Air-Conditioning)
6)	Manufacturing of instrumentation devices and systems
7)	Uranium conversion, enrichment and fuel reprocessing
8)	Manufacturing of control and command systems
9)	Manufacturing of nuclear fuel assemblies
10)	Construction/civil works
11)	Inspection and testing services (including non-destructive testing)
12)	Site services (erection/installation, outage, maintenance)
13)	Commissioning
14)	Dismantling/decommissioning
15)	Nuclear waste management
16)	Engineering (design) services (also valid for 1 to 15)
17)	Software development

### **A.3 Knowledge of ISO 19443**

The knowledge of ISO 19443 shall be justified by the certification body through training on:

a) ISO 9001<sup>[1]</sup> quality management system requirements,

and

b) ISO 19443 specific nuclear requirements.

Duration of the ISO 19443 training shall be at least 3 days with at least 30 % of the total course time being used for nuclear industry related workshops and case studies.

The certification body shall retain documented information on both training contents and the demonstration of having successfully completed a written examination.

### **A.4 General professional competences**

All personnel involved in ISO 19443 auditing shall have a level of competence based on the following scoring model addressing education ([A.4.1](#) of this standard) and work experience considering also quality and auditing experience ([A.4.2](#) of this standard).

The 3 criteria, to be applied concomitantly, justifying sufficient general professional competences are as follows:

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**Criteria #1:** The auditor or audit team leader shall have a minimum of 2 years of professional experience in nuclear industry.

and

**Criteria #2:** The auditor or audit team leader education and experience shall be evaluated in order to check if a minimum of 10 credits, necessary to get the qualification, can be justified.

and

**Criteria #3:** The auditor shall have participated in a minimum of 3 quality management system audits within a period of time not exceeding 12 months prior to the date of qualification, 1 audit of which shall be in the nuclear field.

The audit team leader shall have participated in a minimum of 3 quality management system audits, within a period of time not exceeding 12 months including at least 2 ISO 19443 audits and at least 1 audit of quality management system as audit team leader.

**A.4.1 Education****Table A.3 — Educational credit(s)**

<b>Education level</b>	<b>Number of credits</b> (noncumulative / maximum of 4 credits)
Master's degree (or equivalent) in engineering or science (e.g. electrical, electronic, mechanical), mathematics, physics, civil works, quality management from a recognized (State Agency or National Professional or Technical Society) institution in the country of origin	4 credits
License/Bachelor's degree (or equivalent) in engineering or science (e.g. electrical, electronic, mechanical), mathematics, physics, civil works, quality management from a recognized (State Agency or National Professional or Technical Society) institution in the country of origin	3 credits
Degree (or equivalent) in engineering or science (e.g. electrical, electronic, mechanical), mathematics, physics, civil works, quality management from a recognized (State Agency or National Professional or Technical Society) institution in the country of origin	2 credits

Equivalence of education degree level shall be substantiated by the certification body.

**ISO/TS 23406:2024(en)****A.4.2 Work experience****Table A.4 — Work experience credit(s)**

<b>Work experience</b>		<b>Number of credits</b> (cumulative/maximum of 8 credits)
Technical experience in engineering, manufacturing, construction, operation, maintenance or dismantling in accordance with Technological sector(s) (see <a href="#">Table A.1</a> )		1 credit for each full year with a maximum of 5 credits for this aspect of experience
Additional credit	→ If more than 2 years of the above industrial experience have been in the nuclear field	+1 credit
	→ if 2 or more years of the above industrial experience have been in quality management	+ 1 credit
	→ if 2 or more years of the above industrial experience have been in auditing quality management	+1 credit

**A.4.3 Possible supplemental credit**

The certification body manager may add 1 supplemental credit for relevant and demonstrable professional history.

**ISO/TS 23406:2024(en)****Annex B**  
(informative)**Summary of audit results****Table B.1 — Sample table**

<b>ISO 19443</b>		<b>Audit performance</b>		<b>Conformity status</b>	
<b>Assessed clauses and subclauses</b>	<b>Title</b>	<b>Evidence checked during the audit</b>	<b>Auditor(s) involved</b>	<b>Conform</b>	<b>Non-conform (including non-conformity number)</b>

**ISO/TS 23406:2024(en)****Annex C**  
(normative)**Eligibility criteria for multi-site sampling**

- The organization shall have a single management system.
- The organization shall identify its central function. The central function is part of the organization and shall not be subcontracted to an external organization.
- The central function shall have organizational authority to define, establish and maintain the single management system.
- The organization's single management system shall be subject to a centralized management review.
- All sites shall be subject to the organization's internal audit programme.
- The central function shall be responsible for ensuring that data is collected and analysed from all sites and shall be able to demonstrate its authority and ability to initiate organizational change as required in regard, but not limited, to:
  - system documentation and system changes;
  - management review;
  - complaints;
  - evaluation of corrective actions;
  - internal audit planning and evaluation of the results; and
  - statutory and regulatory requirements pertaining to the applicable standard(s).

NOTE The central function is where operational control and authority from the top management of the organization is exerted over every site. There is no requirement for the central function to be located in a single site.

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### Bibliography

- [1] ISO 9001, *Quality management systems — Requirements*
- [2] ISO/IEC/TS 17023:2013, *Conformity assessment, Guidelines for determining the duration of management system certification audits*
- [3] IAF MD5, IAF mandatory document for duration of QMS and EMS audits



**ICS 03.120.20; 27.120.01**

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