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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)

*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)*

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## Foreword

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

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

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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).

## 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.

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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)

## 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.

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.

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 supervision and/or examination of an audit report (internal to the certification body or by 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.

NOTE A good practice is to share the list of public data related to certification with 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.

### 8.2 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.