TECHNICAL SPECIFICATION

ISO/TS 23406

First edition
2020-01

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)

Reference number
ISO/TS 23406:2020(E)

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Published in Switzerland

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Foreword

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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).

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This document was prepared by Technical Committee ISO/TC 85, *Nuclear energy, nuclear technologies and radiological protection*.

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.

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 is recommended for use 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, *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.

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.

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, 6.2.1 and 6.2.2, 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 standard 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 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,

— absence of significant or recurrent complaint related to his auditing activities.

At any time, the CB shall:

— 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,

consider taking appropriate action, such as: training, withdrawing or suspending auditor qualification. The CB shall identify the appropriate criteria and relevant process in their management system.

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 follows:

The certification body's certification function shall have at least one person(s) 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 advisors

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 advisors.

7.5 Outsourcing

The requirements of ISO/IEC 17021-1:2015, 7.5 are complemented by the following requirement:

The Certification 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 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.

8.2 Certification documents

The requirements of ISO/IEC 17021-1:2015, 8.2, apply.

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.

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.

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:

This table is intended to be used when the entire organization is undergoing an ISO 19443 audit, without being already ISO 9001 certified. The minimum duration for initial, 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.

If the activities to be certified according to ISO 19443 are only part of a broader organization, the Certification Body has to consider the number of employees involved in the nuclear specific activities and to increase the time specified by Table 1 to take into account the Quality Management System support functions.

If the Certification Body is already performing the ISO 9001 certification of the organization, the Certification Body has to apply without reduction the “recertification” duration given in Table 1 in order to transition to ISO 19443 certification.

The above applies 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 w/o Design and development (§8.3)		
	Initial	Annual Surveillance	Recertification	Initial	Annual Surveillance	Recertification
1-5	2,0	1,0	2,0	2,0	1,0	1,5

NOTE These requirements are consistent with IAF MD 5. Where there is a conflict between this standard and IAF MD 5 (i.e., this standard does not allow reductions to the audit duration), this standard shall take precedence.

Table 1 *(continued)*

Number of Employees	ISO 19443			ISO 19443 w/o Design and development (§8.3)		
	Initial	Annual Surveillance	Recertification	Initial	Annual Surveillance	Recertification
6-10	2,5	1,0	2,0	2,5	1,0	1,5
11-15	3,0	1,5	2,5	2,5	1,0	2,0
16-25	3,5	1,5	3,0	3,0	1,5	2,5
26-45	5,0	2,0	4,0	4,5	2,0	3,5
46-65	6,0	2,5	4,5	5,0	2,0	4,0
66-85	7,0	3,0	5,5	6,0	2,5	4,5
86-100	8,0	3,0	6,0	7,0	3,0	5,0
101-125	8,5	3,5	6,5	7,5	3,0	5,5
126-175	9,5	4,0	7,0	8,0	3,5	6,0
176-275	10,5	4,0	8,0	9,0	3,5	6,5
276-425	12,0	5,0	9,0	10,0	4,5	7,5
426-625	13,0	5,5	9,5	11,0	4,5	8,0
626-875	14,0	5,5	10,5	12,0	5,0	8,5
876-1 000	15,0	6,0	11,0	12,5	5,0	9,0
1 001-1 175	16,0	6,5	12,0	13,5	5,5	10,0
1 176-1 550	17,0	7,0	12,5	14,5	6,0	11,0
1 551-2 025	18,0	7,0	13,5	15,0	6,0	11,5
2 026-2 675	19,0	7,5	14,0	16,0	6,5	12,0
2 676-3 450	20,0	8,0	14,5	17,0	7,0	12,5
3 451-4 350	21,0	8,0	15,5	17,5	7,0	13,0
4 351-5 450	22,0	8,5	16,0	18,5	7,5	13,5
5 451-6 800	23,0	9,0	16,5	19,0	7,5	14,0
6 801-8 500	24,0	9,0	17,5	20,0	8,0	14,5
8 501-10 700	25,0	9,5	18,0	21,0	8,0	15,0
10 701-14 564	26,0	10,0	18,5	21,5	8,5	15,5
14 565-19 630	27,0	10,0	19,5	22,5	8,5	16,0
19631-24 695	28,0	10,5	20,0	23,0	9,0	16,5
24 696-33 571	29,0	11,0	20,5	24,0	9,0	17,0
33 572-45 031	30,0	11,0	21,5	25,0	9,5	17,5
45 032-59 258	31,0	11,5	22,0	25,5	9,5	18,5
59 259-79 784	32,0	12,0	22,5	26,5	10,0	19,0
79 785-101 635	33,0	12,0	23,5	27,0	10,0	19,5
NOTE These requirements are consistent with IAF MD 5. Where there is a conflict between this standard and IAF MD 5 (i.e., this standard does not allow reductions to the audit duration), this standard shall take precedence.						

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

9.1.5 Multisite 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 multiple site certification structures.