ISO/DTS 23406:2023(E)

ISO/TC 85

Secretariat:-_AFNOR

Date: 2023-<mark>11-20</mark>x

Nuclear sector-_— Requirements for bodies providing audit and certification of <u>Qualityquality</u> 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 documentsdocument 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<u>ISO draws attention</u> to the possibility that <u>some of the elementsimplementation</u> of this document may <u>beinvolve</u> the <u>subjectuse of (a) patent(s)</u>. ISO takes no position concerning the evidence, <u>validity or applicability of any claimed patent rights-in respect thereof</u>. 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. ISO shall not be held responsible for identifying any or all such patent rights. <u>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 <u>www.iso.org/patents</u>).</u>

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), see 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 (<u>ISO/TS 23406:2020</u>), which has been technically revised.

The main changes compared to the previous edition are as follows:

— <u>— Clarification</u> 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

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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 <u>JSO/IEC</u><u>17021-1</u> requirements, this document has been developed for the nuclear sector to assist in the conformity assessment and certification according to JSO_19443.

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TECHNICAL SPECIFICATION

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Nuclear sector-_- Requirements for bodies providing audit and certification of <u>Qualityquality</u> 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.

<<u>std>ISO</u> 9000, <u>Quality management systems — Fundamentals and vocabulary</u></std>

<std>ISO/IEC 17000, Conformity assessment Vocabulary and general principles</std>

<std>ISO/IEC 17021-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 <a href="https://www.systems-audit-au

<std>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 <u>ISO 9000</u>, <u>ISO/IEC 17000</u>, <u>ISO/IEC 17021-1</u> and <u>ISO 19443 apply. ISO and IEC maintain terminology databases for use in standardization at the following addresses:</u>

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 <u>https://www.electropedia.org/</u>https://www.electropedia.org/

4 Principles

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

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5 General requirements		
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The certification agreement shall include provision that the certification body is informed by the client of	\swarrow	Formatted
any starting, interruption or resumption of all activities on ITNS products or services.		Formatted: Adjust space between Latin and Asian text, Adjust
5.2 Management of impartiality		space between Asian text and numbers Formatted: Adjust space between Latin and Asian text, Adjust
The requirements of JSO/IEC 17021-1:2015, 5.2, apply.		space between Asian text and numbers, Tab stops: Not at 0.71 cm
5.3 Liability and financing	\swarrow	Formatted
The requirements of ISO/IEC 17021-1:2015, 5.3, apply.	\setminus	Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers
6 Structural requirements		Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers, Tab stops: Not at 0.71 cm
6.1 Organizational structure and top management		Formatted
The requirements of JSO/IEC 17021-1:2015, 6.1, apply.	\setminus	Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers
6.2 Operational control	\backslash	Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers, Tab stops: Not at 0.71 cm
The requirements of ISO/IEC 17021-1:2015, 6.2 apply and 6.2.2 is complemented as follows.	$\langle \rangle \rangle$	Formatted
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.		Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers
7 Resource requirements Document Preview	$\left\ \right\ $	Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers, Tab stops: Not at 0.71 cm
7.1 Competence of personnel		Commented [eXtyles5]: No section matches the in-text citation "6.2.2". Please supply the missing section or delete the citation.
7.1.1 General considerations ISO/DTS 23406	$\setminus $	Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers
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7.1.2 Determination of competence criteria	\mathbf{N}	Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers, Tab stops: Not at 0.71 cm
The requirements of JSO/IEC_17021-1:2015, 7.1.2, apply, and JSO/IEC_17021-1:2015, Annex A, is complemented by Annex A Annex A of this document.	$\langle \rangle$	Formatted
7.1.3 Evaluation processes	. 11	Formatted
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The requirements of ISO/IEC 17021-1:2015, 7.1.3, apply and are complemented as follows.	$\langle N \rangle$	Formatted
— — Satisfactory evaluation of auditor competence shall result in a documented auditor qualification.	$\langle \rangle$	Formatted
— — The initial qualification shall be based on requirements given in Annex A Annex A and is valid for	$\langle N \rangle$	Formatted
3 years.		Formatted
Qualification renewal for a 3-year period shall be based on demonstration of:		Formatted
 — performance of at least 6 JS0 19443 certification, recertification or surveillance audits in 3 years 	\searrow	Formatted
with a minimum of 20 days of audit,		Formatted
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 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: <u>ISO/IEC_17021-1</u>, <u>ISO_19443 and sufficient nuclear industry experience to understand the sector specificities and assess</u> the contents of the certification audit report and the relevance of its conclusions.

7.3 Use of individual external auditors and external technical experts 27-46b2-b46

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 $\frac{\text{Table A.1}\text{Table A.1}}{\text{Table to any other organization.}}$

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.

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8 Information requirements		
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The certification body shall make publicly available and accessible:	\sim	Formatted Formatted: Adjust space between Latin and Asian text, Adjust
<u>a)</u> the list of certifications issued;		space between Asian text and numbers Formatted: Numbered + Level: 1 + Numbering Style: a, b, c,
b)_b-list of data related to certification as listed in 8.2.2 of ISO/IEC17021-1:2015, 8.2.2.		+ Start at: 1 + Alignment: Left + Aligned at: 0 cm + Indent at: 0 cm, Adjust space between Latin and Asian text, Adjust
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.	\backslash	space between Asian text and numbers, Tab stops: Not at 0.7 cm + 1.4 cm + 2.1 cm + 2.8 cm + 3.5 cm + 4.2 cm + 4.9 cm + 5.6 cm + 6.3 cm + 7 cm
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8.2 Certification documents		Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers, Tab stops: Not at 0.71 cm
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The certification body shall mention on the certificate "for ITNS activities" before the scope of the certified activities.		Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers
8.3 Reference to certification and marks		Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers, Tab stops: Not at
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8.4 Confidentiality	\backslash	Formatted Formatted: Adjust space between Latin and Asian text, Adjust
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The requirements of ISO/IEC_17021-1:2015, 8.4 apply and are complemented as follows.		Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers, Tab stops: Not at 0.71 cm
listed in 8.2.2 of ISO/IEC 17021-1:2015, 8.2.2.		Formatted
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		Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers
collecting the list of public data related to certification.		Formatted
8.5 ^h Information exchange between a certification body and its client ⁹ c ²⁷ -46b ² -b ⁴ d ⁸	-81ð	Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers, Tab stops: Not at 0.7 cm + 1.4 cm + 2.1 cm + 2.8 cm + 3.5 cm + 4.2 cm + 4.9
The requirements of ISO/IEC_17021-1;2015, 8.5 apply and are complemented as follows.	$I \setminus$	cm + 5.6 cm + 6.3 cm + 7 cm
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.	\backslash	Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers, Tab stops: Not at 0.71 cm
The certification body shall provide information and update clients on the data it has transmitted when		Formatted
drawing up the lists of certifications issued.		Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers
9 Process requirements		Formatted: Adjust space between Latin and Asian text, Adjust space between Asian text and numbers, Tab stops: Not at 0.71 cm
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The requirements of ISO/IEC_17021-1:2015, 9.1.1 apply.		Formatted
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