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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

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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).

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).

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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.

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.

To allow some flexibility when planning audit schedules from one certification cycle to the next; the audit plan shall ensure that the maximum duration between each site's audit schedule is not greater than 48 months.

Table 2 — Multiple site organization audit frequency

Category	Organization scope	Audit duration and frequency
1	Meets the eligibility requirements for sampling given in Annex C	See Table 1 for duration calculations. The audit duration of each audited site shall be established by using the number of employees of the site. Annual surveillance (Frequency for Years 1 and 2) — Year 1: Central function and approximately 50 % of sites (rounded up to the next integer), — Year 2: Central function and remaining sites not audited in Year 1. Recertification (Frequency for Year 3) — Central function and all sites.
2	Does not meet the eligibility requirements for sampling given in Annex C	Each site shall be treated individually, and certification processed accordingly.

9.1.6 Multiple management systems standards

The requirements of ISO/IEC 17021-1:2015, 9.1.6, apply.

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

9.2 Planning audits

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

The same audit team leader shall be limited to a maximum of two consecutive certification cycles at the 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; with 9.4.5.3 complemented as follows:

Non-conformity shall be recorded even if closed during the audit.

9.4.8 complemented as follows:

Audit report shall contain evidence regarding conformity and effectiveness and any non-conformity to all clauses of ISO 19443. For each clause, relevant documented information shall be recorded.

9.4.8.3 complemented as follows:

d) informative Annex B. provides a typical summary sheet.

9.4.9 complemented as follows:

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 containment action, 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

— report within 7 calendar days, after the audit, the specific containment actions, including correction, and reach agreement on those actions with the audit team leader within the next 14 calendar days.

NOTE 1 Containment action and correction can be reviewed during the audit.

9.4.10 complemented as follows:

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 9.6.2.2 (Surveillance audit) is complemented as follows:

i) systematic re-assessment of the following ISO 19443 chapters:

- classification (6.1.3),
- graded approach (6.1.4),
- leadership (3.5.1) 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 (7.8.4),
- surveillance and control activities (8.5.1),
- nonconformity and corrective action (10.2).

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, Clause 10, apply.

Annex A
(normative)

Competence criteria

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 parenthesis.

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.2)
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.2)
Knowledge of ISO 19443	X (see ISO/IEC 17021-1:2015, A.4.1)	X (see ISO/IEC 17021-1:2015, A.3.2)	X (see A.3)
General professional competences	X (see ISO/IEC 17021-1:2015, A.4.4)		X (see A.4)
NOTE Risk and complexity are other considerations when deciding the level of expertise needed for any of these functions.			

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
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 clients technology:

— Nuclear safety including nuclear safety culture,

— Risks assessment techniques,

— Graded approach principles,

— Definition and grading 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.

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 CV, other external or internal technical qualification …) and/or interviews.

Documented information of assessment shall be retained.

Table A.2 — Typical technological sector(s)

Technological sector(s) — Typical
1. Manufacturing of wrought metal works (e.g. foundary, 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 NDT)
12. Site services (erection/installation, outage, maintenance)
13. Commissioning
14. Dismantling / decommissioning
15. 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 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:

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)

EDUCATION LEVEL	NUMBER OF CREDITS (noncumulative / maximum of 4 credits)
Master degree (or equivalent) in engineering (e.g. electrical, electronic, mechanical), mathematics, physics, civil works, quality management from an accredited (State Agency or National Professional or Technical Society) institution in the country of origin	4 credits
License/Bachelor degree (or equivalent) in engineering (e. g. electrical, electronic, mechanical), mathematics, physics, civil works, quality management from an accredited (State Agency or National Professional or Technical Society) institution in the country of origin	3 credits
Degree (or equivalent) in engineering (e. g. electrical, electronic, mechanical), mathematics, physics, civil works, quality management from an accredited (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.

A.4.2 Work experience

Table A.4 — Work experience credit(s)

WORK EXPERIENCE	NUMBER OF CREDITS (cumulative/maximum of 8 credits)
Technical experience in engineering, manufacturing, construction, operation, maintenance or dismantling in accordance with Technological sector(s) (see Table A.1)	1 credit for each full year with a maximum of 5 credits for this aspect of experience

Table A.4 *(continued)*

WORK EXPERIENCE		NUMBER OF CREDITS (cumulative/maximum of 8 credits)
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.