SLOVENSKI STANDARD
kSIST-TS FprCEN ISO/TS 23406:2021

01-september-2021

Jedrski sektor - Zahteve za organe, ki presojajo in certificirajo sisteme vodenja kakovosti za organizacije, ki dobavljajo izdelke in storitve, pomembne za jedrsko varnost (ITNS) (ISO/TS 23406:2020)

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 23406:2020)

Nuklearsektor - Anforderungen an Stellen, die Qualitätsmanagementsysteme für Organisationen, die für die nukleare Sicherheit wichtige Produkte und Dienstleistungen liefern, prüfen und zertifizieren (ITNS) (ISO/TS 23406:2020)

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 23406:2020)

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Ta slovenski standard je istoveten z: **FprCEN ISO/TS 23406**

ICS:

03.120.20	Certificiranje proizvodov in podjetij. Ugotavljanje skladnosti	Product and company certification. Conformity assessment
27.120.01	Jedrska energija na splošno	Nuclear energy in general

kSIST-TS FprCEN ISO/TS 23406:2021 **en,fr,de**

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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 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.

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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 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 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)*

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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.

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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.

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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

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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),

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