SLOVENSKI STANDARD
SIST EN ISO 19443:2022

01-september-2022

Sistemi vodenja kakovosti - Posebne zahteve za uporabo standarda ISO 9001:2015 v organizacijah v dobavni verigi sektorja jedrske energije, ki dobavljajo izdelke in storitve, pomembne za jedrsko varnost (ITNS) (ISO 19443:2018)

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) (ISO 19443:2018)

Qualitätsmanagementsysteme - Spezifische Anforderungen für die Anwendung von ISO 9001 für die Organisationen in der Lieferkette auf dem Sektor der Kernenergie, die für die nukleare Sicherheit wichtige Produkte und Dienstleistungen (ITNS) liefern (ISO 19443:2018)

Systèmes de management de la qualité - Exigences spécifiques pour l'application de l'ISO 9001:2015 par les organisations de la chaîne d'approvisionnement du secteur de l'énergie nucléaire fournissant des produits ou services importants pour la sûreté nucléaire (IPSN) (ISO 19443:2018)

Ta slovenski standard je istoveten z: **EN ISO 19443:2022**

ICS:

03.100.70	Sistemi vodenja	Management systems
03.120.10	Vodenje in zagotavljanje kakovosti	Quality management and quality assurance
27.120.01	Jedrska energija na splošno	Nuclear energy in general

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EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

EN ISO 19443

August 2022

ICS 03.120.10; 27.120.01

English Version

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) (ISO 19443:2018)

Systèmes de management de la qualité - Exigences spécifiques pour l'application de l'ISO 9001:2015 par les organisations de la chaîne d'approvisionnement du secteur de l'énergie nucléaire fournissant des produits ou services importants pour la sûreté nucléaire (IPSN) (ISO 19443:2018)

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This European Standard was approved by CEN on 24 July 2022.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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European foreword

The text of ISO 19443:2018 has been prepared by Technical Committee ISO/TC 85 "Nuclear energy, nuclear technologies, and radiological protection" of the International Organization for Standardization (ISO) and has been taken over as EN ISO 19443:2022 by Technical Committee CEN/TC 430 "Nuclear energy, nuclear technologies, and radiological protection" the secretariat of which is held by AFNOR.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by February 2023, and conflicting national standards shall be withdrawn at the latest by February 2023.

Attention is drawn to the possibility that some of the elements of this document may be the subject of patent rights. CEN shall not be held responsible for identifying any or all such patent rights.

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organizations of the following countries are bound to implement this European Standard: Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and the United Kingdom.

Endorsement notice

The text of ISO 19443:2018 has been approved by CEN as EN ISO 19443:2022 without any modification.

Annex A
(informative)

A-deviations

A-deviation: National deviation due to regulations, the alteration of which is for the time being outside the competence of the CEN-CENELEC national member.

This European Standard does not fall under any Directive/Regulation of the EU.

In the relevant CEN-CENELEC countries, these A-deviations are valid instead of the respective provisions of the European Standard until the national situation causing the A-deviation has changed.

Clause	Deviation
all	Germany In Germany, the development and establishment of safety regulations in the fields of nuclear technology is reserved for the Nuclear Safety Standards Commission (KTA). Furthermore the Federal Institute for Materials Research and Testing (BAM) sets standards for safety for the transport of radioactive materials. The latest edition of the referenced document (including any amendments) applies. In Germany, - KTA 1401 "General requirements regarding quality assurance" (Federal Gazette), - KTA 1404 “Documentation During the Construction and Operation of Nuclear Power Plants” (Federal Gazette), - BAM GGR-011 “Quality Assurance Measures of Packagings for Competent Authority Approved Package Designs for the Transport of Radioactive Material” - and BAM GGR-016 “Quality Assurance Measures of Packagings for Non-Competent Authority Approved Package Designs for the Transport of Radioactive Material” apply to the aspects dealt with in this European standard. The requirements of KTA 1401, KTA 1404, BAM GGR-011 and BAM GGR-016 take precedence over the requirements of this standard.

For explanation:

The cited KTA safety standards are mandatory due to publication in Federal Gazette (german: Bundesanzeiger – BAnz), which is the central platform for official (legal) announcements and notices on the federal level. BAM is a senior scientific and technical Federal institute with responsibility to the Federal Ministry for Economic Affairs and Energy (BMWi). BAM-GGR 011 and 016 are published in the Official Bulletin of the Federal Institute BAM (volume 48, 3/2018 and volume 44, 04/2014). According to the administrative regulation RSEB (Official Bulletin of the Federal Ministry of Transport and Digital Infrastructure - VkBl. 2019, p. 306), BAM as competent authority may publish - via its official bulletin in its BAM-GGR rules - mandatory requirements for its field of competence.

INTERNATIONAL STANDARD

ISO 19443

First edition
2018-05

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)

Systèmes de management de la qualité — Exigences spécifiques pour l'application de l'ISO 9001:2015 par les organisations de la chaîne d'approvisionnement du secteur de l'énergie nucléaire fournissant des produits ou services importants pour la sûreté nucléaire (IPNS)

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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).

Any trade name used in this document is information given for the convenience of users and does not constitute an endorsement.

For an explanation on 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 the following URL: www.iso.org/iso/foreword.html.

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

Introduction

ISO collaborates closely with the International Atomic Energy Agency (IAEA). The IAEA establishes standards for safety for use by its member states in the framework of national regulations. ISO standards in the field of nuclear safety are complementary technical documents.

In this document, the text reproduced from ISO 9001:2015 is placed in boxes, in order to distinguish it from the sector-specific requirements for nuclear safety given for each clause. It is understood that the requirements of each clause include requirements for nuclear safety. Whenever the ISO 9001:2015 text refers to "this International Standard", this applies to this document, including the text outside the boxes.

Informative annexes referenced in ISO 9001:2015 are not included in this document.

0.1 General

ISO 9001:2015, Quality management systems — Requirements

0.1 General

The adoption of a quality management system is a strategic decision for an organization that can help to improve its overall performance and provide a sound basis for sustainable development initiatives.

The potential benefits to an organization of implementing a quality management system based on this International Standard are:

a) the ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements;

b) facilitating opportunities to enhance customer satisfaction;

c) addressing risks and opportunities associated with its context and objectives;

d) the ability to demonstrate conformity to specified quality management system requirements.

This International Standard can be used by internal and external parties.

It is not the intent of this International Standard to imply the need for:

— uniformity in the structure of different quality management systems;

— alignment of documentation to the clause structure of this International Standard;

— the use of the specific terminology of this International Standard within the organization.

The quality management system requirements specified in this International Standard are complementary to requirements for products and services.

This International Standard employs the process approach, which incorporates the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking.

The process approach enables an organization to plan its processes and their interactions.

The PDCA cycle enables an organization to ensure that its processes are adequately resourced and managed, and that opportunities for improvement are identified and acted on.

Risk-based thinking enables an organization to determine the factors that could cause its processes and its quality management system to deviate from the planned results, to put in place preventive controls to minimize negative effects and to make maximum use of opportunities as they arise (see Clause A.4).

Consistently meeting requirements and addressing future needs and expectations poses a challenge for organizations in an increasingly dynamic and complex environment. To achieve this objective, the organization might find it necessary to adopt various forms of improvement in addition to correction and continual improvement, such as breakthrough change, innovation and re-organization.

In this International Standard, the following verbal forms are used:

— "shall" indicates a requirement;

— "should" indicates a recommendation;

— "may" indicates a permission;

— "can" indicates a possibility or a capability.

Information marked as "NOTE" is for guidance in understanding or clarifying the associated requirement.

0.2 Quality management principles

ISO 9001:2015, Quality management systems — Requirements

0.2 Quality management principles

This International Standard is based on the quality management principles described in ISO 9000. The descriptions include a statement of each principle, a rationale of why the principle is important for the organization, some examples of benefits associated with the principle and examples of typical actions to improve the organization's performance when applying the principle.

The quality management principles are:

— customer focus;

— leadership;

— engagement of people;

— process approach;

— improvement;

— evidence-based decision making;

— relationship management.

The following also apply:

— nuclear safety culture;

— determination of ITNS items and activites;

— graded approach to the application of quality requirements.

0.3 Process approach

0.3.1 General

ISO 9001:2015, Quality management systems — Requirements

0.3 Process approach

0.3.1 General

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. Specific requirements considered essential to the adoption of a process approach are included in 4.4.

Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle (see 0.3.2) with an overall focus on risk-based thinking (see 0.3.3) aimed at taking advantage of opportunities and preventing undesirable results.

The application of the process approach in a quality management system enables:

a) understanding and consistency in meeting requirements;

b) the consideration of processes in terms of added value;

c) the achievement of effective process performance;

d) improvement of processes based on evaluation of data and information.

Figure 1 gives a schematic representation of any process and shows the interaction of its elements. The monitoring and measuring checkpoints, which are necessary for control, are specific to each process and will vary depending on the related risks.

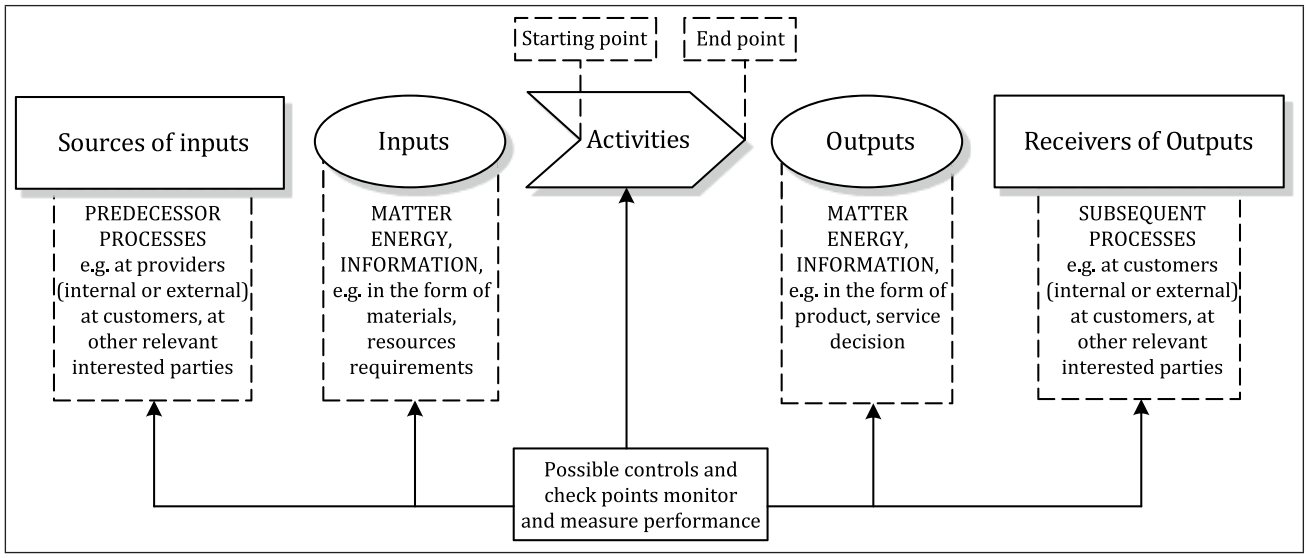

Figure 1 — Schematic representation of the elements of a single process