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Sistemi vodenja kakovosti - Navodila za uporabo standarda ISO 19443:2018 (ISO/TR 4450:2020)

Quality management systems - Guidance for the application of ISO 19443:2018 (ISO/TR 4450:2020)

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27.120.01	Jedrska energija na splošno	Nuclear energy in general

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Foreword

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ISO collaborates closely with the International Electrotechnical Commission (IEC) on all matters of electrotechnical standardization.

The relationship of ISO standards to the IAEA safety standards (http://www-ns.iaea.org/standards/) needs to be understood to avoid confusions.

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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Introduction

As general consideration, this guideline document:

— has been developed to assist users to apply the quality management system requirements of ISO 19443:2018 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS)[1],

— does not add to, subtract from, or in any way modify those requirements,

— does not prescribe mandatory approaches to implementation, or provide any preferred method of interpretation of ISO 19443:2018 requirements supplementing those of ISO 9001:2015[2], but only provide examples of possible solutions an organization can implement to meet the requirements,

— proposes also good practices for some clauses of ISO 9001 when applied to ISO 19443.

Where there is no supplementary text to ISO 9001[2] (refer also to Annex A which gives a global picture of additional requirements of ISO 19443:2018 versus ISO 9001:2015), the sentence "*No ISO 19443 additional requirement to ISO 9001"* has been included. In this case, for guidance on the initial text of ISO 9001, refer to:

- ISO 9001:2015[2], Annex A,
- ISO/TS 9002[3], and
- ISO/IAF Auditing Practices Group[4].

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Where it is considered that the added text is self-explanatory and thus no guidance has been added, the sentence "*No supplementary guidance provided* " has been included.

This guidance follows the layout of ISO 19443 and thus, users need to clearly understand the vocabulary of ISO 9000 and ISO 9001, which underlie it, before addressing the added text in ISO 19443.

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The delivery of all products or services will involve tiers (See Figure 1) to which the Licensee requirements will be cascaded through Contractor(s) using technical specifications, procedures, management system (including Quality Assurance and Quality Control) requirements, and other contractual documents.

At each level, the external provider (called hereby "contractor", "supplier" or "sub-supplier") will be potentially in position to be "the organization" considered by ISO 19443.

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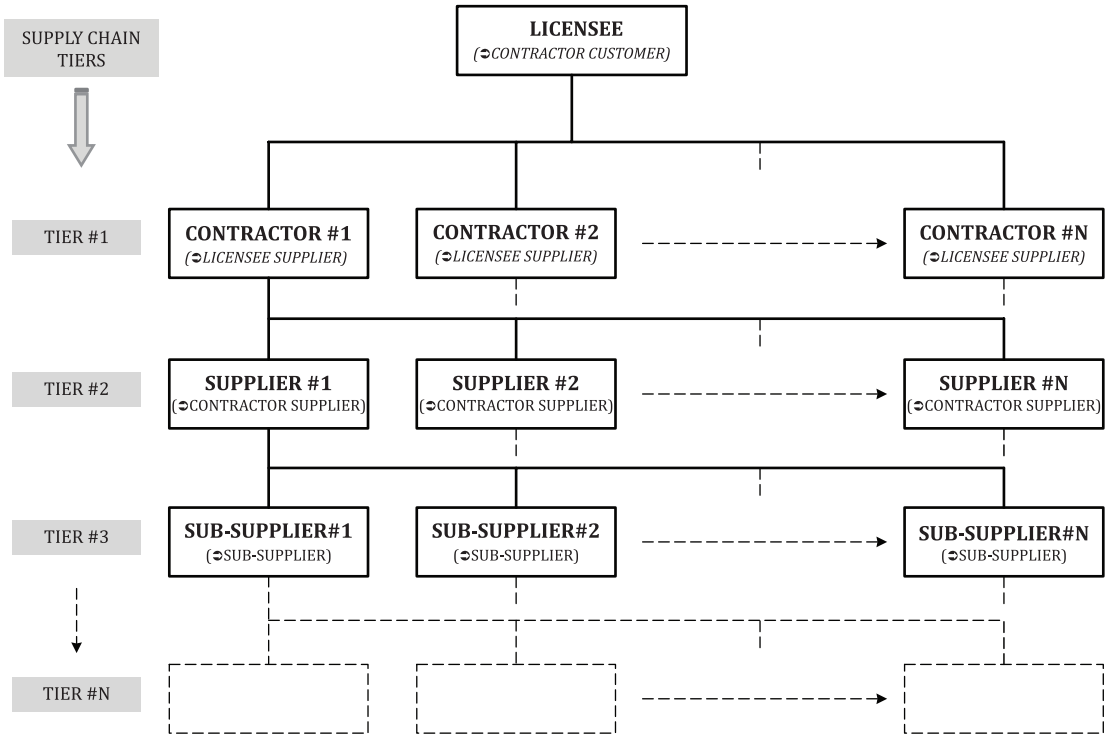

Figure 1 — Schematic breakdown of tiers.

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0.1 General

No ISO 19443 additional requirement to ISO 9001.

0.2 Quality management principles

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No supplementary guidance provided.

0/3 Process approach

No ISO 19443 additional requirement to ISO 9001.

0.4 Relationship with other management system standards

No supplementary guidance provided.

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Quality management systems — Guidance for the application of ISO 19443:2018

1 Scope

This document provides guidance on the implementation of the ISO 19443 requirements, with examples of possible steps an organization can take to meet the requirements.

It does not add to, subtract from, or in any way modify those requirements.

This document does not prescribe mandatory approaches to implementation, or provide any preferred method of interpretation.

2 Normative references

There are no normative references in this document.

No ISO 19443 additional requirement to ISO 9001.

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3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

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— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Context of the organization

4.1 Understanding the organization and its context

As part of risk-based thinking of ISO 19443:2018, 0.3.3, the organization should consider any risks and the nuclear safety implications to its activities.

Refer also to Annex B.

4.2 Understanding the needs and expectations of interested parties

No ISO 19443 additional requirement to ISO 9001.

4.3 Determining the scope of the quality management system

No ISO 19443 additional requirement to ISO 9001.

4.4 Quality management system and its processes

4.4.1 *No ISO 19443 additional requirement to ISO 9001.*

4.4.2 *No ISO 19443 additional requirement to ISO 9001.*

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