

---

---

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

*Systèmes de management de la qualité — Lignes directrices pour  
l'application de l'ISO 19443:2018*

**iTeh Standards**  
**(<https://standards.itih.ai>)**  
**Document Preview**

[ISO/TR 4450:2020](https://standards.itih.ai/catalog/standards/iso/ad1afa8d-bc7f-4d79-bd86-3aa9b1b17420/iso-tr-4450-2020)

<https://standards.itih.ai/catalog/standards/iso/ad1afa8d-bc7f-4d79-bd86-3aa9b1b17420/iso-tr-4450-2020>



**iTeh Standards**  
**(<https://standards.iteh.ai>)**  
**Document Preview**

[ISO/TR 4450:2020](https://standards.iteh.ai/catalog/standards/iso/ad1afa8d-bc7f-4d79-bd86-3aa9b1b17420/iso-tr-4450-2020)

<https://standards.iteh.ai/catalog/standards/iso/ad1afa8d-bc7f-4d79-bd86-3aa9b1b17420/iso-tr-4450-2020>



**COPYRIGHT PROTECTED DOCUMENT**

© ISO 2020

All rights reserved. Unless otherwise specified, or required in the context of its implementation, no part of this publication may be reproduced or utilized otherwise in any form or by any means, electronic or mechanical, including photocopying, or posting on the internet or an intranet, without prior written permission. Permission can be requested from either ISO at the address below or ISO's member body in the country of the requester.

ISO copyright office  
CP 401 • Ch. de Blandonnet 8  
CH-1214 Vernier, Geneva  
Phone: +41 22 749 01 11  
Email: [copyright@iso.org](mailto:copyright@iso.org)  
Website: [www.iso.org](http://www.iso.org)

Published in Switzerland

# Contents

	Page
Foreword .....	v
Introduction .....	vi
<b>1 Scope</b> .....	<b>1</b>
<b>2 Normative references</b> .....	<b>1</b>
<b>3 Terms and definitions</b> .....	<b>1</b>
<b>4 Context of the organization</b> .....	<b>1</b>
4.1 Understanding the organization and its context .....	1
4.2 Understanding the needs and expectations of interested parties .....	1
4.3 Determining the scope of the quality management system .....	1
4.4 Quality management system and its processes .....	1
<b>5 Leadership</b> .....	<b>2</b>
5.1 Leadership and commitment .....	2
5.1.1 General .....	2
5.1.2 Customer focus .....	2
5.1.3 Nuclear safety culture .....	2
5.2 Policy .....	3
5.2.1 Establishing the quality policy .....	3
5.2.2 Communicating the quality policy .....	3
5.3 Organizational roles, responsibilities and authorities .....	3
<b>6 Planning</b> .....	<b>3</b>
6.1 Actions to address risks and opportunities .....	3
6.2 Quality objectives and planning to achieve them .....	6
6.3 Planning of changes .....	6
<b>7 Support</b> .....	<b>6</b>
7.1 Resources .....	6
7.1.1 General .....	6
7.1.2 People .....	7
7.1.3 Infrastructure .....	7
7.1.4 Environment for the operation of processes .....	7
7.1.5 Monitoring and measuring resources .....	7
7.1.6 Organizational knowledge .....	8
7.2 Competence .....	8
7.3 Awareness .....	8
7.4 Communication .....	8
7.5 Documented information .....	8
7.5.1 General .....	9
7.5.2 Creating and updating .....	9
7.5.3 Control of documented information .....	9
<b>8 Operation</b> .....	<b>10</b>
8.1 Operational planning and control .....	10
8.1.1 Provisions for Counterfeit, Fraudulent or Suspect (CFS) items .....	10
8.2 Requirements for products and services .....	10
8.2.1 Customer communication .....	10
8.2.2 Determination of requirements related for products and services .....	10
8.2.3 Review of requirements related for products and services .....	10
8.2.4 Changes to requirements for products and services .....	10
8.3 Design and development of products and services .....	10
8.4 Control of externally provided processes, products and services .....	10
8.4.1 General .....	10
8.4.2 Type and extent of control .....	11
8.4.3 Information for external providers .....	12

8.5	Production and service provision.....	12
8.5.1	Control of production and service provision.....	12
8.5.2	Identification and traceability.....	12
8.5.3	Property belonging to customers or external providers.....	12
8.5.4	Preservation.....	12
8.5.5	Post-delivery activities.....	12
8.5.6	Control of changes.....	13
8.6	Release of products and services.....	13
8.7	Control of nonconforming outputs.....	13
<b>9</b>	<b>Performance evaluation.....</b>	<b>13</b>
9.1	Monitoring, measurement, analysis and evaluation.....	13
9.1.1	General.....	13
9.1.2	Customer satisfaction.....	13
9.1.3	Analysis and evaluation.....	13
9.2	Internal audit.....	13
9.3	Management review.....	13
9.3.1	General.....	13
9.3.2	Management review inputs.....	13
9.3.3	Management review outputs.....	13
<b>10</b>	<b>Improvement.....</b>	<b>14</b>
10.1	General.....	14
10.2	Nonconformity and corrective action.....	14
10.3	Continual improvement.....	14
<b>Annex A</b>	<b>(informative) Additional requirements of ISO 19443:2018 versus ISO 9001:2015.....</b>	<b>15</b>
<b>Annex B</b>	<b>(informative) How to perform a risk analysis for the project?.....</b>	<b>18</b>
<b>Annex C</b>	<b>(informative) Determination of ITNS items and activities.....</b>	<b>22</b>
<b>Annex D</b>	<b>(informative) Practical example of determination of ITNS items and activities.....</b>	<b>24</b>
<b>Annex E</b>	<b>(informative) Typical (general) example for graded approach.....</b>	<b>27</b>
<b>Annex F</b>	<b>(informative) Practical example of graded approach.....</b>	<b>29</b>
<b>Annex G</b>	<b>(informative) Metrological guidelines.....</b>	<b>32</b>
<b>Annex H</b>	<b>(informative) Competence and qualification.....</b>	<b>35</b>
<b>Annex I</b>	<b>(informative) Awareness training for personnel.....</b>	<b>38</b>
<b>Annex J</b>	<b>(informative) List of ISO 19443 additional requirements related to documented information.....</b>	<b>42</b>
<b>Annex K</b>	<b>(informative) Good practices for 8.3.....</b>	<b>45</b>
<b>Annex L</b>	<b>(informative) Demonstration of the evidence of provisions for monitoring activities.....</b>	<b>50</b>
<b>Annex M</b>	<b>(informative) Example of scheme for non-conformance information and request for approval along supply chain.....</b>	<b>53</b>
<b>Bibliography</b>	<b>.....</b>	<b>54</b>

## 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 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](http://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](http://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 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](http://www.iso.org/iso/foreword.html).

This document was prepared by the Technical Committee ISO/TC 85, *Nuclear energy, nuclear technologies, and radiological protection* WG 4, *Management systems and conformity assessment*.

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](http://www.iso.org/members.html).

## 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)<sup>[1]</sup>,
- 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<sup>[2]</sup>, 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<sup>[2]</sup> (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<sup>[2]</sup>, Annex A,
- ISO/TS 9002<sup>[3]</sup>, and
- ISO/IAF Auditing Practices Group<sup>[4]</sup>.

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.

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.

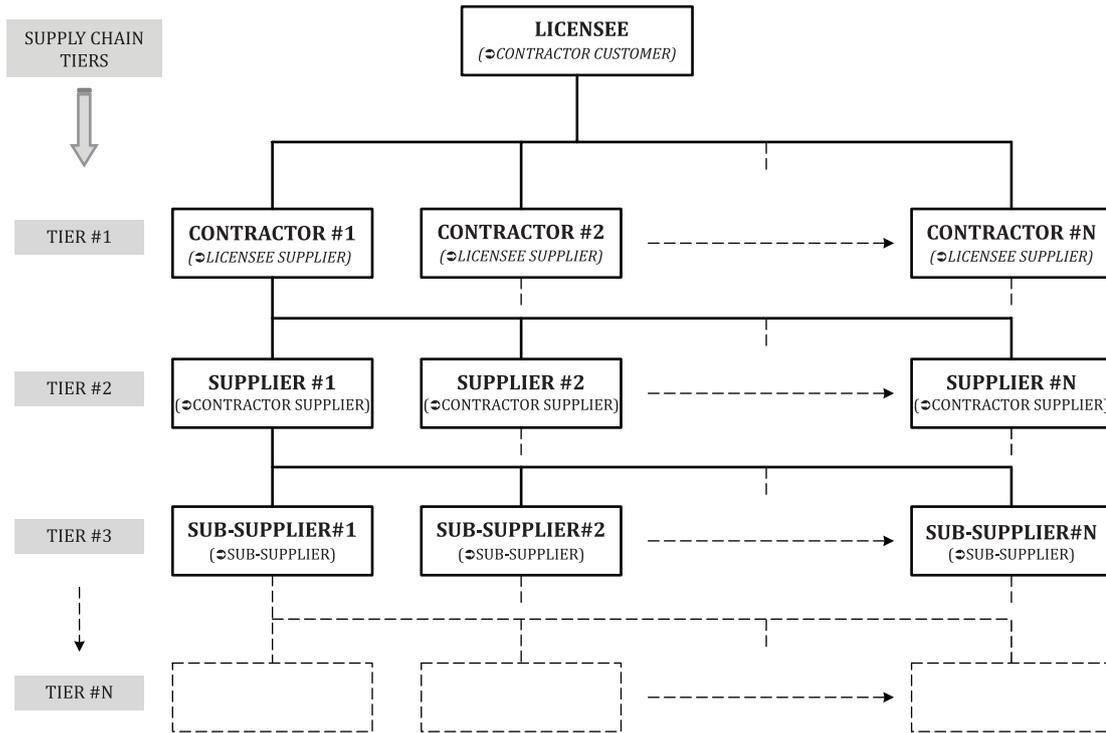


Figure 1 — Schematic breakdown of tiers.

**0.1 General**

No ISO 19443 additional requirement to ISO 9001.

**0.2 Quality management principles**

No supplementary guidance provided. [ISO/TR 4450:2020](https://standards.iteh.ai/catalog/standards/iso/ad1afa8d-bc7f-4d79-bd86-3aa9b1b17420/iso-tr-4450-2020)

<https://standards.iteh.ai/catalog/standards/iso/ad1afa8d-bc7f-4d79-bd86-3aa9b1b17420/iso-tr-4450-2020>

**0/3 Process approach**

No ISO 19443 additional requirement to ISO 9001.

**0.4 Relationship with other management system standards**

No supplementary guidance provided.