

# DIN EN ISO 19443:2022-11 (E)

## 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)

---

<b>Contents</b>		<b>Page</b>
European foreword.....		4
Annex (informative) A-deviations.....		5
Foreword.....		6
Introduction.....		7
<b>1</b>	<b>Scope</b> .....	<b>13</b>
<b>2</b>	<b>Normative references</b> .....	<b>13</b>
<b>3</b>	<b>Terms and definitions</b> .....	<b>14</b>
<b>4</b>	<b>Context of the organization</b> .....	<b>16</b>
4.1	Understanding the organization and its context.....	16
4.2	Understanding the needs and expectations of interested parties.....	16
4.3	Determining the scope of the quality management system.....	17
4.4	Quality management system and its processes.....	17
<b>5</b>	<b>Leadership</b> .....	<b>18</b>
5.1	Leadership and commitment.....	18
5.1.1	General.....	18
5.1.2	Customer focus.....	19
5.1.3	Nuclear safety culture.....	19
5.2	Policy.....	20
5.2.1	Establishing the quality policy.....	20
5.2.2	Communicating the quality policy.....	20
5.3	Organizational roles, responsibilities and authorities.....	21
<b>6</b>	<b>Planning</b> .....	<b>22</b>
6.1	Actions to address risks and opportunities.....	22
6.2	Quality objectives and planning to achieve them.....	23
6.3	Planning of changes.....	24
<b>7</b>	<b>Support</b> .....	<b>25</b>
7.1	Resources.....	25
7.1.1	General.....	25
7.1.2	People.....	25
7.1.3	Infrastructure.....	25
7.1.4	Environment for the operation of processes.....	26
7.1.5	Monitoring and measuring resources.....	26
7.1.6	Organizational knowledge.....	27
7.2	Competence.....	28
7.3	Awareness.....	29
7.4	Communication.....	29
7.5	Documented information.....	30
7.5.1	General.....	30
7.5.2	Creating and updating.....	30
7.5.3	Control of documented information.....	31
<b>8</b>	<b>Operation</b> .....	<b>32</b>
8.1	Operational planning and control.....	32
8.1.1	Provisions for counterfeit, fraudulent or suspect (CFS) items.....	32

8.2	Requirements for products and services .....	33
8.2.1	Customer communication.....	33
8.2.2	Determination of requirements related for products and services.....	33
8.2.3	Review of the requirements for products and services .....	34
8.2.4	Changes to requirements for products and services .....	35
8.3	Design and development of products and services.....	35
8.3.1	General.....	35
8.3.2	Design and development planning.....	35
8.3.3	Design and development inputs.....	36
8.3.4	Design and development controls .....	36
8.3.5	Design and development outputs .....	38
8.3.6	Design and development changes.....	38
8.4	Control of externally provided processes, products and services .....	39
8.4.1	General.....	39
8.4.2	Type and extent of control.....	40
8.4.3	Information for external providers.....	41
8.5	Production and service provision.....	43
8.5.1	Control of production and service provision.....	43
8.5.2	Identification and traceability.....	44
8.5.3	Property belonging to customers or external providers.....	45
8.5.4	Preservation.....	45
8.5.5	Post-delivery activities .....	46
8.5.6	Control of changes.....	46
8.6	Release of products and services .....	47
8.7	Control of nonconforming outputs .....	47
<b>9</b>	<b>Performance evaluation .....</b>	<b>48</b>
9.1	Monitoring, measurement, analysis and evaluation.....	48
9.1.1	General.....	48
9.1.2	Customer satisfaction .....	49
9.1.3	Analysis and evaluation .....	49
9.2	Internal audit.....	50
9.3	Management review.....	51
9.3.1	General.....	51
9.3.2	Management review inputs.....	51
<b>10</b>	<b>Improvement.....</b>	<b>52</b>
10.1	General.....	52
10.2	Nonconformity and corrective action .....	53
10.3	Continual improvement .....	54
	<b>Bibliography.....</b>	<b>55</b>