ISO/TR 4450:2020 (E)

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

Contents

Foreword

Introduction

1 Scope

2 Normative references

3 Terms and definitions

4 Context of the organization

4.1 Understanding the organization and its context
4.2 Understanding the needs and expectations of interested parties
4.3 Determining the scope of the quality management system
4.4 Quality management system and its processes

5 Leadership

5.1 Leadership and commitment
5.1.1 General
5.1.2 Customer focus
5.1.3 Nuclear safety culture
5.2 Policy
5.2.1 Establishing the quality policy
5.2.2 Communicating the quality policy
5.3 Organizational roles, responsibilities and authorities

6 Planning

6.1 Actions to address risks and opportunities
6.2 Quality objectives and planning to achieve them
6.3 Planning of changes

7 Support

7.1 Resources
7.1.1 General
7.1.2 People
7.1.3 Infrastructure
7.1.4 Environment for the operation of processes
7.1.5 Monitoring and measuring resources
7.1.5.1 General
7.1.5.2 Measurement traceability
7.1.6 Organizational knowledge
7.2 Competence
7.3 Awareness
7.4 Communication
7.5 Documented information
7.5.1 General
7.5.2 Creating and updating
7.5.3 Control of documented information

8 Operation

8.1 Operational planning and control
8.1.1 Provisions for Counterfeit, Fraudulent or Suspect (CFS) items
8.2 Requirements for products and services

8.2.1 Customer communication
8.2.2 Determination of requirements related for products and services
8.2.3 Review of requirements related for products and services
8.2.4 Changes to requirements for products and services
8.3 Design and development of products and services
8.4 Control of externally provided processes, products and services
8.4.1 General
8.4.2 Type and extent of control
8.4.3 Information for external providers
8.5 Production and service provision
8.5.1 Control of production and service provision
8.5.1.1 Control of production equipment
8.5.1.2 Monitoring and measurement activities
8.5.2 Identification and traceability
8.5.3 Property belonging to customers or external providers
8.5.4 Preservation
8.5.5 Post-delivery activities
8.5.6 Control of changes
8.6 Release of products and services
8.7 Control of nonconforming outputs

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation
9.1.1 General
9.1.2 Customer satisfaction
9.1.3 Analysis and evaluation
9.2 Internal audit
9.3 Management review
9.3.1 General
9.3.2 Management review inputs
9.3.3 Management review outputs

10 Improvement

10.1 General
10.2 Nonconformity and corrective action
10.3 Continual improvement

Annex A (informative) Additional requirements of ISO 19443:2018 versus ISO 9001:2015

Annex B (informative) How to perform a risk analysis for the project?

Annex C (informative) Determination of ITNS items and activities

Annex D (informative) Practical example of determination of ITNS items and activities

Annex E (informative) Typical (general) example for graded approach

Annex F (informative) Practical example of graded approach

Annex G (informative) Metrological guidelines

Annex H (informative) Competence and qualification

Annex I (informative) Awareness training for personnel

Annex J (informative) List of ISO 19443 additional requirements related to documented information

Annex K (informative) Good practices for 8.34 4 For more detailed guidance, refer to IEC 61160[36].

Annex L (informative) Demonstration of the evidence of provisions for monitoring activities

Annex M (informative) Example of scheme for non-conformance information and request for approval along supply chain

Page count: 55