
**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)**

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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)*

ISO 19443:2018

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ISO copyright office
CP 401 • Ch. de Blandonnet 8
CH-1214 Vernier, Geneva
Phone: +41 22 749 01 11
Fax: +41 22 749 09 47
Email: copyright@iso.org
Website: www.iso.org

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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.

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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.

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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 activities;
- graded approach to the application of quality requirements.