DIN EN ISO 19443

ICS 03.120.10; 27.120.01 Einsprüche bis 2021-05-26

Entwurf

Qualitätsmanagementsysteme – Spezifische Anforderungen für die Anwendung der ISO 9001 und den IAEA GR-S-Anforderungen an die Organisationen in der Lieferkette auf dem Sektor der Kernenergie (ISO 19443:2018); Englische Fassung prEN ISO 19443:2021

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); English version prEN ISO 19443:2021

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 (IPSN) (ISO 19443:2018); Version anglaise prEN ISO 19443:2021

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Nationales Vorwort

Der Text von ISO 19443:2018 wurde vom Technischen Komitee ISO/TC 85 „Nuclear energy, nuclear technologies, and radiological protection“ der Internationalen Organisation für Normung (ISO) erarbeitet und als prEN ISO 19443:2021 durch das Technische Komitee CEN/TC 430 „Kernenergie, Kerntechnik und Strahlenschutz“ übernommen, dessen Sekretariat von AFNOR (Frankreich) gehalten wird.

Das zuständige deutsche Normungsgremium ist der Arbeitsausschuss NA 062-07-49 AA „Qualitätsmanagement in der Kerntechnik“ im DIN-Normenausschuss Materialprüfung (NMP).

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Für die in diesem Dokument zitierten Dokumente wird im Folgenden auf die entsprechenden deutschen Dokumente hingewiesen:

ISO 9000:2015	siehe	DIN EN ISO 9000:2015-11
ISO 9001:2015	siehe	DIN EN ISO 9001:2015-11

Aktuelle Informationen zu diesem Dokument können über die Internetseiten von DIN (www.din.de) durch eine Suche nach der Dokumentennummer aufgerufen werden.

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Nationaler Anhang NA
(informativ)

Begriffe

Reihenfolge und Inhalt der folgenden Begriffe sind identisch mit denen im Abschnitt Begriffe der Englischen Fassung.

3 Begriffe

ISO 9001:2015, Quality management systems — Requirements

3 Begriffe

Für die Anwendung dieses Dokuments gelten die Begriffe nach ISO 9000:2015 und die folgenden Begriffe.

3.1
Aktivität
Tätigkeit, die zur Herstellung der Produkte oder Erbringung der Dienstleistungen beiträgt

3.2
handelsüblicher Gegenstand oder Aktivität
Gegenstand (siehe 3.6) oder Aktivität (siehe 3.1), der/die die nukleare Sicherheit beeinträchtigt und der/die nicht in Übereinstimmung mit spezifischen Anforderungen für den Nuklearbetrieb entwickelt, hergestellt oder ausgeführt wurde

Anmerkung 1 zum Begriff: Zu den handelsüblichen Gegenständen zählen keine Gegenstände, bei denen die Konstruktion und der Herstellungsprozess eine prozessbegleitende Prüfung und Verifizierung erfordern, um sicherzustellen, dass Mängel oder Abweichungen von der Norm erkannt und korrigiert werden (d. h. bei denen ein oder mehrere kritische Merkmale der Einheit nicht verifiziert werden können). Wesentliche Merkmale sind wichtige Konstruktions-, Material- und Leistungsmerkmale eines handelsüblichen Gegenstandes, die nach ihrer Verifizierung eine angemessene Gewähr dafür bieten, dass der Gegenstand seine vorgesehene Sicherheitsfunktion erfüllen wird.

Anmerkung 2 zum Begriff: Die Bestimmung der wesentlichen Merkmale, die Mittel zum Nachweis und die Abnahme für vorgesehene Sicherheitsfunktionen liegen in der Verantwortung des Kunden.

3.3 Gefälschter/betrügerischer/verdächtiger Gegenstand (CFS-Gegenstand, en: counterfeit/fraudulent/suspect)

3.3.1
gefälschter Gegenstand
Gegenstand, der absichtlich hergestellt, aufgearbeitet oder verändert wird, um ohne Genehmigung Originalprodukte zu imitieren, um sich als echt auszugeben

[QUELLE: IAEA NP-T-3.21]

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3.3.2
betrügerischer Gegenstand
Gegenstand, der absichtlich falsch präsentiert wird mit der Absicht zu täuschen

Anmerkung 1 zum Begriff: Zu den betrügerischen Gegenständen gehören Artikel, die mit falscher Kennzeichnung, gefälschter oder ungenauer Zertifizierung versehen sind. Dazu können auch Artikel gehören, die von Unternehmen verkauft werden, die das Recht erworben haben, eine bestimmte Menge eines Artikels herzustellen, aber eine größere Menge als genehmigt produzieren und den Überschuss als legitimen Bestand verkaufen.

[QUELLE: IAEA NP-T-3.21]

3.3.3
verdächtiger Gegenstand
Gegenstand, bei dem es einen Hinweis oder Verdacht gibt, dass er nicht echt sein könnte

[QUELLE: IAEA NP-T-3.21]

3.4
stufenweiser Ansatz
Prozess oder Verfahren, mit dem sichergestellt wird, dass die Anwendung der Anforderungen in Bezug auf Qualitätsmanagement, Dokumentation, Überwachung und Beurteilung der Bedeutung für die nukleare Sicherheit angemessen ist

3.5
wichtig für die nukleare Sicherheit
ITNS, en: important to nuclear safety
Eigenschaft eines Produkts, einer Dienstleistung, eines Gegenstands oder einer Aktivität, deren Ausfall zu einer übermäßigen Strahlenbelastung für Menschen oder die Umwelt führen könnte

3.6
Gegenstand
allumfassender Begriff, der anstelle einer der folgenden Begriffe verwendet wird: Baugruppe, Komponente, Ausrüstung, Material, Modul, Teil, Software, Struktur, Unterbaugruppe, Untersystem, System oder Einheit

Anmerkung 1 zum Begriff: Diese Definition ersetzt die Definition aus ISO 9000.

3.7
Lizenzinhaber
Inhaber einer aktuellen Genehmigung, die die Atomaufsichtsbehörde einer Organisation erteilt hat, die die Verantwortung für die Standortwahl, die Planung, den Bau, die Inbetriebnahme, den Betrieb oder die Stilllegung einer Atomkraftwerksanlage trägt

3.8
nukleare Sicherheit
Erreichen von ordnungsgemäßen Betriebsbedingungen, Vermeidung von Unfällen und Verminderung von unfallbedingten Folgen, was zum Schutz der Arbeitnehmer, der Öffentlichkeit und der Umwelt vor übermäßiger Strahlenbelastung führt

[QUELLE: IAEA Sicherheits-Glossar]

Anmerkung 1 zum Begriff: Die Einführung eines Qualitätsmanagementsystems ist für die Gewährleistung der nuklearen Sicherheit unerlässlich.

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Nationaler Anhang NB
(informativ)

Literaturhinweise

DIN EN ISO 9000:2015-11, *Qualitätsmanagementsysteme — Grundlagen und Begriffe (ISO 9000:2015); Deutsche und Englische Fassung EN ISO 9000:2015*

DIN EN ISO 9001:2015-11, *Qualitätsmanagementsysteme — Anforderungen (ISO 9001:2015); Deutsche und Englische Fassung EN ISO 9001:2015*

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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.

This document was prepared by Technical Committee ISO/TC 85, *Nuclear energy, nuclear technologies, and radiological protection*.

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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.

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).

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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 activites;

— graded approach to the application of quality requirements.

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0.3 Process approach

0.3.1 General

ISO 9001:2015, Quality management systems — Requirements

0.3 Process approach

0.3.1 General

This International Standard promotes the adoption of a process approach when developing, implementing and improving the effectiveness of a quality management system, to enhance customer satisfaction by meeting customer requirements. Specific requirements considered essential to the adoption of a process approach are included in 4.4.

Understanding and managing interrelated processes as a system contributes to the organization's effectiveness and efficiency in achieving its intended results. This approach enables the organization to control the interrelationships and interdependencies among the processes of the system, so that the overall performance of the organization can be enhanced.

The process approach involves the systematic definition and management of processes, and their interactions, so as to achieve the intended results in accordance with the quality policy and strategic direction of the organization. Management of the processes and the system as a whole can be achieved using the PDCA cycle (see 0.3.2) with an overall focus on risk-based thinking (see 0.3.3) aimed at taking advantage of opportunities and preventing undesirable results.

The application of the process approach in a quality management system enables:

a) understanding and consistency in meeting requirements;

b) the consideration of processes in terms of added value;

c) the achievement of effective process performance;

d) improvement of processes based on evaluation of data and information.

Figure 1 gives a schematic representation of any process and shows the interaction of its elements. The monitoring and measuring checkpoints, which are necessary for control, are specific to each process and will vary depending on the related risks.

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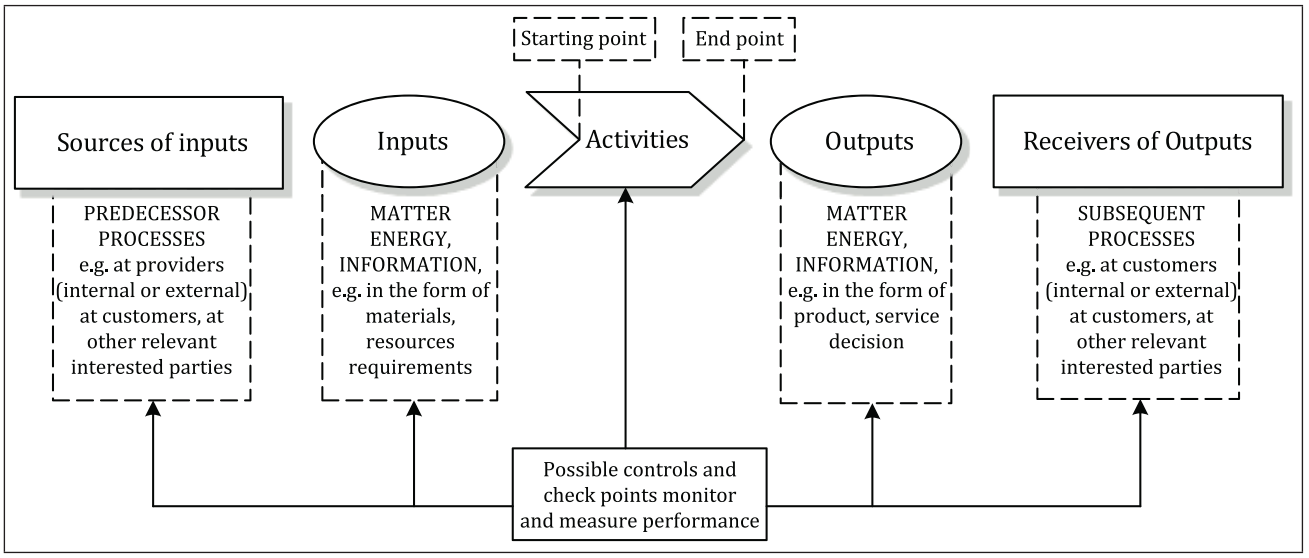

Figure 1 — Schematic representation of the elements of a single process

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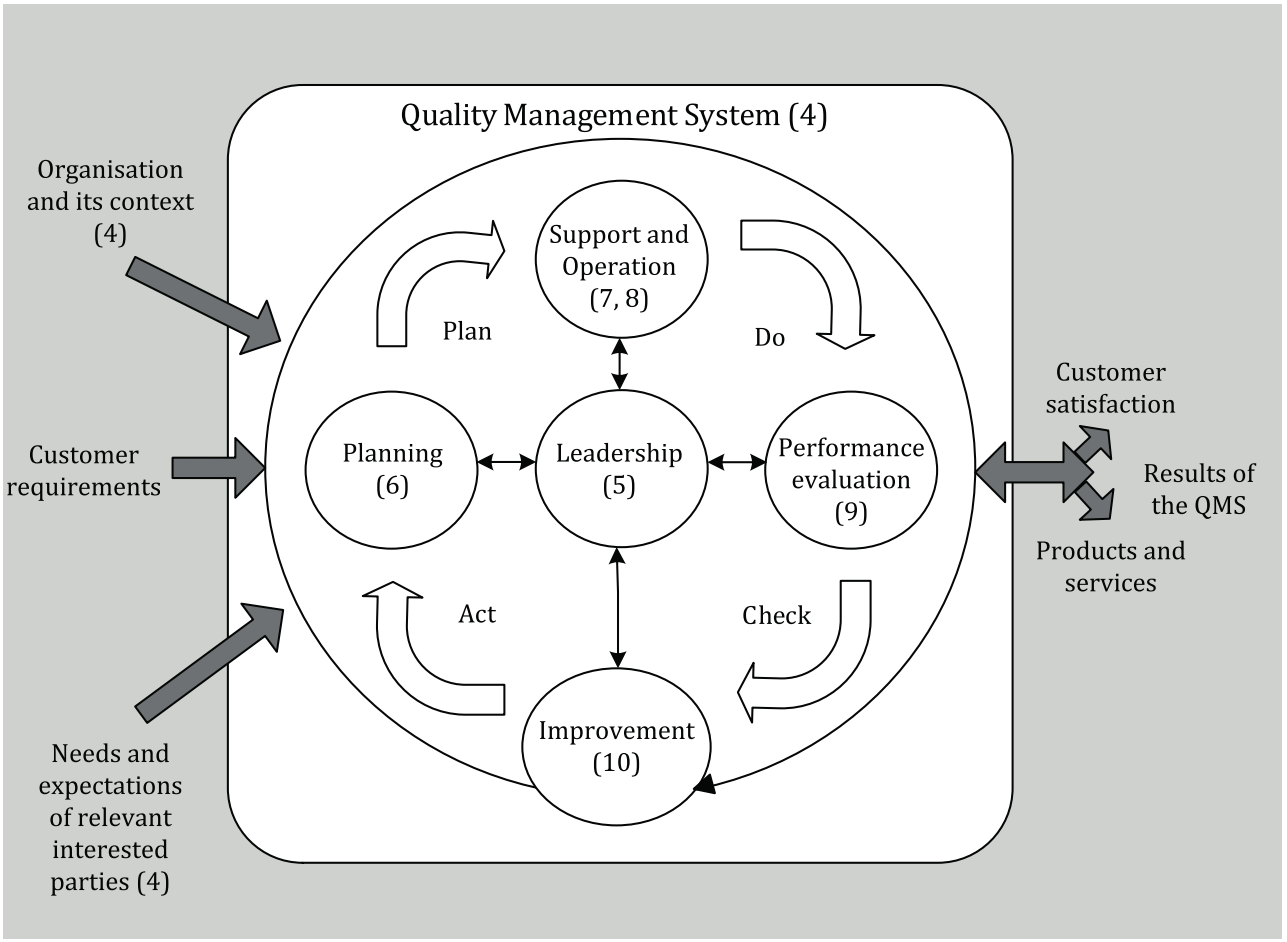
0.3.2 Plan-Do-Check-Act cycle

ISO 9001:2015, Quality management systems — Requirements

0.3.2 Plan-Do-Check-Act cycle

The PDCA cycle can be applied to all processes and to the quality management system as a whole. Figure 2 illustrates how Clauses 4 to 10 can be grouped in relation to the PDCA cycle.



NOTE Numbers in brackets refer to the clauses in this International Standard.

Figure 2 — Representation of the structure of this International Standard in the PDCA cycle

The PDCA cycle can be briefly described as follows:

— **Plan**: establish the objectives of the system and its processes, and the resources needed to deliver results in accordance with customers' requirements and the organization's policies, and identify and address risks and opportunities;

— **Do**: implement what was planned;

— **Check**: monitor and (where applicable) measure processes and the resulting products and services against policies, objectives, requirements and planned activities, and report the results;

— **Act**: take actions to improve performance, as necessary.

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0.3.3 Risk-based thinking

ISO 9001:2015, Quality management systems — Requirements

0.3.3 Risk-based thinking

Risk-based thinking (see Clause A.4) is essential for achieving an effective quality management system. The concept of risk-based thinking has been implicit in previous editions of this International Standard including, for example, carrying out preventive action to eliminate potential nonconformities, analysing any nonconformity that do occur, and taking action to prevent recurrence that is appropriate for the effects of the nonconformity.

To conform to the requirements of this International Standard, an organization needs to plan and implement actions to address risks and opportunities. Addressing both risks and opportunities establishes a basis for increasing the effectiveness of the quality management system, achieving improved results and preventing negative effects.

Opportunities can arise as a result of a situation favourable to achieving an intended result, for example, a set of circumstances that allow the organization to attract customers, develop new products and services, reduce waste or improve productivity. Actions to address opportunities can also include consideration of associated risks. Risk is the effect of uncertainty and any such uncertainty can have positive or negative effects. A positive deviation arising from a risk can provide an opportunity, but not all positive effects of risk result in opportunities.

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0.4 Relationship with other management system standards

ISO 9001:2015, Quality management systems — Requirements

0.4 Relationship with other management system standards

This International Standard applies the framework developed by ISO to improve alignment among its International Standards for management systems (see Clause A.1).

This International Standard enables an organization to use the process approach, coupled with the PDCA cycle and risk-based thinking, to align or integrate its quality management system with the requirements of other management system standards.

This International Standard relates to ISO 9000 and ISO 9004 as follows:

— ISO 9000, *Quality management systems — Fundamentals and vocabulary* provides essential background for the proper understanding and implementation of this International Standard;

— ISO 9004, *Managing for the sustained success of an organization — A quality management approach* provides guidance for organizations that choose to progress beyond the requirements of this International Standard.

Annex B provides details of other International Standards on quality management and quality management systems that have been developed by ISO/TC 176.

This International Standard does not include requirements specific to other management systems, such as those for environmental management, occupational health and safety management, security management, nuclear accounting and control or financial management.

Sector-specific quality management system standards based on the requirements of this International Standard have been developed for a number of sectors. Some of these standards specify additional quality management system requirements, while others are limited to providing guidance to the application of this International Standard within the particular sector.

A matrix showing the correlation between the clauses of this edition of this International Standard and the previous edition (ISO 9001:2008) can be found on the ISO/TC 176/SC 2 open access web site at: www.iso.org/tc176/sc02/public.

Management system requirements specific to security management, and nuclear material accounting and control are not addressed in this International Standard.

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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)

1 Scope

ISO 9001:2015, Quality management systems — Requirements

1 Scope

This International Standard specifies requirements for a quality management system when an organization:

a) needs to demonstrate its ability to consistently provide products and services that meet customer and applicable statutory and regulatory requirements, and

b) aims to enhance customer satisfaction through the effective application of the system, including processes for improvement of the system and the assurance of conformity to customer and applicable statutory and regulatory requirements.

All the requirements of this International Standard are generic and are intended to be applicable to any organization, regardless of its type or size, or the products and services it provides.

NOTE 1 In this International Standard, the terms “product” or “service” only apply to products and services intended for, or required by, a customer.

NOTE 2 Statutory and regulatory requirements can be expressed as legal requirements.

This International Standard applies to organizations supplying ITNS products or services.

Application of this standard to organizations performing activities on a licensed nuclear site is subject to prior agreement by the Licensee.

Requirements specified in this International Standard are complementary (not alternative) to customer and applicable statutory and regulatory requirements.

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2 Normative references

ISO 9001:2015, Quality management systems — Requirements

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

ISO 9000:2015, *Quality management systems — Fundamentals and vocabulary*

3 Terms and definitions

ISO 9001:2015, Quality management systems — Requirements

3 Terms and definitions

For the purposes of this document, the terms and definitions given in ISO 9000:2015 and the following apply.

3.1
activity
task which contributes to the realization of the products or services

3.2
commercial grade item or activity
item (see 3.6) or activity (see 3.1) that affects nuclear safety and that was not designed, manufactured or performed in accordance with specific nuclear requirements

Note 1 to entry: Commercial-grade items do not include items where the design and manufacturing process require in-process inspection and verification to ensure that defects or failures to comply are identified and corrected (i.e. where one or more critical characteristics of the item cannot be verified). Critical characteristics are important design, material, and performance characteristics of a commercial grade item that, once verified, will provide reasonable assurance that the item will perform its intended safety function.

Note 2 to entry: The determination of the critical characteristics, the means for verification and acceptance for intended safety functions are the responsibility of the customer.

3.3 Counterfeit/fraudulent/suspect (CFS) item

3.3.1
counterfeit items
items that are intentionally manufactured, refurbished or altered to imitate original products without authorization in order to pass themselves off as genuine

[SOURCE: IAEA NP-T-3.21]

3.3.2
fraudulent items
items that are intentionally misrepresented with intent to deceive

Note 1 to entry: Fraudulent items include items provided with incorrect identification, falsified or inaccurate certification. They may also include items sold by entities that have acquired the legal right to manufacture a specified quantity of an item but produce a larger quantity than authorized and sell the excess as legitimate inventory.

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