TECHNICAL REPORT

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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

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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 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).

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 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.

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.

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)[1],

— 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[2], 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[2] (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[2], Annex A,
- ISO/TS 9002[3], and
- ISO/IAF Auditing Practices Group[4].

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.

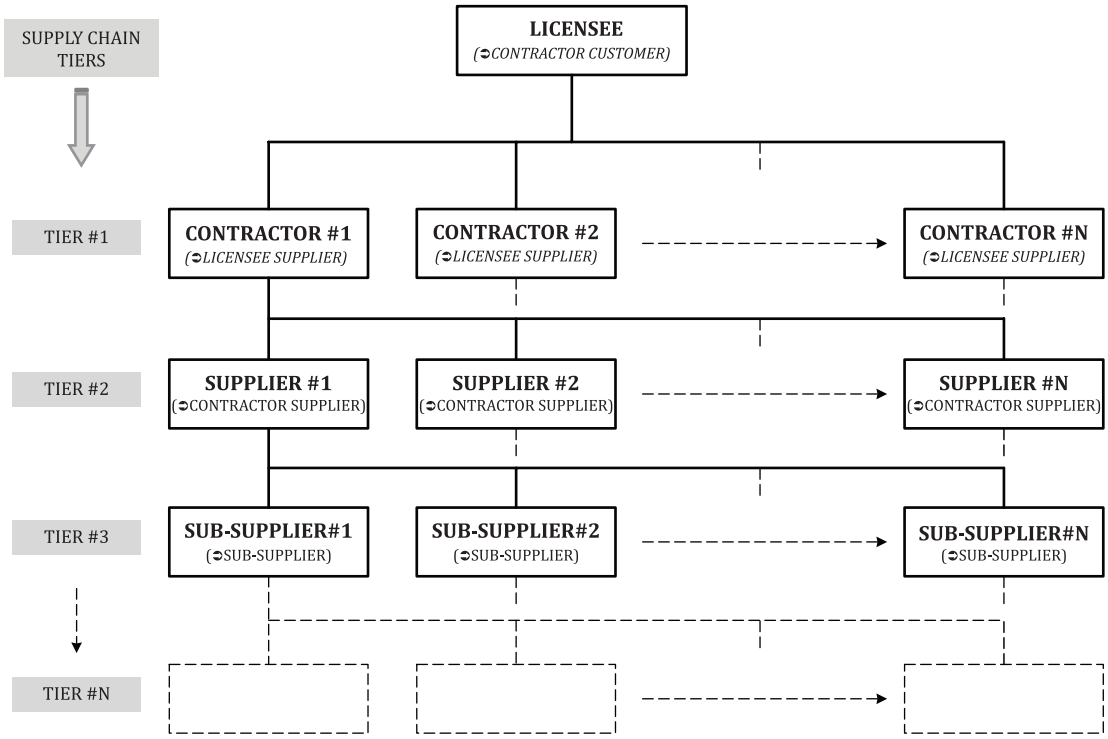


Figure 1 — Schematic breakdown of tiers.

0.1 General

No ISO 19443 additional requirement to ISO 9001.

0.2 Quality management principles

No supplementary guidance provided.

0/3 Process approach

No ISO 19443 additional requirement to ISO 9001.

0.4 Relationship with other management system standards

No supplementary guidance provided.

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

1 Scope

This document provides guidance on the implementation of the ISO 19443 requirements, with examples of possible steps an organization can take to meet the requirements.

It does not add to, subtract from, or in any way modify those requirements.

This document does not prescribe mandatory approaches to implementation, or provide any preferred method of interpretation.

2 Normative references

There are no normative references in this document.

No ISO 19443 additional requirement to ISO 9001.

3 Terms and definitions

No terms and definitions are listed in this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— ISO Online browsing platform: available at https://www.iso.org/obp

— IEC Electropedia: available at http://www.electropedia.org/

4 Context of the organization

4.1 Understanding the organization and its context

As part of risk-based thinking of ISO 19443:2018, 0.3.3, the organization should consider any risks and the nuclear safety implications to its activities.

Refer also to Annex B.

4.2 Understanding the needs and expectations of interested parties

No ISO 19443 additional requirement to ISO 9001.

4.3 Determining the scope of the quality management system

No ISO 19443 additional requirement to ISO 9001.

4.4 Quality management system and its processes

4.4.1 *No ISO 19443 additional requirement to ISO 9001.*

4.4.2 *No ISO 19443 additional requirement to ISO 9001.*

4.4.3 Refer to ISO 9000:2015[5] for definition of quality manual or quality plan and to following standards referenced in ISO 9001:2015, Annex B:

— ISO 10005, *Quality management systems — Guidelines for quality plans*[6]. This document provides guidance on establishing and using quality plans as a means of relating requirements of the process, product, project or contract, to work methods and practices that support product realization. Benefits of establishing a quality plan are increased confidence that requirements will be met, that processes are in control and the motivation that this can give to those involved.

— ISO 10006, *Quality management systems — Guidelines for quality management in projects*[7]. This document is applicable to projects from the small to large, from simple to complex, from an individual project to being part of a portfolio of projects. ISO 10006 is to be used by personnel managing projects and who need to ensure that their organization is applying the practices contained in the ISO quality management

The intent of this subclause is for the organization to demonstrate compliance with ISO 19443 requirements, whatever the form, format or media. Quality manual and/or quality plan are examples of typical ways to comply with this clause, but any other means (e.g. matrix, correspondence table, etc.) can be used.

5 Leadership

Material can be found as guidelines for whole chapter 5 in the following documents.

— IAEA, Safety Series No.75-INSAG-4, 1991 – Safety Culture[21]

— INPO – "Principles for a Strong Nuclear Safety Culture"[22]

— WANO – Principles PL | 2013-1 - Traits of a Healthy Nuclear Safety Culture[23]

— IAEA, No.INSAG-10, 1996 – Defence in Depth in Nuclear Safety[24]

— AIEA, No.INSAG-13, 1999 – Management of Operational Safety in Nuclear Power Plants[25]

— IAEA, No.INSAG-15, 2002 – Key Practical Issues in Strengthening Safety Culture[26]

— IAEA Bulletin 50-1 – September 2008 – The mind-set of nuclear safety[27]

— IAEA General Safety Requirements - GSR Part 2:2016 - Leadership and Management for Safety[28]

— IAEA Safety Guide No. GS-G-3.1:2006 - Application of the Management System for Facilities and Activities[29]

— IAEA Safety Reports Series No 83:2016 - Performing Safety Culture Self-assessments[30]

5.1 Leadership and commitment

5.1.1 General

No supplementary guidance provided.

5.1.2 Customer focus

No ISO 19443 additional requirement to ISO 9001.

5.1.3 Nuclear safety culture

Definition of IAEA Safety glossary[8]:

The assembly of characteristics and attitudes in organizations and individuals which establishes that, as an overriding priority, protection and safety issues receive the attention warranted by their significance.

Section 5.1.3 of the standard addresses the principles of nuclear safety culture as a contribution to nuclear safety, see Figure 2:

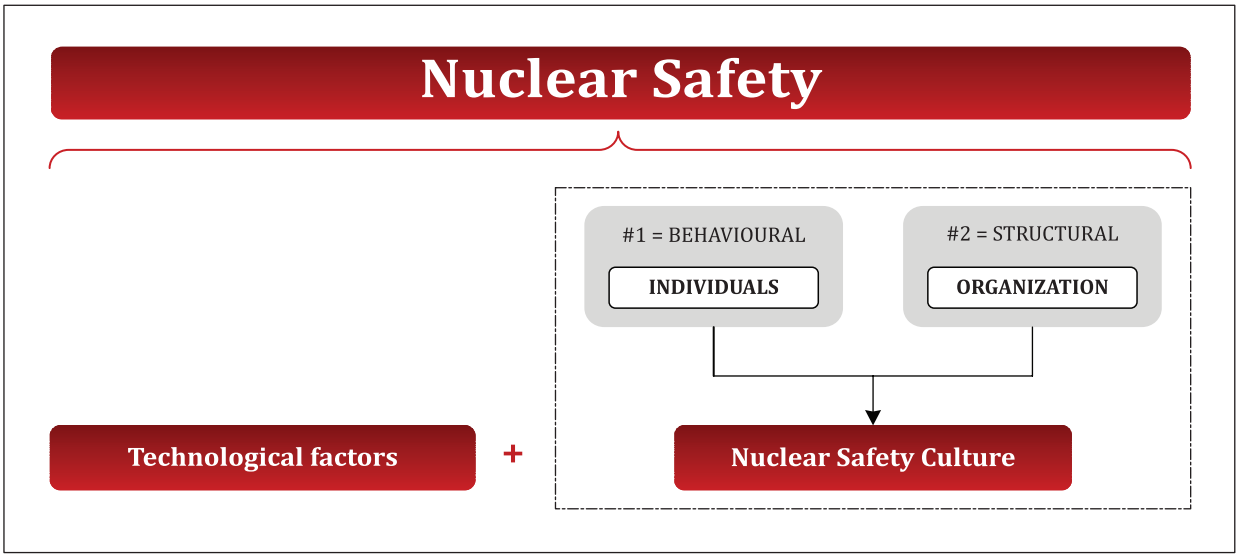


Figure 2 — Nuclear safety and nuclear safety culture

5.2 Policy

5.2.1 Establishing the quality policy

Appropriate nuclear safety considerations of 5.2.1 e) should take into account nuclear safety culture aspects.

It's up to the organization to develop separated policies for quality and safety or an integrated one.

5.2.2 Communicating the quality policy

No ISO 19443 additional requirement to ISO 9001.

5.3 Organizational roles, responsibilities and authorities

No supplementary guidance provided.

6 Planning

6.1 Actions to address risks and opportunities

No supplementary guidance provided.

6.1.1 The only ISO 19443 additional requirement to ISO 9001 is the requirement to maintain and retain documented information issued to identify actions to address risks and opportunities. As reminder of the state of the art, the following can be considered as a good practice for both 6.1.1 and 6.1.2.

The organization should develop a documented risk management method, related to the achievement of applicable requirements. This includes, as appropriate to the organization and the product:

a) assignment of responsibilities for risk management;

b) definition of risk criteria (e.g., likelihood, consequences, risk acceptance), which could require use of probabilistic model;

c) identification, assessment and communication of risks throughout product realization including supply chain;

d) identification, implementation and management of actions to mitigate risks that exceed the defined risk acceptance criteria;

e) tolerability of risks remaining after implementation of mitigating actions.

See Annex B for proposed practical solution.

6.1.2 See above 6.1.1.

6.1.3 Determination of ITNS items and activities

Depending on the context of the product or service, the determination of ITNS items and activities can generally be performed by the following technical analysis performed in two consecutive steps as shown in Figure 3.

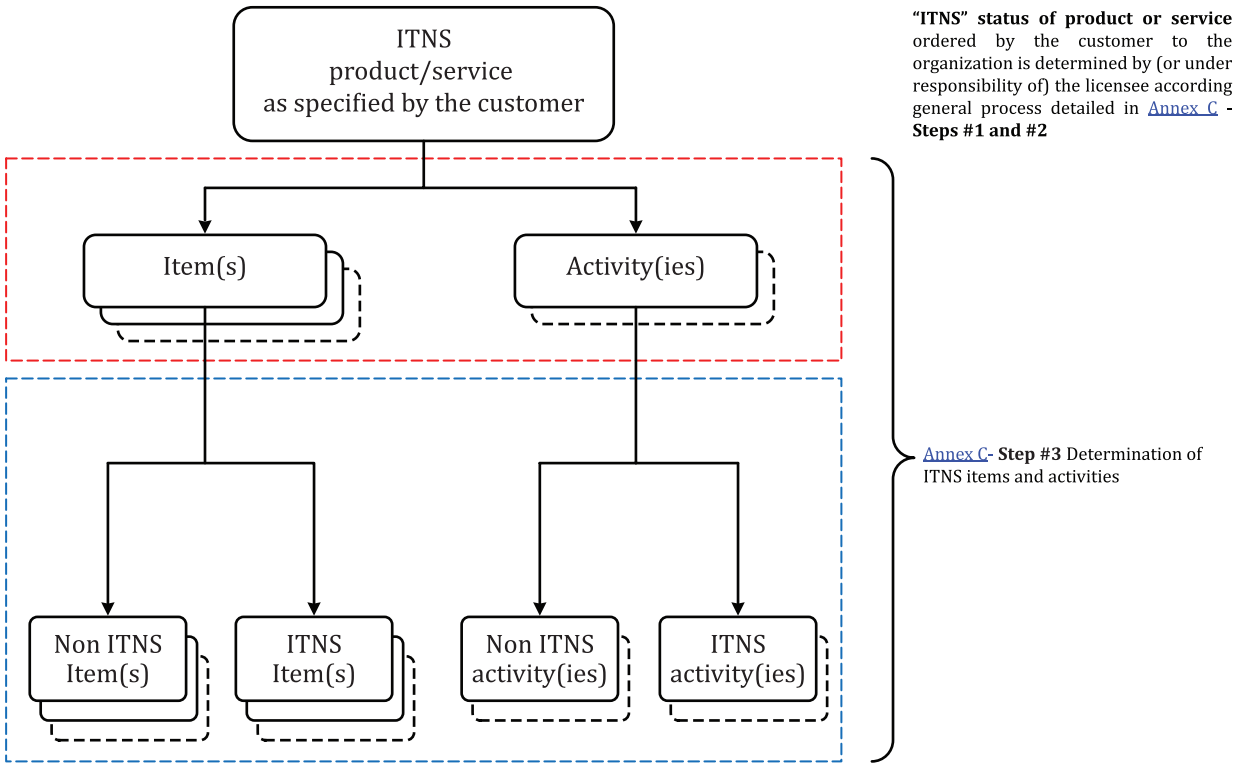


Figure 3 — Determination of ITNS items and activities (see practical example In Annex D)

Annex D - Step #3 is performed in two steps.

— **Step #3-1**: The product or service would normally be broken down in different items or activities [see ISO 19443:2018, 6.1.3 a)]. When relevant and depending on the complexity of product and service, following analysis methods can be used: F.A.S.T. (Functional Analysis System Technique), Value engineering, etc.

— **Step #3-2**: Identification of the impact of the potential failure or malfunction of each item or activity on the product or service function(s) specified by the customer as related to nuclear safety [see ISO 19443:2018, 6.1.3 b)]:

  — a risk analysis, performed for each item or activity, would support this identification, considering that the conclusion should be formulated in a binary sense (ITNS or non-ITNS);

  — it is recommended to refer to one of the different type of risk analysis methods as listed in IEC/ISO 31010[9], e.g. Failure modes and effects analysis (FMEA).

    NOTE When appropriate, design/construction codes or standards can be used for identification of the impact of the potential failure or malfunction of each item or activity on the above function(s) related to nuclear safety.

For a practical example (electromechanical pump) of ITNS determination, refer to Annex D.

6.1.4 Graded approach to the application of quality requirements

The intent of the ISO 19443 is to define the graded approach as it should be applied by the organization to the items constituting and/or activities resulting in the ITNS product or service ordered by the customer. A practical understanding of the requirement would be:

Items and/or activities supplied by the organization itself:

— **Quality management**. Set of requirements are those of ISO 19443 since the product or service supplied by the organization to its customer is ITNS. However, the organization can grade, for each item or activity, the conditions in which the implementation of all ISO 19443 requirements is performed, to the extent authorized by ISO 19443 provisions, with a particular focus on:

  — **Documentation** requirements. As an example, grading provisions could address number and extent (complexity, level of detail, …) of documented information (from a single certificate of compliance to a full set of lifetime records, procedures, plans, specifications, drawings, reports, …) the organization maintains and retains for the item or activity, having regard to the appropriate level of assurance to be established, based on the level of risk (i.e. ITNS or not),

  — **Monitoring and measurement** requirements. Grading examples could be, but not limited to:

    — Conditions for review and/or approval of documented information.

    — Internal assessment and oversight of processes (internal audit, inspection, document review …). It's recommended that the oversight particularly takes into consideration the processes "the result of which the specified quality cannot be readily determined by inspection of test of the product".

    — Design and development : number and type of reviews (e.g. peer reviews), methods of verification, means of validation (e.g. testing, alternative calculations, mock-ups, …).

    — Production control: sampling procedures, witness/hold points on ITP, resources, gate reviews …

Items and/or activities supplied by an external provider:

— **Quality management**. The set of requirements determined as applicable for the external provider could be, but not limited to:

  — for externally provided "ITNS items and activities": ISO 19443,

  — for externally provided "non ITNS items and activities", one of the following given as examples: ISO 9001, specific quality management requirements, industrial good practices, no particular ones.

— **Documentation requirements**. As an example, grading provisions could address number and extent (complexity, level of detail, …) of documented information, defined having regard to the appropriate level of assurance to be established, based on the level of risk (i.e. ITNS or not):

  — the organization should issue for control of externally provided item and activities,

  — the external provider should maintain and retain for the item or activity (from a single certificate of compliance to a full set of lifetime records, procedures, plans, specifications, drawings, reports, …),

— **Monitoring and measurement** requirements. Grading examples could be, but not limited to:

  — Conditions for review and/or approval by the organization of documented information issued by the external provider,

  — External provider assessment and processes oversight (audit, inspection, document review, design and development reviews, …) through sampling rules, witness/hold points, gate reviews … It's recommended that the oversight particularly takes into consideration the processes "the result of which the specified quality cannot be readily determined by inspection of test of the product".

Refer to Annex E for typical general example of grading and to Annex F for a practical simplified example (electromechanical pump) of grading.

For more general information, refer to:

— IAEA-TECDOC-1740[10];

— IAEA-Technical Report-328[11].

6.2 Quality objectives and planning to achieve them

6.2.1 *No supplementary guidance provided.*

6.2.2 *No ISO 19443 additional requirement to ISO 9001.*

6.3 Planning of changes

No supplementary guidance provided.

7 Support

7.1 Resources

7.1.1 General

No supplementary guidance provided.

7.1.2 People

No ISO 19443 additional requirement to ISO 9001.

7.1.3 Infrastructure

No ISO 19443 additional requirement to ISO 9001.

7.1.4 Environment for the operation of processes

b) *Psychological*

Nuclear safety culture studies have identified that it is important that the workforce can be open with reporting when they have made mistakes. Experience has shown that this requires management to have a ***non-blaming*** approach, though still considering the root-causes of mistakes may require changes in activities, retraining or ultimately removal from ITNS work.

c) *Physical*

Cleanliness is a significant matter in the manufacture, assembly and construction of Structures Systems and Components (SSCs) that will be subject to ionising radiation.

7.1.5 Monitoring and measuring resources

7.1.5.1 General

Nuclear SSCs frequently require fine tolerances and thus, it is necessary to put the emphasis on measuring resources requirements within nuclear context compared to current industrial practices. Therefore, particular attention is drawn to situations (See Figure G.1) where:

— the measuring interval of the measuring equipment is much higher than the measurand (e.g. when use of a ruler of 0,3 m rather than a micrometer 0 mm to 25 mm for the acceptance of a measurand of 0,5 mm),

— the measured value is close to the specified limits (boundaries of specification zone) and therefore, due to measurement uncertainty, the real value may be outside the specification zone,

— the measurement uncertainty is much lower than the tolerance given in the specification.

To avoid or minimize incorrect judgement of conformity to requirements, it is suggested, as a good practice, to select measuring equipment which has:

— a measuring interval close to the measurand (e.g. manometer range 0 bar to 100 bar for a measured value of 80 bar),

— a measurement accuracy with a minimum coverage factor of 8 compared with the value of the tolerance (e.g. use of a calliper with a measurement accuracy of $1/100^{th}$ mm when the tolerance is $1/10^{th}$ mm).

As a good practice, the organization should also:

— maintain a monitoring and measuring equipment register, and define the process employed for their calibration/verification including details of equipment type, unique identification, location, frequency of checks, check method and acceptance criteria,

— ensure that environmental conditions are suitable for the calibration, inspection, measurement and testing being carried out.

7.1.5.2 Measurement traceability

The monitoring and measuring equipment (e.g. measuring instrument, software, measurement standard or auxiliary apparatus or combination thereof) necessary to perform a measurement process needs a metrological confirmation by verification and/or calibration when it is used to certify the conformity of the product.

This metrological confirmation ensures that measuring equipment conforms to the requirements for its intended use, taking into account calibration or verification, as referred to in Annex G.

7.1.6 Organizational knowledge

No ISO 19443 additional requirement to ISO 9001.

7.2 Competence

For definition of **Competence** refer to ISO 9000 and, for **Qualification**, interpretation is provided in ISO 9000 and examples given in Annex H.

Examples for knowledge and skills which can be taken into account for competence are given in Annex H.

Examples for demonstration of ability to pronounce qualification are given in Annex H.

7.3 Awareness

This awareness training for persons involved (including workers and managers) in ITNS products and services realization should consider nuclear safety culture topics [see ISO 19443:2018, 5.1.3 a)] such as:

— What nuclear safety is;

— What an ITNS product, service, item or activity is;

— Importance and impact of individual's role in achieving nuclear safety;

— How individuals know they are working on ITNS;

— What my role is in preventing CFS Items being brought into the organization;

— Management: leadership, decision-making and creating a respectful work environment;

— Expected behavior : questioning attitude, adherence to procedures, transparency in reporting issues, events and NCR; …

Refer to Annex I for more detailed material.

7.4 Communication

No supplementary guidance provided.

7.5 Documented information

To confirm that the specified requirements have been met, the documentation is of great importance in the nuclear industry ("culture of the proof") by demonstrating

— effective performance of an action (traceability), and

— conformance with applicable requirements.

This is why ISO 19443 as added to ISO 9001 additional requirements for documented information. Those additional requirements are identified in the table of Annex J.

7.5.1 General

No ISO 19443 additional requirements to ISO 9001.

For supplementary guidance, see good practices proposed by ISO 9001:2015, A.6 and ISO/TS 9002.

7.5.2 Creating and updating

Comprehensive identification of documented information is necessary especially for products and services that will need to be replicated during the life of a nuclear facility.

Translation of documented information is not just a question of languages (Refer also to Annex H for competence) but could also include measurement systems considerations and information (e.g. metric/imperial, US/British liquid volumes) and date conventions (e.g. DD/MM/YYYY vs MM/DD/YYYY). It is useful to indicate where translations have been made, when and by whom.

Consideration should be given to making a clear statement at the outset as to the systems to be applied and abbreviations used, e.g. SI units as defined in ISO 80000 series[12].

The degree of review and approval of documented information will generally depend on the safety determination of the product and services addressed. For lower grades, a suitably qualified and experienced person from within the work unit may be acceptable but as the importance is raised the need to move towards persons from either other work units or even different organizations may be called for. The management of the organization need to decide the approaches to be taken and authorize people to undertake the reviews and approvals. In principal, no one should review their own work.

7.5.3 Control of documented information

Traceability and ***authentication*** have been included, linked to the requirements added into 7.5.2.

It is important that management draw workers attention to changed documentation information that is appropriate to their activities. Revision marking systems should be used to identify discrete elements of text that have been altered.

Obsolete documented information should at least be marked as such, but if possible should be withdrawn/archived so that it cannot be inadvertently used.

For electronic documented information revision marking modes are one means of identifying changes.

Under certain circumstances, a temporary/interim documented information may be required to control an activity for a limited period, waiting their formal update. A practical example could be a work instruction modified by hand with a mark-up. This should clearly (e.g. in coloured inks) identify what the change is, who has made the modification (only authorized personnel should modify the documented information) and, if possible, relate to a document control note which sets out the history and justification for the change. Any correction method which would make the change illegible, such as the use of correcting fluid or tape, should not be permitted.

Maintenance of the documented information is a typical mean to ensure that the requirements of 7.5.3 are met.

For additional information and guidelines on management systems for records, refer to ISO 30300 series[13] which constitutes a reference point for information management and for the creation and control of documented information.

7.5.3.1 *See above 7.5.3 guidelines.*

7.5.3.2 *See above 7.5.3 guidelines.*

8 Operation

8.1 Operational planning and control

For project management, further guidance is given in ISO 10006[7] and ISO 21500[14].

For configuration management, further guidance is given in ISO 10007[15], IEEE 828[16] and IEEE 1042[17].

8.1.1 Provisions for Counterfeit, Fraudulent or Suspect (CFS) items

The wording “at all levels of operations” includes the organization itself.

For more information, refer to:

— IAEA Nuclear Energy Series No. NP-T-3.21:2016[18],

— IAEA Tecdoc 1169:2000[19],

— IAEA Technical Report No. NP-T-3.26:2019[20].

8.2 Requirements for products and services

8.2.1 Customer communication

No supplementary guidance provided.

8.2.2 Determination of requirements related for products and services

No ISO 19443 additional requirement to ISO 9001.

8.2.3 Review of requirements related for products and services

8.2.3.1 *No supplementary guidance provided.*

8.2.3.2 *No supplementary guidance provided.*

8.2.4 Changes to requirements for products and services

No supplementary guidance provided.

8.3 Design and development of products and services

For supplementary guidance and good practices proposed for the whole of 8.3, refer to Annex K.

8.4 Control of externally provided processes, products and services

8.4.1 General

Criteria for the external providers evaluation and selection should consider topics such as:

— **T**echnical: Ability to provide a product or service compliant right first time including qualification requirements e.g. compliance with codes and standards as applicable,

— **Q**uality and nuclear safety culture: Compliance of Quality Management System with the applicable specified requirements, lessons learnt from previous orders: number of complaints raised by the organization, completeness of quality documentation provided for previous deliveries, monitoring results, qualification of personnel…

— **R**esponsiveness: Ability to answer rapidly to organization (needs, Complaint Resolution Time etc.),

— **D**elivery: Respect of schedule, on time in full,

— **C**ost: Value for money.

Typical documented information on external provider assessment could be assessment files, approved external providers lists, etc.

When demonstrating equivalence of provisions taken when an external provider, responsible for an ITNS items or activities, cannot demonstrate that its quality management system meets the requirements of ISO 19443, a good practice could be to for the organization to issue a document (e.g. a quality plan) identifying those of the requirements:

— fulfilled by the external supplier's quality management system, and

— covered by the organization's specific provisions taken for the requirements for which the quality management system of the external provider doesn't offer adequate or sufficient provisions.

8.4.2 Type and extent of control

Commercial grade items

Commercial-grade items may be specified, procured and installed into ITNS products and can be defined as items that:

a) are generally utilised in non-nuclear applications and are therefore not designed or manufactured to nuclear specific requirements,

b) can be ordered by an organization based on the specification and characteristics defined in a manufacturer or supplier catalogue. This type of item is often referred to as "commercial off the shelf",

c) have not been subject to any modifications from their original design, specification, service application or operating parameters defined in above catalogue.

The following are examples of services that could be determined as ITNS activities:

— repair services;

— testing services;

— fabrication/machining/cleaning/manufacturing services;

— engineering/technical services;

— calibration services;

— computer software services.

Monitoring of commercial grade items

In order to ensure that the external provider processes are controlled and specified requirements for items and/or activities are met, a good practice for monitoring of an external supplier would include part or all of the following:

— periodic meetings organized with the external provider and, when relevant, other stakeholders;

— review of documented information supplied by the external provider;

— oversight of external provider by the organization, e.g. surveillance and/or audit.

Traceability of surveillance activities is generally maintained through the use of documented information such as "Quality Control Plan" (QCP), "Inspection Test Plan" (ITP), Follow-Up Document (FUD), etc. A suggested model and contents for such documented information is attached in Annex L.

The organization should utilize an appropriate assessment process (e.g. audit, test, inspection, document review) of external providers to verify that items supplied as commercial grade meet the specified critical characteristics for the intended use.

8.4.3 Information for external providers

No supplementary guidance provided.

8.5 Production and service provision

8.5.1 Control of production and service provision

No supplementary guidance provided.

8.5.1.1 Control of production equipment

The intent of this subclause is to identify computer controlled production equipment which has to be properly validated prior to release. In particular, this validation would apply when computer controlled production equipment:

— provides data which confirms product conformity;

— controls special processes (e.g. welding, heat-treatment, non-destructive testing, etc.);

— is required to be validated by contract, standard, code or regulation.

8.5.1.2 Monitoring and measurement activities

No supplementary guidance provided.

8.5.2 Identification and traceability

No supplementary guidance provided.

8.5.3 Property belonging to customers or external providers

No ISO 19443 additional requirement to ISO 9001.

8.5.4 Preservation

No supplementary guidance provided.

8.5.5 Post-delivery activities

No supplementary guidance provided.

8.5.6 Control of changes

No ISO 19443 additional requirement to ISO 9001.

8.6 Release of products and services

No supplementary guidance provided.

8.7 Control of nonconforming outputs

8.7.1 For supplementary guidance, refer to Annex M (Example of scheme for Non-conformance information and request for approval along the supply chain).

8.7.2 Refer to ISO/TS 9002:2016, 8.7.

9 Performance evaluation

9.1 Monitoring, measurement, analysis and evaluation

9.1.1 General

No supplementary guidance provided.

9.1.2 Customer satisfaction

No ISO 19443 additional requirement to ISO 9001.

9.1.3 Analysis and evaluation

Nuclear safety culture has been added into the evaluation to allow for early identification of underlying organizational issues that may, positively or negatively, alter the organizations performance.

9.2 Internal audit

9.2.1 *No supplementary guidance provided.*

9.2.2 *No supplementary guidance provided.*

9.3 Management review

9.3.1 General

No supplementary guidance provided.

9.3.2 Management review inputs

No supplementary guidance provided.

9.3.3 Management review outputs

No ISO 19443 additional requirement to ISO 9001.

10 Improvement

10.1 General

Methods for identifying good practices can be: toolbox talks, quality forums, quality improvement groups, benchmarking, etc.

10.2 Nonconformity and corrective action

10.2.1 Wording "without undue delay" has to be understood as "without unjustified delay and for which the timeframe should be agreed between the organization, its customer and, if applicable, involved authorities".

10.2.2 *No ISO 19443 additional requirement to ISO 9001.*

10.3 Continual improvement

No supplementary guidance provided.

Annex A
(informative)

Additional requirements of ISO 19443:2018 versus ISO 9001:2015

Table A.1 — Additional requirements of ISO 19443:2018 versus ISO 9001:2015

ISO 19443:2018 chapter and title containing additional requirements or new chapter versus ISO 9001:2015 *(text in italic is not related to requirements but given for information)*		Additional (requirements)	New (chapter)
0.1	*General*		
0.2	*Quality management principles*	*x*	
0.3	*Process approach*		
0.4	*Relationship with other management system standards*	*x*	
1.	**Scope**	**x**	
2.	**Normative references**	**x**	
3.	**Terms and definitions**	**x**	
4.	**Context of the organization**		
4.1	Understanding the organization and its context	x	
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		
4.4.1			
4.4.2			
4.4.3			x
5.	**Leadership**		
5.1	Leadership and commitment		
5.1.1	General	x	
5.1.2	Customer focus		
5.1.3	Nuclear safety culture		x
5.2	Policy		
5.2.1	Establishing the quality policy	x	
5.2.2	Communicating the quality policy		
5.3	Organizational roles, responsibilities and authorities	x	
6.	**Planning**		
6.1	Actions to address risks and opportunities		
6.1.1		x	
6.1.2		x	
6.1.3	Determination of ITNS items and activities		x
6.1.4	Graded approach to the application of quality requirements		x
6.2	Quality objectives and planning to achieve them		
6.2.1		x	
6.2.2			

Table A.1 *(continued)*

ISO 19443:2018 chapter and title containing additional requirements or new chapter versus ISO 9001:2015 *(text in italic is not related to requirements but given for information)*		Additional (requirements)	New (chapter)
6.3	Planning of changes	x	
7.	**Support**		
7.1	Resources		
7.1.1	General	x	
7.1.2	People		
7.1.3	Infrastructure		
7.1.4	Environment for the operation of processes	x	
7.1.5	Monitoring and measuring resources		
7.1.5.1	General	x	
7.1.5.2	Measurement traceability	x	
7.1.6	Organizational knowledge		
7.2	Competence	x	
7.3	Awareness	x	
7.4	Communication	*(Note only)*	
7.5	Documented information		
7.5.1	General		
7.5.2	Creating and updating	x	
7.5.3	Control of documented information		
7.5.3.1		x	
7.5.3.2		x	
8.	**Operation**		
8.1	Operational planning and control	x	
8.1.1	Provisions for Counterfeit, Fraudulent or Suspect (CFS) items		x
8.2	Requirements for products and services		
8.2.1	Customer communication	x	
8.2.2	Determination of requirements related for products and services		
8.2.3	Review of requirements related for products and services		
8.2.3.1		x	
8.2.3.2		x	
8.2.4	Changes to requirements for products and services	x	
8.3	Design and development of products and services		
8.3.1	General	x	
8.3.2	Design and development planning	x	
8.3.3	Design and development inputs		
8.3.4	Design and development controls	x	
8.3.4.1	Design and development verification and validation testing		x
8.3.5	Design and development outputs	x	
8.3.6	Design and development changes	x	
8.4	Control of externally provided processes, products and services		
8.4.1	General	X	
8.4.2	Type and extent of control	X	

Table A.1 *(continued)*

ISO 19443:2018 chapter and title containing additional requirements or new chapter versus ISO 9001:2015 *(text in italic is not related to requirements but given for information)*		Additional (requirements)	New (chapter)
8.4.3	Information for external providers	X	
8.5	Production and service provision		
8.5.1	Control of production and service provision	x	
8.5.1.1	Control of production equipment		X
8.5.1.2	Monitoring and measurement activities		X
8.5.2	Identification and traceability	X	
8.5.3	Property belonging to customers or external providers		
8.5.4	Preservation	X	
8.5.5	Post-delivery activities	X	
8.5.6	Control of changes		
8.6	Release of products and services	X	
8.7	Control of nonconforming outputs		
8.7.1		X	
8.7.2		X	
9.	**Performance evaluation**		
9.1	Monitoring, measurement, analysis and evaluation		
9.1.1	General	X	
9.1.2	Customer satisfaction		
9.1.3	Analysis and evaluation	X	
9.2	Internal audit		
9.2.1		X	
9.2.2		X	
9.3	Management review		
9.3.1	General	X	
9.3.2	Management review inputs	X	
9.3.3	Management review outputs		
10.	**Improvement**		
10.1	General	X	
10.2	Nonconformity and corrective action		
10.2.1		X	
10.2.2			
10.3	Continual improvement	x	

Annex B
(informative)

How to perform a risk analysis for the project?

The following is to be considered as an example, keeping in mind that complexity of risk analysis should be linked to the complexity of product or service supplied. The effective risk analysis should be performed by the organization having regard to its own context and to the specific aspects of the product or service to be supplied.

The risk analysis can be performed in 5 consecutive steps as shown in Figure B.1.

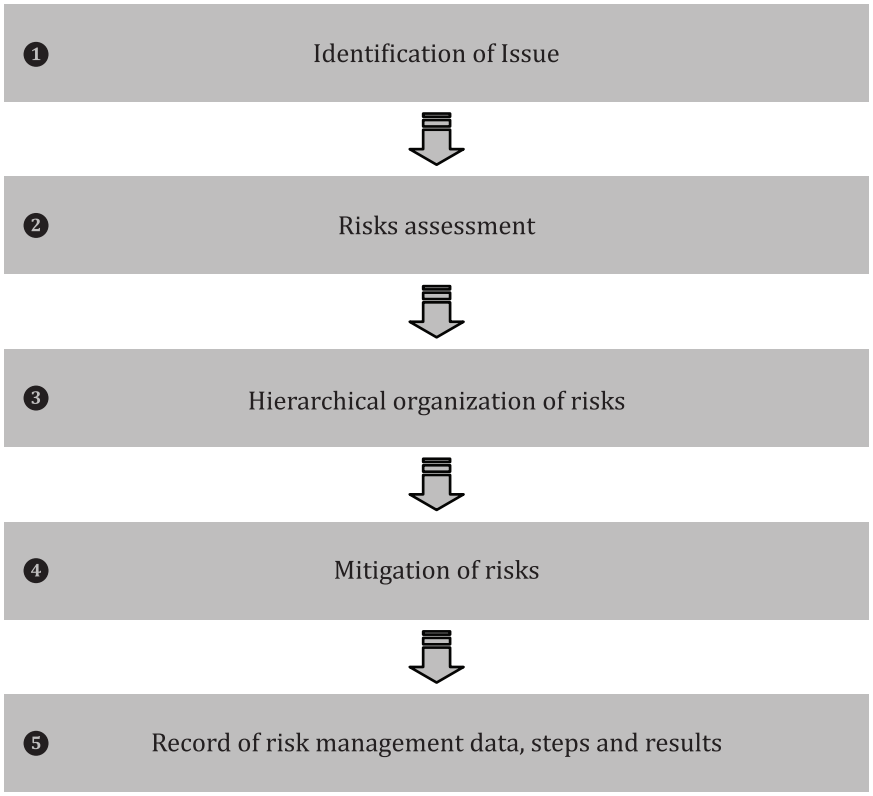


Figure B.1 — Risk analysis for the project

STEP❶: Identification of the dangerous situations

Table B.1 — Indicative list of dangerous situations by topic

TOPIC	Yes	No	Examples
Financial	☐	☐	Unrealistic cost estimates
	☐	☐	Variation of unfavorable exchange rate
	☐	☐	Too low profitability of the project/order
Contractual	☐	☐	Poor understanding of customer needs or specifications
	☐	☐	Difficult to meet contractual obligations in the project or order
	☐	☐	Poor analysis of the impact of changes
	☐	☐	Bad impact of the analysis of requirements traceability
	☐	☐	Bad impact of the analysis of requirements for quality assurance
	☐	☐	Poor analysis of the impact of documentary constraints
	☐	☐	Constraints imposed for unrealistic calendar or without margins
Legal	☐	☐	Poor control aspects and regulatory requirements applicable to the performance of the product
Purchasing	☐	☐	Unavailability of materials/components
	☐	☐	Purchase price of materials/components incompatible with the budget
	☐	☐	Poor transmission of contractual requirements to subcontractors
	☐	☐	Suppliers are imposed or not permitted by the customer
	☐	☐	Unfavorable political developments in the country of the subcontractor
	☐	☐	Supply "single source"
	☐	☐	Misunderstanding of the project needs by subcontractors
	☐	☐	Insufficient ability of the supplier as part of project requirements or order
Project Management	☐	☐	Industrial Organization unclear or inadequate
	☐	☐	Restructuring, planned or expected
Quality Management System	☐	☐	Do not address correctly one or more of the following: • organizational functions non-existent or inadequate, • organization of organizational and decision interfaces, • inconsistent schedules of different stakeholders, • loss of knowledge and know-how, • safety culture of the company (incl. questioning attitude toward the customer), • methods and communication tools, • insufficient or not available human or technical resources, • imprecision of the evidence to provide for quality assurance aspects, • methods and communication tools, • planning management.

Table B.1 *(continued)*

TOPIC	Yes	No	Examples
Technical and Realization	☐	☐	Inadequate industrial base
	☐	☐	Production logistics difficult to implement
	☐	☐	The technologies considered are immature or poorly controlled
	☐	☐	Principles or concepts proposed are not validated (by the owner, the customer, the Authorities, etc.)
	☐	☐	Loss of information on the current configuration of the project or order
	☐	☐	Production process inappropriate against constraints on nuclear safety
	☐	☐	False or incomplete input data
	☐	☐	Not sufficient or inappropriate computing resources
	☐	☐	Non respect of the domain of validity or qualification of codes, standards and software used
	☐	☐	Testing representativeness difficult to obtain
	☐	☐	Test facilities unsuitable or absent
	☐	☐	Compliance evidences difficult or impossible to demonstrate
	☐	☐	Simulation models or tests not validated for conditions of use
HSE	☐	☐	Rules for information protection unclear
	☐	☐	Inadequate level of restriction
	☐	☐	Contractual or regulatory requirements not taken into account (assembly sites)
Human aspects	☐	☐	Cultural differences which may cause misunderstandings
	☐	☐	Poor control of the contractual language
	☐	☐	Poor communication within the company (needs, data, information)
	☐	☐	Objectives or issues inadequately shared (training in safety culture insufficient or absent)
	☐	☐	Training time required for the project or order is too large relative to the constraints of schedule completion
	☐	☐	Poor management of skills and/or qualifications
	☐	☐	Skills and/or qualifications available too remote from the needs required

STEP❷: Risks assessment

→ ***Assessment of the risk occurrence:***

Table B.2 — Assessment of the risk occurrence

OCCURRENCE Level	ASSESSMENT	
	Qualitative	Quantitative (P=likelihood)
1	Low	$P < 20\ \%$
2	Medium	$20\ \% \leq P < 40\ \%$
3	High	$40\ \% \leq P < 60\ \%$
4	Critical	$P > 60\ \%$

→ ***Assessment of the severity of the impact of risks:***

The highest of the five possible criteria should be taken into consideration, an impact on safety being unacceptable in all cases.

Table B.3 — Assessment of the severity of the impact of risks

SEVERITY Level	IMPACT on				
	Safety	Conformity	Performance	Delivery Planning (D)	Costs (C)
1	**unacceptable**	Low	Low	D < 5 %	C < 2 %
2		Medium	Medium	5 % ≤ D < 10 %	2 % ≤ C < 5 %
3		High	High	10 % ≤ D < 20 %	5 % ≤ C < 10 %
4		Critical	Critical	D > 20 %	C > 10 %

STEP❸: Hierarchical organization of risks (determining the criticality)

Table B.4 — Hierarchical organization of risks

		SEVERITY Level			
		1	2	3	4
OCCURRENCE Level	1				
	2				
	3				
	4				

STEP❹: Mitigation of risks

The risks have not to be mitigated but should be kept in mind.

The risks should be examined again for reduction action (by acting on the occurrence or severity) = moving from orange to yellow or placed under observation in case of impossibility of reduction

The risks should be addressed and a solution should be found to eliminate them = moving from red to orange

STEP❺: Record of risks management data, steps and results

To ensure traceability of the risk management performed, it's suggested to draft such a table to record all data, steps and results.

Table B.4 — Record of risks management data, steps and results

Risk identified	Initial risk assessment			Mitigation action			Final risk assessment		
	Occurrence	Severity	Criticality	What	Who	When	Occurrence	Severity	Criticality
#1:									
#2:									

Annex C
(informative)

Determination of ITNS items and activities

The following STEPS #1 to #3 explain the understanding of ISO 19443 requirements for ***determination of ITNS items and activities***.

STEP #1: The Preliminary Safety Analysis Report (PSAR) describes the systems and determines the main design and construction choices

Before implementing any construction activity for a nuclear facility (e.g. design and development, manufacturing and commissioning), a PSAR[1)] is issued under the responsibility of the Licensee. The STEP #1 indicates the process by which all Systems of the nuclear facility are identified, see Figure C.1.

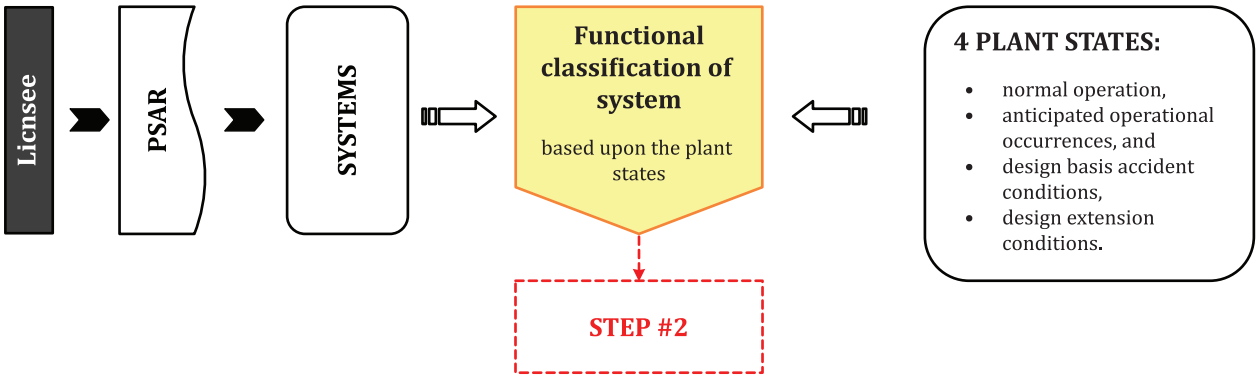


Figure C.1 — Functional classification of systems

STEP #2: Classification of all Systems Structures and Components (SSC) by the licensee

The STEP #2 indicates the process by which all SSCs of the nuclear facility are classified having regard to their safety function(s).

The classification of SSCs is a critical activity and will usually only be carried out by the Licensee or by a tier 1 contractor using standards or formalised procedures, see Figure C.2.

For an ITNS product/service constituting the SSCs, the output of this process should be

— a Safety Class,

— a purchasing specification including quality requirements and technical requirements (see notes 1 and 2 below).

1) Refer to IAEA GS-G-4.1[31]

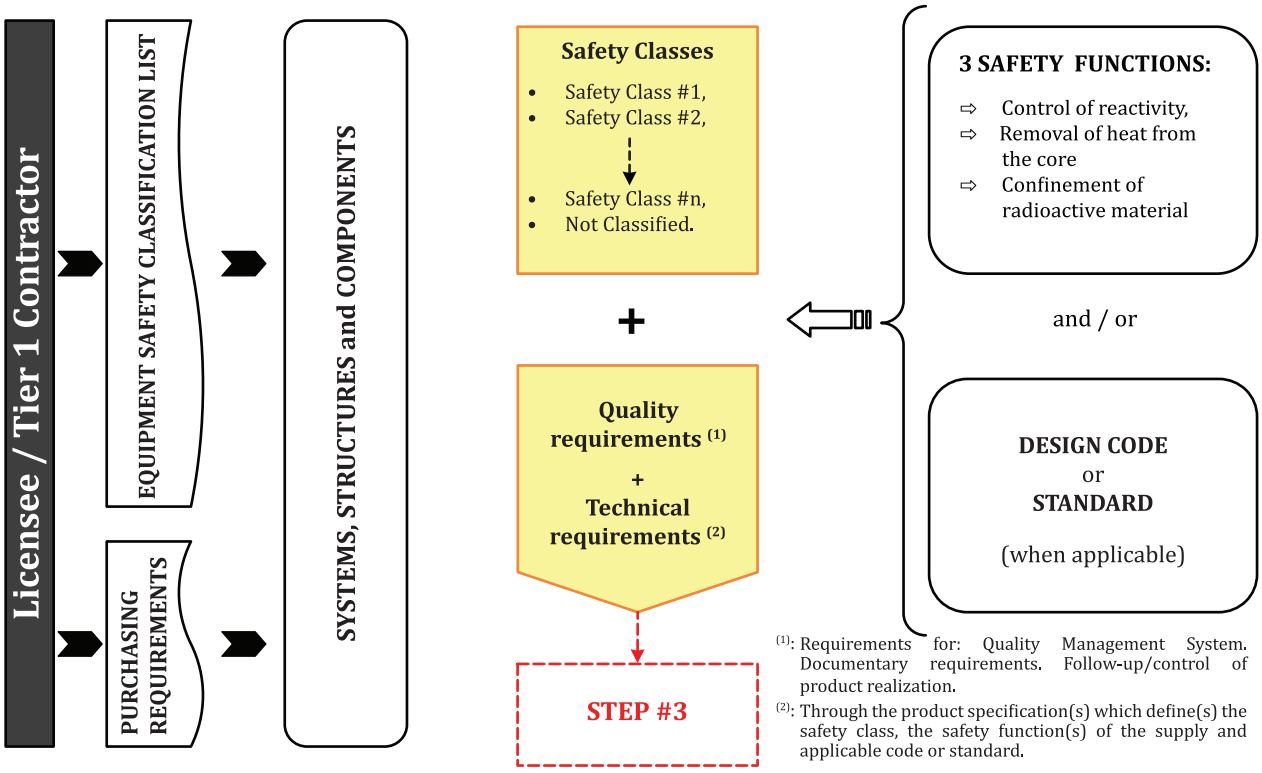


Figure C.2 — Classification of SSC

STEP #3: Determination of ITNS Items and activities

The "determination" requirement of ISO 19443:2018 for the supplier of the ITNS product (e.g. the "organization" in the context of ISO 19443:2018) consists in a continuation of the above processes (STEPS #1 and #2), continuation which can be schematized as shown in Figure C.3:

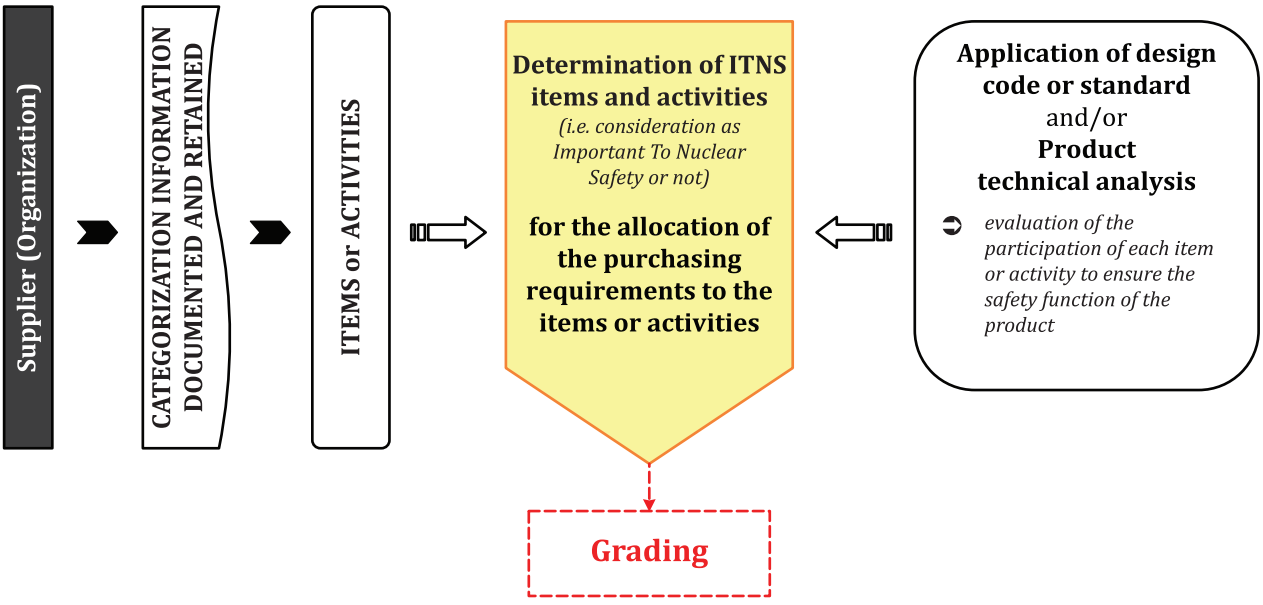


Figure C.3 — Determination of ITNS items and activities

Annex D
(informative)

Practical example of determination of ITNS items and activities

NOTE This example is not a real example but is just given to illustrate the expected determination activities to be performed by an organization on an ITNS product. The method for determination is not detailed (refer to 6.1.3) and the result presented cannot be considered as the only possible output.

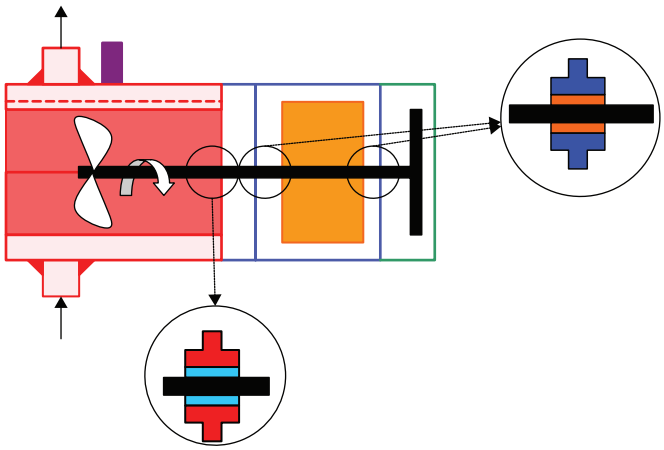


Figure D.1 — Electro-mechanical pump

Assumptions:

— The pump is classified as an ITNS product safety class 2,

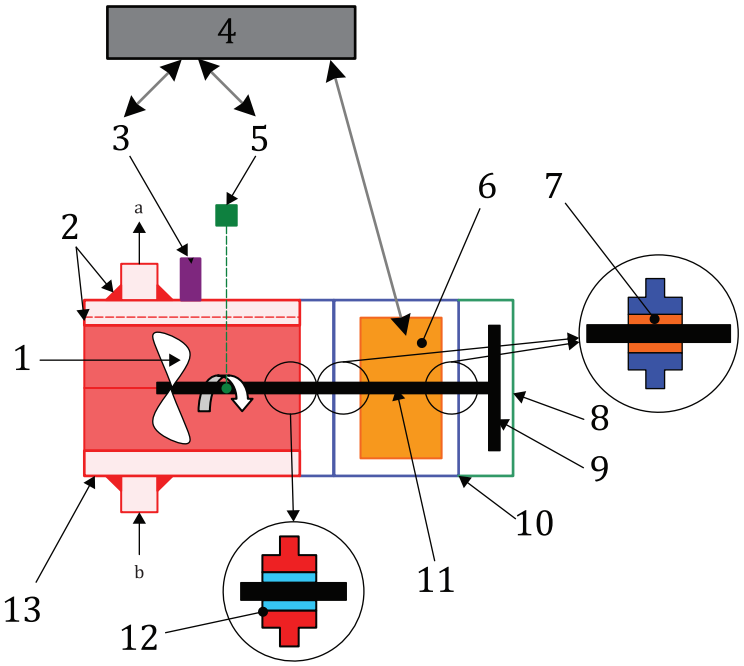
— The pump is very specific and thus not covered by any code or standard,

— Safety functions (SF) indicated in pump technical specification issued by the contractor are:

  — SF #1: Confinement of fluid for a design pressure of 12 bar at a design temperature of 200 °C,

  — SF #2: Minimum flow = 5 m^3/h, when pressure is >4 bar.

Breakdown in items and activities and ITNS determination



Key

1 impeller
2 welds
3 pressure sensor
4 command system
5 rotation sensor
6 motor
7 bearing
8 fly wheel pan
9 fly wheel
10 motor frame
11 shaft
12 shaft seal
13 pump casing
a Outlet flow.
b Inlet flow.

Figure D.2 — Breakdown of electro-mechanical pump

The following tables are showing a **possible output** for determination of ITNS items and activities. This kind of output should be issued by the organization after performance of an adequate risk assessment technique (refer to chapter 6.1.3).

Working assumptions: The organization is designing the pump, purchasing to external providers some of the components with their own design and testing (e.g. welded pump casing), and is assembling/ manufacturing/testing the pump.

Items

Table D.1 — Electro-mechanical pump — Determination of ITNS items

Part name	Determination		Safety function (SF) concerned
	ITNS	Non ITNS	
Pump casing	x		SF #1
Motor frame		x	
Fly wheel pan		x	
Fly wheel		x	
Shaft		x	
Shaft seal	x		SF #1
Impeller		x	
Motor		x	
Bearing		x	
Rotation sensor	x		SF #2
Pressure sensor	x		SF #2
Command system	x		SF #2

Activities

Table D.2 — Electro-mechanical pump — Determination of ITNS activities

Name	Determination		Safety function (SF) concerned
	ITNS	Non ITNS	
Welding of pump casing	x		SF #1
Hydrotest of pump casing	x		SF #1
Shop testing performed by sub provider of command system	x		SF #2
Assembling of pump components	x		SF #1
Casing and frame painting		x	
Assembled pump tightness testing	x		SF #1
Assembled pump functional testing	x		SF #2

Annex E
(informative)

Typical (general) example for graded approach

The following table is showing a **possible output** for graded approach to the application of quality requirements for ITNS items and activities (refer to 6.1.4).

Table E.1 — Typical (general) example for graded approach

ITEM or ACTIVITY		REQUIREMENTS								
			DOCUMENTATION						MONITORING and MEASUREMENT	
			Document(s)		Record(s)				performed by	
Status	Impact	QMS for external provider	To be issued by the organization before sub-contracting	To be issued by the organization before manufacturing	To be issued by the organization	Monitoring records to be issued by the organization	End Of Manufacturing Report (EOMR)	Certificate of compliance to the order	The organization on its own activities	The organization on its supplier(s) activities
Important To Nuclear Safety **(ITNS)**	Impact on nuclear safety	ISO 19443	Technical specification(s)	Preparatory documents for the Order + individual Inspection Test Plan Preparatory documents for the Order + individual or batch Inspection Test Plan	All manufacturing and inspection records	Monitoring report for the supplier(s) records	Issued by the organization manufacturing the item or activity	Issued by the supplier of the product, item or activity	The organization should perform monitoring of its own activities in accordance with documented provisions which define the frequency and scope of intervention	The organization should perform monitoring of its suppliers activities in accordance with the agreed levels of intervention in the QC plans
NOT Important To Nuclear Safety **(NOT ITNS)**	No impact on nuclear safety	Similar to ISO9001	Technical specification(s) when necessary	Preparatory documents when required by the technical specification(s)	Only manufacturing and inspection records required by the technical specification(s)	/	/		On a case by case basis	Receiving inspection only if required by the technical specification(s)

Annex F
(informative)

Practical example of graded approach

The following tables are showing a **possible output** for graded approach for the example given in Annex D (sub provider is considered here as already audited and approved).

Table F.1 — Electro-mechanical pump — Example for Graded approach on items

ITEMS			REQUIREMENTS								
				DOCUMENTATION						MONITORING and MEASUREMENT	
				Document(s)		Record(s)				performed by	
Description	ITNS Status	External provider	QMS for external provider	To be issued by the organization before sub-contracting	To be issued by the organization before manufacturing	To be issued by the organization	Monitoring records to be issued by the organization	End Of Manufacturing Report (EOMR)	Certificate of compliance to the order	The organization on its own activities	The organization on its supplier(s) activities
Pump casing	YES	YES	19443	Technical specification		/	Approval of calculation note and review EOMR	Required to supplier	Required to supplier		Approval of calculation note and review of EOMR
Motor frame	NO	NO			Preparatory documents for the Order (specific quality plan, design, manufacturing and testing docs, + Inspection and test plan	Internal manufacturing and inspection records required by the order				In accordance with the organization Inspection and Test Plan (ITP)	
Fly wheel pan	NO	NO									
Fly wheel	NO	NO									
Shaft	NO	NO									
Shaft seal	YES	NO									
Impeller	NO	NO									
Bearing	NO	NO									
Motor	NO	YES	≈ 9001	Purchasing order					Required to supplier		Review of Certificate of compliance with the order
Rotation sensor	YES	YES	19443	Technical specification			Review of EOMR	Required to supplier	Required to supplier		Review of EOMR
Pressure sensor	YES	YES	19443								
Command system	YES	YES	19443								

Table F.2 — Electro-mechanical pump — Example for Graded approach on activities

ACTIVITIES			REQUIREMENTS								
				DOCUMENTATION						MONITORING and MEASUREMENT	
				Document(s)		Record(s)				performed by	
Description	ITNS Status	External provider	QMS for external provider	To be issued by the organization before sub-contracting	To be issued by the organization before manufacturing	To be issued by the organization	Monitoring records to be issued by the organization	End Of Manufacturing Report (EOMR)	Certificate of compliance to the order	The organization on its own activities	The organization on its supplier(s) activities
Welding of pump casing	YES	YES	19443	Technical specification			Approval of welding book report	Required to supplier	Required to supplier		Approval of welding book
Hydrotest of pump casing	YES	YES	19443	Technical specification			Approval of hydrotest procedure + Review of hydrotest report				Witness of hydrotest
Assembling of pump components	YES	NO									
Casing and frame painting	NO	NO									
Assembled pump tightness testing	YES	NO									
Assembled pump functional testing	YES	NO									

Annex G
(informative)

Metrological guidelines

Focus on metrological confirmation of a measuring equipment

The status of metrological confirmation of a measuring equipment can be obtained from a laboratory which can be internal or external to the organization, by the following two ways.

Calibration: calibration of measuring equipment establishes a relation between measured values and those provided by measurement standards, with measurement uncertainties.

As a result, users correct values measured by measuring equipment using the calibration data given by the "calibration certificate", taking into account the relevant measurement uncertainties.

NOTE 1 A calibration may be expressed by a statement, calibration function, calibration diagram, calibration curve, or calibration table.

NOTE 2 Calibration should not be confused with adjustment of a measuring system, often mistakenly called "self-calibration".

Verification: confirmation through the provision of objective evidence that specified requirements have been fulfilled by a given measuring equipment.

As a result, when using the "verified" measuring equipment, no correction is necessary.

NOTE 3 The provision can be given through a "verification certificate" giving the confirmation that a target measurement uncertainty is met (e.g. confirmation of the quality class of a manometer or confirmation that the manufacturer's specifications are met).

Focus on accuracy and specification zone

The following definitions are repeated to provide better understanding of the guidelines (examples are given for pressure measurement but can be extended to any other physical parameter):

Measuring interval[2)]

Set of values of quantities of the same kind that can be measured by a given measuring instrument or measuring system with specified instrumental uncertainty, under defined conditions.

(Example: manometer having a measuring interval of 0 bar to 100 bar, sometimes called as "measuring range" as in ISO 19443)

Measurand2)

Quantity intended to be measured.

(Example: nominal pressure value of 80 bar for a hydraulic test)

2) Definition from ISO/IEC Guide 99[32].

Specification zone[3)]

Variate values of the physical parameter between and including the specified values of the upper and lower bounds of the permissible value.

(Example: pressure of 80 bar ± 2 bar)

Measurement accuracy

Closeness of agreement between a measured quantity value and a true value of a quantity value *(accuracy is expressed in units of magnitude [absolute error] or percentage [relative error].*

(Example: for a pressure measurement, the construction may require for the manometer an accuracy of 1 %)

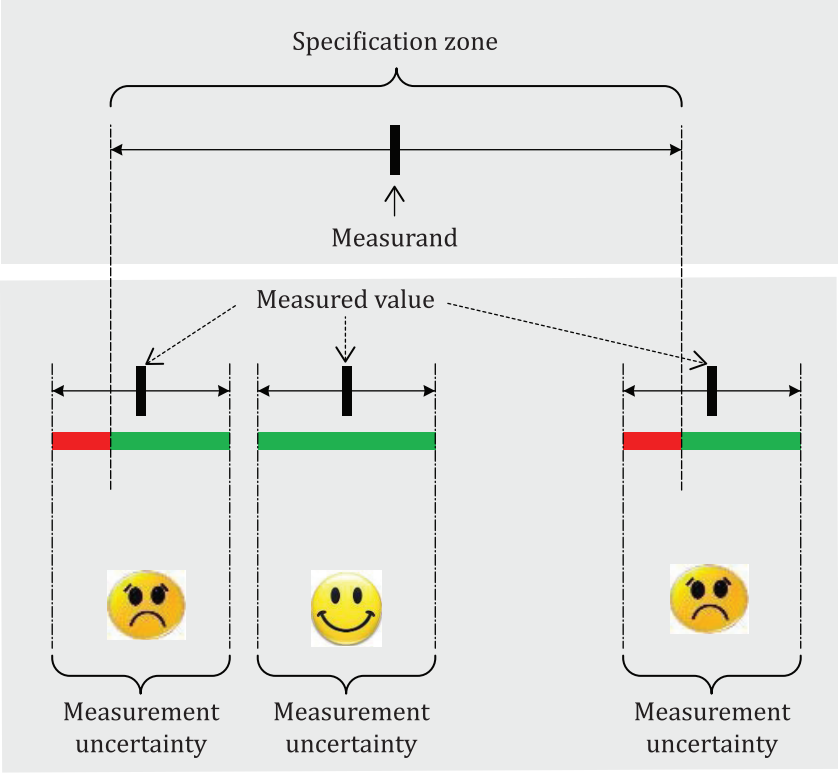
Measured value

Quantity value representing a measurement result.

Measurement uncertainty

Non-negative parameter characterizing the dispersion of the quantity values being attributed to the quantity intended to be measured, based on the information used.

Note (from present guidelines): Information used includes components arising from many factors as measurement accuracy of the measuring equipment, conditions of measurement, etc. …



Key

out of specification

conformity

Figure G.1 — Demonstration of compliance to the specification

3) Definition adapted from ISO 14253-1[33].

NOTE Measurement performed to determine mechanical properties of material (e.g. tensile strength) cannot take into account measurement uncertainties as design calculation includes safety factors which cover such uncertainties.

Annex H
(informative)

Competence and qualification

Competence: As an example, to determine the competence of an individual, the following knowledge and skills can be taken into account:

— initial education;

— complementary specific training;

— on the job training;

— professional knowledge: technical, use of software, organizational, regulations, foreign language (read/write/speak); …

— personal specific external certifications;

— personal behaviour (may be, depending of the job: communication ability, diplomatic, open-minded, perceptive, observant, self-reliant, organized, decisive, …);

— work experience (duration and fields);

— …

The documented information retained as evidence for competence of an individual may be performed through the establishment of a skills matrix, which has to be updated and reviewed periodically.

The matrix may take into consideration the following:

— different jobs and functions existing in the organization and having an impact on the quality of the product;

— abilities necessary to perform satisfactorily these jobs and functions (e.g.: foreign language knowledge, software knowledge, …);

An example of skills matrix is given hereafter.

Table H.1 — Example of skills matrix

	DESIGN ACTIVITIES (1)				MANUFACTURING ACTIVITIES (1) (3)							INSPECTION ACTIVITIES (1) (3)							LANGUAGES SKILLS (1) and (2)			
	Design and risk analysis	Drawings issuance	Design calculations on software #1	Design calculations on software #2	Cutting	Forming	Welding	Heat treatement	Cabling	Assembling	Painting	NDT (DPT)	NDT (MP)	NDT (UT)	Visual inspection of welds	Visual inspection on coating	Dimensional inspections	Dimensional inspections on 3D machine	English	German	Spanish	Chinese
Indiv. A	1	x	x																R1 W1 S1	R1 W1		
Indiv.B	2	x		x			MM/YY MM/YY					MM/YY MM/YY								R2 W2 S2		

NOTES

(1) One or more levels can exist, depending on the job. These levels (L1, L2, L3 …) should be defined together with the correspondence task/required level, when applicable.

(2) Knowledge for Read (R), Write (W) and Speak (S) can be defined, together with the correspondence task (e.g. for document: elaboration, verification, approval)/required level, when applicable. When applicable, reference to and use of international levels of competence (e.g. TOIEC, TOEFL, CECRL …) is recommended.

(3) For qualifications - here in grey columns - it's suggested to add initial qualifications date and qualification date of validity.

***Qualification**:* The word "qualification" can be understood as the result of the demonstration of the ability of an individual to fulfil specified requirements for a required function (e.g.: welder qualification, inspector qualification, auditor qualification …).

As an example, the delivery of a qualification for an individual can be either:

— required by ISO 19443 as for internal auditors (refer to 9.2.2 c),

— required by manufacturing code or standard (e.g. NDT inspector qualification, welder qualification),

— the decision of the organization to increase the confidence level which can be given to the works and tasks performed by the individual. It's recommended that the organization considers specific activities which may have a critical impact on quality or safety (e.g. inspection activities).

The demonstration of ability should be:

— performed against established and relevant requirements, pass or fail criteria or ratings, e.g.:

Table H.2 — Requirement or Rating for qualification of personnel

Knowledge, skill, ability	Requirement or rating
Initial education	Minimum level of education (e.g. bachelor, master)
Complementary specific training	Coverage of the training
On the job training	Number or duration of on the job training operations
Professional: technical, use of software, organizational, regulations, foreign language (read/write/speak), etc.	Evaluation during interviews, written exams or practical tests,
Personal behaviour and soft skills	Evaluation during interviews
Medical abilities (e.g. colour vision)	Medical examination
Work experience (duration and fields)	Number of years of experience in an identical or closely related field

— based on one or on a combination of the above knowledges or skills, and

— recorded.

Maintenance of qualification should take into account:

— maintenance of proficiency (e.g. performing the tasks a minimum of time within a specified period),

— withdrawal or renewal of qualification.

Annex I
(informative)

Awareness training for personnel

The purpose of this Annex is to provide guidance to organisations in order to ensure that all personnel involved in the supply of ITNS products or services in their own organisation or in organisations in their supply chain are aware of their responsibilities related to maintaining nuclear safety (refer to 7.3).

All activities involved in the supply of ITNS products or services can and do influence nuclear safety.

— Management: leadership, decision-making and creating a respectful work environment.

— Expected behaviour: questioning attitude, adherence to procedures, transparency in reporting issues, events and NCR, and in addition.

What Nuclear Safety is

Nuclear safety can have different meanings to different people. Typically, within the nuclear energy sector, it can be defined as:

"the protection of workers, the public and the environment from undue radiological hazard by achievement of proper operating conditions, prevention of accidents and the mitigation of accident consequences."

Why is nuclear safety so important?

Learning has been gathered across the years from a number of significant events which have shaped the approach to nuclear safety.

→ Windscale, 1957 - UK – contributory factors: nuclear technology is new and different.

→ Three Mile Island, 1979 - USA – contributory factors: management of off-normal situations, emergency preparedness, national arrangements (human factors).

→ Chernobyl, 1986 - Soviet Union - contributory factors: nuclear safety culture, conservative decision making (organizational factors).

→ Fukushima, 2011 - Japan – contributory factors: lack of learning from international experience, questioning attitude, beyond design basis accident readiness.

Robust nuclear safety is essential because the loss of control of radioactive inventory has the potential for significant implications for workers, the public and the environment. Wider and longer lasting economic damage for communities and the sector are also potential consequences.

How is Nuclear Safety achieved in the supply chain of the nuclear energy sector?

Any supplier involved in the supply of ITNS products or services is a key partner in ensuring the appropriate level of Nuclear Safety is achieved.

The basis of nuclear safety is usually achieved by ensuring any organisation supplying ITNS products or services either directly or indirectly, should do so in accordance with the agreed quality, schedule and safety procedures aligned to the customer's requirements.

What an ITNS product, service, item or activity is

Refer to Annex C and 6.1.3 and 6.1.4.

It's recommended to illustrate the "Determination of ITNS items and activities" and "Graded approach to the application of quality requirements" processes, using examples related to the ITNS product or service the organization is about or is likely to supply.

Importance and impact of individual's role in achieving nuclear safety

Each individual should question his activities or raise concerns, internally and externally, and propose changes/improvements where they can add value and are applicable. This involvement is the basis of a strong quality and nuclear safety culture within the organization.

Some examples are given hereafter but, for a better efficiency, it's strongly recommended that the organization uses for examples given during the awareness training, some typical situations related to the ITNS product or service the organization is about or is likely to supply.

Physical Controls

Manufacture of high grade material bolts was contracted to a Tier 2 supplier. Drawings and specification were supplied by the Tier 2 supplier giving details of the material specification and certification to be provided by the manufacturer. The Tier 2 supplier subcontracted the work to Tier 3/Tier 4/Tier 5 suppliers, who then subcontracted the work to the final manufacturer.

During the subcontracting stages, errors and assumptions were made about the material to be used and the certification to be provided. This resulted in the bolts inadvertently being manufactured from a lower grade material and without the required certification. The bolts were supplied but none of the suppliers involved had noticed the errors that had been made. Following receipt inspection it was found that the bolts had been manufactured from the wrong grade of material and the bolts were rejected. Each supplier in the supply chain had failed to thoroughly check the material supplied and that the supporting certification was correct.

Local administrative controls

A supplier made large containers. The lid had an O-ring seal which was held in place by a particular type of sealant. Issues were found with the sealant life and a design change was made by the customer and passed on to the organisation. An audit of the workplace discovered that the procedure on the workshop still referenced the old sealant. A process existed to review and revise procedures but had not been implemented on this procedure.

CFSI

A supply chain organisation was suspicious of some electronic components they had just received; the surface texture did not feel right. The customer was notified and the component was quarantined, investigated and subsequently shown to be counterfeit or fraudulent. The top surface of the component had been sanded down and re-marked. This discovery and the notification both to the customer and other members of the supply chain may have prevented the issue from having a wider impact on the rest of the supply chain.

This component may have been destined for a harmless use or something more critical, however the supply chain organisation did not know but adopted a questioning attitude and took the correct action.

Competent Persons

A Design Engineer has been asked to design some safety related electronic circuitry. However this individual considers not having sufficient knowledge or experience for the task. At this point, the issue was raised with management and training and guidance asked. Failure to raise the issue could mean that the equipment may have to undergo redesign, or worse still delivery to the customer of unsafe equipment.

Culture

A time served welder with a long standing record of high quality is instructed by supervision to complete a complex weld configuration that had not been previously welded. It was needed urgently

so that it could be radiographed that night to push the job on. The welder was uncertain if personal qualifications were current.

Does the welder proceed with the welding to keep the job going? Or is it more appropriate to check with welding supervision whether personal qualifications are current?

A customer expectation would be that the welder would speak up and question the instruction to weld. If it was revealed at a later date that the welder was out of qualification then the weld itself would be considered as non-compliant and could be rejected. This could result in the weld being cut out and scrapped. This could them impact on the reputation of the organisation and its workers.

Nuclear safety is everyone's responsibility and the effective implementation of nuclear safety protects the employees, the public and the environment.

How individuals know they are working on ITNS

The organization should explain the means considered to identify during the design and manufacturing processes, the items and activities being determined as ITNS. A good practice is to use pre-job briefings to make individuals aware of the ITNS nature of their work.

What my role is in preventing CFS Items being brought into the organization

Examples are given in documents listed in section 8.1.1 of these guidelines.

Management: leadership, decision-making and creating a respectful work environment

Management should consider the following aspects, for which some detailed explanations and examples are given in the documents referenced in Annex A of these guidelines.

Table I.1 — Management/IAEA/INPO/WANO documents

	IAEA, Safety Series No.75-INSAG-4 "Safety Culture"[21]	INPO – "Principles for a Strong Nuclear Safety Culture"[22]	WANO – Principles PL | 2013-1 - Traits of a Healthy Nuclear Safety Culture[23]
Leadership	Refer to Chapter 3.2 which contains related elements	Refer particularly to Chapters 1, 2, 3 4, 8	Refer to attributes LA.1 to LA.8
Decision-making			Refer to attributes DM.1 to DM.3
Respectful work environment			Refer to attributes WE.1 to WE.4

Expected behaviour: questioning attitude, adherence to procedures, transparency in reporting issues, events and NCR

Expected behaviour should consider the following aspects, for which some detailed explanations and examples are given in the documents referenced in Annex A of these guidelines.

Table I.2 — Expected behaviour/IAEA/INPO/WANO documents

	IAEA, Safety Series No.75-INSAG-4 "Safety Culture" [21]	INPO – "Principles for a Strong Nuclear Safety Culture" [22]	WANO – Principles PL | 2013-1 - Traits of a Healthy Nuclear Safety Culture[23]
Questioning attitude	Refer particularly to Item #60	See Chapter 6	e.g. Attributes QA.1 to QA.4
Adherence to procedures	Refer particularly to Item #61		e.g. Attributes PA.2, WP.4
Transparency in reporting issues, events and NCR	Refer particularly to Item #62		e.g. Attribute C0.3

NOTE Some examples for evaluation of expected behaviour can be found in the Annex "Safety culture indicators" of IAEA, Safety Series No.75-INSAG-4 "Safety Culture"[21].

Annex J
(informative)

List of ISO 19443 additional requirements related to documented information

Table J.1 — Additional documented information requirements for each ISO 19443 clause

ISO 19443:2018 chapter and title		Documented information			
		"Maintained"		"Retained"	
		ISO 9001	ISO 19443	ISO 9001	ISO 19443
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	x			
4.4	Quality management system and its processes				
4.4.1					
4.4.2		x		x	
4.4.3			x		
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	x			
5.3	Organizational roles, responsibilities and authorities				
6.	**Planning**				
6.1	Actions to address risks and opportunities				
6.1.1			x		x
6.1.2			x		x
6.1.3	Determination of ITNS items and activities		x		x
6.1.4	Graded approach to the application of quality requirements		x		x
6.2	Quality objectives and planning to achieve them				
6.2.1		x			
6.2.2					
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				

Table J.1 *(continued)*

ISO 19443:2018 chapter and title		Documented information			
		"Maintained"		"Retained"	
		ISO 9001	ISO 19443	ISO 9001	ISO 19443
7.1.5.1	General			x	
7.1.5.2	Measurement traceability			x	x
7.1.6	Organizational knowledge				
7.2	Competence			x	
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				
7.5.3.1					
7.5.3.2				x	
8.	**Operation**				
8.1	Operational planning and control	x		x	
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				
8.2.3.1					
8.2.3.2				x	
8.2.4	Changes to requirements for products and services				
8.3	Design and development of products and services				
8.3.1	General				
8.3.2	Design and development planning				
8.3.3	Design and development inputs			x	
8.3.4	Design and development controls		x	x	
8.3.4.1	Design and development verification and validation testing				
8.3.5	Design and development outputs			x	
8.3.6	Design and development changes			x	
8.4	Control of externally provided processes, products and services				
8.4.1	General		x	x	x
8.4.2	Type and extent of control				
8.4.3	Information for external providers				x
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				x
8.5.2	Identification and traceability			x	
8.5.3	Property belonging to customers or external providers			x	
8.5.4	Preservation				
8.5.5	Post-delivery activities				
8.5.6	Control of changes			x	
8.6	Release of products and services			x	
8.7	Control of nonconforming outputs				
8.7.1			x		

Table J.1 *(continued)*

ISO 19443:2018 chapter and title		Documented information			
		"Maintained"		"Retained"	
		ISO 9001	ISO 19443	ISO 9001	ISO 19443
8.7.2				x	
9.	**Performance evaluation**				
9.1	Monitoring, measurement, analysis and evaluation				
9.1.1	General			x	
9.1.2	Customer satisfaction				
9.1.3	Analysis and evaluation				
9.2	Internal audit				
9.2.1					
9.2.2				x	
9.3	Management review				
9.3.1	General				
9.3.2	Management review inputs				
9.3.3	Management review outputs			x	
10.	**Improvement**				
10.1	General				
10.2	Nonconformity and corrective action				
10.2.1					
10.2.2				x	
10.3	Continual improvement				

NOTE Grey boxes in ISO 9001 columns indicates that the corresponding chapter doesn't exist in ISO 9001:2015 and has been added in ISO 19443:2018.

Annex K
(informative)

Good practices for 8.3[4)]

Design ***interfaces*** should be considered during planning as result of the analysis of interaction between internal or external design activities which may affect, or may be affected, by the one or more of the other activities performed by the organization.

Other activities may be (non-exhaustive list):

— process and system;

— layout;

— transport to site (mode of transport, transport conditions, inco terms, etc.);

— erection and commissioning;

— compliance with regulations;

— safety and radiation protection.

The result of the interface analysis should be materialized and therefore formalized in the technical specifications in order to ensure effectiveness of communication between all these activities and the clarification of respective roles and responsibilities.

As an example, for a tank, the design interfaces may be characterized as follows.

Table L.1 — Example of design interfaces

	Others activities taken into account		
	Layout	Transport to site	Safety and radiation protection
Data resulting from interfaces analysis	Dimensions, weight, supports, handling, etc.	Dimensions, weight, handling, mode of transport, access to site, regulations, etc.	Drain position, cleanliness, safety classification, etc.

Design and development process should integrate at least the following chronological stages, based on a “V” cycle adapted to general design activities (not valid for software development).

4) For more detailed guidance, refer to IEC 61160[36].

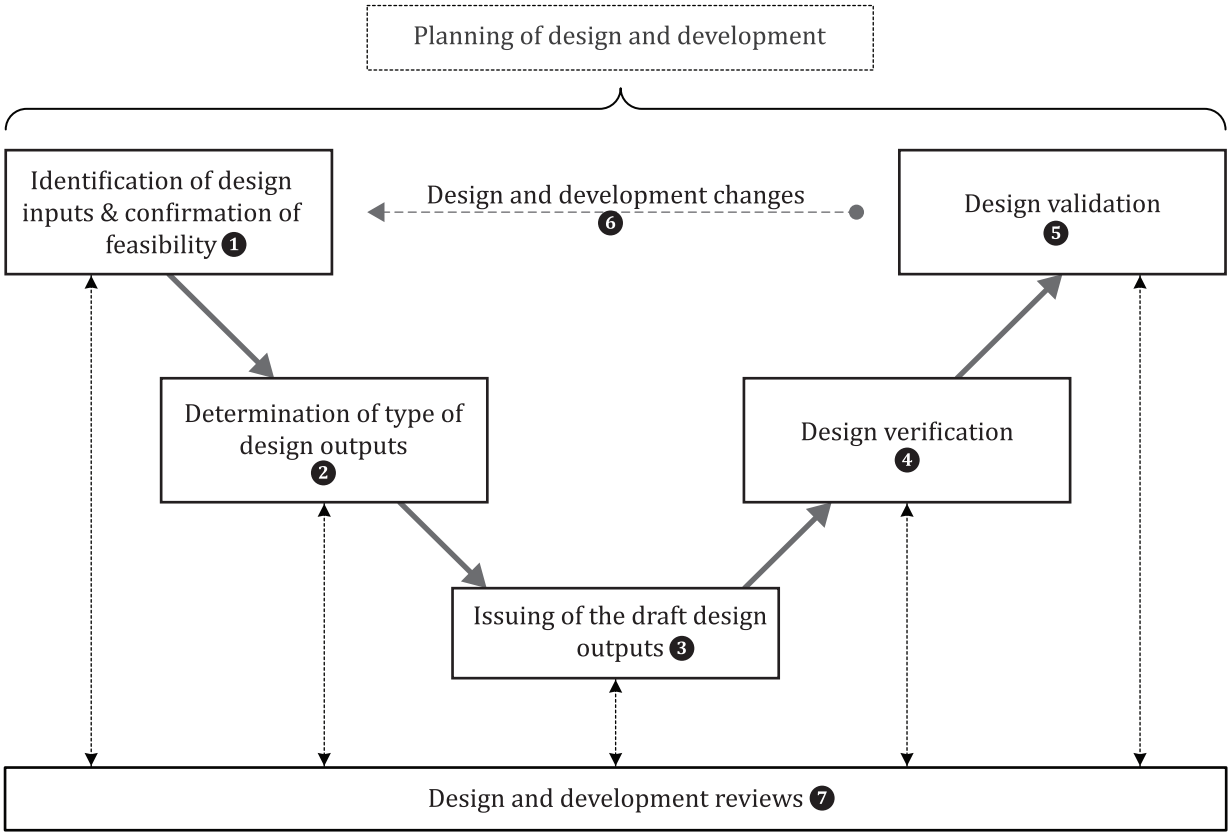


Figure K.1 — Design and development process

The above design process can be commented as follows.

1 Identification of design inputs and confirmation of feasibility

The analysis of technical specification(s) issued by the customer should result in:

— Identification of each design input = contractual or statutory requirement contained in the technical specification(s),

— Determination of design input acceptability by the organization. As an example, the status of acceptability can be: to be clarified, accepted, partially accepted, not accepted …

NOTE "To be clarified", "Not accepted" or "partially accepted" status can exist at the stage of preliminary design before issuance of submission of tenders, acceptance of contracts or orders, acceptance of changes to contracts or orders. In this case, the corresponding open points should be discussed with the customer before to progress to the next design stage.

2 Determination of type of design outputs

The organization should ensure all design inputs are considered and linked to design outputs which could typically be:

— **Design** = drawing, physical description, part list, etc.

— **Analysis** = calculation note (mechanical, flow, thermal, etc.), technical data sheet, risk analysis, instructions of use, etc.

— **Test** = test procedure and report, etc.

— **Similarity** = description of similar product already manufactured or tested.

For **Commercial Grade Items**, the conditions under which they can be used as ITNS items or activities (called as "critical characteristics" in 8.4.2 - Type and extent of control, are:

For physical items:

— important characteristics of an item which are measurable attributes that can be verified to provide assurance that the item will perform it's intended safety function,

— dependent on the item type, usage and environment into which it will be used and the nature of the safety function relative to the systems into which it is placed.

Typically critical characteristics for physical items can include:

— Material Characteristics related to the physical attributes of the materials used in the manufacture of the item. These can include chemical composition, ductility, hardness, concentration, tensile strength, density, resistance, conductivity, viscosity, capacitance, colour, and permeability.

— Physical characteristics related to the physical arrangement of the materials used in the manufacture of the item. These can include dimensions, quantities, weights, shapes, surface finish, scales and ranges.

— Functional characteristics related to the operation of the item. These can include, speed, time, response, accuracy, repeatability, reliability, outputs (e.g., voltage, current, pressure, volume, and temperature), power, strength, capacity, leakage, and noise.

— Qualification characteristics relate to specific qualifications and endorsements the item should meet to ensure it will perform its intended function. These can include environmental and seismic qualifications, and endorsements from independent agencies and authorities.

— Identification characteristics relate to the markings and labels on the item or its container. These markings and labels can include the manufacturer's item identification (e.g., part number, model number, and manufacturer's name) and other critical characteristics (e.g., size, type, range, weight, and pressure).

For services:

— the definition of critical characteristics can be expanded to also address quality controls performed on the ITNS items or products likely to be impacted by the considered service. Thus, the definition in the context of services is expanded to be:

The monitoring over a commercial grade service, which once selected to be verified, provide reasonable assurance that the service provided meets specified requirements. Verification of these controls will provide reasonable assurance that the safety function of plant equipment impacted by the service will not be adversely affected.

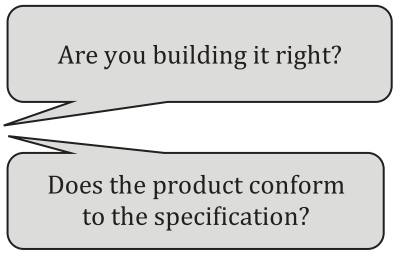
❸ **Issuing of the draft design outputs**

Issuing of the draft design outputs.

❹ **Design verification**

Verification is a process. It uses objective evidence to confirm that specified requirements (design inputs) have been met through the issued design outputs.

Verification meaning can be expressed by the questions:



Whenever specified requirements have been met, the ***verified status*** is achieved.

The outputs of ***Design and development verification*** are objective evidences to confirm that design and development outputs meet specified design input requirements.

There are many means, methods or tools (non-exhaustive list) to verify that requirements have been met:

means
- Performance of tests
- Performance of alternative calculations
- Comparison of a new design specification with a proven design specification

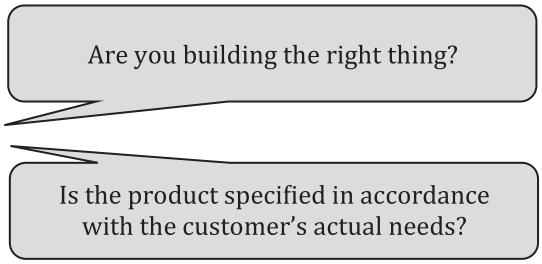
methods
- Review of documents before issuance
- Peer review results

tools
- Traceability analysis
- Tests exhaustiveness
- Worst case analysis

❺ Design validation

Validation is a process which uses objective evidence to confirm that the requirements which define an intended use or application have been met.

Validation meaning can be expressed by the questions:



Whenever all requirements have been met, the ***validated status*** is achieved.

The outputs of ***validation process*** are objective evidence to confirm that products meet the requirements for their intended use or application.

❻ Design and development changes

The following steps may be used to assess the changes:

- Identification of the reason of change,
- Description of the modification,
- Identification of the interfaces: impact on other product(s), data or process (es),

— Assessment of the consequences of the modification (technical, financial, timing …).

❼ Design and development reviews

Considering the complexity of the product, reviews should vary in size in terms of:

— quantity,

— number and quality of attendants (which may be organization representatives, customer representatives or Contractor representatives, …),

Before progressing to the next sequential stage, each design stage should be formally reviewed, with a review status, e.g.:

— reviewed without additional actions,

— reviewed with conditions/clarifications to be performed,

The sequential stages planned by the organization for design and development phases should be closed by a final "Design and development review" to ensure the design process has been performed according to planned provisions.

Annex L
(informative)

Demonstration of the evidence of provisions for monitoring activities

The document used for such demonstration should:

1. Be **drafted** keeping in mind the following aspects and inputs:
   a) Content of specifications (contractual, regulations, codes and standards),
   b) ITNS status of items and activities constituting or related to the product,
   c) Manufacturing processes which needs to be qualified prior to manufacture,
   d) Organization knowledge and lessons learned for similar products,
2. **Identify** the reference to the product specification with its revision index.
3. **Contain** the designation of the component assemblies, sub-assemblies and parts concerned, (complexity of the product which might require equipment breakdown in sub-parts and issuance of sub-QCP, or sub-ITP, sub-FUD …). As an example, welding sequences and claddings are considered to be a part.
4. **List** the chronological steps describing the realization of the product. For each operation described, the reference[5)] of the technical document which the supplier intends to apply (drawings, procedures, internal instructions, relevant paragraphs of the construction code or standard):
   e) design phases;
   f) prerequisites[6)], as issuance of contractual and/or regulatory documentation;
   g) procurement;
   h) manufacturing (with traceability related operations[7)]);
   i) inspection during manufacturing;
   j) workshop assembling;
   k) final workshop testing or inspection;
   l) packing;
   m) delivery;
   n) (eventually) on site erection;
   o) (eventually) final site testing or inspection;

5) Indication of the revision index can be reported only at the time of the performance step.

6) Prerequisites may exist all along the realization of the product. Examples: procurement specifications, welding book, manufacturing procedures, NDT procedures …

7) At each phase of the product realization link between product and associated documentation shall be defined without ambiguity.

p) …

❺ Indicate the type of intervention(s) to be performed by the organization (or its external provider in case of sub-contracted inspection) or other parties as the customer, the contractor, the owner or the statutory third party to ensure the control of the production:

Hold Point: this point is used by an entity to designate an operation which the organization is not allowed to perform or begin without the entity inspector presence or formal authorization (entity may mean the organization itself, the customer, the contractor, the owner or the Regulator).

Witness point: this point is used by an entity to designate an operation which the entity inspector requires to be notified about in due time [8] before performance, but which the organization is allowed to perform or begin without the entity inspector presence or formal authorization (entity may mean the organization itself, the customer, the contractor, the owner or the Regulator).

NOTE *In case of monitoring performed by the organization for sub-contracted items or activities, in addition to the aspects and inputs listed in above point ❶, the level of the quality management system of the sub-supplier should also be taken into account for its monitoring level or depth.*

❻ Indicate reference of the production or monitoring and tests records if required,

❼ Identify, if any, reference of the non-conformance reports and brief description of action taken such as:

q) the reject,

r) the use-as-is,

s) the repair or rework and reference of the appropriate files.

A typical frame for this kind of document, generally called “Quality Control Plan” (QCP), “Inspection Test Plan” (ITP), Follow-Up Document (FUD)… is suggested in the next page.

8) “Due time” means contractually defined or mutually agreed between the entity and the organization.

Table L.1 — Typical Inspection and Test Plan

ORGANIZATION Name and/or Logo	*(Title of)* ***Inspection and Test Plan (ITP) / Project name / .....***	Reference	Revision

Equipment		Technical specification(s)		Rev.	Code / Standard		Safety or Statutory Classification	

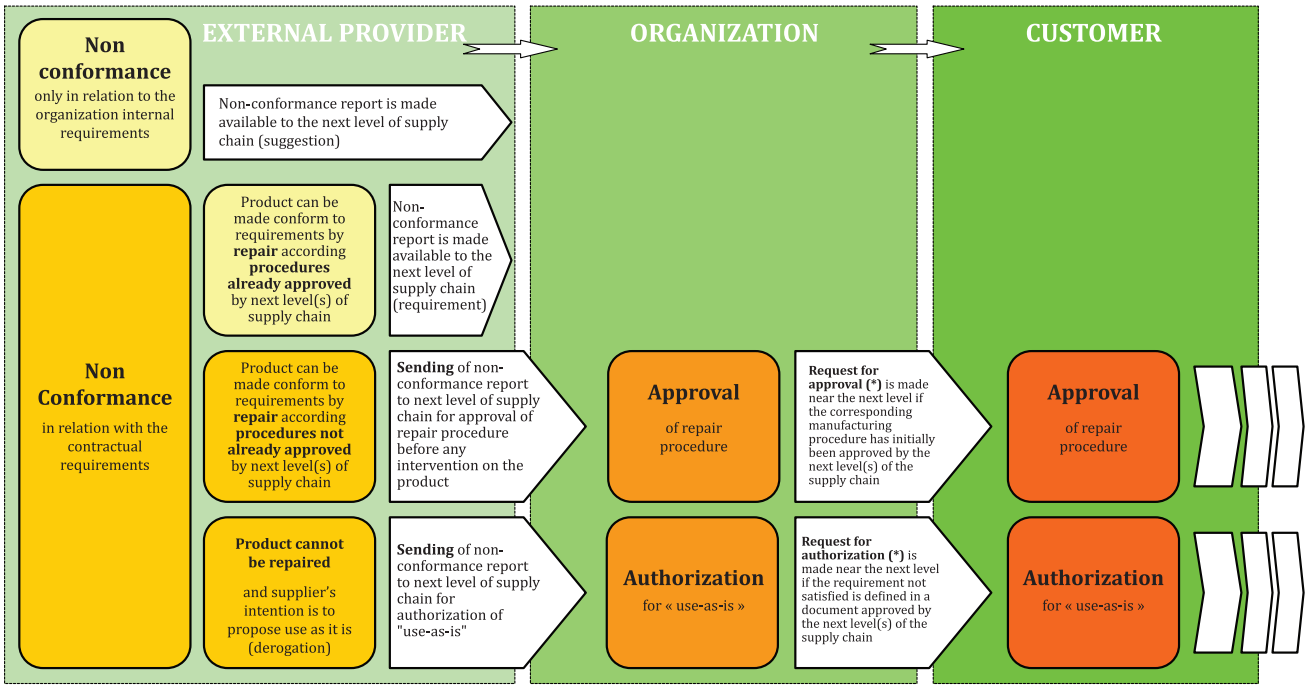
PRODUCTION ACTIVITY			PROCEDURE(S)		ORGANIZATION Performer			ORGANIZATION Monitoring			CUSTOMER Monitoring			CONTRACTOR Monitoring			OWNER Monitoring			AUTHORITIES Monitoring			RESULT	REMARKS
N°	DESCRIPTION	HFS	REFERENCE	REV.	Name	Date & Visa	Record N°	Interv.	Name	Date & Visa	Interv.	Name	Date & Visa	Interv.	Name	Date & Visa	Interv.	Name	Date & Visa	Interv.	Name	Date & Visa		
(1)	(2)	(3)	(4)	(5)			(6)	(7)															(8)	(9)
1																								
2																								
3																								
n																								

Additional comments

(1) No of Chronological / Sequential production operation from Design to Commissionning
(2) Understandable description of the production activity (e.g. "Shell #1 forming " or "Seam #2 welding ")
(3) Indicate (e.g. by a "x") if the activity has been classified as Important To Nuclear Safety (ITNS)
(4) Reference of the Organization procedure which has to be applied for the performance of the activity
(5) The revision may be only indicated at the time of performance of the activity to ensure correct and updated information
(6) Record may be an inspection record, a measurement record, a test record, ...
(7) Type of intervention to be performed : Hold point (H), Witness point(W), or any other indication specific to the project
(8) Global result of the inspection/test and surveillances ➲ may be : Conforms (C), Repair (R), Non-Conformance (NC), Use-as-is (U), ...
(9) Additional information, e.g. : reference of non-conformance report, repair procedure and its acceptance, use-as-is authorization, ...

Annex M
(informative)

Example of scheme for non-conformance information and request for approval along supply chain



(*): Request may be performed through the opening of a new non-conformance report or through any other method

Figure M.1 — Example of scheme for non-conformance information and request for approval along supply chain

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