ITNS items and activities

**1. Subject**

**1.1 Purpose**

**1.2 Scope**

**1.3 Glossary**

**2. Responsibility**

**3. Documents**

**3.1 Procedures**

**3.2 Instructions and records**

**4. Requirements of ISO 19443**

**5. Development**

**5.1 Determination**

**5.2 Project Kick-off**

**5.3 Breakdown of products and services into items and activities**

**5.4 Impact analysis (consequence assessment)**

**5.5 ITNS criteria and classification**

**5.6 Review**

**5.7 Communication**

**5.8 Maintenance and update**

History

|  |  |  |
| --- | --- | --- |
|  |  |  |
|  |  |  |
|  |  |  |
|  |  |  |
| All | Creation | 01/01/2025 |
| **Page** | **Change** | **Date** |

**1. Subject**

**1.1 Purpose**

The purpose of this procedure is to:

* define the methodology for identifying and classifying products, services, items, and activities provided by the organization that are “Important To Nuclear Safety”
* ensure that appropriate quality management controls, commensurate with their safety significance, are applied to these ITNS elements
* apply the appropriate level of quality rigor and meet the demanding safety requirements of the nuclear energy sector

**1.2 Scope**

This procedure applies to all products, services, items, and activities within the organization's scope of ISO 19443 certification that are supplied to the nuclear energy sector.

The relevant internal and external issues for the QMS and actions to address risks identified and improvements opportunities found are taken into account.

**1.3 Glossary**

QMS – quality management system

ITNS – important to nuclear safety

Customer Safety Classification - The safety classification provided by the nuclear operator (licensee) for the overall system or component

Graded Approach - A method of applying management system requirements with a level of rigor commensurate with the safety significance, complexity, and unique characteristics of the item or activity

CFSI – counterfeit, fraudulent or suspect items

**2. Responsibility**

The project manager is responsible for ensuring the strict application of this procedure.

**3. Documents**

**3.1 Procedures**

Scope of the QMS

Process control

Risk management

Graded approach

**3.2 Instructions and records**

ITNS items and activities

Graded approach

List of risks

Records of ITNS determination (analysis reports, classification matrices, approval records)

Customer specifications related to safety classification

**4. Requirements of ISO 19443 version 2018**

6.1.3 Determination of ITNS items and activities

The organization shall

a) break down ITNS products and services into items and activities, and

b) determine the items and activities, i.e those whose potential failure or malfunction may jeopardize the products and/or services safety function(s) specified by the customer in line with Licensee’s safety classification of Systems, Structures and Components.

The organization shall maintain and retain related documented information.

**5. Development**

**5.1 Determination**

The determination of ITNS (Important to Nuclear Safety) items and activities is a crucial step, as these are the elements that will be subject to the heightened quality management requirements of the ISO 19443 standard. This process inherently involves a graded approach, where the level of quality control and rigor applied is commensurate with the safety significance of the item or activity.

**5.2 Project Kick-off**

For each new product or service supplied to the nuclear sector, or upon significant modification of existing ones, the project manager initiates the determination process.

The project manager obtains and reviews the customer's technical specifications, safety classifications, and any specific requirements related to safety significance. The customer's classification is the primary input for the overall system/component.

**5.3 Breakdown of products and services into items and activities**

The project manager systematically breaks down the supplied product or service into its constituent items (e.g., components, sub-assemblies, materials, software) and associated activities (e.g., design, manufacturing, testing, installation, maintenance, calibration, inspection, procurement).

This decomposition should go to a level that allows for a meaningful assessment of safety significance.

**5.4 Impact analysis (consequence assessment)**

For each identified item and activity, the project manager conducts a systematic analysis to determine the potential consequences if it were to fail or malfunction. This analysis should focus specifically on its impact on nuclear safety.

Methods that can be used:

* Failure Mode and Effects Analysis (FMEA): Identify potential failure modes, their causes, and their effects on nuclear safety. This is a common and highly effective tool
* Hazard Analysis: Identify potential hazards associated with the item/activity and assess their consequences
* Design Basis Accidents (DBA) / Beyond Design Basis Accidents (BDBA) analysis: Understand how the failure of an item or activity might contribute to or prevent a nuclear accident scenario
* Direct Linkage to Safety Functions: Determine if the item/activity directly supports or is part of a safety function required for nuclear safety (e.g., reactor trip, emergency core cooling, containment integrity, radiation monitoring)

Key questions to ask for each item/activity:

* Could its failure (or improper execution of an activity) directly or indirectly lead to an uncontrolled release of radioactive material?
* Could it prevent a safety system from performing its function?
* Could it lead to undue radiation exposure for workers or the public?
* Could it compromise the integrity of physical barriers designed to prevent radioactive release?

**5.5 ITNS criteria and classification**

Based on the impact analysis, the project manager classifies each item and activity as either:

* ITNS (Important to Nuclear Safety): If its failure could result in undue radiation exposure of people or the environment
* Non-ITNS (Not Important to Nuclear Safety): If its failure does not have a direct or indirect impact on nuclear safety as defined above

When a customer provides a safety classification (e.g., Safety Class 1, 2, 3), the project manager should align its ITNS determination with that classification. Typically, items classified as safety class 1, 2, or 3 by the customer would be considered ITNS by the supplier.

The project manager considers the "graded approach": For ITNS items, he considers further sub-classification if the customer's requirements or the organization's internal processes warrant different levels of rigor within ITNS (e.g., highly ITNS vs. moderately ITNS). The stringency of QMS controls will then be scaled accordingly.

**5.6 Review**

The project manager documents the rationale for the ITNS determination for each item and activity. This includes:

* description of the item/activity
* reference to customer specifications/safety classification
* results of the impact analysis (e.g., FMEA report)
* final ITNS classification
* date of determination and names of personnel involved

The determination should be reviewed and approved by relevant competent personnel (e.g., engineering, quality, project management)

**5.7 Communication**

The project manager communicates the ITNS classification internally to all relevant departments and personnel (e.g., procurement, manufacturing, quality control, design).

The specific, enhanced quality management system requirements of ISO 19443 are applied to all identified ITNS items and activities. This includes:

* more rigorous supplier qualification and control
* enhanced traceability
* specific controls for CFSI prevention
* more stringent verification and validation
* specific competence requirements
* enhanced documented information control

**5.8 Maintenance and update**

The ITNS determination is a living document. It shall be reviewed and updated:

* upon changes to customer requirements or safety classifications
* upon design changes or modifications to the product/service
* as part of management review or internal audit findings
* periodically, as defined by the organization's QMS (e.g., annually)