Graded approach

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**1. Subject**

**1.1 Purpose**

The purpose of this procedure is to:

* define the systematic process for applying quality management requirements with a level of rigor commensurate with the safety significance and complexity of products, services, items, and activities important to nuclear safety (ITNS)
* optimize resource allocation while maintaining the highest level of nuclear safety

**1.2 Scope**

This procedure applies to all processes, products, services, and activities within the organization's ISO 19443 scope, particularly those identified as ITNS. It influences the depth and stringency of controls in design, procurement, manufacturing, testing, installation, and maintenance.

**1.3 Glossary**

QMS – quality management system

Risk – likelihood of occurrence of a threat or an opportunity

Graded Approach - the process of ensuring that the level of analysis, documentation, and actions used to comply with requirements are commensurate with the relative importance to nuclear safety, the magnitude of any hazard involved, the life-cycle stage, and other relevant factors

ITNS - Important to Nuclear Safety

QL - Quality Levels

**2. Responsibility**

Top management is responsible for ensuring the strict application of this procedure and ensures it is effectively applied without compromising safety. The heads of departments implement the specific quality requirements defined by the graded approach for their respective activities.

**3. Documents**

**3.1 Procedures**

Scope of the QMS

Process control

Risk management

ITNS items and activities

**3.2 Instructions and records**

List of risks

Action plan

Quality plans

**4. Requirements of standards**

**4.1 Requirements of ISO 19443 version 2018**

6.1.4 Graded approach to the application of quality requirements

For items and activities, the organization shall grade the application of requirements related to quality management, documentation, monitoring and measurement taking account of the

a) requirements for ITNS products or services as specified by the customer,

b) complexity of each item or activity, and

c) organizational aspects.

The organisation shall maintain and retain related documented information.

**5. Development**

**5.1 Quality Levels**

The "graded approach" is a fundamental principle in nuclear safety and quality management, especially highlighted in standards like ISO 19443 and IAEA Safety Standards. It ensures that the application of quality requirements, controls, and resources is commensurate with the safety significance, complexity, and unique characteristics of an item, activity, or process. It's about applying the right level of rigor, not less rigor where it's critical.

This systematic procedure ensures that the graded approach is not a means to relax safety requirements, but rather a robust tool for optimizing the application of quality controls, focusing resources where they matter most for nuclear safety.

Based on the organization's context, customer requirements, and the nuclear safety significance, the project leader defines a clear set of Quality Levels (QLs).

Each QL must correspond to a defined set of quality management requirements and associated rigor:

* QL-1 (Highest Safety Significance / Category 1 ITNS): applies to items/activities whose failure could directly cause a severe nuclear accident or significantly compromise a fundamental safety function. Requires the fullest application of ISO 19443 requirements, often with additional customer-specific or regulatory controls (e.g., specific codes like RCC-M, ASME NQA-1)
  + example controls: independent verification/validation, mandatory hold points, 100% inspection, highly detailed documentation, specific personnel certifications, stringent supplier audits
* QL-2 (Moderate Safety Significance / Category 2 ITNS): applies to items/activities whose failure could degrade a safety function or lead to a minor radiological release, but is generally mitigated by other safety systems. Requires a tailored application of ISO 19443 requirements, with reduced but still robust controls compared to QL-1
  + example controls: reviews, sampling inspections, less frequent but still comprehensive supplier assessments, standard documentation
* QL-3 (Low Safety Significance / Non-ITNS, or supporting ITNS): applies to items/activities that are non-ITNS but whose failure might have indirect or minor impact on operational reliability or quality, without direct nuclear safety consequences. Requires application of ISO 9001 general quality requirements, possibly with selected elements of ISO 19443 deemed relevant
  + example controls: standard commercial practices, basic quality checks, vendor declarations

**5.2 ITNS Classification**

For each product, service, item, and activity, follow the "Important to Nuclear Safety (ITNS) Items and Activities" procedure. This step is a prerequisite for applying the graded approach.

The output of this step is the classification (e.g., ITNS Category 1, ITNS Category 2, Non-ITNS).

**5.3 Initial Quality Level**

Based on the ITNS classification determined in step 5.2, you can assign an initial Quality Level (QL) using a pre-defined mapping matrix (e.g., ITNS Cat 1 = QL-1, ITNS Cat 2 = QL-2, Non-ITNS = QL-3).

**5.4 Graded Approach Tailoring**

For each assigned QL, especially for ITNS items/activities, you can perform a detailed review to identify which specific ISO 19443 (and potentially other customer/regulatory) requirements are applicable, and to what depth and rigor they should be applied.

This tailoring process is often done by a multidisciplinary team (engineering, quality, safety, project management).

Factors to consider for tailoring:

* safety significance (primary factor): the potential consequences of failure
* complexity: how intricate the design, manufacturing, or operation is
* maturity of technology: proven vs. novel designs/processes
* standardization: availability of industry codes, standards, and best practices
* life-cycle stage: requirements might differ for design, manufacturing, installation, or in-service inspection
* operational experience: lessons learned from similar items/activities
* customer and regulatory requirements: specific mandates from the nuclear operator or national regulators
* cost-benefit analysis: while safety is paramount, the graded approach allows for efficient resource allocation without compromising safety

Examples of tailoring decisions:

* documentation: amount of detail, level of review, retention period
* inspection/testing: frequency, type (e.g., NDE, destructive), witness points
* personnel qualification: specific certifications, level of experience, independent verification
* supplier control: depth of audit, frequency of surveillance, required quality documentation from supplier
* design review: number of review stages, independence of reviewers

**5.5 Documentation**

You can document the specific quality requirements and their level of application for each item/activity or category. This can be done through:

* quality plans: detailing the QMS requirements applicable to a specific project or product
* matrices: mapping ITNS classifications to specific QMS clause requirements and defining the associated rigor (e.g., "Full Compliance," "Partial Compliance - specify elements," "Not Applicable")
* technical specifications: directly incorporating graded quality requirements

Make sure the rationale for tailoring, especially for any deviation from full application for ITNS, is clearly justified and approved by relevant authorities (e.g., quality and safety manager, engineering manager).

**5.6 Implementation**

Implement the tailored quality requirements in the relevant operational processes (e.g., design, procurement, production).

Conduct internal audits and management reviews to verify that the graded approach is being applied consistently and effectively, and that it is achieving its intended safety objectives.

**5.7 Review and Update**

The graded approach methodology and its specific application should be reviewed and updated periodically, or whenever significant changes occur, such as:

* new products/services or major design changes
* changes in customer requirements or regulatory mandates
* significant non-conformities or lessons learned from operational experience
* changes in the organization's capabilities or processes