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Making Our World
SAFE, SECURE + RESILIENT

LESSONS LEARNED FROM IMPLEMENTING ISO 9001/19443

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Two Different Audiences

Nuclear

- + Appendix B
Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants
- + NQA-1
Quality Assurance Requirements for Nuclear Facility Applications
- + Licensed nuclear facilities

ISO 9001/19443

- + ISO 9001
Quality Management Systems - Requirements
- + ISO 19443
Specific requirements for the application of ISO 9001:2015 by organizations in the supply chain of the nuclear energy sector supplying products and services important to nuclear safety (ITNS) organizations supplying ITNS products or services.
- + Organizations supplying products or services that are important to nuclear safety

Two Separate Goals

Appendix B

Prevent or mitigate the consequences of postulated accidents that could cause undue risk to the **health and safety of the public**.

NQA-1

Part I is to be applied using a graded approach to any structure, system, component, activity, or organization that is essential to the safe, reliable, and efficient performance of a nuclear facility and to any activities independent of a facility that may affect performance ... of those activities.

ISO 9001 / 19443

Consistently provide products and services that meet customer and applicable statutory and regulatory requirements

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

Where Does it Apply?

NQA-1

+ For Licensees

Part 1, Introduction Section 300: The organization invoking this Part shall be responsible for specifying applicable requirements and appropriately relating them to specific items, activities, and services.

+ For Suppliers

Part 1, Req. 4 Section 100: To the extent necessary, procurement documents shall require Suppliers to have a quality assurance program consistent with the applicable requirements of this Standard.

Quality assurance requirements apply to specific items, activities, and services as determined by the licensee.

ISO 9001 / 19443

Clause 4.3: The organization shall determine the boundaries and applicability of the quality management system to establish its scope.

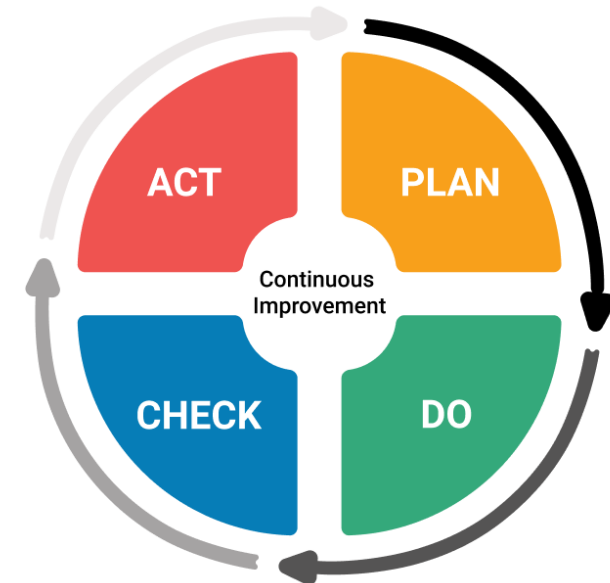
The ISO system applies to all work performed under the defined scope.

Holistic Approach

Context of the Organization

- + Internal and External Issues
 - + Needs and Expectations of Interested Parties
 - + Products and Services
-
- + QMS and Processes
 - Inputs required and outputs expected
 - Sequence and interaction
 - Criteria and methods of monitoring
 - Resources
 - Responsibilities
 - Risks and Opportunities
 - Evaluation and Implementation
 - Process Improvements
 - Documentation (Quality Manual or Quality Plan)

SCOPE



Leadership

- + Commitment
 - Top Management Shall Demonstrate a Commitment to the QMS
- + Policy
 - Top Management Shall Establish the Quality Policy
- + Organizational Role, Responsibilities, and Authorities
 - Top Management Assigns Roles For Responsibilities and Authorities

Planning

- + Addressing Risks and Opportunities
 - Plan Actions to Address Risks and Opportunities
 - Break down products and services important to nuclear safety into items and activities and determine how they meet the requirements specified by the customer's safety classification
 - Apply a Graded Approach to the application of Quality Requirements
- + Quality Objectives
 - Established at relevant functions, levels and processes
 - Planning for objectives
- + System Changes

Support

- + Resources
 - People
 - Infrastructure
 - Environment
 - Monitoring and Measurement
 - Knowledge
- + Competence
- + Awareness
- + Communication
- + Documentation

Operation

- + Planning and Control
- + Product and Service Requirements
 - Determination of overall requirements of products and services
 - Review of the requirements
 - Focus is on customer requirements
 - Documentation is required for the results of these reviews
 - When changes are required, they shall be managed.

Design and Development

ISO 9000: Set of processes that transform requirements for an object into more detailed requirements for that object.

Object: Anything perceivable or conceivable

- + Processes, detailed enough to demonstrate products or services meet the requirements
 - Internal and external interfaces
 - Organization must demonstrate design tools (computer programs) are valid for the application
- + Planning
- + Inputs
- + Controls
- + Validation Testing
- + Outputs
- + Changes

Control of Externally Provided Processes, Products and Services

- + The organization shall ensure that externally provided processes, products, and services conform to requirements.
- + Controls are to be defined both for the provider and to the output provided by the provider.
- + Information provided to the supplier must be adequate to ensure the items / services can be supplied with the requisite level of quality.

Production and Service Provision

Controls

- + Controls
 - Production and service provision shall be provided under controlled conditions
- + Identification and Traceability
- + Property belonging to customers or external providers
- + Preservation of product and service outputs
- + Post-Delivery activities
- + Change Control
- + Product / Service release
- + Nonconforming outputs

Performance Evaluation

- + Monitoring and measurement
 - For product / service conformity
 - Customer satisfaction
- + Internal Audit

Management Review

+ Inputs

- Status of actions from previous reviews
- Changes in external and internal issues
- Performance and effectiveness of the QMS
 - Customer satisfaction / feedback
 - Quality objectives and how they have been met
 - Process performance conformity
 - Nonconformities and corrective actions
 - Monitoring / measurement results
 - Audit results
 - Performance of external providers
- Adequacy of resources
- Effectiveness of actions to address risks and opportunities
- Opportunities for improvement, including lessons learned from nuclear experience

Management Review

- + Opportunities for Improvement
- + Any needed changes to the QMS
- + Resource needs

Improvement

- + Opportunities for Improvement
 - Improving products and services
 - Correcting, preventing or reducing undesired effects
 - Improving the performance / effectiveness of the QMS
 - Lessons learned
 - Risk mitigation
- + Nonconformity and Corrective Action
- + Continual Improvement

Summary

- + ISO 9001 / 19443 offers advantages when for nuclear QMS
 - Holistic approach requiring top management participation
 - Emphasis on planning
 - Goal is customer satisfaction, aligned with nuclear safety