Breakfast Keynote

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Considerations for Developing a QA Program

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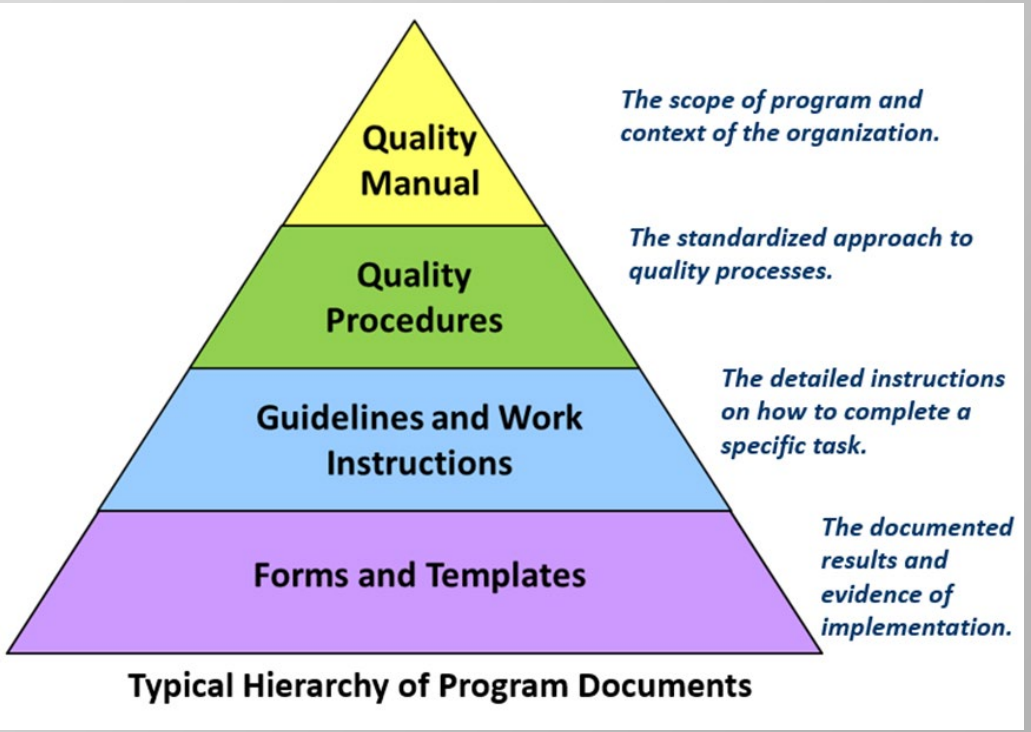
What is the QA Program?

How does it provide value?



Typical Hierarchy of Program Documents

Quality Assurance (QA): all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service. *(NQA-1 definition)*

The QA Program:

- Defines roles and responsibilities for implementing the QA Program.
- Ensures the right personnel are involved in quality related activities and key decisions.
- Establishes standards and best practices for performing quality related activities.
- Ensures minimum requirements are defined.
- Defines requirements to ensure that objective evidence is documented as work is performed.
- Provides forms and templates for recording objective evidence and assisting with procedure compliance.
- Defines processes that, when implemented properly, provide assurance the product or service satisfies applicable requirements.

18 Criteria from 10CFR50, Appendix B:

I. Organization
II. Quality Assurance Program
III. Design Control
IV. Procurement Document Control
V. Instructions, Procedures, and Drawings
VI. Document Control
VII. Control of Purchased Material, Equipment, and Services
VIII. Identification and Control of Materials, Parts, and Components
IX. Control of Special Processes
X. Inspection
XI. Test Control
XII. Control of Measuring and Test Equipment
XIII. Handling, Storage and Shipping
XIV. Inspection, Test, and Operating Status
XV. Nonconforming Materials, Parts, or Components
XVI. Corrective Action
XVII. Quality Assurance Records
XVIII. Audits

Quality Assurance Program Description (QAPD):

- A description of the QA program for a nuclear power plant or a fuel reprocessing plant that discusses how the applicable requirements of 10CFR50, Appendix B will be satisfied.
- NRC approval required for NRC licensed activities.
- NEI 11-04 provides a generic template for a QAPD based on the requirements of ASME NQA-1.
- Provides commitment for procedures and instructions that control quality-related activities to be developed prior to commencement of those activities.

Plan Early and Continually

DO THIS

- Integrate QA Program development into project planning activities.
- Establish the framework for the program based on applicable regulations and standards.
- Define the organizational structure and roles responsible for specific quality activities. *(engineering, procurement, etc.)*
- Establish basic quality requirements early in the project; Develop new procedures and update existing procedures as needed to support project activities.
- Establish nuclear safety culture and expectations for procedural compliance. *(behaviors are equally important to procedures)*
- Ensure the infrastructure to support the program *(IT network, communication systems, electronic workflows, etc.)* is in place, as needed to implement the program effectively.

Plan Early and Continually

NOT THAT

- X Delay development of the QA program; may result in back-fitting and increase the risk for rework.
  - ✓ Plan accordingly to ensure processes *(procedures, equipment, training, etc.)* are in place when needed.
- X Define or set expectations that the quality team is solely responsible for quality.
  - ✓ Process owners should be responsible for quality in their areas of responsibility.
- X Isolate process owners from development of procedures and instructions for their area.
  - ✓ Process owners should be engaged to ensure procedures and instructions satisfy their needs.
  - ✓ QA personnel assist to ensure compliance with applicable regulatory and standards requirements.
- X Delay development of processes for self-assessment, corrective action, and continual improvement.
  - ✓ Process owners should periodically assess program implementation and discuss issues and opportunities for improvement with management.
- X Apply most restrictive or least restrictive requirements to everything.
  - ✓ Define and implement a graded approach to right-size requirements for the application and associated risk.

What is a Graded Approach?

Graded Approach: the process employed, once the applicability of the requirement to the scope of the organization's activity has been determined, to ensure that the levels of analyses, documentation, and actions used to comply with requirements are commensurate with the following:

- the relative importance to nuclear safety.
- the magnitude of any hazard involved.
- the life-cycle stage of a facility or item.
- the mission of a facility.
- the particular characteristics of a facility or item.
- the relative importance to radiological and non-radiological hazards.
- any other relevant factors.

(NQA-1 definition)

The Standard…fosters the application of these [NQA-1] requirements in a manner consistent with the relative importance of the item or activity (i.e., a "graded approach").

(NQA-1 forward)

What is a Graded Approach?

Nuclear QA regulations and standards tend to define more restrictive requirements for activities such as:

- Supplier qualification
- Independent verification
- Software development, verification, and use
- Personnel qualifications

The QA program defines actions to provide adequate confidence of meeting the requirements.

A graded approach defines levels of actions needed to provide adequate confidence based on the relative risk and consequences of failing to meet requirements.

Trust Verify

We always expect requirements to be satisfied.

Graded Approach

Based on the risk and consequence of failure, to what extent can we afford to Trust that a given requirement is satisfied?

Develop and Implement a Graded Approach

DO THIS

- Establish the graded approach to procurement and manufacturing as part of the design and licensing process.
  - ✓ Categorize SSCs based on their importance to ensuring nuclear safety.
  - ✓ Ensure acceptance criteria are specified appropriately for the application.
  - ✓ Define requirements for verifying design attributes to satisfy regulatory requirements based on the risk *(design margin)* and consequences of failing to meet the requirements.
    - *Required inspections and tests*
    - *Required supplier audits and surveillance*

Develop and Implement a Graded Approach

NOT THAT

- X Wait for the regulator or QA personnel to determine what seems reasonable for your application.
  - ✓ Document your approach and technical justification.
- X Present cost and schedule concerns as the reason for a graded approach when seeking acceptance by QA personnel or the regulator.
  - ✓ Present reasoning in terms of acceptable risk and consequences.
- X Assume it's obvious that the risk and consequences of failure are low.
  - ✓ Document your reasoning for the categorization and graded approach. *(PRA, FMEA, etc.)*
  - ✓ Demonstrate by testing, as appropriate.
- X Define safety categorization and acceptance criteria conservatively to expedite regulatory acceptance; increases costs for each installation and life of plant.
  - ✓ Take time to determine the appropriate categorization and acceptance criteria based on risk and consequences.

ANY QUESTIONS?