Module 2: Quality Assurance (QA) Concepts and Principles

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Module 2: Learning Objectives

In this section, we will:

1. **Ensure understanding of the oversight process for nuclear facilities**
   - Role of the NRC, regional inspectors
   - Role of the licensed industry utility
   - Identification of key stakeholders
2. **Define and distinguish between:**
   - Quality management
   - Quality assurance, and
   - Quality control
3. **Explain Process and Procedures Management, Six Sigma**
   - Process
   - Program
   - Procedure
   - Product performance
   - Overview of Six Sigma
4. **Detail the Performance-Based Quality Approach and other Inspection Techniques**

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Objective 1: Ensure Understanding of the Oversight Process of Nuclear Facilities

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Oversight of Nuclear Facilities

The NRC's mission is to ensure adequate protection of health and safety, to promote the common defense and security, and to protect the environment as it applies to reactors, materials and waste.

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Oversight of Nuclear Facilities – Role of the NRC

The **NRC plays three key roles** in providing and maintaining this protection, namely:

1. **Establishing regulations and guides** for the construction and operation of nuclear facilities.

2. **Issuing plant operating license,** including approving plant-specific technical specifications, tech specs, and other licensee documents, which must be followed by the plant operators.

3. **Conducting periodic inspection and oversight** of nuclear Facilities (both those under construction and fully operational)

Is this list comprehensive?

If not, what would you add?

Oversight of Nuclear Facilities – Role of NRC Headquarters

NRC ensures that regulations are implemented by licensees.

For new reactors, **NRC Headquarters develops the regulations and requirements**, and the regions will evaluate the licensees construction activities. Headquarters will **evaluate vendors periodically**, and the regions may assist this effort. As the center of construction inspection, Region II is chartered with the construction inspection program for new reactors.

New construction activities will pull resources from regional offices.

Expect Region II to be busiest based on number of new reactors and fuel facilities planned in the southeastern U.S. region.

Oversight of Nuclear Facilities – Role of the NRC Construction Resident Inspectors

NRC construction resident inspectors:

- Live in the area of the nuclear facilities
- **Significantly increase the NRC's onsite monitoring of the plants**
- Conduct inspections
- Monitor major work projects
- Interact with plant workers
- Maintain an office at the plant during regular business hours
- Provide evening and weekend support, as needed
- **Support scheduled and unscheduled inspection activities** based on status of ongoing work activities, plant events, and ITAAC activities and related requirements

Oversight of Nuclear Facilities – NRC Stakeholders

NRC stakeholders represent a myriad of groups, including:

- **Congress:** The NRC reports to such committees as the House Committee on Energy and Commerce and the Senate Committee on Energy and Natural Resources.
- **Public at large:** The NRC responds to public Concerns about safe operation of nuclear facilities and protection of the environment.
- **Interveners:** The NRC interacts with registered public interest groups (e.g., Union of Concerned Scientists, Greenpeace)
- **Licensees:** The NRC issues licenses to those facilities which have met all regulatory requirements and approval of COLA.
- **Universities:** The NRC teams with universities to provide needed analysis and research & development information.
- **Other government agencies/National labs:** In addition to Congress, the NRC interacts with such agencies as the Departments of Energy, Transportation, Commerce and the Environmental Protection Agency.
- **Foreign governments:** As appropriate, the NRC enters into MOUs with foreign governments.

How do these stakeholders affect the overall NRC mission?

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Oversight of Nuclear Facilities – Role of the Industry

The primary role of utilities and organizations licensed by the NRC is to be directly responsible for the design, construction, testing, and operating the facility in a safe manner.

This means that the **NRC expects licensees** to:

- **Construct and operate** within their license and the NRC regulations
- Be **proactive**
- **Not wait for the NRC** to identify problems

Oversight of Nuclear Facilities – Safety First Review

Conducting QA oversight of vendor fabrication and construction activity early on and in sufficient depth provides key feedback to vendors and licensees about NRC's focus and intent.

Licensees will **take enabling actions** to ensure that they comply with programs and procedures, and ensure their own frequent internal oversight to take **proactive corrective actions** as needed.

Conducting early oversight is anticipated to result in fewer problems later on.

Objective 2: Define and distinguish between Quality Management, Quality Assurance and Quality Control

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Definitions and Discussions – Quality Management

Quality Management (QM), Quality Assurance (QA), and Quality Control (QC) each reference a distinct aspect in the focus of the NRC inspection staff.

Quality Management is a method to ensure customer is satisfied and meets their expectations.

QM establishes processes to ensure and measure customer satisfaction.

What is the Baldrige award?

How do its criteria affect present-thinking regarding QM?

Definitions and Discussions – Quality Assurance

Quality Assurance comprises all those planned and systematic actions necessary to provide adequate confidence that a structure, system, or component will perform satisfactorily in service.

QA is process oriented.

It requires:

- Documentation,
- Adherence to prescribed requirements and
- Verification of satisfactory execution of requirements

Common perceptions and definitions of QA:

- "Conformance with requirements"
- "Doing the right thing, the right way, at the right time, the first time"
- "The customer's definition of quality is what matters"
- "Fitness for intended use"
- "Meeting or exceeding expectations"

How are these perceptions accurate / inaccurate in relation to the NRC definition?

Definitions and Discussions – Quality Control

Quality Control comprises processes and activities related to the physical characteristics of a material, structure, component, or system, which provide a means to control the quality of those items to predetermined requirements.

QC is **system- and hardware-oriented.**

Major Nuclear Industry Quality Standards Applied

Key documents to note for the following discussions:

- **10 CFR 50, Appendix B:** the overarching regulation regarding quality assurance criteria for nuclear facilities and fuel reprocessing plants. It is divided into 18 criteria.
- **ASME NQA-1:** sets forth requirements for the establishment and execution of QA programs for the siting, design, construction, operation, and decommissioning of nuclear facilities.
- **NRC Regulatory Guide (RG) 1.28:** Discusses QA program requirements for design and construction.
- **ANSI N45.2:** similar to the ASME NQA-1 in that it detailed QA programs as they relate to the siting, design and construction, operations and decommissioning of nuclear Facilities. It was superseded by NQA-1.
- **ISO 9000-series:** a family of standards for quality management systems, including, a set of procedures that cover all key processes in the business, monitoring processes to ensure they are effective, keeping adequate records, and facilitating continual improvement. The NRC does not endorse ISO 9000.

Major Nuclear Industry Quality Standards Applied cont'd

The nuclear industry has **shifted from the ANSI N45.2 documents to ASME NQA-1 series**, which provides guidance for implementing 10 CFR 50, Appendix B.

- Key points include implementing training and qualification requirements, guidance on design control, documentation and records management, and certification of lead auditors.

The **ISO 9000-series** quality standards may be used by vendors who **may not be required to meet 10 CFR 50, Appendix B requirements**, or are **foreign vendors**.

To be used in U.S. nuclear facilities, vendor products **must be dedicated to meet 10 CFR 50, Appendix B**.

At present, the **NRC does not endorse ISO-9001 for use in safety-related applications** to meet 10 CFR 50, Appendix B requirements.

Whatever standards are used to develop a quality assurance program, the Quality Assurance Program Description (QAPD) approved by the NRC is the document of record for satisfying 10 CFR 50, Appendix B requirements.

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Additional Quality-related terms

Additional terms that will be referenced as we continue:

Safety-related refers to **critical items or activities in preventing and the release of radioactivity** to protect people, facility and environment. Specifically, it refers to:

- The integrity of the reactor coolant pressure boundary
- The capability to shut down the reactor and maintain it in a safe shutdown condition, and
- The capability to prevent or mitigate the consequences of accidents which could result in potential offsite exposures

Balance-of-plant refers to those components and systems that are **not directly related to preventing radioactive exposure**, nevertheless are imperative to address in maintaining an overall safe and secure nuclear facility.

ITAAC ***(inspections, tests, analyses, and acceptance criteria)*** are **mandatory** for an application for a combined license (COLA).

IROFS ***(items relied on for safety)*** reference the items needed to ensure that a fuel facility maintains the integrity to prevent the release of radioactivity.

Objective 3: Explain Process and Procedures Management, Six Sigma

Definitions and Discussions – Process and Procedures Management

Understanding the intent and application of the following terms can provide key insight to regulatory activities and processes:

- **Process management** includes performance and risk management activities applied to systems and hardware design, fabrication, assembly, construction, operation, maintenance, and decommissioning.
- A **process** is how requirements are translated into a design that is materialized into a physical reality that operates to produce desired results
- A **program** is a hierarchy of written policies, plans, design documents, procedures and instructions to provide control over activities affecting quality of structures, systems, components, and performance.

Definitions and Discussions – Process and Procedures Management cont'd

- **Procedures** describe how to translate requirements into desired outcomes. They provide necessary criteria to be met for success in achieving product and performance objectives.
- **Products** can be items or services. They are the result of a work process.
- **Performance** consists of actions taken to achieve results.

Why are the differences among these terms important?

How does it relate to your NRC responsibilities?

Six Sigma Tool Chest

Vendors may apply Six Sigma applications as part of procedures management. Below is a list of tools, methods and products related to Six Sigma.

- **Analysis of variance****
- **Business process mapping****
- Cause & effect diagram
- Chi-square tests
- **Control Chart****
- Correlation
- Cost-benefit analysis
- Customer survey
- Design of experiments
- **Failure mode and effects analysis (FMECA)****
- General linear model
- **Histograms****
- Homogeneity of variance
- **Pareto chart****
- Process capability
- **Regression analysis****
- Run charts
- SIPOC analysis
- Stratification
- Thought process map

*** Documentation that could be evaluated during an inspection activity*

Objective 4: Detail the Performance-Based Quality Approach and other Inspection Techniques

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Compliance- vs. Performance-Based Inspection Techniques

Two **primary inspection techniques** are used by the NRC – compliance based and performance based. The key differences between the two techniques are captured below.

COMPLIANCE-BASED (NRC Manual 2504)	PERFORMANCE-BASED (NRC Manual 2503)
• Focused on verification of adherence to procedural requirements • Primarily determines degree of success of implementing a QA Program • Focuses on processes rather than end product or outcome	• Concentrated on licensee activities that most significantly affect plant quality • Begins by observing work activities, discrepancies then lead to inspection of other areas • Focuses on results and the end product • Helps to determine effectiveness of a QA Program

What is safety significant about performance-based inspections during construction?

How can you do performance-based inspections at the construction site?

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NUREG CR 5151 Performance-Based Inspection – Understanding its Purpose

To implement a performance-based inspection:

- First, verify that a comprehensive program is established and implemented
- Once a program is base-lined, subsequent inspections can be more performance based in nature

Licensee's requirements or commitments are not changed, only the approach on concentrating resources on those issues most important to safety has changed.

NUREG CR 5151 Performance-Based Inspection – Provides Guidance

Regulatory guide **NUREG/CR-5151**, Performance-Based Inspections, provides:

- guidance for improving the practice of safety assessment and
- quality verification in commercial nuclear power plants

Key focal points include:

- Emphasize **actual observation** of ongoing facility work activities and reduce the emphasis on document and program reviews
- **Utilize personnel** who have the necessary experience and technical capabilities to accurately observe and evaluate the activity
- Concentrate on **activities that are important to safety and reliability**
- **Perform an evaluation** of the activity based on these observations

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Module 2 Review

For the Module 2 Review, we will employ the Qwizdom polling system.

Each participant will:

- Turn on his/her handheld Qwizdom response device
- Respond to the displayed question by pressing the desired option (Multiple Choice by *a, b, c, or d*; True/False by *T or F*) as each question is shown
- Press the "Enter" key to confirm response
- Wait for all participants to respond
- Turn off handheld Qwizdom response device at the end of the review session

Module 2: Summary

In this section we have covered:

1. The oversight process for nuclear facilities
2. Quality management, Quality assurance, and Quality control
3. Process and Procedures Management, Six Sigma
4. The Performance-Based Quality Approach
5. Compliance- and Performance-Based and other Inspection Techniques