Welcome to the

Nuclear Regulatory Commission Quality Assurance Training

U.S.NRC
UNITED STATES NUCLEAR REGULATORY COMMISSION
Protecting People and the Environment

HRTD
Human Resources
Training & Development

Who is the Instructor?

Bill Barley

Experience highlights:

- B.S., Chemical Engineering. Penn State
- Startup of a two unit BWR nuclear plant
- Director of Quality for utility Corporate Nuclear Oversight Board
- Extensive experience with NRC regulations and industry standards
- Prepared various nuclear plant licensing submittals
- Developed and delivered a wide variety of nuclear power training courses
- Plant experience includes:
  - Connecticut Yankee, Columbia, Palo Verde, Shoreham, San Onofre, Diablo Canyon, Oyster Creek, Davis Besse, Pilgrim, D. C. Cook
- Senior Operator License
- American Board of Health Physics Certification

Module 1: Introduction

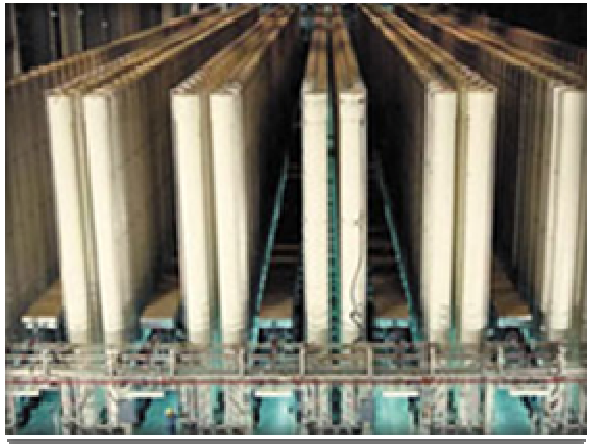
Introduction Agenda

1. What's the Purpose of this Course?
2. Who are the Participants?
3. What are Classroom Expectations?
4. What will I Learn?
5. How will the Information be Presented?
6. How will I be Evaluated?
7. What's the Timeframe?
8. What Student Materials are Provided?
9. How do I use the Student Materials?
10. What Reference and Guidance Documents will be used?
11. Module 1 - Activity 1: Meet Your Match!

What's the Purpose of this Course?

This course is intended to provide the needed guidance and discussion to ensure uniform performance by all inspection staff.

It is imperative that all inspection staff, both experienced and novice, have a consistent understanding and systematic application of applicable nuclear regulations, standards, and positions on quality assurance (QA).

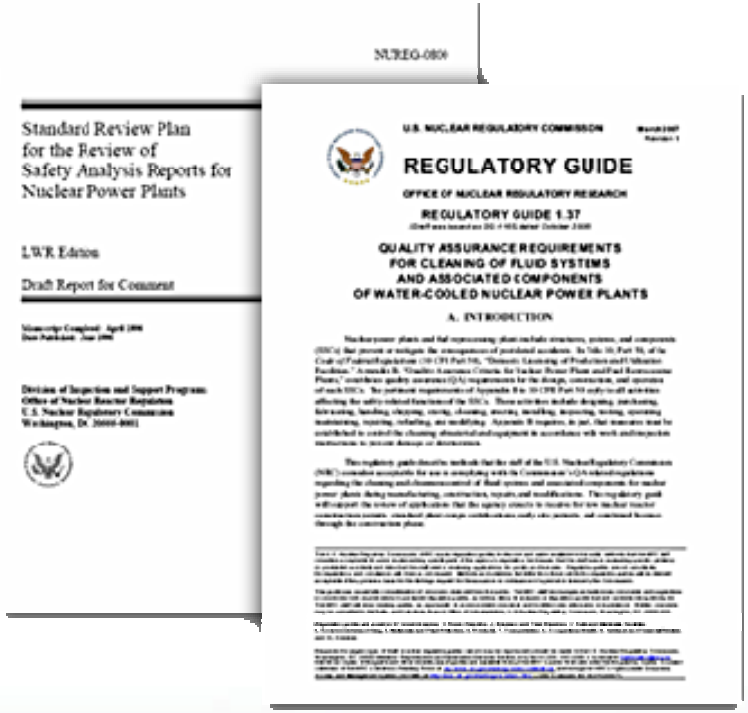


How will I achieve the Purpose of this Course?

Participants will explore all relevant and required regulations, policies, procedures and practices of the NRC to be prepared to participate in inspection activities.

This includes the requirements of regulations, codes, standards, and guidance documents, such as the:

- 10 CFR 50, Appendix B
- ASME NQA-1-1994
- Section 17.5 of NUREG 0800
- ASME Section III
- 10 CFR 21, and
- Generic Letters



Who are the Participants?

- Name
- Current position / location
- Background / experience
- Expectations of the course

What are Classroom Expectations?

Personal electronic devices: Please refrain from using PEDs during class. If you have to take a call or reply to emails, please step out of the room so you don't disrupt the class. All devices should be set to "vibrate" or "silent".

Breaks: We will take regular 15-minute breaks throughout the day. One hour for lunch is allotted for each full day of training.

Smoking: Please refrain from smoking indoors. The instructor will indicate appropriate smoking locations.

Restrooms: The instructor will indicate restroom locations.

What will I Learn?

This Quality Assurance Training course has six primary learning objectives, to:

1. **Understand and apply QA regulations, standards, regulatory position, information notices, and policies, to staff position responsibilities.**

2. **Provide a forum for information exchange and experiences with application of QA principles in nuclear facility construction, testing, operation, and maintenance activities.**

3. **Explain the differences and application of compliance based vs. performance-based quality approaches,**

4. **Demonstrate comprehension of QA concepts through case studies, exercises, quizzes and an exam**

5. **Become familiar with QA concepts to support inspection staff job responsibilities**

6. **Become familiar with international QA standards and alternative QA approaches due to the shift in global vendor fabrication of nuclear components**

How will the Information be Presented?

This training will be based on a combination of:

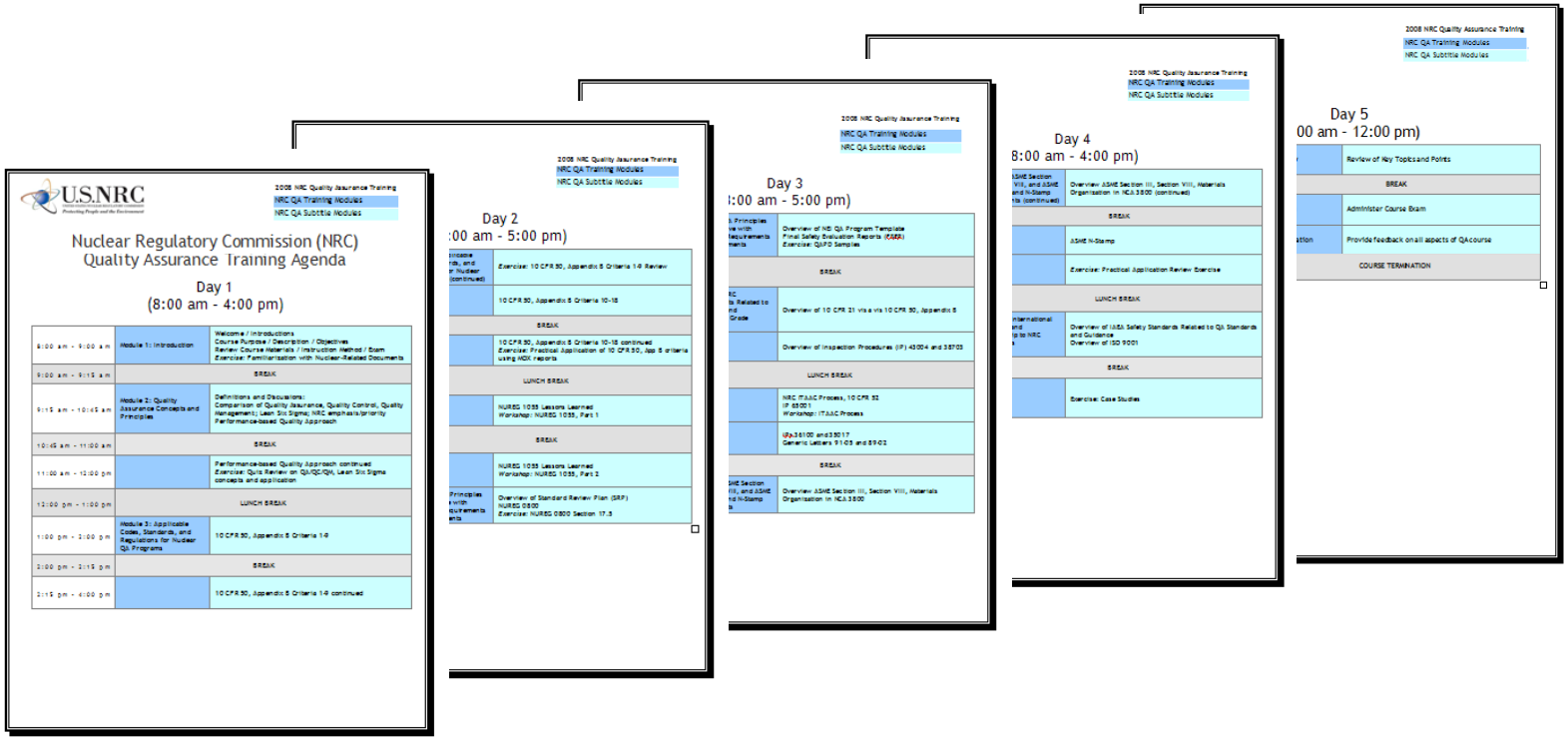
- Lecture
- Discussion
- Activities, and
- Case studies based on actual events and reports

Days 1-4: Presentation of all information material as seven modules

Day 5: Review course material in preparation for the exam. Examination administered (no new material).

What's the Timeframe?

The agenda for the course is provided under the "Agenda" tab in your Student Manual.



How will I be Evaluated?

The format of the exam is as follows:

- Open book
- Multiple choice

Following the exam, we may have a feedback discussion on exam questions and answers.

What Student Materials are Provided?

Each student will be provided with a Student Manual specific to this course.

Included in the Student Manual will be:

- Course agenda
- PowerPoint presentation
- Appendix:
  - Additional reading and explanations, as appropriate
  - Regulation reading and reference materials
    - Matrix resource with links or information on how to access all regulations, codes, standards and guidance documents referenced in the course

How do I use the Student Manual?

Throughout the presentation, you will see key icons to indicate specific concepts or actions. Below you will find the legend for these icons.

Learning Objectives

Key Point

Activity

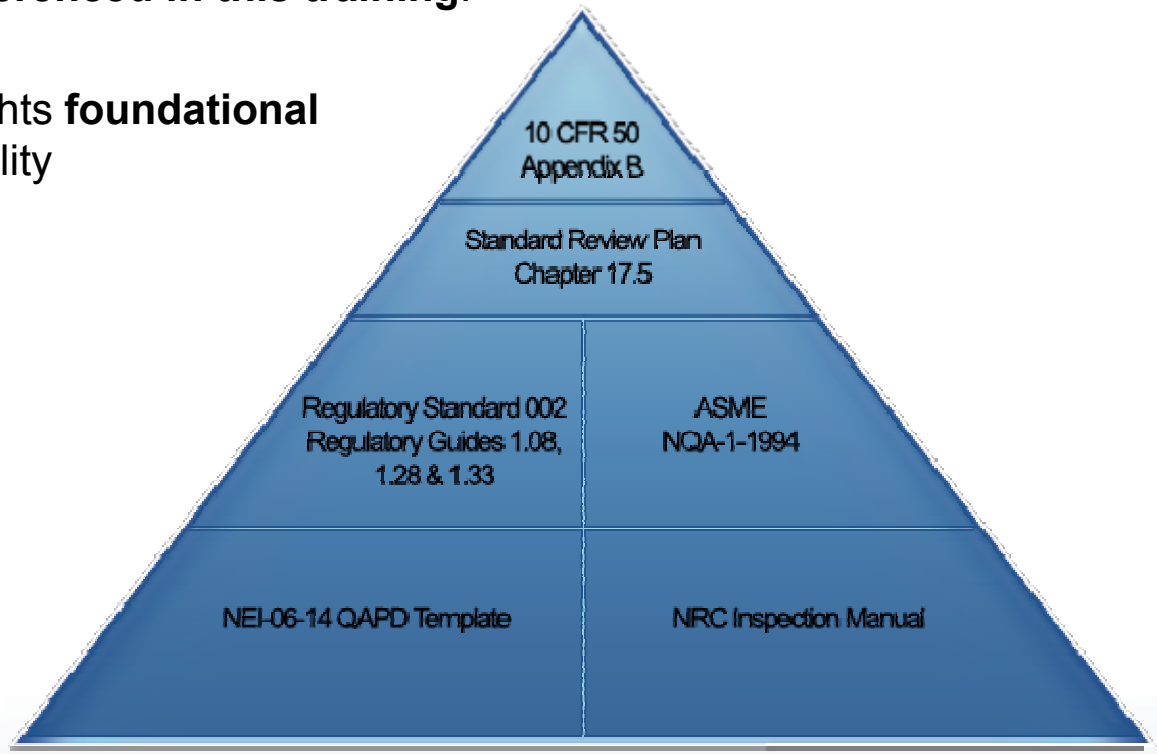
Review

Discussion Point

What Reference and Guidance Documents will be used?

Throughout this course, we will reference multiple regulations, codes, standards and guidance documents. In the Appendix, you will find a "**Key Nuclear-Related Documents Reference Sheet"**, which gives a **brief description of all regulations, codes, standards and guidance documents referenced in this training**.

The pyramid to the right highlights **foundational documents** to any nuclear quality assurance program.



Module 1 Activity 1: Meet your Match!

In this activity, we will review the key documents represented on the pyramid on the previous slide.

Each participant will:

- Pick a strip of paper that includes an identifying factor of one of the key documents
- Mingle with classmates to determine who has factors related to yours (typically 3 total)
- (Use “Key Nuclear-Related Documents Reference Sheet” found in the Appendix as a resource.)
- Once you “meet your match”, review the “Key Nuclear-Related Documents Reference Sheet” that pertains to your factors and, as a group, identify one additional factor where applicable.
- Present your 3 original factors plus the additional one found as a group (3 plus 1) to the class as a whole.

Let's Get Started!

Module 2: Quality Assurance (QA) Concepts and Principles

Module 2: Learning Objectives

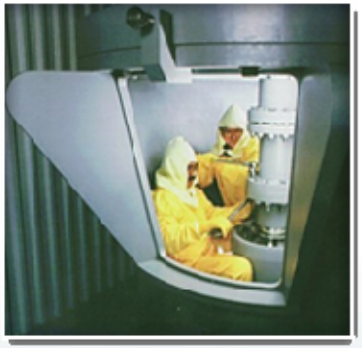
In this section, we will:

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**

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

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 *four* key roles** in providing and maintaining this protection, namely:

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

2. **Reviewing applications and granting permits and licenses** to site and construct nuclear facilities.

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

4. **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**, issues COLs, develops inspection guidance, and provides overall direction for the construction inspection programs. The regions conduct oversight activities of nuclear facilities (operational and under construction). 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 are the eyes and ears of the NRC for on-site activities

- Live in the area of the nuclear facilities
- **Significantly increase the NRC's onsite monitoring of the plants**
- Conduct inspections
- Monitor overall construction projects
- Interact with plant workers and management
- Maintain an office at the plant during regular business hours
- Provide evening and weekend support, as needed; incident/event response
- **Support scheduled and unscheduled inspection activities** based on status of ongoing work activities, plant events, and ITAAC activities and related requirements
- Assess licensee performance
- Disposition findings in accordance with NRC Enforcement Policy
- Interact with plant management
- Interact with the public; provide confidence that construction activities are being conducted safely and in accordance with design 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. Congress provides NRC with its budget. NRC is accountable to Congress to accomplish its mission.
- **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. NRC also inspects university nuclear programs (research, test reactors, etc)
- **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, OSHA.
- **Foreign governments:** As appropriate, the NRC enters into agreements with foreign governments
- **Vendors**
- **Local 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
- Licensee are responsible for the safe construction and operation of the facilities. (NRC is responsible to ensure facilities are constructed and operated safely through oversight)

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

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 *systematic approach* to ensure customer and *performance results* meet 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.

Additional Quality-related terms

Additional terms that will be referenced as we continue:

Currently, "safety-related structures, systems, and components" in 10 CFR 50.2 (Definitions) and 10 CFR 50.65 (Maintenance Rule), and "safety-related electrical equipment" in 10 CFR 50.49 (Environmental Qualifications Rule) are defined as those structures, systems and components that are relied upon to remain functional during and following design basis. **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

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?

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

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

- 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
- Based on internal procedures and problem identification and resolution (P&IR)

PERFORMANCE-BASED SECY 97-231

- Performance-based inspection techniques (inspecting for outcomes) have for the most part replaced the more traditional inspection techniques
- SECY-87-220, "Assurance of Quality," was issued to inform the Commission about the staff's shift in emphasis from "compliance-based" inspections of licensee quality verification organizations to "performance-oriented" inspections of these organizations
- One method utilized is "vertical slice" of licensee QA program

Is there any change in approach to inspections for fuel facilities?

Discuss current observations

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.

Some vendors may use portions of a Six Sigma Tool Chest as part of their inspection documentation for trends and performance indicators

Vendors may apply various tools as part of process management. Below is a list of tools, methods and products related to QM.

- **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*

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**

Module 3: Applicable Codes, Standards and Regulations for Nuclear QA Programs

Learning Objectives

1. **Comprehend the Purpose, Application and Expectation of the 10 CFR 50, Appendix B**

2. **Identify the 18 criteria requirements of 10 CFR 50, Appendix B and how they drive development of Industry Standards**

3. **Apply requirements of 10 CFR 50, Appendix B to in-class exercise and case scenarios**

4. **Detail the Lessons Learned from NUREG 1055**

Objective 1: Comprehend the Purpose, Application and Expectation of 10 CFR 50, Appendix B

10 CFR 50, Appendix B – Foundation of the QA Program

10 CFR 50, Appendix B is the **foundation of the QA Program**.

10 CFR 50, Appendix B

- Is made up of a total of **18 criteria** on which quality assurance standards are built
- Evolved from the aerospace industry
- **Provides the basis** for:
  - Quality assurance program
  - NUREG-0800 (Standard Review Plan)
  - ASME NQA-1 industry standard
- Covers important aspects of assuring nuclear safety


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Appendix B to Part 50--Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants

Introduction. Every applicant for a construction permit is required by the provisions of § 50.34 to include in its preliminary safety analysis report a description of the quality assurance program to be applied to the design, fabrication, construction, and testing of the structures, systems, and components of the facility. Every applicant for an operating license is required to include, in its final safety analysis report, information pertaining to the managerial and administrative controls to be used to assure safe operation. Every applicant for a combined license under part 52 of this chapter is required by the provisions of § 52.79 of this chapter to include in its final safety analysis report a description of the quality assurance applied to the design, and to be applied to the fabrication, construction, and testing of the structures, systems, and components of the facility and to the managerial and administrative controls to be used to assure safe operation. For applications submitted after September 27, 2007, every applicant for an early site permit under part 52 of this chapter is required by the provisions of § 52.17 of this chapter to include in its site safety analysis report a description of the quality assurance program applied to site activities related to the design, fabrication, construction, and testing of the structures, systems, and components of a facility or facilities that may be constructed on the site. Every applicant for a design approval or design certification under part 52 of this chapter is required by the provisions of 10 CFR 52.137 and 52.47, respectively, to include in its final safety analysis reports a description of the quality assurance program applied to the design of the structures, systems, and components of the facility. Every applicant for a manufacturing license under part 52 of this chapter is required by the provisions of 10 CFR 52.157 to include in its final safety analysis report a description of the quality assurance program applied to the design, and to be applied to the manufacture of, the structures, systems, and components of the reactor. Nuclear power plants and fuel reprocessing plants include structures, systems, and components that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. This appendix establishes quality assurance requirements for the design, manufacture, construction, and operation of those structures, systems, and components. The pertinent requirements of this appendix apply to all activities affecting the safety-related functions of those structures, systems, and components; these activities include designing, purchasing, fabricating, handling, shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing, refueling, and modifying.

As used in this appendix, "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. Quality assurance includes quality control, which comprises those quality assurance actions related to the physical characteristics of a material, structure, component, or system which provide a means to control the quality of the material, structure, component, or system to predetermined requirements.

I. Organization

The applicant [1] shall be responsible for the establishment and execution of the quality assurance program. The applicant may delegate to others, such as contractors, agents, or consultants, the work of establishing and executing the quality assurance program, or any part thereof, but shall retain responsibility for the quality assurance program. The authority and duties of persons and organizations performing activities affecting the safety-related functions of structures, systems, and components shall be clearly established and delineated in writing. These activities include both the performing functions of attaining quality objectives and the quality assurance functions. The quality assurance functions are those of (1) assuring that an appropriate quality assurance program is established and effectively executed, and (2) verifying, such as by checking, auditing, and inspecting, that activities affecting the safety-related functions have been correctly performed. The persons and organizations performing quality assurance functions shall have sufficient authority and organizational freedom to identify quality problems; to initiate, recommend, or provide solutions; and to verify implementation of solutions. These persons and organizations performing quality assurance functions shall report to a management level so that the required authority and organizational freedom, including sufficient independence from cost and schedule when opposed to safety considerations, are provided. Because of the many variables involved, such as the number of personnel, the type of activity being performed, and the location or locations where activities are performed, the organizational structure for executing the quality assurance program may

10 CFR 50, Appendix B – Importance to Stakeholders

10 CFR 50, Appendix B is **a federal regulation** and provides key importance to stakeholders:

- Provides a **common basis** for
  - Establishing a quality assurance program
  - Reference in inspection activities related to QA
- **Used by all stakeholders in evaluating effectiveness of QA activities**
- IAEA originally formed its guidance documents on this regulation

10 CFR 50, Appendix B – Expectations

10 CFR 50, Appendix B is the **foundation for a solid QA approach**.

- **Defining regulation** that provides a solid foundation for development of a comprehensive QA Program

- Licensees must **define and demonstrate adherence** to these criteria in a documented program

- QA program should be **broadly applied** and ensure that safety-related items will **perform satisfactorily in service**, and **protect the public and the environment**

Objective 2: Identify the 18 criteria requirements of 10 CFR 50, Appendix B and how they drive development of Industry Standards

10 CFR 50, Appendix B – 18 Criteria at a Glance

The following are the **18 criteria topics** indicated in the 10 CFR 50, Appendix B:

1. Organization
2. Quality Assurance Program
3. **Design Control**
4. **Procurement Document Control**
5. **Instructions, Procedures, and Drawings**
6. Document Control
7. **Control of Purchased Material, Equipment, and Services**
8. Identification and Control of Materials, Parts, and Components
9. Control of Special Processes
10. Inspection
11. Test Control
12. Control of Measuring and Test Equipment (M&TE)
13. Handling, Storage, and Shipping
14. Inspection, Test, and Operating Status
15. Nonconforming Materials, Parts, or Components
16. **Corrective Action**
17. **Quality Assurance Records**
18. **Audits**

10 CFR 50, Appendix B – Industry Expectations: Overview

Industry expectations on how to implement the 18 requirements or 10 CFR 50, Appendix B are **based on the American Society of Mechanical Engineers (ASME) NQA-1-1994**, Quality Assurance Program Requirement for Nuclear Facilities.

In 1975, ASME accepted the overall responsibility to develop and maintain nuclear power QA standards. In 1979, 1983, and 1989, ASME issued versions of requirements referencing "Quality Assurance Requirements for Nuclear Power Plants" which merged the focus of ANSI requirements and early iterations of the NQA standards series.

In the 1990s, **ASME restructured the NQA standards into a single, multipart document. Initially, issued as the NQA-1-1994**, that standard included criteria and non-mandatory guidance to establish and implement a QA program for any nuclear facility application.

Key regulations explain why it is key to know **how to implement** 10 CFR 50, Appendix B, including **10 CFR 52, 10 CFR 50.34,** and **50.55(a)**.

10 CFR 50, Appendix B – Criterion 1: Organization

REQUIREMENT (10 CFR 50, Appendix B)	EXECUTION EXPECTATION (NQA-1 and NUREG 0800)
• Establish and execute a QA Program • Verify that activities affecting safety have been correctly performed • Authority and duties of persons or organizations affecting safety-related items or activities shall be established and defined in writing • Persons and orgs performing QA functions shall have sufficient authority and organizational freedom to identify quality problems initiate and recommend solutions and verify implementation • Report to a management level such that the required authority and org freedom including sufficient independence from cost and schedule considerations	• Define the QA program to meet NUREG 0800, Section 17.5 requirements • Provide a detailed organization description • QA/QC staff will be given proper authority to report problems: Expect this to be defined and authority clearly specified in QA program documentation • QA Manager should report to an executive position • Freedom from cost and schedule pressures • Control of nonconforming items and activities • Specification of methods to verify quality implementation and authorized staff to perform this activity

Freedom from cost and schedule pressures, what does it mean, and what would you expect?

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10 CFR 50, Appendix B – Criterion 2: QA Program

REQUIREMENT (10 CFR 50, Appendix B)	EXECUTION EXPECTATION (NQA-1 and NUREG 0800)
• Applicant shall establish a QA program at the earliest practical time • Identify structures, systems, and components to be covered by quality assurance program • QA controls activities affecting quality of identified, systems, structures, and components to an extent consistent with their importance to safety • Controlled conditions • Special processes • Regularly review status of the QA program • Indoctrination and training of personnel performing quality affecting activities • Assess program regularly	• Submit QA program to meet NUREG-0800 • Develop detailed procedures and instructions • Develop safety-related equipment list and activity list (Q-List) • Describe specific controls for safety-related items, and use "tailored approach" • Need for special qualifications for welders and NDE staff • Need to conduct management assessments of the QA program • Need to train staff on QA program requirements and assure all staff are qualified for their positions • Need to evaluate performance on a regular basis (physical and capability) • Train and qualify NDE staff and auditors • Required to test inspection personnel

What are the documents you would expect to see to evaluate training, qualification, and certification of staff?

10 CFR 50, Appendix B – Criterion 3: Design Control

REQUIREMENT (10 CFR 50, Appendix B)
• Document design basis • Need for design specifications and drawings traceable to the design basis • Proper application of QA standards specified in the design documents • Deviations controlled • Selection and suitability of safety-related components • Identification of design interfaces • Design procedures • Verify adequacy of design by design reviews, alternate calculations, suitable testing programs • Independence of person verifying design • Design changes handled in same manner as original design • Qualified staff

EXECUTION EXPECTATION (NQA-1 and NUREG 0800)
• Design input (design criteria controlled) • Control of design documents • Application of quality standards in specifications, drawings, and other design documents • Control of design analyses, use of computer programs that are validated • Controls of computer codes • Controls of design verification process • Staff qualification for design • Design review expectations: traceability from input to output • Requirements specified for qualification tests • Change controls and records of design verification as well as any changes

What would you expect to see during construction inspections?

How does the DCD impact activities?

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10 CFR 50, Appendix B – Criterion 4: Procurement Document Control

REQUIREMENT (10 CFR 50, Appendix B)	EXECUTION EXPECTATION (NQA-1 and NUREG 0800)
• Specification of regulatory, design bases, other requirements in procurement documents • Require contractors and subcontractors to provide a quality assurance program	• Procurement documents should specify provisions for: ○ Scope of work ○ Technical Requirements ○ QA program Requirements ○ Right of access ○ Documentation requirements ○ Reporting of nonconformances ○ 10 CFR 21 requirements ○ Spare and replacement parts ○ Review of suppliers ○ Control of changes

Why is this important?

10 CFR 50, Appendix B – Criterion 5: Instructions, Procedures, and Drawings

REQUIREMENT (10 CFR 50, Appendix B)	EXECUTION EXPECTATION (NQA-1 and NUREG 0800)
• Quality affecting activities shall be prescribed by documented instructions, procedures, or drawings • Should have quantitative and qualitative acceptance criteria	• Need to have a detailed level of procedures and instructions commensurate with the work being performed • Procedures and instructions must contain the quantitative and qualitative acceptance criteria • Tolerances should be specified

Why are procedures and instructions necessary if we have a QAPD?

10 CFR 50, Appendix B – Criterion 6: Document Control

REQUIREMENT (10 CFR 50, Appendix B)	EXECUTION EXPECTATION (NQA-1 and NUREG 0800)
• Measures shall be established to control documents such as instructions, procedures, and drawings, including changes thereto, which prescribe activities affecting quality. • Changes are controlled	• Need for identification of all documents to be controlled • Review of documents for adequacy • Changes to documents need to be reviewed by same organization as original • Correct revision of documents available at work location

How is this requirement met when using electronic document systems?

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10 CFR 50, Appendix B – Criterion 7: Control of Purchased Material, Equipment, and Services

REQUIREMENT (10 CFR 50, Appendix B)	EXECUTION EXPECTATION (NQA-1 and NUREG 0800)

• Measures shall be established to assure that purchased material, equipment, and services, conform to procurement documents
• Provisions for source evaluation and selection, objective evidence furnished by contractor, examination of items upon delivery
• Documentary evidence of conformance to procurement requirements
• Effectiveness of quality control shall be assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services
	• Need for procurement planning
	  ○ What
	  ○ Who
	  ○ How
	  ○ When
	• Evaluation of suppliers (RG 1.28)
	• Verification of capability of suppliers or contractors
	• Must have approved suppliers list
	• Provision for source evaluation and selection
	• Bid evaluation process
	• Supplier performance evaluation
	• Receipt inspection requirements
	• Certificates of conformances
	• Source verification
	• Control of non-conformances 10 CFR 21*
	• Commercial grade items (CGI)*

What if there is only a single source supplier for manufacturing a safety-related item?

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10 CFR 50, Appendix B – Criterion 8: Identification and Control of Materials, Parts, and Components

REQUIREMENT (10 CFR 50, Appendix B)	EXECUTION EXPECTATION (NQA-1 and NUREG 0800)
• Measures shall be established for the identification and control of materials, parts, and components, including partially fabricated assemblies • These measures shall assure that identification of the item is maintained by heat number, part number, serial number on the item or on records traceable to the item • Designed to prevent use of incorrect or defective material, parts, and components	• Item identification • Physical identification • Markings • Identification and traceability of items • Limited life items • Maintaining identification of stored items

Why is traceability important?

What would you expect for marking on items on components?

10 CFR 50, Appendix B – Criterion 9: Control of Special Processes

REQUIREMENT (10 CFR 50, Appendix B)	EXECUTION EXPECTATION (NQA-1 and NUREG 0800)
• Measures shall be established to assure that special processes, including welding, heat treating, and non-destructive testing, are controlled and accomplished by qualified personnel using qualified procedures	• Process control: Instructions, procedures, and drawings • Qualification of personnel • Qualification of procedures and processes • Acceptance criteria • Records • Special Requirements

What are the types of potential problems or issues one could occur in current nuclear facility construction related to this criterion?

Module 3 Activity 1: 10 CFR 50, Appendix B, Criteria 1-9 Review

Let's do a quick review of the first nine criteria.

In this activity, we will match the title of each criteria on the left with a corresponding detail on the right. (Hint: There is one extra detail on the right-hand side than there are criteria on the left.)

Each participant will:

- Partner with 1-2 other participant(s)
- Using 10 CFR 50, Appendix B found in the appendix of the Student Manual or PowerPoint slides 53-61, match each criterion with the appropriate corresponding detail
- Once you have completed the exercise, let the instructor know.
- The class will then review the correct answers together. See how well you did!

10 CFR 50, Appendix B – Criterion 10: Inspection

REQUIREMENT (10 CFR 50, Appendix B)	EXECUTION EXPECTATION (NQA-1 and NUREG 0800)
• Program for inspection of safety related activities to conform with documented instructions, procedures, and drawings • Examinations, measurements, or tests of material or products processed • If inspection of processed material or products is impossible or disadvantageous, indirect control by monitoring processes, methods, equipment, and personnel shall be provided. • Mandatory hold points	• Inspection planning • Reporting independence • Staff Qualification • Inspection hold points • Sampling • In process inspection • Monitoring • Resolution of nonconformances • Inspection requirements • Acceptance • Modifications repairs, or replacements • Inservice inspection • Records

Discuss inspection approaches:
What issues have you encountered or expect to encounter during inspections?

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10 CFR 50, Appendix B – Criterion 11: Test Control

REQUIREMENT (10 CFR 50, Appendix B)	EXECUTION EXPECTATION (NQA-1 and NUREG 0800)
• Establish test program to assure all testing required to demonstrate that structures, systems, and components will operate satisfactorily in service. • Written test procedures • Test program includes pre-operational tests • Test program includes all pre-requisites such as test instrumentation is available, test performed under suitable environmental conditions • Test results documented	• Tests shall be planned, executed, documented, and evaluated • Test requirements and acceptance criteria shall be documented and approved • Test procedures available and approved • Prerequisites: calibrated instrumentation, appropriate equipment, trained personnel, suitable environment, provisions for data acquisition • Documented test results • Test records • Computer program validation and verification • Calculations • Test problems for verification of tests

Describe potential scenarios regarding test completion times (e.g., ITAAC, pre-op, etc).

10 CFR 50, Appendix B – Criterion 12: Control of Measuring and Test Equipment (M&TE)

REQUIREMENT (10 CFR 50, Appendix B)	EXECUTION EXPECTATION (NQA-1 and NUREG 0800)
• Measures shall be established to assure that tools, gages, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods to maintain accuracy within necessary limits	• Control of M&TE • Maintain calibration cycle • Control of out of calibration M&TE • Proper handling and storage of M&TE • Records shall be maintained and equipment shall be marked to indicate status

What would be the NRC's view if a licensee used an out of calibration piece of M&TE for test acceptance?

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10 CFR 50, Appendix B – Criterion 13: Handling, Storage and Shipping

REQUIREMENT (10 CFR 50, Appendix B)	EXECUTION EXPECTATION (NQA-1 and NUREG 0800)
• Measures shall be established to control the handling, storage, and shipping, cleaning, and preservation of material and equipment in accordance with work and inspection instructions to prevent damage or deterioration. • Specify protective environment	• Handling, storage, and shipping of items shall be conducted in accordance with appropriate procedures and instructions • Special handling tools shall be utilized and controlled • Special handling equipment shall be inspected (cranes) • Operators of special handling and lifting equipment shell be experienced and trained in use of equipment • Special marking

Where do you think the emphasis is for today's nuclear facility construction with regards to this criterion?

10 CFR 50, Appendix B – Criterion 14: Inspection, Test, and Operating Status

REQUIREMENT (10 CFR 50, Appendix B)	EXECUTION EXPECTATION (NQA-1 and NUREG 0800)
• Measures shall be established to indicate, by the use of markings such as stamps, tags, labels, routing cards, or other suitable means, the status of inspections and tests performed upon individual items of the nuclear power plant or fuel reprocessing plant. • These measures shall provide for the identification of items which have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent bypassing of such inspections and tests. • Measures shall also be established for indicating the operating status of structures, systems, and components of the nuclear power plant or fuel reprocessing plant, such as by tagging valves and switches, to prevent inadvertent operation	• Status of inspection and tests shall be noted on equipment or traceable • Status to be maintained through marking or segregation • Nonconformance control & historical influence • Lock-out & Tag-out System • Status may be noted on "shop travelers"

What are some of the status systems observed at nuclear facilities, vendors, etc?

Would you expect similar controls in foreign fabricators?

10 CFR 50, Appendix B – Criterion 15: Nonconforming Materials, Parts or Components

REQUIREMENT (10 CFR 50, Appendix B)	EXECUTION EXPECTATION (NQA-1 and NUREG 0800)
• Measures shall be established to control materials, parts, or components which do not conform to requirements in order to prevent their inadvertent use or installation • These measures shall include, as appropriate, procedures for identification, documentation, segregation, disposition, and notification to affected organizations • Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures	• Non-conforming materials ID, disposition & segregation (life-cycle management) • Roles, responsibilities, authorities & accountabilities • Disposition of nonconformances • Stop work authority • Competency of personnel • Repair vs. Rework • Specification of design review and change control methods and risk boundaries • As-built drawing currency

How does this requirement relate to 10 CFR 21? (A brief overview of this document can be found in the Appendix.)

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10 CFR 50, Appendix B – Criterion 16: Corrective Action

REQUIREMENT (10 CFR 50, Appendix B)	EXECUTION EXPECTATION (NQA-1 and NUREG 0800)
• Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and non-conformances are promptly identified and corrected. • In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. • The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.	• Identify basic and causal factors for conditions adverse to quality • Root Cause Analyses and CAPs • Authority commensurate with responsibility • Verify qualifications to develop recommendations to resolve safety-related adverse conditions and preclude recurrence • Verify competency of decision-making process • Determine degree of risk mitigation and probability of recurrence • Follow-up to verify effective corrective action • Search for systemic (or similar) applications • Lessons Learned Program

What are the documents and records you would expect to see to evaluate the corrective action process effectiveness?

10 CFR 50, Appendix B – Criterion 17: Quality Assurance Records

REQUIREMENT (10 CFR 50, Appendix B)	EXECUTION EXPECTATION (NQA-1 and NUREG 0800)
• Sufficient records shall be maintained to furnish evidence of activities affecting quality. • The records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses. • The records shall also include closely-related data such as qualifications of personnel, procedures, and equipment. • Inspection and test records shall, as a minimum, identify the inspector or data recorder, the type of observation, the results, the acceptability, and the action taken in connection with any deficiencies noted. • Records shall be identifiable and retrievable. • Consistent with applicable regulatory requirements, the applicant shall establish requirements concerning record retention, such as duration, location, and assigned responsibility.	• Establish a records system • Validate records • Establish records index • Records index to relate to item or activity (traceability) • Records retention Life-time control of specified quality records • Application of quality standards in identifying, generating, gathering, verifying, handling, storing and retrieving, disposal and disposition of quality records • Control of software and hard-copy • Continual verification of records quality • Records storage redundancy and security • Change controls and records of design verification as well as any changes

What are the expectations relating to lifetime records, and how does changing technology play into consideration?

10 CFR 50, Appendix B – Criterion 18: Audits

REQUIREMENT (10 CFR 50, Appendix B)
• A comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. • The audits shall be performed in accordance with the written procedures or check lists by appropriately trained personnel not having direct responsibilities in the areas being audited. • Audit results shall be documented and reviewed by management having responsibility in the area audited. • Follow-up action, including re-audit of deficient areas, shall be taken where indicated.

EXECUTION EXPECTATION (NQA-1 and NUREG 0800)

• An ordered audit program to specify schedules and provisions for:
  ○ Audit Planning: Purpose and Scope of Audit
  ○ Verification Requirements
  ○ Independence from area being audited
  ○ Right of access & authorities
  ○ Documentation requirements
  ○ Audit reporting
  ○ Responses
• Personnel requirements
• Certified Lead Auditors or team leaders
• Effective close-out of findings
• No repeat findings
• Management accountability

How do you judge effective audit programs for licensees?

What would you look for?

Module 3 Activity 2: NRC Inspection Report Practical Application of 10 CFR 50, Appendix B Criteria

In this exercise, we will review past NRC reports to determine 10 CFR 50, Appendix B application.

Each participant will:

- Form a group of 4-5 individuals
- Using 10 CFR 50, Appendix B found in the appendix of the Student Manual, identify which related criteria are referenced in the report provided to your group.
- Once referenced, determine if there was any violation.
- Once complete, the class will rejoin.
- Each group will present 1-2 of the drafted violation/satisfaction paragraphs to the class.

Objective 4: Understand the Lessons Learned of NUREG 1055

NUREG 1055 – Overview

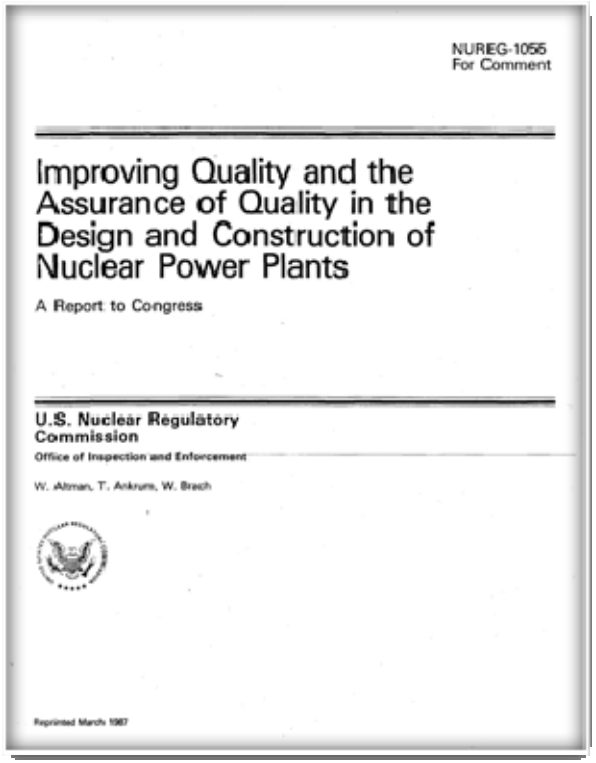
NUREG 1055 came about as a **report to Congress** was written in 1984 that became the **impetus of change** to the current requirements for new nuclear plants 10 CFR 52.

The purpose of this was to **improve quality** and the assurance of quality in the **design and construction** of nuclear power plants.

It **provided lessons learned** that have been reinforced in “NRC Information Notices 2007-04: Construction Experience Related to the Assurance of Quality in the Construction of Nuclear Facilities”.

Sites included:

- Zimmer
- Marble Hill
- South Texas
- Midland
- Diablo Canyon



NUREG 1055 – Program Assumptions

The NRC made a **tacit but incorrect assumption** that there was a **uniform level of industry and licensee competence**.

- NRC **inspection presence** at construction sites was **sporadic** (before the NRC resident inspector program was implemented).
- NRC inspection program was **slow to synthesize** scattered quality-related inspection findings (i.e., not broadcasted)
- **Limited NRC inspection resources** were so prioritized to address operations first, construction second, and design last, that inadequate inspection of the design process resulted.
- The **threshold for reacting to construction-related problems was set higher than for operational problems** because of
  - No immediate threat to public health and safety posed by construction deficiencies,
  - An attitude that construction problems would be found during an intensive period of startup testing prior to issuance of an operating license
  - An attitude that required a project-wide pervasive breakdown to be demonstrated before strong enforcement action would be taken for construction quality problems.

NUREG 1055 – Lessons Learned: Principal Conclusions

The **principal conclusion** of the study is that nuclear construction projects having significant quality-related problems in their design or construction were characterized by the **inability or failure of utility management to effectively implement a management system that ensured adequate control** of all aspects of the project.

Such as:

- Breakdown in QA program part of overall breakdown in project management
- Utilities not prepared for nuclear work
- Design not complete prior to starting construction
- Changing regulatory and political climate
- Failure to implement QA of the design process
- Lack of understanding of QA as a management tool
- Inadequate QA/QC staffing by licensees and contractors
- QA organization responsible for achievement of quality

NUREG 1055 – Lessons Learned

Some important **lessons learned** when problems could occur, **warning signs**:

- A first-time utility with staffs or an architect/engineer, construction manager, or constructors (vendors and fabricators) that have **inadequate nuclear design or construction experience**;
- A very **large growth in the number of nuclear power plants being constructed** that can overwhelm the industry's and NRC's capabilities;
- A long **delay before nuclear plant construction activities start again**, resulting in a dearth of experience in the industry;
- **Regulatory actions** at federal and state levels **that undercut quality**.

NUREG 1055 – Focus of the Inspection Program

The inspection program was oriented to **focus heavily on paperwork** at the expense of examining either actual work in progress or QA program implementation.

The inspection program **focused on detail** rather than on whether the overall management process for the project was working.

Sample Projects include:

- Zimmer
- Marble Hill
- South Texas
- Midland
- Diablo Canyon

Why was this a problem?

NUREG 1055 – Workshop, Task 1

In this workshop, we will **complete two tasks**: 1) consider an applicant for COL approval based on a situational study and 2) through a sample case study debate the actions of a licensee with regards to the related regulations, policies and procedures.

For the NUREG 1055 Workshop, Task 1 -

Each participant will:

- Break into group of 4-5 participants
- Meet in your respective groups.
- What elements/concerns would need to be considered in this situation based on the lessons learned from NUREG 1055?
- Support your decision based on NRC requirements.
- Identify what you documents you would need to review and evaluate to make a decision.
- Determine what criteria should apply to your decision on whether or not this applicant should be considered.
- Consider the applicable portions of NUREG 1055 lessons learned and use this in your decision making.
- Present your results to the class

NUREG 1055 – Workshop, Task 2

For the NUREG 1055 Workshop, Task 2 -

Each participant will:

- Break into group of 4-5 participants
- Determine:
  - What Lessons did NRC learn from this situation?
  - What actions did NRC take to address the problems?
  - Present your results to the class.

Module 3 Review

For the Module 3 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 3: Summary

In this section we have covered:

1. **The purpose, application and expectations of the 10 CFR 50, Appendix B**
2. **The 18 criteria requirements of 10 CFR 50, Appendix B**
3. **How the 10 CFR 50, Appendix B drives development of industry standards such as the NQA-1**
4. **Lessons learned from the NUREG 1055**

Module 4: Identify QA Principles in Perspective with Regulatory Requirements and Enforcements

Learning Objectives

1. **Understand the requirements of NUREG 0800 Standard Review Plan (SRP) for the Review of Safety Analysis Reports for Nuclear Facilities**

2. **Identify correlations between 10 CFR 50, Appendix B and NEI 06-14**

3. **Understand the purpose, application, and process of Safety Evaluation Reports (SER)**

4. **Review QA Program Template and sample approved commercial QAPD**

Objective 1: Understand the requirements of NUREG 0800 (SRP) for the Review of Safety Analysis Reports for Nuclear Facilities

NUREG 0800 Standard Review Plan (SRP) at a glance

The **NUREG 0800 SRP**:

- Provides **guidance to the licensing project manager** and all review organizations performing the review of the material contained in the applicant's safety analysis report
- Covers the **technical and administrative requirements**
- Contains 19 chapters

NUREG 0800 Standard Review Plan (SRP) – Chapter 17

Chapter 17 is entitled “Quality Assurance” and provides guidance on:

- 17.1: QA during the Design and Construction Phases
- 17.2: QA during the Operations Phase
- 17.3: QA Program Description (QAPD)
- 17.4: Reliability Assurance Program (RAP)
- 17.5: QAPD Design Certification, Early Site Permit and New License Applicants
- 17.6: Maintenance Rule

Which parts of Section 17 would you expect to use, reference, or be involved with in your positions?

Why?

NUREG 0800 – 17.1 Quality Assurance During the Design Phase

The **applicant** (and its principal contractors such as the NSSS vendor, A/E, constructor and construction manager) **must establish a QA program for the design and construction phases** in accordance with Appendix B to 10 CFR Part 50.

Section 17.1 provides for the submittal of a **description of the quality assurance (QA) program** for the **design and construction phases** in each application for:

- A construction permit (CP),
- A manufacturing license, or
- A standardized design approval in accordance

with the applicable portion of this section of the SRP.

For the case of construction permits (CP):

When referencing a standard design that includes an approved QA program directly or by reference, the applicant does not need to conform to new or revised regulatory guides unless they contain regulatory positions determined to be significant to safety, as indicated in the implementation section of each guide.

NUREG 0800 – 17.2 QA during the Operations Phase

Section 17.2 explains that the applicant must:

- **Establish a QA program for the operations phase**, including activities such as operation, maintenance, and modification of the nuclear power plant,
- Establish the QA Program **in accordance with Appendix B to 10 CFR 50**

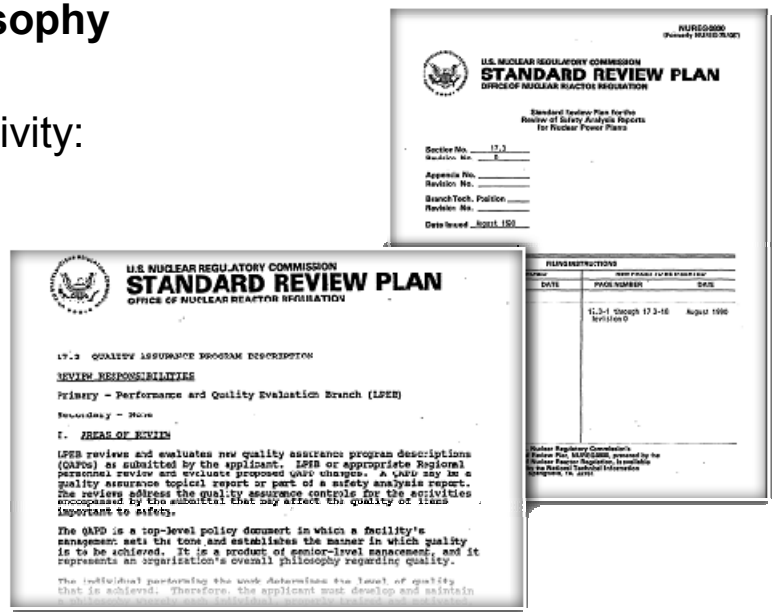
The QA program description (QAPD) presented in the FSAR **must discuss how each criterion of Appendix B will be met.**

This section also **provides guidelines for review of QA programs based upon** American National Standards Institute **(ANSI) N45.2**, Quality Assurance Program Requirements for Nuclear Power Plants and its daughter standards.

NUREG 0800 – 17.3 QAPD

Section 17.3 details the QAPD, which is:

- A **top-level policy document** in which a facility's management sets the tone and establishes the manner in which quality is to be achieved.
- A product of senior-level management,
- Represents an **organization's overall philosophy regarding quality**.
- Organized into the three discrete areas of activity:
  - Management,
  - Performance/Verification, and
  - Self-assessment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17.3 QUALITY ASSURANCE PROGRAM DESCRIPTION

REVIEW RESPONSIBILITIES

Primary - Performance and Quality Evaluation Branch (LPEB)

I. AREAS OF REVIEW

LPEB reviews and evaluates new quality assurance program descriptions (QAPDs) as submitted by the applicant. LPEB or appropriate Regional personnel review and evaluate proposed QAPD changes. A QAPD may be a quality assurance topical report or part of a safety analysis report. The reviews address the quality assurance controls for the activities encompassed by the submittal that may affect the quality of items important to safety.

The QAPD is a top-level policy document in which a facility's management sets the tone and establishes the manner in which quality is to be achieved. It is a product of senior-level management, and it represents an organization's overall philosophy regarding quality.

NUREG 0800 – 17.3 QAPD

Section 17.3 provides guidelines for **review of a QAPD** developed following American Society of Mechanical Engineers (ASME) Standards:

- NQA-1, “Quality Assurance Program for Nuclear Facilities,” and
- NQA-2, “Quality Assurance Requirements for Nuclear Facility Applications”

NUREG 0800 – 17.4 Reliability Assurance Program (RAP)

Section 17.4 provides **guidance for reviewing reliability assurance programs (RAPs).**

The RAP provides reasonable assurance that:

- An **advanced reactor** is designed, constructed, and operated in a manner that is **consistent with the assumptions and risk insights for risk-significant structures, systems, and components (SSCs)**
- The risk-significant **SSCs do not degrade to an unacceptable level**.

NUREG 0800 17.5 – Design Certification, Early Site Permits, and New License Applicants: Overview

The QA staff reviews and evaluates QA program descriptions (QAPDs) submitted by applicants for a:

- Design certification (DC),
- Combined license (COL),
- Early site permit (ESP),
- Construction permit (CP), and
- Operating license (OL)

QAPDs submitted by applicants for DC, COL, ESP, CP, and OL are **reviewed and evaluated in accordance with the applicable sections of the SRP**.

NUREG-0800

U.S. NUCLEAR REGULATORY COMMISSION

STANDARD REVIEW PLAN

17.5 QUALITY ASSURANCE PROGRAM DESCRIPTION - DESIGN CERTIFICATION, EARLY SITE PERMIT AND NEW LICENSE APPLICANTS

REVIEW RESPONSIBILITIES

Primary - The organization responsible for quality assurance (QA)

Secondary - None

I. AREAS OF REVIEW

The QA staff reviews and evaluates QA program descriptions (QAPDs) submitted by applicants for a design certification (DC), combined license (COL), early site permit (ESP), construction permit (CP), and operating license (OL). QAPDs submitted by applicants for DC, COL, ESP, CP, and OL are reviewed and evaluated in accordance with the applicable sections of this standard review plan (SRP).

A QAPD submitted by a DC applicant may be a QA topical report or part of a safety analysis report (SAR). A QAPD submitted by a DC applicant would only address design QA activities in support of a DC. The QAPD would not address construction and design QA activities that occur once construction begins. The QAPD submitted by the DC applicant would be reviewed and evaluated by the NRC prior to NRC approval of the DC.

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USNRC STANDARD REVIEW PLAN

NUREG 0800 17.5 – Design Certification, Early Site Permits, and New License Applicants: Applicants

A QAPD submitted by a **DC applicant**:

- May be a QA topical report or part of a safety analysis report (SAR)
- Would only address design QA activities in support of a DC and not construction activities.

A QAPD submitted by a **COL applicant**:

- Applies to all phases of a facility's life, including design, construction, and operation.
- May address construction and operational QA activities in separate QAPDs.

A QAPD submitted by an **ESP applicant**:

- Would apply to site suitability QA activities.

DC, ESP, CP, OL, and COL applicants are identified as an "applicant" and COL holders are identified as a "holder" throughout this Section 17.5.

NUREG 0800 17.5 – Design Certification, Early Site Permits, and New License Applicants: Applicants cont'd

An applicant is required to **identify differences between** the:

- Design features,
- Analytical techniques, and
- Procedural measures proposed for its facility and the SRP acceptance criteria 17.5-6 March 2007

► The applicant must provide a detailed description of the differences between their submittal and the Standard Review Plan acceptance criteria.

The applicant is also required to **evaluate** how the proposed alternatives to the SRP acceptance criteria provide **acceptable methods of compliance** with the NRC regulations.

NUREG 0800 17.5 – Design Certification, Early Site Permits, and New License Applicants: QA Program

Section 17.5 outlines a standardized QA program for DC, ESP, CP, OL and COL applicants and holders.

SRP Section 17.5 is **based on**:

- ASME standard NQA-1 (1994 Edition)
- Regulatory Guide (RG) 1.8, “Qualification and Training of Personnel for Nuclear Power Plants,” Revision 3
- RG 1.28, “Quality Assurance Program Requirements (Design and Construction),” Revision 3
- RG 1.33, “Quality Assurance Program Requirements (Operation),” Revision 2, and
- NRC Review Standard (RS)-002, “Processing Applications for Early Site Permits”

NUREG 0800 17.5 – Design Certification, Early Site Permits, and New License Applicants: Additional Criteria

In addition to the 18 criteria of 10 CFR 50, Appendix B, **Section 17.5 adds five additional subject areas**:

- Training and qualification-QA
- Training and qualification-inspection and test
- QA program commitments
- Non safety-related Structures, Systems, and Components (SSC) QC
- Independent review

Module 4 Activity 1: NUREG 0800, Section 17.5 Search and Discover

Let's do a quick review of NUREG 0800 (SRP) 17.5.

In this activity, we will do a scavenger hunt for 15 answers found throughout Section 17.5.

Each participant will:

- Partner with 3-5 other participants
- Using Section NUREG 0800 17.5, identify the appropriate answers (including reference location) for each question
- Once you have completed the activity, let the instructor know.
- The class will then review the correct answers together. See how well you did!

NUREG 0800 17.6 – Maintenance Rule

Section 17.6 addresses the Maintenance Rule program based on the requirements of 10 CFR 50.65.

Specific areas of review are:

- Scoping
- Monitoring
- Periodic evaluation
- Maintenance risk assessment and management
- Maintenance rule training and qualification
- Interface with RAP
- Maintenance Rule program implementation

Objective 2: Identify correlations between 10 CFR 50, Appendix B and NEI 06-14

NEI 06-14 Quality Assurance – Overview

The Nuclear Energy Institute **(NEI) 06-14** provides a template for **establishing a top-level policy** document that:

- Defines the quality policy and
- Assigns major functional responsibilities that conforms to NUREG 0800, 10 CFR 50 Appendix B, and the nuclear industry standards NQA-1.

This technical report was developed by the NEI New Plant Quality Assurance Task Force for use by early site permit (ESP) applicants and combined license (COL) applicants and holders **for new plant construction and operation**.

In addition, NEI 06-14:

- Provides **additional guidance for new plant owners**, particularly to 10 CFR 50, Appendix B.
- Was **approved by the NRC** as an **acceptable format for a QAPD.**

NEI 06-14 Quality Assurance – Criteria 1-3

In relation to *10 CFR 50, Appendix B,* ***Criterion 1: Organization*****,** the NEI 06-14 states that:

- The QAPD template allows management to size the quality assurance organization commensurate with the duties and responsibilities assigned

In relation to *10 CFR 50, Appendix B,* ***Criterion 2: Quality Assurance Program*****,** the NEI 06-14 indicates that:

- The QAPD template also provides the minimum training requirements for managers responsible for QAPD implementation, in addition to the minimum training requirements for the individual responsible for planning, implementing, and maintaining the QAPD. The QAPD template follows draft SRP Section 17.5, paragraph II.W for providing guidance

In relation to *10 CFR 50, Appendix B,* ***Criterion 3: Design Control*****,** the NEI 06-14 establishes that:

- The necessary measures to control the design, design changes, and temporary modifications (e.g., temporary bypass lines, electrical jumpers and lifted wires, and temporary setpoints) of items that are subject to the provisions of the QAPD.

NEI 06-14 Quality Assurance – Criteria 4-6

In relation to *10 CFR 50, Appendix B,* ***Criterion 4: Procurement Document Control*****,** NEI 06-14 establishes that:

- The QAPD proposes that procurement documents allow the supplier to work under the applicant's QAPD, including implementing procedures, in lieu of the supplier having its own quality assurance program.
  - Procurement documents for commercial-grade items that the applicant or holder will procure as safety-related items shall contain technical and quality requirements such that the procured item can be appropriately dedicated.

In relation to *10 CFR 50, Appendix B,* ***Criterion 5: Instructions, Procedures, and Drawings*****,** the NEI 06-14 establishes:

- No new guidance that differs from NUREG 0800 or 10 CFR 50 App B

In relation to *10 CFR 50, Appendix B,* ***Criterion 6: Document Control*****,** the NEI 06-14 establishes:

- If temporary procedure changes are necessary during the operational phase, changes that clearly do not alter the intent of the approved procedure may be implemented provided that **two members** of the staff knowledgeable in the areas affected by the procedure approve the changes.

NEI 06-14 Quality Assurance – Criterion 7

In relation to *10 CFR 50, Appendix B,* ***Criterion 7: Control of Purchased Material, Equipment, and Services*****,** the NEI 06-14 proposes that:

- Other 10 CFR Part 50 licensees (i.e., other than the applicant or holder), authorized nuclear inspection agencies, the National Institute of Standards and Technology (NIST), and other State and Federal agencies that may **provide items or services to the applicant or holder are not required to be evaluated or audited.**
- **Procurement source evaluation and selection measures is not required**, provided each of the following conditions are met:
  - Purchase documents **for commercial grade calibration services** impose additional technical and administrative requirements to satisfy QAPD and technical requirements
  - Purchase documents require reporting as-found calibration data when calibrated items are found to be out of tolerance
  - A documented review of the supplier's accreditation will be performed and will include a verification of the following:
    - The calibration laboratory holds a domestic accreditation by the National Voluntary Laboratory Accreditation Program (NVLAP) or the American Association for Laboratory Accreditation, as recognized by NVLAP through the International Laboratory Accreditation Cooperation Mutual Recognition Arrangement.
    - The accreditation is based on ANS/ISO/IEC 17025
    - The published scope of the accreditation for the calibration laboratory

NEI 06-14 Quality Assurance – Criteria 8-10

In relation to *10 CFR 50, Appendix B,* ***Criterion 8: Identification and Control of Materials, Parts, and Components*****,** the NEI 06-14 proposes that:

- The identification of items is maintained throughout fabrication, erection, installation, and use so that the item can be **traced** to its documentation, consistent with the item's effect on safety.

In relation to *10 CFR 50, Appendix B,* ***Criterion 9: Control of Special Processes*****,** the NEI 06-14 proposes that:

- No unique requirements above SRP and industry standards.

In relation to *10 CFR 50, Appendix B,* ***Criterion 10: Inspection*****,** the NEI 06-14 proposes that:

- The QAPD template commits the applicant or licensee, as applicable, to the definition of safety systems equipment from IEEE 603-1980 but does not commit the applicant or holder to the balance of IEEE 603-1980.
  - The following is the definition of safety system in IEEE 603-1980:
    - Those systems (the reactor trip system, an engineered safety feature, or both, including all their auxiliary supporting features and other auxiliary feature) which provide a safety function. A safety system is comprised of more than one safety group of which any one safety group can provide the safety function.

NEI 06-14 Quality Assurance – Criteria 11-12

In relation to *10 CFR 50, Appendix B,* ***Criterion 11: Test Control*****,** the NEI 06-14:

- Commits to NQA-1 1984 Supplement 11S-2 for computer software used in applications affecting safety

In relation to *10 CFR 50, Appendix B,* ***Criterion 12: Control of Measuring and Test Equipment*****,** the NEI 06-14 proposes that:

- As an alternative to the NQA-1-1994, Subpart 2.4, Section 7.2.1, calibration labeling requirements, the required calibration information be maintained in suitable documentation traceable to the device for measuring and test equipment which is impossible or impractical to mark because of equipment size or configuration.
- This alternative is consistent with the staff guidance provided in draft SRP 17.5, paragraph II.L.3.

NEI 06-14 Quality Assurance – Criteria 13-14

In relation to *10 CFR 50, Appendix B,* ***Criterion 13: Handling, Storage and Shipping*****,** the NEI 06-14 proposes that:

- As an alternative to the NQA-1-1994, Subpart 2.2, Section 6.6, "Storage Records," the QAPD template provides for documents to establish control of storage areas that describe those authorized to access the area and the requirements for recording access of personnel.
- The QAPD template proposes not to consider these records as quality records.
- The plants will retain these records in accordance with the plants' administrative controls.
- The staff determined that the proposed alternative is acceptable, on the basis that these records do not meet the classification of a quality record as defined in NQA-1-1994, Supplement 17S-1, Section 2.

In relation to *10 CFR 50, Appendix B,* ***Criterion 14: Inspection, Test, and Operating Status*****,** the NEI 06-14 proposes that:

- No special requirements beyond the industry standards or NUREG-0800.

NEI 06-14 Quality Assurance – Criteria 15-16

In relation to *10 CFR 50, Appendix B,* ***Criterion 15: Nonconforming Materials, Parts, or Components*****,** the NEI 06-14 proposes that:

- Nonconformances are evaluated for their impact on operability of quality SSCs to ensure that the final condition does not adversely affect safety, operation, or maintenance of the item or service.
- Results of evaluations of conditions adverse to quality are analyzed to identify quality trends, documented, and reported to **upper management** in accordance with applicable procedures.

In relation to *10 CFR 50, Appendix B,* ***Criterion 16: Corrective Action*****,** the NEI 06-14 proposes that:

- Reports of conditions adverse to quality are analyzed to identify trends. **Significant conditions adverse to quality** are documented and reported to responsible management. In the case of suppliers working on safety-related activities or similar situations, the applicant or holder, as applicable, may delegate specific responsibility for the corrective action program, but the applicant or holder maintains responsibility for the program's effectiveness.
  - The QAPD template provides for establishing the necessary measures to implement a program to identify, evaluate, and report defects and noncompliances in accordance with the requirements of 10 CFR 50.55(e) and/or 10 CFR Part 21, as applicable.

NEI 06-14 Quality Assurance – Criteria 17-18

In relation to *10 CFR 50, Appendix B,* ***Criterion 17: Quality Assurance*** **Records,** the NEI 06-14 proposes that:

- As an **alternative** to the NQA-1-1994, Supplement 17S-1, Section 4.2(b), requirements for records to be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets or on shelving in containers, the QAPD template proposes that hard records be stored in steel cabinets or on shelving in containers, except that methods other than binders, folders, or envelopes may be used to organize records for storage.

In relation to *10 CFR 50, Appendix B,* ***Criterion 18: Audits*****,** the NEI 06-14 proposes that:

- Internal audits are performed with a frequency commensurate with safety significance and in such a manner as to ensure that an audit of all applicable quality assurance program elements is completed for each functional area within a period of 2 years after the determination that the program is well established.

NEI 06-14 Quality Assurance – Non-safety Related Safety System Components (SSC)

Nonsafety-Related SSCs are significant contributors to plant safety.

The QAPD template:

- Follows the guidance of draft SRP Section 17.5, paragraph II.V.1, for **establishing specific program controls** applied to nonsafety-related SSCs that are significant contributors to plant safety and to which Appendix B does not apply
- Applies specific controls to those items in a selected manner, **targeting those characteristics or critical attributes** that render the SSC a significant contributor to plant safety consistent with applicable sections of the QAPD

Objective 3: Understand the purpose and application of Safety Evaluation Reports (SER) process

Final Safety-Evaluation Reports (FSERs) – Objectives

The purpose of a final safety evaluation report (FSER):

- Is to ensure that there are no significant safety-related hazards
- And that an analysis of potential safety-related issues has been performed

The SER indicates the **acceptance of the docketed submittal** and becomes a **reference document** in the Combined License Application (COLA) under 10 CFR 52.

COL applicants will also be subject to the requirements of:

- 10 CFR Part 52, Subpart C, “Combined Licenses,” and
- Any requirements resulting from the staff’s review of this standard design.

Final Safety-Evaluation Reports (FSERs) – Section 17 QA conclusion

COLA-related QAPDs are reviewed to identify issues with regard to QA implementation audits, lack of ability to validate and verify compliance, and any **exceptions taken to various regulatory guides (RGs).**

The staff reach **conclusions** regarding adherence to NUREG 0800 Section 17.5 to determine that the licensee:

- Maintains a QA program reviewed and approved by the NRC that **complies with the requirements of 10 CFR Part 50, Appendix B**.
- Provides an **adequate basis for all exceptions to the regulatory positions** contained in QA-related RGs.
- **Identifies appropriately graded QA guidelines** regarding the QA controls applied to non-safety-related SSCs within the Regulatory Treatment of Non-Safety Systems (RTNSS) process for this risk-significant equipment.

Safety Analysis Reports – Process

Background – Safety Analysis Reports (SARs)

Preliminary SAR (PSAR) and Final (FSAR) are documents produced by Applicant for the NRC. They describe site and facility, and licensee commitments in administration, construction, operation, radiation protection, waste management, emergency planning, and physical security.

- PSAR and FSAR contents are prescribed in 10 CFR 50.34(a) and (b)

- PSAR is reviewed by NRC during CP process
- FSAR is reviewed by NRC during OL process.
- PSAR remains substantially unchanged after issuance of CP
- FSAR is developed during construction (from PSAR), and incorporates changes due to changes in design, equipment, and regulatory requirements

Final Safety-Evaluation Reports (FSERs) – Process (Cont'd)

- NRC Staff documents PSAR or FSAR review results in an SER and supplements (SSERs)
- Separate SER and SSERs are developed for PSAR and for FSAR for a given facility
- The process outlined by the FSERs provides:
  - Basis for decision, and
  - Provides details for issuing the SER

What changed in the SER process due to 10 CFR 52 regulations?

Final Safety-Evaluation Reports (FSERs) – Process (Cont'd)

One-Step Licensing (or Combined Licenses) is discussed in 10CFR52, Subpart C (sections 52.71 through 52.103)

- The OL Review is combined into the CP Review which ends with the issuance of a combined CP-OL (or COL). The Applicant produces only one SAR, it must contain all the information that is required for both a CP and an OL.
- SAR will be updated periodically throughout plant construction and operation. Feasible because design finalization occurs much earlier in the design-construction process than for first generation plants.
- The NRC issues one SER (with supplements) and the Advisory Committee on Reactor Safeguards (ACRS) conducts one review of the facility.

Module 4 Activity 2: Determination Approval of QAPD Samples

In this activity, we will review the actual Quality Assurance Program Descriptions (QAPD) to compare requirements of 10 CFR 50, Appendix B with the requirements of NUREG 0800 and NEI 06-14.

Each participant will:

- Form four groups
- Choose 1 criteria of 10 CFR 50, Appendix B to identify within the provided QAPD
- Compare the QAPD against NUREG 0800 and NEI 06-14 (as provided in this PowerPoint) to note the added depth they provide to 10 CFR 50, Appendix B requirements
- Answer the following questions:
  - Does the applicant commit to NQA-1?
  - If not, why not? How? Were any exceptions taken?
- As a group, prepare your answers on paper or flip chart, as provided.

Module 4 Review

For the Module 4 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 4: Summary

In this section, we have covered:

1. **The NUREG 0800 (SRP)**

2. **The NEI 06-14 as it relates to the 10 CFR 50, Appendix B and as a guidance document to meet NUERG 0800 for new facilities**

3. **Safety Evaluation Reports (SER)**

4. **Application of NEI 06-14 as it relates to QAPD submissions**

Module 5: NRC Requirements Related to Inspection and Commercial Grade Dedication

Learning Objectives

1. **Develop an understanding of 10 CFR 21, the relationship to procurement and vendors, and responsibilities of licensees for implementation**

2. **Identify the requirements of Commercial Grade Items (CGIs) in NRC IPs 43004 and 38703**

3. **Understand NRC QA Procedures through Inspection Procedures 35021, 35752 and 40504**

4. **Understand NRC Inspection Procedures through 10 CFR 52, NRC IPs 65001, 36100, 35017 and Generic Letter 91-05**

5. **Identify NRC concerns regarding counterfeit parts as identified in NRC Generic Letter 89-02**

Objective 1: Develop an understanding of 10 CFR 21, the relationship to procurement and vendors, and responsibilities of licensees for implementation

10 CFR 21 – Reporting of Defects and Noncompliance: Overview

10 CFR 21 establishes the **requirement** to **immediately notify** the NRC:

- Of the **reasonable potential** of **substantial safety hazards,** followed by
- **Written notification** of evaluation results whether the **facility, activity, or basic component supplied** to such a facility or activity contains **defects**, which could create a substantial safety hazard.

Exemption: Suppliers of commercial grade items are exempt from the provisions of this part to the extent that they supply commercial grade items.

10CFR 50.55(e) applies to holders of construction permits and COLs under 10 CFR 52, and establishes the **requirement to evaluate** deviations and failures to comply to identify defects and failures to comply associated with substantial safety hazards, **and to notify** the NRC of **defects** which could create a substantial safety hazard.

10 CFR 21 – Reporting of Defects and Noncompliance: Definitions: Defect

Defect means:

- A deviation in a basic component that **could create a substantial safety hazard**
- The installation, use, or operation of a basic component containing a defect
- A deviation in a portion of a facility subject to the:
  - Early site permit,
  - Standard design certification,
  - Standard design approval,
  - Construction permit,
  - Combined license or manufacturing licensing requirements of part 50 or part 52, provided the **deviation could create a substantial safety hazard**, and the portion of the facility containing the deviation has been offered to the purchaser for acceptance
- A condition or circumstance involving a basic component that could contribute to the **exceeding of a safety limit**, or
- An error, omission or other circumstance in a design certification, or standard design approval that could create a substantial safety hazard.

10 CFR 21 – Reporting of Defects and Noncompliance: Definitions: Basic Component, Deviation, Evaluation, Non-Conformance

Basic Component:

- A safety-related item. It includes design, inspection, testing or consulting services important to safety that are associated With the component hardware, whether these services are performed by the component supplier or other

Deviation:

- A departure from the technical requirements included in a procurement document, or specified in early site permit information, a standard design certification or standard design approval.

Evaluation:

- The process of determining whether a particular deviation could create a substantial hazard or determining whether a failure to comply is associated with a substantial safety hazard.

Non-conformance:

- Failure to meet a specification or requirement of 10 CFR 50, Appendix B.

10 CFR 21 – Reporting of Defects and Noncompliance: Definitions: Notification, Substantial Safety Hazard

Notification:

- The telephonic communication to the NRC Operations Center and written transmittal of information to the NRC Document Control Desk.
- Two working days are allotted from notification to phone call to the NRC
- Within 30 days, must provide final report.

Substantial safety hazard:

- A loss of safety function to the extent that there is a major reduction in the degree of protection provided to public health and safety for any facility or activity licensed or otherwise approved or regulated by the NRC, other than for export.

10 CFR 21 – Reporting of Defects and Noncompliance: Commercial Grade Item (CGI)

When applied to nuclear power plants licensed pursuant to 10 CFR Part 30, 40, 50 (specifically 50.55(e)), 52, 60, commercial grade item:

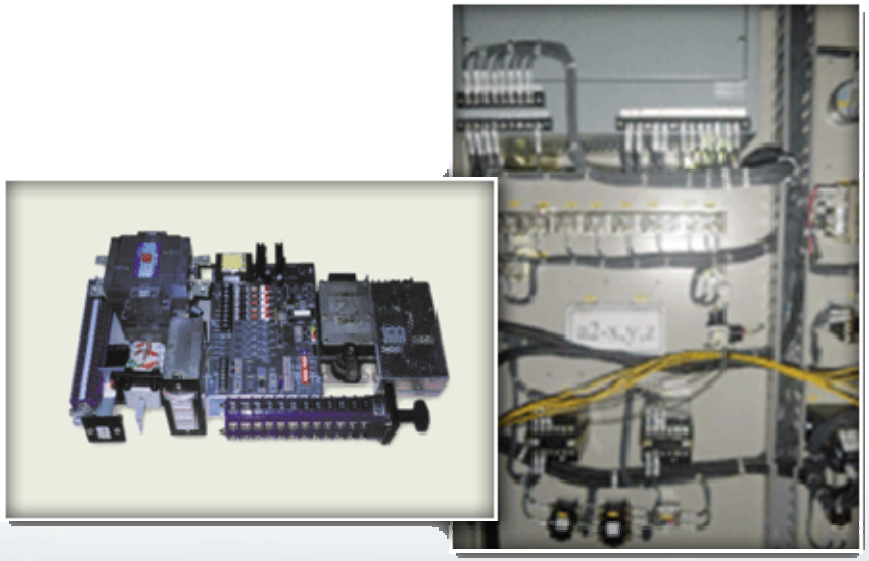
- Is a structure, system, or component, or part thereof that **affects its safety function**, that was not designed and manufactured as a basic component.
- does not include items where the design and manufacturing process require in-process inspections and verifications to ensure that defects or failures to comply are identified and corrected (i.e., one or more critical characteristics of the item cannot be verified).



10 CFR 21 – Reporting of Defects and Noncompliance: Commercial Grade Item (CGI) cont'd

When applied to facilities and activities licensed pursuant to 10 CFR Parts 20, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71 or 72, commercial grade item means that it is:

- **Not subject to design or specification requirements** that are unique to those facilities or activities;
- **Used in applications other than those facilities or activities**; and
- To be ordered from the manufacturer/supplier on the basis of specifications set forth in the manufacturer's published product description (e.g., a catalog).



10 CFR 21 – Reporting of Defects and Noncompliance: Dedication

When applied to nuclear power plants licensed pursuant to 10 CFR Part 30, 40, 50, 60 dedication is:

- An **acceptance process** undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended safety function and,
- **Deemed equivalent** to an item designed and manufactured under a 10 CFR 50, Appendix B, quality assurance program.

This assurance is achieved by:

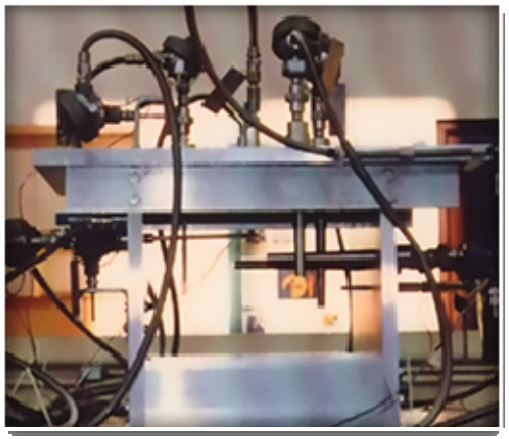
- **Identifying the critical characteristics** of the item and
- **Verifying their acceptability** by inspections, tests, or analyses performed by the purchaser or third-party dedicating entity after delivery, supplemented as necessary by one or more of the following:
  - Commercial grade surveys
  - Product inspections or **witness and hold points** at the manufacturer's facility, and
  - Analysis of historical records for acceptable performance. In all cases, the dedication process must be conducted in accordance with the applicable provisions of 10 CFR Part 50, appendix B.

10 CFR 21 – Reporting of Defects and Noncompliance: Dedication cont'd

When applied to facilities and activities licensed pursuant to 10 CFR Parts 30, 40, 50 (other than nuclear power plants), 60, 61, 63, 70, 71, or 72, dedication:

- Occurs after receipt when that item is designated for use as a basic component, if licensee is conducting the dedication, as opposed to a 3rd party.

The **process is considered complete** when the item is designated for **use as a basic component**.

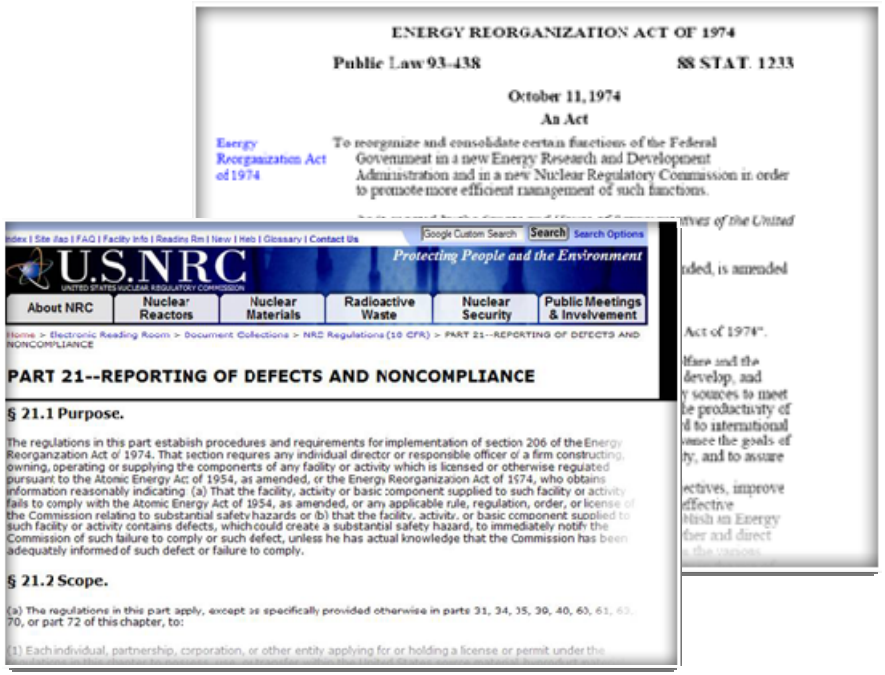


10 CFR 21 – Reporting of Defects and Noncompliance: Posting

Each individual, partnership, corporation, dedicating entity, or other entity subject to the regulations in this part shall post current copies of --

- The regulations in 10 CFR 21
- Section 206 of the Energy Reorganization Act of 1974, and
- Procedures adopted pursuant to the regulations in this part

These **documents must be posted in a conspicuous position** on any premises within the United States where the activities subject to 10 CFR 21 are conducted.



A similar posting requirement exists for 10CFR 50.55(e).

10 CFR 21 – Reporting of Defects and Noncompliance: Procedures for Notification: Evaluations and Deviations

Permit holders and licensees are required to adopt appropriate **procedures** for notification of failure to comply (or existence of a defect and its evaluation). Any facility subject to this regulation must adopt the following appropriate procedures, including to:

- **Evaluate deviations and failures** to comply to identify defects and failures to comply associated with substantial safety hazards, in all cases **within 60 days** of discovery,
  - If such an evaluation cannot be completed **within 60 days**, an **interim report** must be prepared and submitted to the Commission.
  - The interim report should:
    - » Describe the deviation or failure to comply that is being evaluated
    - » Should also state when the evaluation will be completed.
    - » Be submitted in writing within 60 days of discovery of the deviation or failure to comply.
- Ensure that a director or responsible officer subject to the regulations of this part is informed in all cases, **within the 5 working days** after completion of the evaluation

The **dedicating entity** is responsible for :

- Identifying and evaluating deviations
- Reporting defects and failures to comply for the dedicated item, and
- Maintaining auditable records of the dedication process

A similar requirement exists for 10 CFR 50.55(e).

10 CFR 21 – Reporting of Defects and Noncompliance: Procedures for Notification:10 CFRs 21 and 50.55(e)

REQUIREMENT 10 CFR 21	REQUIREMENT 10 CFR 50.55(e)
• **Initial notification by facsimile** to the NRC Operations Center **within 2 days** following receipt of information by the director or responsible corporate officer on the identification of a defect or a failure to comply. **Does not apply to interim reports**. • **Written notification** to **NRC's Document Control Desk within 30 days** following receipt of information by the director or responsible corporate officer on the identification of a defect or a failure to comply.	• **Initial notification is by facsimile** to the NRC Operations Center **within 2 days** following receipt of information by the director or responsible corporate officer on the identification of a defect or a failure to comply. • **Written notification** shall be submitted **to the NRC Document Control Desk**, with a **copy to the appropriate Regional Administrator** and **a copy to the appropriate NRC resident** inspector **within 30 days** following receipt of information by the director or responsible corporate officer of a defect or a failure to comply.

10 CFR 21 – Reporting of Defects and Noncompliance: Failure to Notify

Failure to notify refers to:

- **Any director or responsible officer of an entity** (including dedicating entity) who **knowingly and consciously fails to provide the notice** required as by § 21.21.

- **Any NRC licensee or applicant for a license** (including an applicant for, or holder of, a permit), applicant for a design certification **who fails to provide the notice** required by § 21.21, or otherwise fails to comply with the applicable requirements.

10 CFR 21 – Reporting of Defects and Noncompliance: Procurement Documents

Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations should **ensure that each procurement document** for a facility, or a basic component issued by him, her or it on or after January 6, 1978, **specifies that the provisions of 10 CFR Part 21 apply**.

How would you expect to see this requirement met?

How would it be accomplished?

10 CFR 21 – Reporting of Defects and Noncompliance: Inspection

Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part **must permit the Commission to inspect records, premises, activities, and basic components** as necessary to accomplish the purposes of this part.

10 CFR 21 – Reporting of Defects and Noncompliance: Records

REQUIREMENT 10 CFR 21	REQUIREMENT 10 CFR 50.55(e)
• **Retain evaluations** of all deviations and failures to comply for a **minimum of 5 years after the date of the evaluation**;	• **Retain records of evaluations** of all deviations and failures to comply under paragraph for …**minimum of 10 years after the date of the evaluation**; • **Retain records of all interim reports** to the Commission….for the minimum time period of **10 years** • Maintaining records in accordance with this section satisfies the recordkeeping obligations under Part 21

In **coordination with 10 CFR Part 21**, the requirements of **50.55(e)** are satisfied when the defect or failure to comply associated with a substantial safety hazard **has been previously reported under Part 21 or under 50.55(e).**

10 CFR 21 – Reporting of Defects and Noncompliance: Maintenance and Inspection of Records

Each individual, corporation, partnership, dedicating entity, or other entity subject to the regulations in this part must **prepare and maintain records**, specifically:

- **Retain evaluations of all deviations and failures** to comply for a **minimum of five years** after the date of the evaluation

Applicants for standard design certification **must comply with subparts B and E of Part 52.**

The Commission must be **granted the opportunity** to inspect records pertaining to basic components that relate to:

- The identification and evaluation of deviations, and
- the reporting of defects and failures to comply, including (any advice given to purchasers or licensees on the placement, erection, installation, operation, maintenance, modification, or inspection of a basic component.

Module 5 – Objective 1 Review

For the Module 5 – Objective 1 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

Objective 2: Identify the requirements of Commercial Grade Items (CGIs) in NRC IPs 43004 and 38703

Commercial Grade Items (CGI) Requirements – Background

Commercial Grade Dedication is required based on the following:

- Because of the decrease in the number of qualified nuclear-grade vendors, **licensees are increasing the number of commercial grade replacement parts** that they procure and dedicate for use in safety-related applications.
- Since commercial grade dedications have increased in number, the NRC has developed this **inspection procedure to provide guidance** to:
  - Assist the inspector in assessing the effectiveness of the implementation of the licensee's commercial grade procurement practices, and
  - Provide for early identification of any adverse trends or emerging problems

NRC IP 43004 “Inspection of Commercial-Grade Dedication Programs”: Objectives

The objective of this portion of the NRC IP 43004 is to verify that the dedicating entity’s:

- **Commercial-grade dedication program** satisfies the requirements of Appendix B to 10 CFR 50, Appendix B, with regard to the procurement and acceptance of commercial-grade items CGIs) for use as basic components.
- **Process for dedicating CGIs** meets the applicable portions of Appendix B

NRC INSPECTION MANUAL

INSPECTION PROCEDURE 43004

INSPECTION OF COMMERCIAL GRADE DEDICATION PROGRAMS

PROGRAM APPLICABILITY: 2504, 2527, 3700

43004-01 INSPECTION OBJECTIVES

01.01 To verify that the dedicating entity's commercial-grade dedication program satisfies the requirements of Appendix B to 10 CFR Part 50 (Appendix B) with regard to the procurement and acceptance of commercial-grade items (CGIs) for use as basic components in accordance with 10 CFR Part 21.

01.02 To verify that the dedicating entity's process for dedicating CGIs, as implemented, meets the applicable portions of Appendix B and provides reasonable assurance that CGIs will perform their intended safety function.

43004-02 INSPECTION REQUIREMENTS

02.01 Verify that the dedicating entity has established adequate controls for performing technical evaluations of items or services to be dedicated. The includes the review of materials, parts, equipment, and processes for suitability of application as established in Criterion III of Appendix B.

02.02 Verify that the dedicating entity has established adequate controls for the acceptance of a CGI using the criteria established in Criterion VI of Appendix B.

02.03 Verify that the dedicating entity has properly developed and implemented a plan for commercial-grade dedications.

43004-03 INSPECTION GUIDANCE

The inspector should verify that the entity inspected has a dedicaion program that meets the applicable portions of Appendix B and 10 CFR Part 21.

03.01 Verify that the dedicating entity has established adequate controls for the technical

Issue Date: 10/03/07 1 43004

NRC IP 43004 “Inspection of Commercial-Grade Dedication Programs”: Requirements

The requirements regarding CGIs are to verify that the dedicating entity has:

- Established **adequate controls** for **performing technical evaluations** of items or services to be dedicated
- Established adequate controls for the **acceptance of a CGI** using the criteria established in Criterion VII of Appendix B.
- Properly **developed and implemented a plan** for **commercial-grade dedications**.
- Established **adequate controls** for the **technical evaluation** of the items or services to be dedicated.

NRC IP 43004 “Inspection of Commercial-Grade Dedication Programs”: Requirements cont’d

Additional requirements outlined by the NRC IP 43004 include:

- **Technical Evaluations** identify the necessary technical and quality requirements that ensure the item will meet the intended design conditions.
  - They are conducted and documented by the responsible engineering organization.

- **Like-for-Like Commercial-Grade Item Replacement** is a replacement of an item with one that is identical. An equivalency evaluation is needed:
  - If differences from the original item are identified in the replacement item, then the item is not identical, but similar to the item being replaced, and
  - To determine if any changes in design, material, manufacturing process, safety, form, fit, function or interchangeability could impact the alternate replacement item’s ability to function under all design and ultimately the component's ability to perform its required safety function

In **NRC Generic Letter 89-02**, NRC staff conditionally endorsed the guidelines contained in EPRI NP-5652, "Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07)," that was issued by EPRI in June 1988 for evaluating commercial-grade products for suitability for use in safety-related applications.

NRC IP 43004 “Inspection of Commercial-Grade Dedication Programs”: Requirements cont’d

Additional requirements outlined by the NRC IP 43004 include ASME XI, which provides:

- Rules for the examination, inservice testing and inspection, and repair and replacement of components and systems in light water cooled and liquid metal cooled nuclear power plants.
- Rules for inspection and testing of components of gas cooled nuclear power plants have been deleted in the 1995 Edition.

NRC IP 38703 “Commercial Grade Dedication” – Objectives

The objective in having this inspection on commercial grade dedication is to:

- Determine whether **the failure of a safety-related structure, system, component (SSC),** or part thereof, to perform its intended safety function was the **result of a deficient commercial grade item** (CGI) **dedication process**.
- **Verify that the licensee's process** for dedicating CGIs, as implemented:
  - **Meets the applicable portions** of Appendix B to 10 CFR Part 50, and
  - **Provides reasonable assurance** that CGIs will perform their intended safety function.

NRC IP 38703 “Commercial Grade Dedication” – Background

The need for the NRC IP 38703 is due to:

- The **decrease in the number of qualified nuclear-grade vendors**: licensees are increasing the number of commercial grade replacement parts that they procure and dedicate for use in safety-related applications, and
- The **increase in commercial grade dedications**:
  - The Nuclear Regulatory Commission (NRC) has developed this inspection procedure to provide guidance to assist the inspector in assessing the effectiveness of the implementation of the licensee's commercial grade procurement practices and provide for early identification of any adverse trends or emerging problems.

NRC IP 38703 “Commercial Grade Dedication” – Reactive Inspection Requirements

Reactive Inspection Requirements include:

- **Initial Evaluation:**
  - Review licensee’s evaluation of failed item;
  - if failed item was dedicated, review complete procurement and dedication process to determine thoroughness
- **Further Assessments:**
  - If it is determined that the dedicated item failed as the result of certain critical characteristics not being identified and/or properly verified, perform the following assessments:
    - » Determine if other CGIs from the same accepted lot or batch as the failed dedicated CGI have been similarly dedicated and installed in other safety-related applications.
    - » If possible select and evaluate, as in step 1 above, at least three other dedicated CGIs having similar applications and critical characteristics as the CGI(s) that resulted in the identified failures.
    - » If, after performing step 2 above, it is determined that there were weaknesses in the commercial grade dedication process, the inspector should perform a more comprehensive inspection of the licensee's dedication process

Module 5 – Objective 2 Review

For the Module 5 – Objective 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

Objective 3: Understand NRC QA Procedures through Inspection Procedures 35021, 35752 and 40504

NRC IP 35021 – Post-Docketing Implementation of QA Activities Related to Design, Procurement and Construction – Overview

The objective of the **NRC IP 35021** is to:

- Determine if the applicant/constructor QA organization is **executing the QA program** in the areas of **design, procurement and construction.**
- Ensure that the QA program being implemented is **consistent with the program described in the application for a COL.**
- Verify that the applicant/contractor organization **assigned responsibility for vendor surveillance and for measuring related QA program effectiveness** exists by reviewing selected applicant vendor surveillance QA procedures for adequacy.
  - During construction, inspection is accomplished by continuing the review that was begun in other QA procedures.
- Review the QA program construction procedures and **verify the presence of the applicant's organization and individuals assigned responsibilities** for performance or surveillance of related QA program effectiveness.

NRC IP 35752 – Procurement Control & Receipt, Storage and Handling of Equipment and Materials – Overview

The objective of **NRC IP 35753** is to:

- Verify the COL holder has **developed and implemented a quality assurance (QA) program** relating to the **control of procurement activities**;
- **Verify the control of receipt, storage and handling of equipment and materials** that is in conformance with the NRC approved QAP.
- Assure that **procurement of equipment and materials and selection of suppliers will be accomplished in accordance** with the COL holder's **documented controls**.
  - Defined methods of control must be sufficiently definitive to prevent the non-conservative method of controls from being used for purchasing safety related items.

When documentation in the form of certification is used at the site in lieu of original records establishing quality of materials or components important to safety, **IP 35752 provides inspection guidelines to be used**.

NRC IP 40504 – Identification and Resolution of Construction Problems – Overview

The objective of **NRC IP 40504** is to:

- Determine whether NRC requirements regarding the **Problem Identification and Resolution (PI&R) processes are being appropriately implemented** for the facility construction phase.
- Determine whether Problem Identification and Resolution (PI&R) processes have been **adequately described for the facility construction phase**.
- Provide **insights whether safety culture considerations have been adequately considered** for the facility construction phase.
- **Evaluate additional objectives** as the Construction Inspection Program (CIP) enforcement/assessment process is developed.

This IP provides guidance for a **thorough review of the programmatic aspects of a licensee's PI&R processes.**

Reviews under this IP will **apply to both the licensee and its contractors that implement their own QA programs.**

Module 5 – Objective 3 Review

For the Module 5 – Objective 3 Review, we will employ the Qwizdom polling system.

Each participant will:

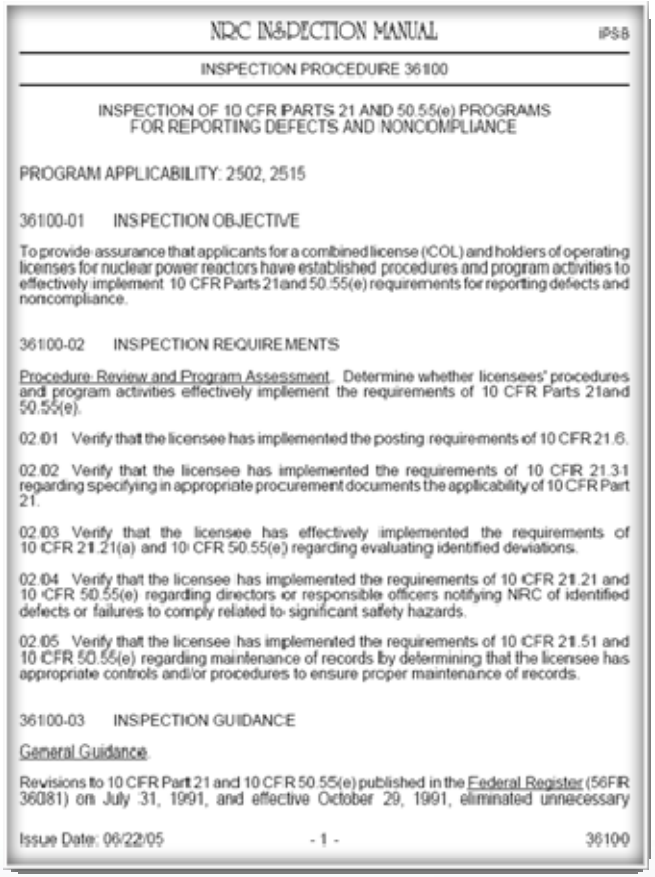
- Turn on his/her handheld Qwizdom response device
- Respond to the displayed question by pressing the desired option (Multiple Choice by *a, b, c, or d*; True/False by *T or F*) as each question is shown
- Press the “Enter” key to confirm response
- Wait for all participants to respond
- Turn off handheld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

Objective 4: Understand NRC Inspection Procedures through 10 CFR 52, NRC IPs 65001, 36100, 35017 and Generic Letter 91-05

NRC IP 36100 – "Inspection of 10 CFR 21 and 50.55(e) Programs for Reporting Defects and Noncompliance": Objective

The objective of the NRC IP 36100 is to:

- **Provide assurance that applicants** for a combined license (COL) and holders of operating licenses for nuclear power reactors **have established procedures and program activities** to effectively implement 10 CFR Parts 21 and 50.55(e) requirements



NRC INSPECTION MANUAL IP88

INSPECTION PROCEDURE 36100

INSPECTION OF 10 CFR PARTS 21 AND 50.55(e) PROGRAMS FOR REPORTING DEFECTS AND NONCOMPLIANCE

PROGRAM APPLICABILITY: 2502, 2515

36100-01 INSPECTION OBJECTIVE

To provide assurance that applicants for a combined license (COL) and holders of operating licenses for nuclear power reactors have established procedures and program activities to effectively implement 10 CFR Parts 21 and 50.55(e) requirements for reporting defects and noncompliance.

36100-02 INSPECTION REQUIREMENTS

Procedure Review and Program Assessment. Determine whether licensees' procedures and program activities effectively implement the requirements of 10 CFR Parts 21 and 50.55(e).

02.01 Verify that the licensee has implemented the posting requirements of 10 CFR 21.6.

02.02 Verify that the licensee has implemented the requirements of 10 CFR 21.31 regarding specifying in appropriate procurement documents the applicability of 10 CFR Part 21.

02.03 Verify that the licensee has effectively implemented the requirements of 10 CFR 21.21(a) and 10 CFR 50.55(e) regarding evaluating identified deviations.

02.04 Verify that the licensee has implemented the requirements of 10 CFR 21.21 and 10 CFR 50.55(e) regarding directors or responsible officers notifying NRC of identified defects or failures to comply related to significant safety hazards.

02.05 Verify that the licensee has implemented the requirements of 10 CFR 21.51 and 10 CFR 50.55(e) regarding maintenance of records by determining that the licensee has appropriate controls and/or procedures to ensure proper maintenance of records.

36100-03 INSPECTION GUIDANCE

General Guidance

Revisions to 10 CFR Part 21 and 10 CFR 50.55(e) published in the Federal Register (56FR 36081) on July 31, 1991, and effective October 29, 1991, eliminated unnecessary

Issue Date: 06/22/05 - 1 - 36100

NRC IP 36100 – "Inspection of 10 CFR 21 and 50.55(e) Programs for Reporting Defects and Noncompliance": Requirements

The Requirements outlined by the NRC IP 36100 include:

- **Procedure review and Program assessment:**
  - Determine if licensee programs effectively implement 10 CFR 21and 10 CFR 50.55 (e)
  - Posting of 10 CFR 21
  - Procurement documents contain provisions of 10 CFR 21 notifications
  - Licensees have implemented 10 CFR 21.31 requirements regarding evaluating deviations
  - Licensees have implemented regulations regarding directors and/or responsible officers notifying NRC of defects or failures to comply related to significant safety hazards
  - Licensees have maintained appropriate records

NRC Generic Letter 91-05: Licensee Commercial–Grade Procurement and Dedication Programs: Major focal points

The **major focal points** of NRC Generic Letter 91-05 is to:

- Express NRC's position on the key element that licensees must include as part of the dedication process, specifically that commercial- grade procurement and dedication programs **must assure the suitability of equipment for its intended safety-related application**.
- Clarify the elements of effective procurement and commercial-grade dedication programs that were previously provided to licensees in **GL 89-02.**

Since licensees' procurement and dedication programs may contain programmatic deficiencies, the staff has included in the generic letter the **necessary licensee corrective action to address shortcomings identified in specific vendor products or components that directly lead to the component not being suitable for safety-related service.**

NRC Generic Letter 91-05: Licensee Commercial–Grade Procurement and Dedication Programs: Basis for Letter

The **basis for NRC GL 91-05** is that in a number of cases:

- The NRC found that licensees had failed to **adequately maintain programs** as required by 10 CFR Part 50, Appendix B, **to assure the suitability of commercially procured and dedicated equipment for its intended safety-related applications**.
- The staff identified equipment of **indeterminate quality** installed in the licensees' facilities.


U.S.NRC

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April 9, 1991

TO: ALL HOLDERS OF OPERATING LICENSES AND CONSTRUCTION PERMITS FOR NUCLEAR POWER REACTORS

SUBJECT: LICENSEE COMMERCIAL-GRADE PROCUREMENT AND DEDICATION PROGRAMS (GENERIC LETTER 91-05)

This generic letter notifies the industry of the staff's pause in conducting certain procurement inspection and enforcement activities and identifies a number of failures in licensees' commercial-grade dedication programs identified during recent Region inspections performed by the U.S. Nuclear Regulatory Commission (NRC). The pause, which began in March of 1990, will end in late summer of 1991. The purpose of the pause is to allow licensees sufficient time to fully understand and implement guidance developed by industry to improve procurement and commercial-grade dedication programs. This generic letter expresses staff positions regarding certain aspects of licensee commercial-grade procurement and dedication programs which would provide acceptable methods to meet regulatory requirements.

During the period from 1986 to 1989, the NRC conducted 13 team inspections of the licensees' procurement and commercial-grade dedication programs. During these inspections, the NRC staff identified a common, programmatic deficiency in the licensees' control of the procurement and dedication process of commercial-grade items for safety-related applications. In a number of cases, the staff found that licensees had failed to adequately maintain programs as required by 10 CFR Part 50, Appendix B, to assure the suitability of commercially procured and dedicated equipment for its intended safety-related applications. In addition, the staff identified equipment of indeterminate quality installed in the licensees' facilities.

Because of a decrease in the number of qualified nuclear-grade vendors, the NRC staff is aware that there has been a change in the industry's procurement practices. Ten years ago, licensees procured major assemblies from approved vendors who maintained quality assurance programs pursuant to Appendix B of Part 50 of Title 10 of the Code of Federal Regulations (10 CFR). Currently, due to the reduction in the number of qualified nuclear-grade vendors, licensees are increasing the numbers of commercial-grade replacement parts that they procure and dedicate for use in safety-related applications. This is a substantial change from the environment in which 10 CFR Part 50, Appendix B was promulgated. This has necessitated an increased emphasis by licensees and the NRC staff to maintain procurement and dedication programs that adhere to the requirements of 10 CFR Part 50, Appendix B, and thus assure the quality of items purchased and installed in safety-related applications. Therefore, dedication processes for commercial-grade parts have increased in importance and NRC inspections have determined that a number of licensees have not satisfactorily performed this procurement and dedication process.

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GENERIC LETTER 91-05 -2-

The industry has been made fully aware of the NRC's concerns in this program area. In the past, escalated enforcement cases have provided notice to the

NRC Generic Letter 91-05: Dedication Issues: Selection, Verification, and Sampling

The **basis for the selection and verification** of critical characteristics includes:

- Consideration of Item's Safety Function
- Graded Quality Assurance
- Consideration of Failure Modes
- Reasonable Assurance
- Engineering Judgment

To **best determine sampling approaches**, consider:

- Established Heat Traceability (Materials)
- Established Lot/Batch Control (Items)
- Material and Items With No Lot/Batch Control

NRC IP 35017: QA Implementation Inspection

The NRC IP 35017 references **post-docking development** of the QA Program for design and procurement activities.

Its specific objectives include to verify:

- **Adequacy** of implementing procedures
- **Effectiveness** of implementing procedures
- **Licensee oversight** of contractor activities

Module 5 – Objective 4 Review

For the Module 5 – Objective 4 Review, we will employ the Qwizdom polling system.

Each participant will:

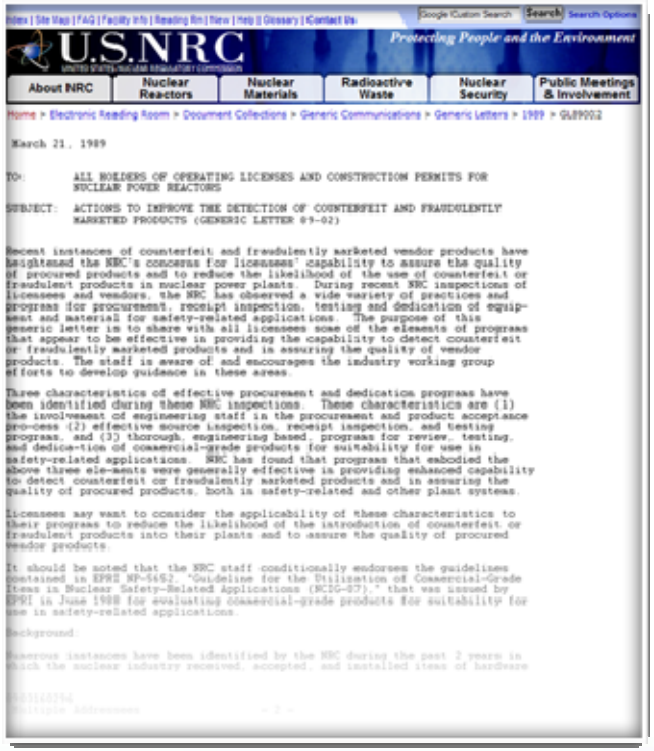
- Turn on his/her handheld Qwizdom response device
- Respond to the displayed question by pressing the desired option (Multiple Choice by *a, b, c, or d*; True/False by *T or F*) as each question is shown
- Press the “Enter” key to confirm response
- Wait for all participants to respond
- Turn off handheld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

Objective 5: Identify NRC concerns regarding counterfeit parts as identified in NRC Generic Letter 89-02

NRC Generic Letter 89-02 – Counterfeit Parts: Purpose

The **purpose** of the NRC Generic Letter 89-02 is to:

- Share with all licensees some of the elements of programs that appear to be effective in **providing the capability to detect counterfeit or fraudulently marketed products** and
- **Assure the quality of vendor products**


U.S.NRC

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March 21, 1989

TO: ALL HOLDERS OF OPERATING LICENSES AND CONSTRUCTION PERMITS FOR NUCLEAR POWER REACTORS

SUBJECT: ACTIONS TO IMPROVE THE DETECTION OF COUNTERFEIT AND FRAUDULENTLY MARKETED PRODUCTS (GENERIC LETTER 89-02)

Recent instances of counterfeit and fraudulently marketed vendor products have heightened the NRC's concerns for licensees' capability to assure the quality of procured products and to reduce the likelihood of the use of counterfeit or fraudulent products in nuclear power plants. During recent NRC inspections of licensees and vendors, the NRC has observed a wide variety of practices and programs for procurement, receipt inspection, testing and dedication of equipment and material for safety-related applications. The purpose of this generic letter is to share with all licensees some of the elements of programs that appear to be effective in providing the capability to detect counterfeit or fraudulently marketed products and in assuring the quality of vendor products. The staff is aware of and encourages the industry working group efforts to develop guidance in these areas.

Three characteristics of effective procurement and dedication programs have been identified during these NRC inspections. These characteristics are (1) the involvement of engineering staff in the procurement and product acceptance process (2) effective source inspection, receipt inspection, and testing programs, and (3) thorough, engineering based, programs for review, testing, and dedication of commercial-grade products for suitability for use in safety-related applications. NRC has found that programs that embodied the above three elements were generally effective in providing enhanced capability to detect counterfeit or fraudulently marketed products and in assuring the quality of procured products, both in safety-related and other plant systems.

Licensees may want to consider the applicability of these characteristics to their programs to reduce the likelihood of the introduction of counterfeit or fraudulent products into their plants and to assure the quality of procured vendor products.

It should be noted that the NRC staff conditionally endorses the guidelines contained in EPRI NP-5652, "Guideline for the Utilization of Commercial-Grade Items in Nuclear Safety-Related Applications (NCIG-07)," that was issued by EPRI in June 1988 for evaluating commercial-grade products for suitability for use in safety-related applications.

Background

Numerous instances have been identified by the NRC during the past 2 years in which the nuclear industry received, accepted, and installed items of hardware

NRC Generic Letter 89-02 – Counterfeit Parts: Background

Due to instances of counterfeit and fraudulently marketed vendor products, the NRC has **heightened concerns for licensees' capability** to:

- **Assure the quality of procured products** and
- **Reduce the likelihood of the use of counterfeit or fraudulent products** in nuclear facilities

Significant deficiencies have been identified in the programs for dedicating commercial-grade products for use in safety-related applications.

NRC Generic Letter 89-02 – Counterfeit Parts: Effective Approaches, Procurement Controls

Three characteristics of effective procurement and dedication programs have been identified during NRC inspections:

- **Involvement of engineering staff** in the procurement and product acceptance process
- **Effective** source inspection, receipt inspection, and testing programs, and
- **Thorough, engineering-based programs** for review, testing, and dedication of commercial-grade products for suitability for use in safety-related applications.

NRC Generic Letter 89-02 – Counterfeit Parts: Procurement Controls, Engineering Involvement

With engineering involvement, licensee engineering staff would be involved for effective controls in:

- **Development of specifications** to be used for the procurement of products to be used in the plant.
- **Determination of the critical characteristics** of the selected products that are to be verified during product acceptance
- **Determination of specific testing requirements** applicable to the selected products
- Evaluation of test results

The extent of necessary engineering involvement is dependent on the nature and use of the products involved.

NRC Generic Letter 89-02 – Counterfeit Parts: Procurement Controls, Product Acceptance Programs

Licensees with effective product acceptance programs have:

- Included **receipt/source inspection** and appropriate testing criteria, effective vendor audits, special tests and inspections and post-installation tests in their programs.
- Required **identification and verification of the products' critical characteristics**
- **Utilized sampling plans** to perform the required inspections and tests
- Verified the **traceability to the original manufacturers** of procured materials, equipment, and components
- Included **consideration of audit approach, depth of audit, and audit team composition** and have included appropriate engineering/technical representatives

NRC Generic Letter 89-02 – Counterfeit Parts: Procurement Controls, Dedication Progress

With regards to the dedication progress, it is **each licensee's responsibility to provide reasonable assurance that nonconforming products are not introduced into their plants**.

Dedication programs that ensure the adequacy of critical parameters of products used in safety-related applications **can also contribute to the identification of counterfeit or fraudulently marketed vendor products**.

- Acceptance method 1: Use EPRI NP-5652 "Guideline for the Utilization of Commercial- Grade Items in Nuclear Safety-Related Applications (NCIG-07)," to verify the critical characteristics of commercial-grade items intended for safety--related applications

Module 5 – Objective 5 Review

For the Module 5 – Objective 5 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 5: Summary

In this section, we covered:

1. **10 CFR 21 requirements**
2. **Commercial Grade Items and dedication of CGI**
3. **NRC QA Procedures through Inspection Procedures 35021, 35752 and 40504**
4. **NRC Inspection Procedures through NRC IPs 43004, 38703, 36100 and IP 35017**
5. **NRC Generic Letters 91-05 and 89-02**

Module 6: ASME Section III, Section VIII, and ASME NCA 3800 and N-Stamp requirements

Learning Objectives

1. **Recognize the purposes of ASME Section III, VIII, and NCA requirements**
   - Understand NRC endorsement of ASME codes
   - Understand safety-related impacts of codes
   - Understand differences and application of Section III and Section VIII

2. **Understand the N stamp holder requirement and roles of ASME inspector**

Objective 1: Recognize the purposes of ASME Section III, Section VIII and NCA Requirements

ASME Section III – Rules of Construction of Nuclear Facility Components: Overview

10CFR 50.55a, Codes and Standards, endorses the use of **ASME Sections III and XI** for safety-related systems and components of boiling and pressurized water-cooled nuclear power reactors. **The ASME Code is incorporated by reference into 10 CFR 50.55a.**

ASME Section III covers many nuclear components including:

- Pressure vessels, piping, pumps, valves,
- Supports and core support structures,
- pressure relief

Regulation Guide 1.84 "Design, Fabrication, and Materials Code Case Acceptability, ASEM Section III" identifies the **Code Cases** that have been **determined by the NRC to be acceptable alternatives to applicable parts of Section III.**

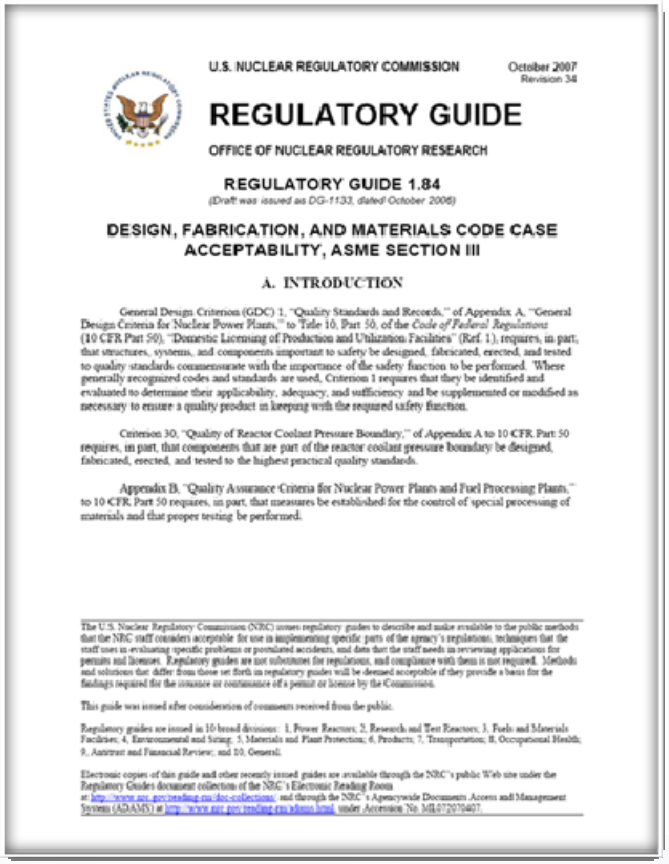
This permits the use of alternatives to the Code requirements referenced in 10 CFR 50.55(a) provided that

- The proposed alternatives result in an acceptable level of quality and safety, and
- That their use is authorized by the Director of the Office of Nuclear Reactors Regulation.

ASME Section III – Rules of Construction of Nuclear Facility Components: NRC Endorsement

Regulation Guide 1.84 “Design, Fabrication, and Materials **Code Case Acceptability**, ASME Section III” endorses ASME Section III indicating that this standard:

- Is **used globally**, and ASME Code symbols are universally recognized
- Will see applications at foreign vendor facilities
- Contains **rules for construction** of nuclear facility components (reactor vessel, steam generator, nuclear steam piping (NSSS)
- Provides for **special welding requirements** and qualification of welders
- Provides for NDE
- Very important to understand the **interfaces with the qualified nuclear inspectors** (ANI) **authorized nuclear inspector supervisor** (ANIS)



U.S. NUCLEAR REGULATORY COMMISSION October 2007
Revision 34

REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 1.84
(Draft was issued as DG-1133, dated October 2005)

DESIGN, FABRICATION, AND MATERIALS CODE CASE ACCEPTABILITY, ASME SECTION III

A. INTRODUCTION

General Design Criterion (GDC) 1, "Quality Standards and Records," of Appendix A, "General Design Criteria for Nuclear Power Plants," to Title 10, Part 50, of the *Code of Federal Regulations* (10 CFR Part 50), "Domestic Licensing of Production and Utilization Facilities" (Ref. 1), requires, in part, that structures, systems, and components important to safety be designed, fabricated, erected, and tested to quality standards commensurate with the importance of the safety function to be performed. Where generally recognized codes and standards are used, Criterion 1 requires that they be identified and evaluated to determine their applicability, adequacy, and sufficiency and be supplemented or modified as necessary to ensure a quality product in keeping with the required safety function.

Criterion 30, "Quality of Reactor Coolant Pressure Boundary," of Appendix A to 10 CFR Part 50 requires, in part, that components that are part of the reactor coolant pressure boundary be designed, fabricated, erected, and tested to the highest practical quality standards.

Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Processing Plants," to 10 CFR Part 50 requires, in part, that measures be established for the control of special processing of materials and that proper testing be performed.

The U.S. Nuclear Regulatory Commission (NRC) issues regulatory guides to describe and make available to the public methods that the NRC staff considers acceptable for use in implementing specific parts of the agency's regulations, techniques that the staff uses in evaluating specific problems or postulated accidents, and data that the staff needs in reviewing applications for permits and licenses. Regulatory guides are not substitutes for regulations, and compliance with them is not required. Methods and solutions that differ from those set forth in regulatory guides will be deemed acceptable if they provide a basis for the findings required for the issuance or continuance of a permit or license by the Commission.

This guide was issued after consideration of comments received from the public.

Regulatory guides are issued in 10 broad divisions: 1, Power Reactors; 2, Research and Test Reactors; 3, Fuels and Materials Facilities; 4, Environmental and Siting; 5, Materials and Plant Protection; 6, Products; 7, Transportation; 8, Occupational Health; 9, Antitrust and Financial Review; and 10, General.

Electronic copies of this guide and other recently issued guides are available through the NRC's public Web site under the Regulatory Guides document collection of the NRC's Electronic Reading Room at http://www.nrc.gov/reading-rm/doc-collections/ and through the NRC's Agencywide Documents Access and Management System (ADAMS) at http://www.nrc.gov/reading-rm/adams.html, under Accession No. ML072070407.

ASME Section III – Rules of Construction of Nuclear Facility Components: Scope

Section III of ASME B&PV Code **governs the activities of nuclear power plant construction/life extension**, including:

- **NCA-1000**: Scope of Section III
- **NCA-2000**: Classification of Nuclear Items
- **NCA-3000**:
  - Responsibilities of Owner and "N" Certificate Holder
  - Design Specifications, Design Reports, Load Capacity Data Sheets, and Design Report Summaries
- **NCA-3800:** Metallic Material Organization's Quality System Programs
  - NCA 3800 is a quality management process that ensures certified suppliers follow strict quality standards during production of pipe for nuclear uses. NCA 3800 requirements result in a comprehensive traceable report on processes and testing.
- **NCA-4000** and **NQA-1-1994**: Quality Assurance Programs
- **NCA-5000** and **QAI-1**: AIA, ANIS, and ANI Responsibilities and Duties

ASME Section III – Rules of Construction of Nuclear Facility Components: Scope cont'd

Section III of ASME B&PV Code governs the activities of nuclear power plant construction/life extension, including (cont'd):

- **NCA-8000**: Stamping and Data Reports
- **NC-2000**, **NC-2400**, **NC4300**, and **NC-4400**: Welding Requirements
- **ND-2000**: Nondestructive Examination (NDE) Requirements
- **ND-2300** and **ND4335**: Impact Testing
- **ND-5500** and **SNT-TC-1A**: NDE Personnel Qualifications
- **NB-6000**: Pressure Tests
- Fundamentals of radiographic testing (RT) and RT Film Review
- Fundamentals of ultrasonic testing (UT)
- **Section III, Division 2:** Primary Containment
- **Section III, Division 3**: Containment Systems for Storage and Transport Packagings of Spent Nuclear Fuel and High-Level Radioactive Material and Waste

ASME Section III – Rules of Construction of Nuclear Facility Components: Highlights, NCA-1000

ASME SECTION III **NCA-1000 scope**:

- Contains rules for the:
  - material,
  - design,
  - fabrication,
  - examination,
  - testing,
  - overpressure,
  - relief,
  - marking,
  - stamping, and
  - preparation of reports by the Certificate Holder for items which are intended to conform to the requirements for class 2 construction
- Covers strength and pressure integrity
- NCA 1100 Covers New Construction

ASME Section III – Rules of Construction of Nuclear Facility Components: Highlights, NCA General

ASME SECTION III **NCA 3850** covers Quality System (QS) Program Requirements:

- **NCA/IWA-3851.1** - General
  - The Material Organization establishes QS Program for control of quality and traceability of material.
  - The Program includes technical aspects and planning for accomplishment of activities affecting quality.

ASME Section III – Rules of Construction of Nuclear Facility Components: Highlights, NCA Scope and Applicability

The **NCA/IWA-3851.2 Scope and Applicability** portion references the following

- Quality Manual defines specific activities included in the scope of work proposed to perform:
  - **Operations**
    - » Performed during melting and heat analysis
    - » Affecting mechanical properties, conversion of product forms including dimension and certification requirements
  - **Testing, examination, repair or treatments** required by the material specification and certification of the results.
  - **Receipt, Identification, verification, handling, storage, and shipment** of material or source material.
  - Qualification of Material Organization (NCA/IWA-3820(b)).
  - **Approval and control of suppliers** of source material or subcontracted services (NCA/WA-3855.3).
  - Use of unqualified source material. (NCA/IWA-3855.5)
- Measures to comply with requirements of NCA/IWA-3800, to assure compliance with the material requirements of Section III

ASME Section III – Rules of Construction of Nuclear Facility Components: Highlights, NCA Identification of Completed Material

NCA/WA-3856.3 Identification of Completed Material details the following:

- The identification of completed material by **marking the material with the specification and grade of material, the heat number or heat code, and additional marking** required by the applicable Division(s) 1, 2, and/or 3 to facilitate traceability to reports of the results of all tests and examinations.
- A marking symbol or code may be used, provided such code or symbol is explained in the Certified Material Test Report. (NCA/WA-3862.1)

ASME Section III – Rules of Construction of Nuclear Facility Components: Highlights, NCA Welding

NCA/WA-3857.3 Welding elaborates on the following:

- Welding repair of material or source material must be performed in accordance with procedures and by welders or welding operators qualified in accordance with the applicable Division(s) 1, 2, and/or 3 and Section IX.

ASME Section III – Rules of Construction of Nuclear Facility Components: Highlights, NCA Certification Requirements for Material Organizations

NCA/WA-3861 Certification Requirements for Material Organizations provides the following guidance:

The Material Organization whose scope of activities includes NCA/WA-3830 provide a **Certified Material Test Report** (CMTR) or Certificate of Compliance (COC).

- The **certification affirms** that:
  - The **contents of the report are correct and accurate**, and
  - That all test results and operations performed by the Material Organization or its subcontractors are **in compliance with the material specification**

- The **Material Organization must**:
  - Transmit all certifications received from Material Organizations, or approved suppliers, to the purchaser at time of shipment.

- The **Certificate Holder must:**
  - Complete operations not completed by the Material Organization
  - Provide a CMTR for all operations performed by him or his approved suppliers
  - Certify the contents of the report are correct and accurate and test results and operations performed are incompliance with the requirements.

ASME Section III – Rules of Construction of Nuclear Facility Components: Highlights, NCA Certification Requirements for Material Organizations cont'd

Guidance regarding **nuclear valves and piping** includes the following:

- **Nuclear valve and piping manufacturers are accredited to the ASME 'N' code stamp** in accordance with the rules and requirements of the American Society of Mechanical Engineers Boiler and Pressure Vessel Code, Section III, Division I, Nuclear Power Plant Components, and addenda, including referenced codes and standards.
  - ASME Section III Class 1, 2 and 3 nuclear valves to comply with subsections NB, NC and ND respectively – Subsection ND defines the requirements for Class 3 valves, NC for Class 2 valves and NB for Class 1 valves - the most stringent.

- The **'N' code symbol stamp** is issued by ASME for qualified and approved manufacturers to identify line valves which the manufacturer certifies to have been **manufactured in compliance with the Code**.

- Advantages of an ASME Certification include:
  - Authorization of manufacturing of Stamped Items
  - Publication in the ASME register of Authorized Manufacturer Competence in using the ASME Code
  - Extensive responsibility as ASME Manufacturer
  - Certified ASME Quality Assurance System

- Verified by Authorized Nuclear Inspector (ANI)

ASME Section III – Rules of Construction of Nuclear Facility Components: Highlights, NCA Qualification of Testing of Valves, etc.

The **qualification of testing of valves, tanks**, etc section indicates the following:

- **Valves and spare parts** essential in preventing the significant release of radioactive material into the environment or essential to maintaining the integrity of the containment requires nuclear qualification **must be tested**
- **Qualification Testing provides additional documentation** to confirm that the equipment will perform its essential function under worst-case environmental and seismic conditions, as well as under normal operating conditions
- **Environmental and seismic conditions** that may be considered include radiation exposure, service life aging, operational cycling, seismic aging and seismic design basis earthquake, and a design basis accident.
- **Actual testing** to verify continued performance of the safety-related function **may be required**. Nuclear Qualification Testing involves the substantiation of a valve's ability to operate under extended normal and adverse conditions by Type Testing
- **Testing is witnessed and approved** by licensee or their representative, vendor QA, and sometimes an ANI.

ASME Section III – Rules of Construction of Nuclear Facility Components: Highlights, NCA Quality Control Considerations

Quality control considerations include the following guidance:

- Quality control is **implemented through a comprehensive set of procedures and instructions** using a quality manual that satisfies the requirements of NCA-3800, or NQA-1 (depending on contractual requirements)
- **Quality is assured through**:
  - Comprehensive, approved and audited controls
  - Witnessed testing at all levels of production
  - Stringent definition and traceability of raw materials, manufacturing process control and procedures
  - Approved non-destructive testing procedures
  - Witnessed testing
  - Special testing
  - Approved and witnessed cleaning procedures of finished valves, prior to witnessed packing and dispatch

ASME Section III – Rules of Construction of Nuclear Facility Components: Highlights, NCA 3800, Metallic Materials Organizations

The **basic requirements of NCA-3800 Metallic Materials Organizations** are:

- Document Quality System Program (QSP)
- Obtain **Certificate of Accreditation** (or alternatively, be qualified by each organization that buys material)
- Quality System Certificate (QSC) Holder **subject to two unannounced audits** between renewal surveys
- **Changes to manual must be approved** by ASME before they are implemented

ASME Section III – Rules of Construction of Nuclear Facility Components: Highlights, NCA 4000, QA Requirements

The **NCA-4000 Quality Assurance** background and requirements include:

- QA Program Required for all organizations
- 10 CFR 50, Appendix B required QA in 1970
- NQA-1-1994 approved by Code
- 10 CFR 50.55a states: "*Quality assurance.* When applying editions and addenda later than the 1989 Edition of Section III, the requirements of NQA–1, "Quality Assurance Requirements for Nuclear Facilities," 1986 Edition through the 1992 Edition, are acceptable for use provided that the edition and addenda of NQA–1 specified in NCA–4000 is used in conjunction with the administrative, quality, and technical provisions contained in the edition and addenda of Section III being used."

ASME Section VIII – Pressure Vessels: Overview

ASME SECTION VIII applies to **pressure vessels and components** that are **not used in nuclear safety-related applications**.

- Provides requirements applicable to the:
  - Design
  - Fabrication
  - Inspection
  - Testing, and
  - Certification of pressure vessels operating at either internal or external pressures exceeding 15 psig.
- **Such vessels may be fired or unfired**. Specific requirements apply to several classes of material used in pressure vessel construction, and also to fabrication methods such as welding, forging and brazing
  - This pressure may be obtained from an external source, a process reaction, by the application of heat from a direct or indirect source, or any combination thereof.
  - Division 3 rules cover **vessels intended for a specific service** and installed in a fixed location or relocated from work site to work site between pressurizations. The operation and maintenance control is retained during the useful life of the vessel by the user who prepares or causes to be prepared the design specifications.
  - Contains **mandatory and non-mandatory appendices** detailing supplementary design criteria, nondestructive examination and inspection acceptance standards. Rules pertaining to the **use of the U, UN and UV Code** symbol stamps are also included.

ASME Section VIII – Pressure Vessels: Overview

ASME Section VIII is organized into **three divisions**:

- Division 1 –Basic Pressure Vessels (Maintenance/Enhancements)
- Division 2 –Engineered Pressure Vessels (New Code)
- Division 3 –High Pressure Vessels (Maintenance/Enhancements

Objective 2: Understand the N-Stamp holder requirements and roles of ASME inspector

ASME N Stamp – Overview

Utilization of the ASME Code Symbol Stamp is a means of complying with the laws and regulations in all 50 U.S. states.

ASME certifies compliance with various N Stamps:

- **N:** Nuclear vessels, pumps, valves, piping systems, storage tanks, core support structures, concrete containments, and transport packaging
- **NA:** Field installation and shop assembly
- **NPT:** Fabrication, with or without design responsibility, for nuclear appurtenances and supports
- **NS:** Nuclear supports
- **NV:** Pressure relief valves
- **N3:** Containment for spent fuel and radioactive waste

ASME N Stamp – ASME N-Stamp Inspectors

Several key aspects to note regarding **ASME N-Stamps and Inspectors**:

- Licensees may face a **challenge in finding qualified suppliers** that are also ASME N-stamp holders.
- Some past suppliers of ASME Code parts and materials are **no longer committed to a quality assurance program** that meets 10 CFR 50, Appendix B, while others have dropped their N-stamp certification.
- Some vendors are willing to furnish ASME Code items to **only the most current Code edition and addenda**.
- Licensees must **resolve issues in a timely and cost-efficient manner** to ensure that the right items are furnished to maintenance organizations when needed.
- Once a Code **stamp is applied**, provisions of the **Code have been satisfied**.

What are options with regards to finding ASME N-stamp holders?

Module 6 Review

For the Module 6 Review, we will conduct a matching activity.

Match each criteria on the left with a corresponding detail on the right. (Hint: There is one extra detail on the right-hand side than there are criteria on the left.)

Each participant will:

- Partner with 1-2 other participant(s)
- Using PowerPoint slides 173-193, match each criterion with the appropriate corresponding detail
- Once you have completed the exercise, let the instructor know.
- The class will then review the correct answers together.

Module 6: Summary

In this section, we have covered:

1. **ASME Section III**
2. **ASME Section VIII**
3. **ASME NCA requirements**
4. **ASME N-stamp use**

Module 6 - Activity 1: Amazing Race

For this activity, each team will be provided the same task to complete. Upon successful completion of a task, the team will be provided with their next task. READ TASK INSTRUCTIONS CAREFULLY!

The winning team will be the one that has successfully completed all tasks within the race.

Some useful terminology:

A **DETOUR** is a choice between two tasks, each with pros and cons.

A **ROADBLOCK** is a task in which only two members of the Team may participate; non-participants must wait for the participant to accomplish the goal and cannot assist.

This race has a **YIELD** point. Teams must stop at the YIELD to do two things before continuing along the course:

1) They must check to see if they have been YIELDed by another team;

2) If no Team has been YIELDed, they must decide whether to use the YIELD or not. If a Team is YIELDed, they must wait until 2 minutes has elapsed out before they may continue with the race.

Module 7: International Standards and Relationship to NRC Regulations

Learning Objectives

1. **Recognize IAEA Safety Standards: Management System for Facilities and Activities GS R-3**

2. **Understand application of international standards that may be used by foreign vendors fabricating safety related or commercial grade items**

Objective 1: Recognize IAEA Safety Standards: Management System for Facilities and Activities GS R-3

IAEA GS R3 – Primary Themes

The **International Atomic Energy Agency** (IAEA) strives to maintain and improve the nuclear industry through the following means:

- **Provides international consensus** on what constitutes a high level of safety for protecting people and the environment
- **Define requirements** for establishing, implementing, assessing and continually improving a management system that integrates safety, health, environmental, security, quality and economic elements to ensure that safety is properly taken into account in all the activities of an organization
- **Ensure that safety is not compromised** by considering the implications of all actions not within separate management systems but with regard to safety as a whole
- Promote a **strong safety culture**
- Requires organizations to use a "**graded application of the management system"**
  - Also applies to products and activities as well
- Requires **management commitment**

IAEA Comparison to NRC 10 CFR 50 App B and NQA-1

10 CFR 50 / NQA-1	IAEA GS R3
• Criterion II/NQA-1 2S1 requires documented QA Program • Criteria I, II/NQA-1 Supplement 2S cover this o Organization and quality program defined o Periodic management assessments • Criterion II/NQA-1 Supplement 2S-1 addresses this o Program shall provide for indoctrination and training for personnel performing activities affecting quality	• *Section 2* requires documented management system • *Section 3* requires organizational policies, planning, and graded QA and senior person assigned to develop and report on performance • *Section 4* is focused on human resources and includes: o Determine amount of resources o Assess competency o Provide and assess infrastructure and working environment

IAEA Comparison to NRC 10 CFR 50 App B and NQA-1

10 CFR 50 / NQA-1	IAEA GS R3
• Criteria 4, 5, 6, 7, 8, 10, 11, 17 and NQA-1 and supplement address these requirements o Procurement document control o Control of procedures, instructions and drawings o Control of documents o Process control o Inspection requirements o Test control o Control of records for licensing	• *Section 5* requires the development of processes and procedures o Determine effectiveness of program o Process measurements are included o Interfaces defined o Promotes process improvement o Controlled conditions o Control of documents o Control of products (includes procurement, inspection, tests, verification, traceability, storage, handling) o Control of records, communication, purchasing, organizational changes

IAEA Comparison to NRC 10 CFR 50 App B and NQA-1

10 CFR 50 / NQA-1	IAEA GS R3
• Criteria II, XV, XVI, XVII, XVIII NQA-1 Supplements 2, 15, 16, 17, 18 o Corrective actions to preclude reoccurrence o Records management o Audits and assessments	• Section 6 focuses on measurement, assessment and improvement. Key themes include: o Monitoring the management system o Management must conduct independent and self assessments o Conduct management system reviews o Review for potential management policy changes o Review nonconformances for causes and corrective actions to preclude recurrence o Maintain status of corrective actions o Identify opportunities for improvement o Include plans for provision of adequate resources

Objective 2: Understand application of international standards that may be used by foreign vendors fabricating safety related or commercial grade items

International Organization for Standardization – Overview

The **International Organization for Standardization** is a nongovernmental organization, which **enables consensus** to be reached **between private/public sectors on international standards** for business, government and society.

Among other guidance, the organizations created the **ISO 9001**:

- An **international quality standards document** dealing directly with quality management and QM records procedures.
- It focuses on **business-process certification** rather than end product/service compliance.

The **NRC does not endorse the ISO 9000 series**.

ISO 9001 – Overview

The **ISO 9001** is widely used by **European Union countries** that have nuclear programs of their own and are **suppliers to the U.S nuclear projects and programs**.

A company or organization that has been independently audited and certified to be in conformance with ISO 9001 can claim to be “ISO 9001 certified” or “ISO 9001 registered”.

- This **does not guarantee compliance or quality of end products and services**, rather it certifies that consistent business processes are being applied.

ISO 9001: Relevance to the U.S. market

The ISO 9001 is **important to the NRC / U.S. nuclear facility** market for several reasons:

- **Chain-of-custody traceability** of materials, components and processes is critical for nuclear quality and safety.
- As the U.S. is the **receiver of a variety of EU products**, it is imperative to have translation of standards consistency and coverage is necessary for quality assurance verification.

Key aspects to note are that:

- Lack of requirement specificity in ISO 9001 means that **licensees and suppliers must accommodate integrated coverage of 10 CFR 50, Appendix B and ISO 9001** provisions in a hierarchy of QA Program documents to demonstrate rated coverage.
- Licensees' Quality Programs must **contain provisions for assuring adequate specification and verification of technical and regulatory requirements** to all suppliers, particularly those having ISO 9001 program.

Module 7 Review

For the Module 7 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 7: Summary

In this section, we have covered:

1. **IAEA safety Standards**

2. **Other international standards that may be used by foreign vendors**

Topics Covered in this Course

The topics below are those that we have covered throughout instruction.

1. **Quality Assurance Concepts and Principles (e.g., QM, QA, Six Sigma)**

2. **Applicable Codes, Standards, and Regulations for Nuclear QA Programs (10 CFR 50, Appendix B, NUREG 1055)**

3. **QA Principles in Perspective with Regulatory Requirements and Enforcements (e.g., NUREG 0800, NEI 06-14)**

4. **NRC Requirements Related to Inspection and Commercial Grade Dedication (e.g., 10 CFR 21, various Inspection Procedures and General Letters)**

5. **ASME Section III, Section VIII, NCA 3800 and N-Stamp**

6. **International Standards and Relationships to NRC Regulations (e.g., IAEA, ISO 9000)**