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

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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

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

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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

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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?

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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.

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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.

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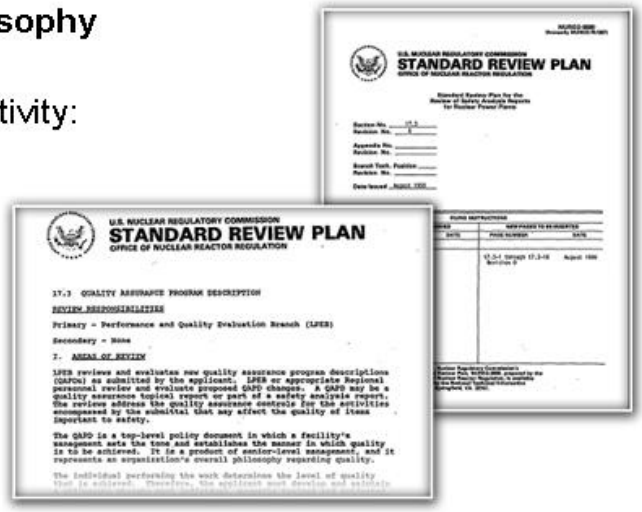
NUREG 0800 – 17.3 QAPD

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)

Secondary - None

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.

The individual performing the work determines the level of 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"

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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**.

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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**.

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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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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.

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

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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"

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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 requirements**:

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

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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!

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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

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

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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.**

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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.

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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.

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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

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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.

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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.

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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.

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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.

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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.

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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

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

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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.

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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.

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Final Safety-Evaluation Reports (FSERs) – Process

The process outlined by the FSERs provides:

- Basis for decision, and
- Provides details for issuing the SER

What was entailed in the SER process prior to 10 CFR 52 regulations?

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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.

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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

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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

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