



Module 7: International Standards and Relationship to NRC Regulations



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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



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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

- 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

IAEA GS R3

- *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

- 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

IAEA GS R3

- *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

- 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

IAEA GS R3

- 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





Case Study Activity



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Case Studies Activity



In this activity, we will review the two case studies based on actual inspection reports.

Each participant will:

- Break into group of 4-5 participants
- Each group will receive two case studies based on an actual inspection report
- Review the situation and the related policies
- Respond to the questions included in the case study, including authoring a sample response that would be included in an inspection report



Final Exam Review



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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)**



Course Review: Jeopardy



In this activity, we will review topics from all material presented on Days 1-4 of this course. The questions and answers are meant to stimulate questions and discussions on key topics – Jeopardy style.

Participants will:

- Divide into 3 groups
- Be prepared to provide the questions to key answers



Final Exam



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Final Exam Format

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.



Course Evaluation and Feedback after Exam

After you have completed the exam, we ask you to provide feedback on this course.

The course evaluation form will include places to comment with regards to such topics as:

- Course materials
- Course instruction
- Course activities and exercises



