

U.S. NUCLEAR REGULATORY COMMISSION 10 CFR PART 71 QUALITY ASSURANCE AND INSPECTION EXPERIENCE

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PATRAM 2010, London, England
Panel Session, 6 October 2010



Presentation Outline

- Regulatory Framework
- NRC Quality Assurance (QA) Program Requirements
- NRC Compliance Assurance Program
- Common Inspection Findings
- Summary



Regulatory Framework

- U. S. Department of Transportation (DOT)
 - Regulates all hazardous material transport including Class 7 radioactive materials
 - Title 49 Code of Federal Regulations (CFR)
- U. S. Nuclear Regulatory Commission (NRC)
 - Through Memorandum of Understanding with DOT, reviews and approves, by issuance of Certificate of Compliance (CoC), Type B and Fissile material packaging designs
 - Title 10 CFR Part 71



NRC QA Program Requirements

- 10 CFR 71.37 requires CoC applicant to submit a QA program description for review and approval by NRC
- Applicant must address how the eighteen (18) criteria specified in Part 71, Subpart H, will be applied
- NRC issues QA Program Approval certificate
- QA Program Approval holder expected to implement NRC QA requirements in working level procedures
- Currently twenty-six (26) CoC/QA Program Approval holders; some with multiple CoCs, some with just one CoC, and three in process of obtaining their first CoC



NRC Compliance Assurance Program

- QAP Approval holder responsible to ensure proper implementation of their NRC-approved QA program
- NRC conducts periodic planned and reactive safety inspections of all CoC/QA Program Approval holders
- Average of once every five (5) years; inspection frequency reduced as dictated by performance
- Inspection guidance contained in NRC Inspection Procedure 86001 and NUREG/CR-6314
- NUREG/CR-6314 breaks inspection areas into four (4) major categories



NRC Compliance Assurance Program (continued)

- Management Controls
 - Quality Assurance Policy
 - Nonconformance Controls
 - Documentation Controls
 - Audit Program
- Design Controls
 - Design Development and Modifications
- Fabrication Controls
 - Material Procurement
 - Fabrication and Assembly
 - Test and Inspection, Tools and Equipment
- Maintenance Controls
 - Maintenance Activities
 - Tools and Equipment



NRC Compliance Assurance Program (continued)

- Scope and extent of inspection dependent upon activities at the inspection site
 - Full-scope inspections
 - Corporate inspections without fabrication
 - Contracted fabrication facilities
- Inspection results documented in publicly available inspection reports
- Noncompliances dispositioned in accordance with NRC Enforcement Policy Manual



Common Inspection Findings

- Thirty-four (34) planned and reactive inspections over last five (5) years of CoC/QA Program Approval holders; five (5) were new QA Program Approval holders and seven (7) were for new CoC packaging designs
- Common Findings In All Categories
 - Failure to incorporate QA Program description statements in appropriate QA procedures
 - Failure to follow procedures affecting quality activities
 - Failure to adequately prescribe activities affecting quality in appropriate procedures
- Design Controls
 - Lack of guidance regarding when packaging modifications require regulatory approval



Common Inspection Findings (continued)

- Management Controls
 - Failure to provide justification for “use-as-is” or “repair” disposition of nonconformance reports
 - Lack of procedural guidance when converting from paper-based systems to electronic QA records
- Fabrication Controls
 - Improper flow-down of QA requirements to vendors/suppliers
- Findings might have been prevented had the CoC/QA Program holders contacted the regulator when they had interpretation or implementation questions

The NRC logo features a stylized atom with a blue nucleus and three intersecting orbits in orange, green, and blue.

Summary

- NRC CoC holders must submit QA Program description
- NRC issues QA Program Approval certificates and the holder implements appropriate quality procedures
- NRC conducts routine planned and reactive safety inspections to verify and assess compliance
- Inspections address Management, Design, Fabrication, and Maintenance Controls, as appropriate
- Nonconformances dispositioned through NRC Enforcement Policy
- CoC/QA Program holders should contact regulator when they have questions on regulatory requirements as failure to do so may result in inspection findings