

10 CFR PART 71 QUALITY ASSURANCE PROGRAM REQUIREMENTS and INSPECTION PROGRAM

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2019 TRTR Conference
September 25, 2019

Introduction



- NMSS Regulatory Framework
- NRC Quality Assurance (QA) Program Requirements
- NRC Compliance Assurance Program
- Inspection Scheduling/Findings
- Summary

Regulatory Framework



US Nuclear Regulatory Commission Quality Assurance Roles and Responsibilities for Radioactive Material Transport

*Title 10 of the Code of Federal Regulations
(10 CFR) Part 71*

Packaging and Transportation of Radioactive Material

*Subpart H
Quality Assurance*

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, “Packaging and Transportation of Radioactive Material”

Regulatory Framework



General License: NRC-approved package

A general License is issued to any licensee of the Commission to transport, deliver to a carrier for transport, licensed material in a package for which a licensee, certificate of compliance, or other approval has been issued by the NRC.

NRC QA Program Requirements



- A secondary CoC holder is normally a user-only of that packaging
- QAP Approval holder is responsible to ensure proper implementation of their NRC-approved QA program in working level procedures
- The QAP specifies commitments made by an organization to meet the requirements of 10 CFR Part 71
- The QAP Approval is the document issued by NRC to identify the conditions of QAP applicability to the requirements of 10 CFR Part 71, Subpart H

NRC Compliance Assurance Program



- QAP Approval holder responsible to ensure proper implementation of their NRC-approved QA program
- NRC Division of Fuel Management / Inspections & Operations Branch conducts periodic planned and reactive safety inspections of Packaging Certificate of Compliance holders/CoC Users/QA Program Approval holders
- Inspection guidance contained in NRC Inspection Procedure 86001 and NUREG/CR-6314

NRC Compliance Assurance Program



- Scope and extent of inspection dependent upon activities at the inspection site
 - Assessment of implementing QA procedures
 - Limited-scope inspections (Operations/Maintenance)
 - Corporate inspections without fabrication
 - Contracted fabrication facilities
- Inspection results documented in publicly available inspection reports
- Noncompliances dispositioned in accordance with NRC Enforcement Policy Manual

NRC Compliance Assurance Program



- Operations (PSAR Chapter 7)
- Acceptance Test and Maintenance Controls
(PSAR Chapter 8)

Inspection Scheduling/Findings



- 1st Time NRC-approved package user/shipper
- QA Program approved by the Commission as satisfying the provisions of 10 CFR 71 Subpart H - 71.17(b)
- Significant Changes to the QA Program
- Submittal in writing before the first use of the package – 71.17(c)(3)
- Request authorization for use of the package under NRC approved package - 71.17(c)(3)(d)
- Event Reports
- 71.95 Reports

Inspection Scheduling/Findings

- Three (3) planned and/or reactive RTR inspections over last five (5) years of QA Program Approval holders
- Inspection Observations
 - 10 CFR 71.115 "Control of purchased material, equipment, and services"
 - ✓ Material spare part procurements (e.g., O-ring gaskets, sealing washers, closure nuts, screws, and studs)
 - ✓ Purchasing of testing and calibration services
 - 10CFR Part 21 "Reporting of Defects and Noncompliance" and 71.95 Reporting

Summary



- NRC CoC package users 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, Operations, and Maintenance Controls, as appropriate
- Nonconformances dispositioned through NRC Enforcement Policy
- QA Program holders should contact regulator when they have questions on regulatory requirements as failure to do so may result in inspection findings

Questions??

