# U. S. Nuclear Regulatory Commission 10 CFR Part 71 Quality Assurance and Inspection Experience

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## ABSTRACT

The U.S. Nuclear Regulatory Commission's (NRC) regulations include requirements for quality assurance programs (QAPs) for entities that engage in the design and fabrication of packagings for the transportation of radioactive materials in Type B and fissile material packages. Prior to commencing activities subject to the NRC's quality assurance (QA) requirements, an applicant for an NRC Certificate of Compliance (CoC) must submit a QAP description to the NRC for review and approval, and once approved, must develop implementing procedures to ensure compliance with the NRC's QA requirements. The NRC conducts independent planned and reactive safety and compliance inspections of CoC/QAP holders to assess the adequacy of QAP implementation. Common findings of CoC/QAP holder design and fabrication (manufacturing) inspections are discussed.

## INTRODUCTION

In the United States, the U. S. Nuclear Regulatory Commission (NRC or Commission) and the U. S. Department of Transportation (DOT) share responsibility for the regulation of radioactive material transport. While DOT's regulations apply to all types of radioactive material transport, NRC imposes additional regulatory requirements on Type B and fissile material packages. NRC's packaging and transportation requirements are codified in Title 10 of the Code of Federal Regulations (CFR) Part 71, "Packaging and Transportation of Radioactive Material."

Quality assurance (QA) requirements are imposed on those who submit an application for approval of a package design under the provisions of Subpart D, "Application for Package Approval," of 10 CFR Part 71. Specifically, an applicant for an approval under Subpart D must, for each proposed package design, include a quality assurance program (QAP) description as required by Subpart H, "Quality Assurance," or reference a previous NRC approved QAP. After NRC inspection staff review determines that the QAP description meets regulatory requirements, a QAP Approval document is issued. After NRC staff's technical review determines that a proposed package design meets regulatory requirements, a Certificate of Compliance (CoC) is issued. The Part 71 QAP requirements apply to CoC holders as well as to applicants for a CoC.

### General Scope and Number of NRC CoC/QAP Holders

As of August 2010, the number of entities holding NRC CoCs/QAPs numbered twenty-six (26). While many of these entities hold multiple CoCs, several hold just one NRC CoC or are first time applicants for an NRC CoC. The CoC/QAP holders/applicants can be categorized (generally) as follows:

(3) Radiography camera devices
(7) Fuel fabricators; packages for shipment of new fuel and powder/pellets
(7) Designers/users of packagings for shipment of medical isotopes
(6) Designers/users of packagings for commercial purposes
(3) Dry cask storage vendors for dual-purpose (Part 71 and 72 certificated) cask designs

This total does not include CoCs held by the U. S. Department of Energy and related entities as they are not subject to NRC inspection.

Seven of the CoC/QAP holders, including the three radiography camera device manufacturers, perform design and fabrication activities at the same location as their headquarters facilities. All of the other holders contract their packaging fabrication activities at locations separate from their headquarters where package design and other supporting functions are usually performed.

**Quality Assurance Program Requirements**

Subpart H of Part 71 contains QA requirements that apply to the design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packagings that are important to safety. As used in 10 CFR Part 71, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. QA includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements.

Prior to commencing activities subject to 10 CFR Part 71, each applicant for a CoC must obtain Commission approval of its QAP. Each applicant is required to file a description of its QAP along with a discussion of which requirements of Subpart H are applicable to their particular activity and how they will be satisfied. There are a total of eighteen criteria delineated in Subpart H that must be addressed by the applicant to the extent applicable. These criteria are (corresponding 10 CFR Part 71 Section in parentheses) as follows:

Quality assurance organization (71.103)
Quality assurance program (71.105)
Package design control (71.107)
Procurement document control (71.109)
Instructions, procedures, and drawings (71.111)
Document control (71.113)
Control of purchased material, equipment, and services (71.115)
Identification and control of materials, parts, and components (71.117)
Control of special processes (71.119)
Internal inspection (71.121)
Test control (71.123)
Control of measuring and test equipment (71.125)
Handling, storage, and shipping control (71.127)
Inspection, test, and operating status (71.129)
Nonconforming materials, parts, and components (71.131)
Corrective action (71.133)
Quality assurance records (71.135)
Audits (71.137)

**Quality Assurance Program Implementation Expectations**

In their program description submittal, the package design applicant must identify to the NRC how each of the eighteen criteria above apply to their particular situation and how the criteria will be satisfied. In developing their QAP, users can refer to general guidance provided by the NRC in Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material." In developing their program, the QAP user is required to apply each of the applicable eighteen criteria in a graded approach, i.e., to an extent that is consistent with its importance to safety. Additional guidance on graded QA is provided by the NRC in NUREG/CR-6407[i], "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety." Based on approval of their QAP description submittal, QAP users will translate the eighteen criteria discussed in its program description submittal into lower-level (working level) implementing procedures governing the conduct of QA activities that are important to safety.

**Compliance Assurance**

While it is incumbent on each QAP/ CoC holder to ensure proper implementation of their NRC-approved QAP description, NRC conducts periodic safety and compliance inspections to assess the adequacy of such implementation. Inspections may be reactive; i.e., they may occur in response to a specific event, or, as is normally the case, they are conducted at periodic intervals.

NRC has developed a program and procedures[ii] for these reactive and planned inspections and is responsible for their implementation. Inspection Procedure 86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packagings," is used in coordination with NUREG/CR-6314, "Quality Assurance Inspections for Shipping and Storage Containers." NUREG/CR-6314 takes the eighteen Subpart H QA criteria and groups them into four major inspection categories and then into sub-categories as described below:

Management Controls

- Quality Assurance Policy
- Nonconformance Controls
- Documentation Controls
- Audit Program

Design Controls

- Design Development
- Modifications

Fabrication Controls

- Material Procurement
- Fabrication and Assembly
- Test and Inspection
- Tools and Equipment

Maintenance Controls

- Maintenance Activities
- Tools and Equipment

Each sub-category is divided into further sub-elements with specific inspection guidance provided for each sub-element. The scope and extent of each inspection depends upon the activities conducted at the site of the inspection. For the few CoC/QAP holders that perform design, fabrication and maintenance activities at one central location, all inspection aspects of NURG/CR-6314 are incorporated into the inspection plan. For locations where design and other non-fabrication activities are conducted, inspections are typically focused in the areas of Management and Design Controls; Fabrication Controls are reviewed with regard to the manner that the headquarters facility qualifies, contracts with, and exercises oversight of off-site fabrication facilities. Inspections at contracted off-site fabrication facilities would focus on the QAP holder's and contract facility's Management and Fabrication Controls; Design Controls would be reviewed with regard to the manner in which the CoC approved packaging design is transmitted to the fabricator and how any deviations during fabrication are reviewed by the CoC holder for modification to the approved design where required. Maintenance Controls are reviewed at those CoC/QAP holders that also transport, or deliver to a carrier for transport, radioactive material. Packaging maintenance history is typically reviewed to verify compliance with each packaging designs' CoC required maintenance requirements.

Routine inspections of each CoC/QAP holder are conducted on a five-year cycle. Flexibility is maintained to reduce the inspection cycle to less than five years in those instances where performance or programmatic concerns have been identified during inspections or where adverse incidents have occurred. All new QAP holders are inspected within several months of approval of their QAP description. Similarly, new CoC packaging designs are inspected during initial fabrication.

Inspection teams usually consist of two to three safety inspectors and are sometimes augmented by NRC technical staff if there is a specific, complex, technical issue that needs to be reviewed during an inspection. Inspections are typically conducted over a five day period (including travel time) and involve in-depth review of QA program documents, interviews with personnel, and observation of field activities. Inspection results are communicated verbally at the end of the inspection and subsequently documented in a publicly available written inspection report. QAP nonconformances to NRC requirements are categorized according to their severity and in accordance with NRC written policy. Simple nonconformances typically require a response by the QAP user as to why the nonconformance occurred and what actions they will take, or have taken, to prevent its recurrence. For severe nonconformances, monetary fines may be imposed, and in some cases, a QAP Approval may be suspended or terminated.

**Common Inspection Findings**

During the last five years, the NRC has conducted thirty-four (34) planned and reactive inspections of Part 71 CoC/QAP holders; of these, five (5) were inspections of new QAP holders and seven (7) were initial fabrication inspections of new packaging designs. Of the five new QAP holders, three were

determined to have marginal or inadequately implemented QAPs, with regard to meeting 10 CFR Part 71 QA requirements, and required one or more re-inspections. Common inspection findings, particularly for new QAP holders and initial packaging fabrication, in the functional areas of Management, Design, and Fabrication Controls are listed below.

Management Controls

- Failure to include engineering justification for non-conformance reports dispositioned as "use-as-is" or "repair"
- Conversion from paper-based to electronic records systems without appropriate controls with regard to access and maintenance of electronic quality records
- Lack of guidance on extent and depth of internal and supplier audits; use of superficial checklists that do not provide for in-depth assessment and documentation of actual performance
- Failure to provide procedural guidance on evaluation of defects with regard to reportability under 10 CFR 21

Design Controls

- Lack of guidance on when certain packaging modifications require regulatory review and approval

Fabrication Controls

- Improper flow-down of QAP holder's Part 71 QA requirements to suppliers/vendors of components and services
- Lack of specificity in Approved Supplier (Vendor) Listings as to authorized materials or services based on scope of supplier audits
- Inadequate methods for tracking welder and non-destructive testing personnel activities for maintaining required proficiency and qualifications
- Failure to follow, or inadequate, procedures for Measuring and Test Equipment with regard to calibration labels, inventory controls, and calibration frequencies, and failure to include calibration blocks within calibrated equipment inventory

Findings Common to the Above Controls

- Failure to incorporate Subpart H regulatory requirements or activities described in the QAP description submitted to NRC in appropriate quality procedures
- Failure to follow procedures affecting quality activities
- Failure to adequately prescribe activities affecting quality in appropriate procedures

Often times the above findings were preventable. It is not unusual for QAP holders' to state that they were unsure about the intent of a regulatory requirement, yet they implemented actions in QA procedures based on what they thought was a correct interpretation, without contacting the regulator for clarification.

## SUMMARY

In summary, the NRC's regulations include requirements for QAPs for NRC CoC holders. A QAP description must be submitted to the NRC for review and approval and the QAP/CoC holder must also develop implementing procedures to ensure compliance with the applicable NRC QA requirements. Trained NRC safety inspectors conduct independent periodic safety and compliance inspections of QAP/CoC holders to assess the adequacy of program implementation. Non-conformances to NRC regulatory requirements are dispositioned according to their severity and in accordance with NRC written policy. QAP/CoC holders should not hesitate to contact the regulator when questions arise as to the meaning or implementation of QA regulatory requirements as failure to do so may result in inspection findings due to misinterpretation by the QAP/CoC holder.

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[i] This document as well as 10 CFR Part 71 and Regulatory Guide 7.10 are all publicly accessible through NRC's website at http://www.nrc.gov/reading-rm/doc-collections/.

[ii] NRC Inspection program Manual Chapters and Inspection Procedures are publicly accessible through NRC's website at http://www.nrc.gov/reading-rm/doc-collections/insp-manual/.