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

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Abstract

The U.S. Nuclear Regulatory Commission's regulations include requirements for quality assurance (QA) programs for entities that engage in activities involving the transportation of radioactive materials in Type B and fissile material packages. Prior to commencing activities subject to the QA requirements, a QA program description must be submitted to the NRC for review and approval. The QA program user must also develop implementing procedures for the user's QA program to ensure compliance with the NRC's QA requirements. The NRC conducts independent periodic inspections of QA program users to assess the adequacy of program implementation.

1. Radioactive Material Transport Regulatory Framework

In the United States, the Nuclear Regulatory Commission (NRC or Commission) and the 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 safety requirements on commercial transport involving Type B packages 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."

NRC's regulations state that a license to transport radioactive material that is granted under the provisions of 10 CFR Part 71, Subpart C, "General Licenses," applies only to a licensee who has a QA program approved by the Commission as satisfying the provisions of Subpart H, "Quality Assurance," of 10 CFR Part 71. The granting of a license also affords NRC an opportunity to perform inspections and to take appropriate regulatory action should a safety or noncompliance matter be identified.

QA requirements are also 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 application for an approval under Subpart D must include, for each proposed package design, a quality assurance program description as required by Subpart H, or a reference to a previously (NRC) approved quality assurance program. After NRC staff's technical review determines that the QA program description and package design meet regulatory requirements, a Certificate of Compliance (CoC) is issued.

There are two general exceptions to the imposition of NRC's QA program requirements. The first involves radioactive material transport conducted by the US Department of Energy (DOE). DOE transports radioactive material under the auspices of their own authority. DOE's transportation activities must also meet DOT transportation requirements. The second exception involves radioactive material transport within and between U.S. Agreement States. These are U.S. States to which, under the Atomic Energy Act of 1954, NRC relinquishes portions of its (NRC's) regulatory authority to license and regulate byproduct materials (radioisotopes); source materials (uranium and thorium); and certain quantities of special nuclear materials. After designation as an Agreement State, the NRC reviews Agreement State programs for continued adequacy to protect public health and safety and compatibility with NRC's regulatory program.

2. 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 packaging 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 the use of any package for the shipment of licensed material subject to 10 CFR Part 71, each licensee must obtain Commission approval of its QA program. Each licensee is required to file a description of its QA program along with a discussion of which requirements of Subpart H are applicable and how they will be satisfied. There are a total of eighteen criteria delineated in Subpart H that must be addressed by the licensee 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)

3. Quality Assurance Program Implementation Expectations

In their program description submittal, the licensee or package design applicant (hereinafter referred to as QA program user) must identify to the NRC how each of the eighteen criteria above apply to their particular situation and how the criteria will be satisfied. Thus, the information supplied to the NRC for review varies as a function of the nature of the activity the QA program user will be engaged in. For example, someone using a general license solely for the transportation of radioactive material in packages purchased or leased for that purpose, would be expected to address criteria governing activities such as procurement, shipping and handling, whereas someone who designs and fabricates packagings would be expected to address criteria on design and testing, as well as material procurement activities. Examples of elements common to all QA program descriptions include the quality organization and program, corrective action, QA records, and audits.

In defining what the NRC staff considers to be an acceptable QA program description submittal, it is easier and perhaps best to first define what the staff has determined to be unacceptable submittals. Generally, this centers around two extremes: either too little or too much information. With respect to the former, the NRC has received, and rejected, QA program descriptions that basically restated the QA program requirements in Section H of Part 71. These program descriptions were rejected as they were simply a restatement of NRC's QA program requirements, not a description of which elements were applicable to the submitter's activities, nor a description of how they would be satisfied. At the other extreme, the NRC has received QA program submittals that were extremely detailed to the point that they contained actual implementing procedures. These programs were also rejected as the NRC staff only reviews QA program descriptions, not detailed implementing procedures.

An acceptable QA program submittal, therefore, is one that lies between these two extremes. An acceptable submittal is one that addresses each of the 18 criteria stated in Section H of Part 71, as applicable to the user's activities, and that provides a description of how each of the applicable criteria will be implemented. Keeping in mind the limitations described above, the extent of detail is left up to the applicant. However, while more detail may be desirable to a QA program user, it does have a potential downside. As discussed further in a subsequent paragraph, any proposed

change to the contents of an NRC approved QA program requires subsequent NRC review and approval prior to implementing such change. The more detailed a QA program, the less flexibility the user will have in the event they need to quickly make changes to activities described in the plan, as the changes will require NRC review and approval before they can be implemented and this will take time to accomplish.

In developing their QA program, users can refer to general guidance provided by NRC in Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material." In developing their program, the QA program 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, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety."

Following a technical review and a determination by the NRC staff that the QA program submittal meets regulatory requirements, NRC issues a Quality Assurance Program Approval. The approval expires five years from the month of issuance and may be renewed prior to expiration at the QA program user's request. Any changes to the approved QA program description require NRC approval. Therefore, if a QA program user desires to make a change in the QA program description that was used as the basis for NRC approval, the change must be submitted for review and approval by the NRC before the change can by implemented. Requests for review and approval of such changes are handled through an amendment of the Quality Assurance Program Approval and do not affect the five year renewal date.

Based on approval of their QA program description submittal, QA program 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.

4. Quality Assurance Program Submittals Based on Other Standards

Occasionally, the NRC staff will receive a QA program description based upon a different QA standard such as the American Society of Mechanical Engineering (ASME) NQA-1, "Quality Assurance Program Requirements for Nuclear Facilities," or the International Organization for Standardization (ISO) 9000 series standards. While these submittals may be found to be acceptable upon staff review, submitters need to be sensitive to the fact that the eighteen 10 CFR Part 71 QA criteria contain requirements that may not be fully addressed by another standard and the submitter may need to augment their program to include these additional requirements.

On 9 July, 2003, the NRC issued a Commission Information paper (SECY-03-0117) titled "Approaches for Adopting More Widely Accepted International Quality Standards." The purpose of the paper was to report the results of the NRC staff's effort to review international quality assurance standards against the existing 10 CFR Part 50 Appendix B (applicable to power reactors) framework and assess approaches for adopting international quality standards for safety-related components in nuclear power plants into the existing regulatory framework. The staff reviewed ISO 9001-2000, "Quality Management System - Requirements," and performed a comparison to Appendix B quality requirements with the results documented in an attachment to the SECY paper. Based on this review, the staff concluded that supplemental quality requirements would need to be applied when implementing ISO 9001 within the existing regulatory framework. Given that the Part 71 Subpart H QA requirements parallel the Part 50 Appendix B QA requirements, many of the issues identified in the SECY attachment would be applicable as well to any ISO-based QA program submittal seeking to satisfy Part 71 Subpart H QA requirements.

For example, while there are many parallels between the eighteen Subpart H QA program criteria and those of ISO 9000, some NRC criteria are not specifically addressed, either in part or wholly, in ISO 9000. For example, ISO 9000 does not specifically address two of the Subpart H criteria, 10 CFR 71.109, "Procurement document control," and 10 CFR 71.111, "Instructions, procedures, and drawings," although some, but not all, elements of these two criteria are in the ISO 9000 requirements. Also, ISO 9000 does not address the independent review of drawings and calculations that 10 CFR 71.107, "Package design control," requires. Consequently, it is important for those who submit QA plans based on a different standard to carefully review the eighteen 10 CFR Part 71 QA criteria, determine which elements are applicable to their activities, and ensure that their QA plan addresses the applicable criteria. If this is not done, the

NRC may require the submittal of additional information regarding how all of the applicable Subpart H criteria will be met. This may require the submitter to make changes to their underlying QA program and delay the NRC approval review.

5. Inspections

While it is incumbent on each Quality Assurance Program Approval and CoC holder to ensure proper implementation of their NRC-approved QA program description, NRC conducts periodic 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 may be conducted at periodic intervals.

NRC has developed a program and procedures for these reactive and planned inspections and is responsible for their implementation. Inspections are conducted by trained and qualified safety inspectors well versed in assessing QA program implementation adequacy. 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 looked at during an inspection. Inspections are typically conducted over a three to five day period 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 written report. QA program nonconformances to NRC requirements are dispositioned according to their severity and in accordance with NRC written policy. Simple nonconformances typically require a response by the QA program 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, the user's QA Program Approval may be suspended or terminated. Suspension or termination of NRC's approval of the user's QA program effectively precludes the conduct of NRC-licensed activities involving the transport, design or fabrication of radioactive material packagings.

6. Summary

In summary, the U.S. Nuclear Regulatory Commission's regulations include requirements for QA programs for users and designers of Type B and fissile material packages. A QA program description must be submitted to the NRC for review and approval and the QA program user must also develop implementing procedures to ensure compliance with the applicable NRC QA requirements. Trained NRC safety inspectors conduct independent periodic safety inspections of QA program users to assess the adequacy of program implementation. QA program nonconformances to NRC requirements are dispositioned according to their severity and in accordance with NRC written policy.