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Synopsis for Developing a QA Program Description for Type B and Fissile Material Packaging

In accordance with DOE O 460.1C, Section 4.a.(3)(a), each DOE entity that participates in the design, fabrication, procurement, use, modification or maintenance of a Type B or fissile radioactive materials packaging must have a QA program that complies with 10 CFR Part 71, Subpart H, and is approved by the DOE Headquarters Certifying Official (HCO). The basis for use of Subpart H of 10 CFR 71 is 49 CFR 173.7(d) that states the following:

> "Packagings made by or under the direction of the U.S. Department of Energy may be used for the transportation of Class 7 materials when evaluated, approved, and certified by the Department of Energy against packaging standards equivalent to those specified in 10 CFR Part 71."

Guidance for the development of a QA program description in accordance with 10 CFR 71, Subpart H, is contained in NRC Regulatory Guide 7.10, Revision 2. The guidance provided herein describes a method for use in preparing and submitting QA program descriptions for review by the staff of the DOE Packaging Certification Program (PCP). Specifically, 10 CFR 71.37(a) requires that the applicant for a Certificate of Compliance (CoC) must describe the quality assurance program for design, fabrication, assembly, testing, maintenance, repair, modification, and use of the packaging. Subpart H of 10 CFR 71, specifies that QA programs of licensees, certificate holders, applicants for a CoC, and packaging users must satisfy each of the applicable criteria specified in 10 CFR 71.101 – 71.137 to an extent that is consistent with their importance to safety.

Subpart H of 10 CFR 71 establishes QA requirements for design, procurement, fabrication, inspection, testing, assembly, handling, storing, maintenance, repair, and modifying packaging components that are important to safety. In order to satisfy requirements for the above activities, the licensee, certificate holder, applicant for a CoC, or user should control the quality of each of the above activities using a graded approach. The QA effort expended should be consistent with the importance to safety for structures, systems, and components. A method for developing a graded approach is contained in Appendix A of NRC Regulatory Guide 7.10. In addition, NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety," provides additional guidance for application of the graded approach. Each DOE entity must submit a description of its QA program for packaging with an explanation of which Subpart H requirements apply and how

those requirements will be satisfied. The user of the QA program should address the regulations delineated in Subpart H to the extent applicable to their respective operations. The types of activities that a DOE entity engages will determine which sections of Subpart H apply to their QA program.

The QA program description should identify how each criterion in Subpart H applies to a particular organization and how those regulations will be satisfied. The individual QA program description will vary depending on the activities for the responsible DOE entity. For example, an organization that only leases a packaging will only address a limited number of criteria in Subpart H. On the other hand, an organization that is responsible for design, fabrication, assembly, testing, repair, and modification will be required to address each of the 18 criteria in Subpart H. The QA program description should not contain either too little or excessive information. Relative to providing too little information, the QA program description should not merely restate the applicable criteria from Subpart H. On the other hand, the QA program description should not be excessively detailed as to include implementing procedures. The minimum criteria that is common to most QA program descriptions for packaging users include as follows: Organization, QA program, procurement activities, control of nonconforming items, corrective actions, QA records, and audits (Ref Quality Assurance Guidance for Packaging of Radioactive and Fissile Materials, DOE/EM/PCP/QA-2010-1). In some cases, a packaging user may procure a packaging for a single shipment. Should the DOE entity's QA program description not encompass the single shipment, the packaging user will be required to submit a QA program description for this single shipment. Typically, a licensee, certificate holder, or an applicant for a CoC is required to provide a QA program description that includes all 18 criteria from Subpart H of 10 CFR 71. In most cases the QA program description will include all Type B and fissile material packaging for a particular DOE entity. The inclusion of excessive detail will result in less flexibility and additional submittals to DOE PCP for approval. As an example for developing the QA program description for the Measuring & Test Equipment criterion, the program description should typically include the following requirements for calibration of Measuring & Test Equipment (M&TE) as follows:

- Label or tag M&TE to indicate the new planned calibration date.
- Identify, maintain, and store calibration records as QA records.
- Establish measures to ensure that in-house reference or transfer standards used in calibrating M&TE are traceable to nationally recognized standards. If no known recognized standard exists, document basis for calibration.
- Validate previous inspection and test results up to the time of previous calibration when M&TE is found to be out of calibration. Repair or replace any measuring equipment that is consistently out of calibration.

Any changes to the DOE PCP approved QA program description by the DOE entity must be submitted to the DOE PCP for review and approval prior to implementation by the DOE entity.