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GRADED APPROACH TO ESTABLISH QA REQUIREMENTS FOR TYPE B AND FISSILE MATERIAL TRANSPORTATION PACKAGINGS

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ABSTRACT

The essence of the graded approach is the establishment of applicable quality assurance (QA) requirements to an extent consistent with the importance to safety of an item, component, system, or activity. The genesis of the graded approach is a study conducted by the U.S. Nuclear Regulatory Commission (NRC) for the U.S. Congress in 1987 to assess the effectiveness of QA activities. That study demonstrated the need to improve the application of QA requirements for the nuclear industry in general. The conclusion of the study indicated that a graded approach for establishing QA requirements is the most viable method to satisfy federal safety standards that result in protecting public health and safety. The application of QA requirements for Type B and fissile material transportation packagings is not based solely on importance to safety or safety-related considerations. The operability of items, components, systems, and activities is considered to be equally important. The nuclear industry, along with regulatory agencies, recognizes the significance of operability considerations, as well as the evaluation of each item, component, system, or activity for safety-related considerations. The graded approach for QA requirements for Type B and fissile material transportation packagings is based on Title 10, Part 71 of the U.S. Code of Federal Regulations (CFR), "Packaging and Transportation of Radioactive Material." Guidance for implementation of the QA requirements specified in §71 is provided in NRC Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material," and ASME NQA-1, "Quality Assurance Requirements for Nuclear Facility Applications." The graded approach for QA requirements is based on criteria for containment, shielding, and subcriticality specified in 10 CFR Part 71.

INTRODUCTION

The graded approach for developing QA requirements has proven to be an effective method for determining and implementing QA requirements for Type B and fissile material transportation packagings. The appropriate use of the graded approach for QA requirements applies the necessary but not excessive level of quality assurance. The basis of the graded approach is the establishment of applicable quality assurance requirements to an extent consistent with the importance to safety of an item, component, system, or activity. The use of the graded approach not only relies on the importance to safety of an item, component, system, or activity; it also relies on the operability and interrelationship of each item, component, system, or activity with other items, components, systems, or activities.

The genesis of the graded approach was based on the accident that occurred at Three Mile Island and also on less severe problems at other nuclear power plants. The U.S. Nuclear Regulatory Commission (NRC) was requested by the United States Congress to study existing and alternate programs for improving quality in the design and construction of nuclear power plants. The results of the study, which was issued in 1987, made it clear that the then-current QA practices had to be improved. The method, referred to as the graded approach for establishment of QA requirements, is based on the process recommended in NUREG-1055 [1]. The U.S. Department of Energy (DOE) and NRC adopted the recommendation to modify QA programs by incorporating the graded approach. In addition to using the graded approach in establishing QA requirements for compliance with Subpart H of §71, specific QA requirements can be identified by using the graded approach for each item or activity associated with a package design that is important-to-safety following the guidance from ASME-NQA-1 [2], NRC Regulatory Guide 7.10 [3], and NUREG/CR-6407 [4].

The major benefit in applying the graded approach is that it provides the package designers, manufacturers and users the ability to select only appropriate QA requirements without degrading quality and safety. NRC Regulatory Guide 7.10 provides guidance for implementation of the QA requirements specified in Subpart H of §71 for Type B and fissile material transportation packagings. ASME-NQA-1 identifies good management practices that apply to any nuclear item, component, system, or facility that can be adapted for Type B and fissile material transportation packaging.

PROCESS FOR APPLICATION OF GRADED APPROACH

In the graded approach, QA requirements are established to an extent consistent with the relative importance to safety of an item, component, system, or activity. The development of the graded approach is based on a three-step process. Initially, the criteria for Type B and fissile material transportation packagings must be established by reviewing federal regulations, NRC guidance documents, and relevant national consensus standards. The criteria for transport packagings are established from Title 10, Part 71 of the U.S. Code of Federal Regulations (CFR) and NRC Regulatory Guide 7.10, Appendix A, as follows:

1) Adequate containment of radioactive material.
2) Assurance of nuclear subcriticality.
3) Adequate shielding of radiation emitted by radioactive contents in the package in compliance with §71.

After the criteria are established, the initial step in the graded approach is the *classification* process. Classification involves the analysis of each item or quality-affecting activity to determine whether its function is important to maintaining the safety of the packaging. Each item or activity is assigned a *Quality Category* on the basis of its relative importance to safety of the packaging based on the *single-failure criteria.* The following definitions are based on guidance provided in Appendix A of NRC Regulatory Guide 7.10 [3].

Single Failure Criteria

Quality Category A

Critical Impact – Items whose failure or malfunction would be critical to safe operations and would directly result in a condition that would adversely affect health and safety. An unsafe condition with a transport package could result from a loss of primary containment with

subsequent release of radioactive material, loss of shielding, or an unsafe geometry compromising criticality control.

Quality Category B

Major Impact – Items whose failure or malfunction would indirectly result in a condition that could adversely affect health and safety in a major way. However, for a transport package, an unsafe condition could result only if a primary event occurs in conjunction with a secondary event or other failure that results in a condition such as a loss of primary containment with a release of radioactive material, loss of shielding, or an unsafe geometry compromising criticality control.

Quality Category C

Minor Impact – Items whose failure or malfunction would not reduce packaging effectiveness and would not result in an unacceptable condition of containment, shielding, or nuclear criticality regardless of other failures in this category.

After a quality category is established for each item or quality-affecting activity, a quality level of effort is assigned to each item or activity on the basis of its design requirements and the following factors:

1) Complexity or uniqueness of an item or quality-affecting activity.
2) Consequences of failure relative to safety or operability.
3) Degree of standardization for an item or a quality-affecting activity.
4) The need for controls over special processes and equipment.
5) The ability to determine functional compliance by means of inspection or testing.

The above factors are used to establish the level of effort for each important-to-safety item or activity. The term *level of effort* is synonymous with *quality requirements* used in this paper. The above factors are specified in §71.105(c).

The use of the above factors may result in upgrading the quality level of effort (QA requirements), not the Quality Category level, for a particular item or quality-affecting activity. At this point, only appropriate QA requirements are selected from NRC Regulatory Guide 7.10 and ASME-NQA-1.

Subpart H of §71 specifies 18 criteria that must be applied by an organization involved in 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*." For a given package design, all of these functions may not apply, and therefore all of the 18 criteria may also not apply depending on the organization's scope. For example, an organization may be responsible for fabrication but not design. Therefore, the criteria in Subpart H pertaining to fabrication will need to be applied in the organization's QA program, but those criteria pertaining to design requirements need not be applied. The appropriate application of QA requirements is crucial to the success of the graded approach.

Currently, the NRC has announced [5] that it plans to issue a proposed rulemaking for §71 that will bring the regulations into compatibility with IAEA TS-R-1 [6] and concurrently "*would make the regulation of Quality Assurance (QA) programs more efficient by removing the requirement for prior approval of QA programs for users of packages, allowing changes that do*

not change commitments to be made without prior NRC approval, and removing the requirement to renew a QA program."

As a result, a draft Regulatory Guide, DG-7009 [7] that is a revision to NRC Regulatory Guide 7.10 has been issued providing guidance on how to apply the revised QA requirements. However, it is noteworthy that Appendix A of DG-7009 contains the same guidance as the currently approved version of NRC Regulatory Guide 7.10 for implementing the graded approach.

REVIEW OF DOE TRANSPORT PACKAGE QA PROGRAMS

In the United States, two entities have the authority to certify Type B and fissile material transportation package designs: the NRC and DOE. The DOE has authority to certify package designs for those "*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*" [8]. For DOE-certified package designs, DOE's Packaging Review Guide [9] specifies that, for each package design DOE reviews and approves, "*an approved QA program applicable to packaging*" is also required.

The DOE Packaging Review Guide [9] specifically notes that:

(a) This QA program "*will likely be an 'umbrella' program that provides QA requirements for all quality-related packaging activities (i.e., not specific to the package submitted for approval)*"; and

(b) It must be confirmed that the Safety Analysis Report for Packaging "*identifies a quality category (e.g., A, B, C) for each structure, system, and component (SSC) important to safety and that these categories are appropriately defined*."

Prior to May 2010, management personnel at DOE headquarters had no authority to approve QA programs for Type B and fissile material transportation packagings. This approval function was left to the DOE operations offices, which combined QA requirements for Type B and fissile material transportation packaging with facility QA programs.

However, in May 2010, DOE's Headquarters Certifying Official (HQCO) was given the authority to approve the QA programs of DOE entities that design, fabricate, test, modify, repair, and use Type B and fissile material transportation packagings. Determining the approval process for individual QA programs that only address Type B and fissile material transportation packagings provides another necessary step toward demonstrating equivalency with the NRC requirements in Subpart H of §71.

To demonstrate each certified package design satisfies the QA requirements of the 18 criteria of Subpart H of §71, a DOE directive issued in July 2010 [10] established a requirement on designers and users of certified packages to submit the applicable QA documentation and a compliance matrix to the proper authority at DOE headquarters for review and approval. The directive further requires that a relevant quality assurance program description (QAPD) be submitted by designers and users of DOE-certified packages to allow a basis for review and approval.

One specific area of concern with regard to these reviews is that each QAPD must demonstrate that it satisfies the graded approach requirements specified in Subpart H of §71.

Since that time, entities involved with DOE-certified packagings have submitted the required documentation. Initially, upon such a submittal, a provisional approval was issued pending review, revision if needed, and approval of the QAPD. Reviews have been undertaken. Some have resulted in comments being sent for resolution, whereas others have been approved. It is anticipated that this effort of reviewing and approving entities involved with DOE-certified packages will continue until all outstanding issues with the entities' QAPDs have been resolved.

These reviews of the entities' QAPDs utilize all of the QA-related requirements that are imposed by Subpart H of §71 and the associated guidance that comes from NRC Regulatory Guide 7.10. The evaluations are structured according to whether each item relates to a requirement or to guidance, and the results of evaluations may be in the form of:

(a) A "***Satisfactory***" evaluation, in which the result indicates that the review does not require an action by the entity;
(b) A "***Finding***," which is the result when the review adds a required action by the entity, noting the requirement that has not been satisfied and elaborating on why the submitted documentation is not in compliance with that requirement; or
(c) An "**Observation**," which is the result when the review notes that the approach taken by the entity is not entirely consistent with the guidance and does not require an action, but represents an opportunity for improvement by the entity.

With regard to the graded approach, the DOE QAPD review specifically addresses the question, derived from §71.101(b) as follows:

> "*Has the Entity demonstrated in its QAPD that it executes the applicable QA criteria following a graded approach to an extent that it is commensurate with the QA requirement's importance to safety in accordance with the packaging design or other packaging-related activities?*"

AUDITS AND INSPECTIONS

By federal law, the DOE is required to have a QA process consistent with the NRC in accordance with 49 CFR 173.7(d). Thus, it is necessary for DOE to conduct Type B and fissile material packaging QA audits consistent with those typically performed by NRC's inspection team (where NRC calls them inspections rather than audits). Thus, beyond reviewing an entity's QAPD, it is not only useful but necessary for DOE to perform audits of the entity's activities to ensure that the QA requirements specified in its QAPD and associated implementation documents are being implemented.

In May 2010 [11], in addition to being authorized to perform QA program approvals, the DOE HQCO was also given the authority to perform QA audits of the relevant DOE entity's QA program. This authority to perform QA audits was a necessary step in demonstrating equivalency of DOE activities with NRC requirements.

The audits that DOE undertakes, and the inspections that NRC undertakes, are compliance based. Auditing is just another area where DOE demonstrates equivalence with the NRC. One way for the DOE to ensure equivalency with NRC is to participate in inspections with the NRC, especially for those entities that may have package designs certified by both the NRC and DOE. In 2013 NRC has invited DOE and the lead author of this paper to join the NRC in two of its inspections, which facilitated a sharing of expertise and transferal of experiences between the two agencies.

The DOE Packaging Certification Program (PCP), Office of Packaging and Transportation, Office of Environmental Management has conducted seven QA Program Audits and three Source Verifications at DOE entities and their contractors on certified fissile material and Type B packagings from September 2006 to August 2011 at the behest of the PCP Manager. QA Program Audits and Source Verifications of critical operations were conducted at select DOE entities and their contractors to ensure compliance of acceptance testing, the establishment and implementation of a QA Program, and packaging operations in accordance with the applicable DOE Certificate of Compliance (CoC) and Chapters 1, 7, 8, and 9 of the Safety Analysis Report for Packagings (SARPs). The Source Verifications and QA Audits resulted in findings in the areas of design, procurement, fabrication, testing, assembly, storage, and use of the packaging. Due to the appropriate timing of source verifications and QA audits, corrective actions were implemented in a timely manner by the DOE entities and their contactors that brought the packaging into compliance with the CoC and SARP. Packaging Models 9975, 9979, and the NAC International, Legal Weight Truck Cask (NAC LWT) were among the packagings audited by the DOE/PCP audit team.

QA TRAINING COURSE

One of the activities undertaken by DOE/PCP is to provide training on topics related to packaging and transportation of radioactive material. Several of these training courses are conducted by Argonne National Laboratory [14]. This includes a course on "*Quality Assurance (QA) for Radioactive Material Transportation Packaging*"; which has been conducted annually since February 1987.

Personnel working in the design, evaluation, certification, use and maintenance of packagings utilized for the transport of fissile material and Type B quantities of radioactive material need to have a sound working knowledge of, and familiarity with, the specific QA requirements in Subpart H of §71. DOE/PCP has issued documents that establish requirements and guidance on QA [11, 12] with a view to assisting personnel involved in these packaging activities in satisfying Subpart H QA requirements. The DOE/PCP-sponsored course on QA for radioactive material transportation packaging includes methods for not only satisfying, in general, the QA requirements of Subpart H, but also applying the graded approach to QA for packaging elements for inclusion in Chapter 9 of the SARP, and satisfying the requirement of the July 2010 DOE directive [10] that each DOE entity subject to DOE Order 460.1C [11] "*that participates in the design, fabrication, procurement, use or maintenance of a hazardous materials packaging must have a QA Program approved and audited by the Headquarters Certifying Official (HCO) that satisfies the requirements of 10 CFR 71, Subpart H, QA, for certified Type B and fissile radioactive material packagings.*"

The QA training course highlights the applicable QA requirements from relevant DOE orders, federal regulations, and NRC regulatory guides. It discusses the application of ASME NQA-1 for Type B and fissile material packaging. It also elaborates on current issues resulting from (a) the differences in emphasis between a compliance-based Subpart H QA program for packaging and a performance-based QA program for DOE nuclear facilities (based on 10 CFR 830 [13]), and (b) the final rule changes in §71 that became effective on October 1, 2004. Applying the graded approach to packaging is one of the main themes of the course and is illustrated through both lecture and class room exercises. An arrangement with U.S. universities is being considered so that

participants could obtain college credit after successfully completing the course, as part of the requirements for a graduate certificate program [14].

CONCLUSION

Implementation of the graded approach for establishing QA requirements for Type B and fissile material packaging audits have the following benefits:

1) Focuses on Important-to-safety items and activities.
2) Incorporates functional and performance requirements in establishing QA requirements.
3) Ensures that packaging QA requirements are consistent with design requirements.
4) Requires teamwork at onset of the design among those responsible for design, fabrication, assembly, testing, operations, and maintenance.
5) Requires a process that develops the appropriate level of QA requirements resulting in compliance with regulatory and safety packaging requirements.

The use of the graded approach in developing QA requirements for Type B and fissile material packaging audits is the most effective method in establishing a QA program for the safe transport of radioactive material.

Within DOE, efforts began in 2010 to ensure that all DOE entities involved with DOE-certified packages and users of NRC-certified packages satisfy the graded approach requirement, which is verified through independent review of the relevant QAPDs and audits and inspections of the package designers' and users' activities. Argonne National Laboratory has been conducting annual QA training courses for DOE; applying the graded approach to transportation packaging is a main theme emphasized in the QA training course.

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