Proceedings of the 19th International Symposium on the Packaging and Transportation of Radioactive Materials
PATRAM 2019
August 4–9, 2019, New Orleans, LA, USA

Quality Assurance for Radioactive Material Packaging

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ABSTRACT

The U.S. Department of Energy Packaging Certification Program (PCP), Office of Packaging and Transportation, Office of Environmental Management sponsors a training course on quality assurance for radioactive material transportation packaging, which has been conducted annually by Argonne National Laboratory since the early 1990s. The course was significantly expanded in 2013, from three to five days, to include quality assurance for dry cask storage systems of spent nuclear fuel and high-level radioactive waste. In 2015, the course became part of the curriculum of the Graduate Certificate in Nuclear Packaging (GCNP) program at the University of Nevada, Reno (UNR). The purpose of the course is to help participants gain the working knowledge of the quality assurance (QA) principles and methods for satisfying those regulatory safety requirements for packagings and casks used in the transportation and storage of radioactive material, including spent fuel and high-level waste. Title 10 of Code of Federal Regulations Parts 71 and 72 that govern packaging and transportation of radioactive material and dry cask storage systems for spent nuclear fuel are addressed, along with DOE Orders and NRC guidance documents, and ASME NQA-1 requirements on organization, quality assurance program, design control, inspection, test control, and corrective action, among others. The course emphasizes a graded approach that is used to establish QA requirements for packaging and cask components important to safety (ITS), software QA, and commercial-grade dedication. The course also addresses planned QA audits and inspections of ITS items and activities at fabrication shops and facilities, as well as the DOE Quality Assurance Approval Program (QAAP) for transportation packagings. The course emphasizes in-class discussions and hands-on exercises, including a mock-loading exercise using a drum-type transportation packaging. The QA course is a required course for the GCNP program, the educational objectives of which are to provide the necessary applied knowledge and skills that mechanical, materials, or nuclear engineers require to be successful as nuclear packaging designers, analysts, and users. Over 50 students have enrolled in the GCNP courses since 2015; the first GCNP Certificate was awarded in 2017. This paper will provide highlights of the QA course, including lessons learned based on feedback received from course participants and future directions.

INTRODUCTION

Historically, during the early years of the twentieth century, the responsibility for quality rested with the craftsman. If the product quality was high, the craftsman was rewarded with additional orders for the product at higher prices. Quality remained the responsibility of the craftsman until the spread of mass production, at which point the responsibility was transferred to the foreman on the production floor. However, in many cases production was stressed over quality. As a result, quality problems often arose. This ultimately led to production facilities assigning independent inspectors to evaluate the quality of products. This was followed by the emergence of a quality control department. During the middle part of the twentieth century, quality assurance requirements and procedures became formalized at national and then international levels. As a result, during the 1960s, the Atomic Safety and Licensing Board (ASLB) of the U.S. Atomic Energy Commission (AEC) determined that the nuclear industry should adopt a compliance-based system for QA programs. This requirement led to the development and publication in 1970 of 10 CFR Part 50, Appendix B, Quality Assurance for Production and Utilization Facilities, including civilian nuclear power reactors. During the 1970s, the American National Standards Institute (ANSI) and the American Society of Mechanical Engineers (ASME) became actively involved in quality assurance and published the ANSI/ASME Standard NQA-1 in 1979. During the 1980s, ANSI and ASME continued their QA standards activities and issued NQA-2 in 1983 for specific applications in nuclear power plants (e.g., the cleaning of fluid systems and associated components, and software QA) and NQA-3 in 1989 for site characterization; however, both NQA-2 and NQA-3 were eventually withdrawn and merged into ASME NQA-1, which was published in 1997 and has since been updated and amended three times, in 2000, 2004, and 2008.

Personnel working in the design, fabrication, evaluation, certification, use, and maintenance of fissile and Type B radioactive material transportation packaging and spent nuclear fuel dry cask storage systems need to have a working knowledge of, and familiarity with, the specific QA requirements in Subpart H and Subpart G of Title 10 of the Code of Federal Regulations Parts 71 and 72 (10 CFR 71 and 10 CFR 72), respectively [1, 2]. The U.S. Nuclear Regulatory Commission (NRC) has issued Regulatory Guide (RG) 7.10 [3] that establishes QA programs for packaging used in transport of radioactive material, whereas U.S. Department of Energy (DOE) Order 460.1D, *Packaging and Transportation Safety* [4], contains specific QA requirements that satisfy Subpart H of 10 CFR 71.

The Packaging Certification Program (PCP), Office of Packaging and Transportation, Office of Environmental Management sponsors a training course on quality assurance for radioactive material transportation packaging that has been conducted annually by Argonne National Laboratory (Argonne) since the early 1990s [5]. The course was significantly expanded in 2013, from three to five days, so that it could address quality assurance for dry cask storage systems (DCSSs) of spent nuclear fuel and high-level radioactive waste. In 2015, the course became part of the curriculum of the Graduate Certificate in Nuclear Packaging (GCNP) program at the University of Nevada, Reno [6].

The purpose of the QA training course is to help participants gain a working knowledge of the quality assurance (QA) principles and methods for satisfying those regulatory safety requirements for packagings and casks used in the transportation and storage of radioactive material, including spent fuel and high-level waste. Issues that are addressed in the course include methods for not only satisfying the QA requirements of Subparts H and G, but also applying the graded approach to QA for packaging elements, and satisfying a recently promulgated requirement that each DOE entity subject to DOE Order 460.1D "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, Quality Assurance for certified Type B and fissile radioactive material packagings." The course highlights the applicable QA requirements from relevant DOE Orders, federal regulations, and NRC regulatory guides; discusses the application of ASME NQA-1 for Type B and fissile material packaging; and elaborates on current issues resulting from the differences in emphasis between a compliance-based QA program (in Subpart H, 10 CFR 71) for packaging and a performance-based QA program for DOE nuclear facilities (based on 10 CFR 830, "Nuclear Safety Management"), and from the final rule changes in 10 CFR 71 that became effective on October 1, 2004.

QUALITY ASSURANCE FOR FISSILE AND TYPE B MATERIAL PACKAGING USED BY DOE ENTITIES

U.S. Department of Transportation (DOT) Regulation 49 CFR 173.7(d) [7] states that Type B and fissile material packagings can be certified by the DOE if they are evaluated against packaging standards equivalent to those in 10 CFR 71. DOE Order 460.1D requires that an application for a fissile or Type B package certification must include a safety analysis report for packaging (SARP), which is the basis for demonstrating that the package design and the packaging procured or fabricated to that design conform with the requirements of 10 CFR Part 71, Subparts E, F, G, and H, and any other applicable standards that the

Assistant Secretary for Environmental Management or a Secretarial Officer/Deputy Administrator in the National Nuclear Security Administration may determine applicable for granting a certificate.

Subpart H of 10 CFR 71 describes a compliance-based QA program for packaging that must be satisfied by these requirements. The key characteristics of the QA program are that it is process-oriented and requires independent verification and documentation of the planned actions. The QA program must be based on 18 QA criteria set forth in Subpart H, and provides requirements for the design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. For package designs reviewed and certified by DOE, the SARP must contain a Chapter 9, which addresses packaging-specific QA requirements.

QUALITY ASSURANCE TRAINING COURSE

The flowchart in Figure 1 depicts the major topics covered in the QA training course, which begins with a discussion of basic QA principles and concepts, regulatory aspects, DOE Orders, packaging QA, and the ASME Code, particularly the development of the ASME NQA-1 [8]. The course also covers 10 CFR 71 and 72 QA program requirements and inspections, design control, welding, software QA, and test requirements, especially the ANSI N14.5 leakage rate tests [9]. Other topics covered in the course include (a) DOE's QA approval program and QA audits; (b) packaging QA related to commercial grade dedication (CGD); (c) graded approach; (d) the DOE RAMPAC website, https://rampac.energy.gov/, and QA guidance; and (e) a mock loading exercise and a graded approach exercise using a transportation packaging.

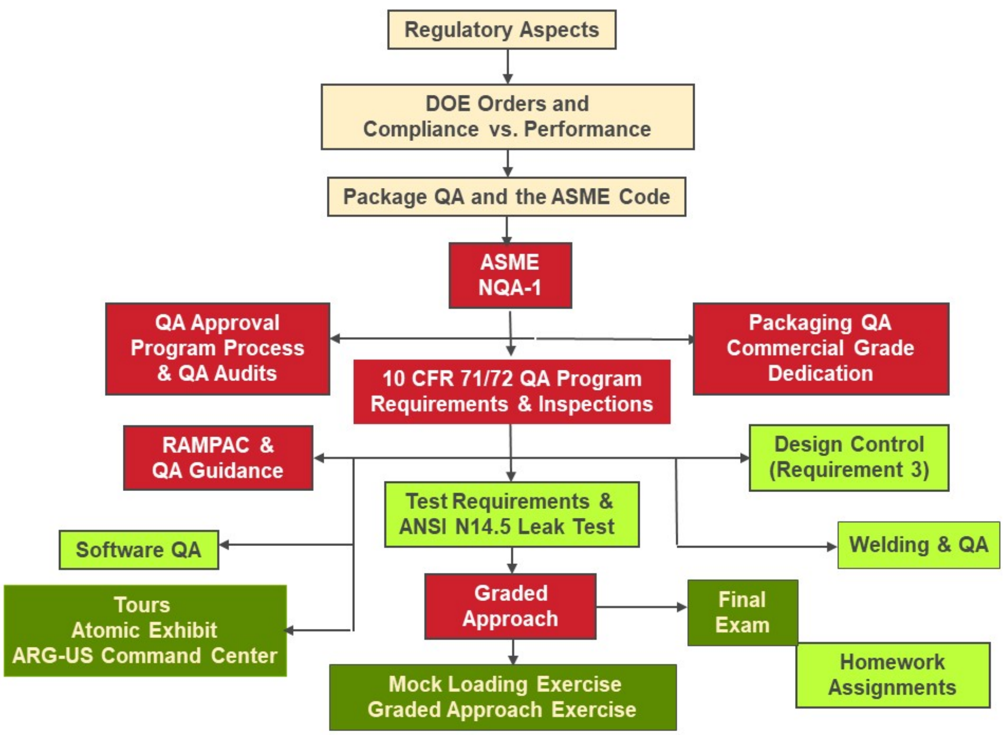

Figure 1. Flowchart covering major topics of the course.

In addition to lectures and discussions, the course also includes homework assignments and problem exercises designed to enhance understanding of QA concepts and principles and their applications to transportation packaging and dry cask storage systems, along with facility tours and a final exam. Selected topics of the QA course are highlighted below.

The ASME NQA-1 Requirements

The standard ASME NQA-1-2008 [8], *Quality Assurance Requirements for Nuclear Facility Applications*, satisfies the QA requirements specified in 10 CFR 71, Subpart H, and 10 CFR 72, Subpart G. The ASME NQA-1 standard represents a unified QA standard; it includes 18 requirements, and describes the essential features of each requirement. The 18 requirements in ASME NQA-1 are fully consistent with the 18-point QA criteria identified in Subpart H of 10 CFR 71 and Subpart G of 10 CFR 72. Organizations that invoke this standard can specify the extent of the requirements to be used; for example, designer and user generally do not follow the same set of requirements. The Argonne QA training course selects two major elements, design control and QA program, for in-depth discussion and illustration on how to effectively apply the requirements of NQA-1 in concert with the 18-point criteria of Subparts H and G. Note that only ANSI/ASME NQA-1-2008 with NQA-1a-2009 addenda is fully endorsed by the NRC as meeting the 18-criteria QA program per Subpart H of 10 CFR 71 [3].

The Compliance-based Approach versus the Performance-based Approach

A compliance-based QA system is one that satisfies all requirements in a multitude of processes (e.g., design control, welding, and nondestructive examination); whereas a performance-based QA system seeks to achieve overall results and objectives (e.g., a leak-tight shipping container). DOE applies a performance-based system of QA programs to its facilities. However, since 49 CFR 173.7 [7] requires that DOE transportation activities involving Type B and fissile material packages must comply with 10 CFR 71, QA for these transportation packages must follow the compliance-based QA system specified in 10 CFR 71, Subpart H.

A key element of a compliance-based QA system is that individuals who verify quality and perform audits must be independent from the individuals who achieve quality for a product, service, or process but are not responsible for cost and schedule. This stipulation has led to the DOE requirement that each DOE entity that participates in the design, fabrication, procurement, use, or maintenance of these packaging must have a QA Program approved by the DOE Headquarters Certifying Official, and that this approval is based on demonstration that the entity satisfies the requirements of Subpart H of 10 CFR 71. The development of Chapter 9 Quality Assurance in a SARP, emphasizing packaging-specific QA requirements for structure, system and components (SSC) in accordance with their importance to safety and how to comply with the requirements of Subpart H are emphasized in the training course.

The Graded Approach in QA

The NRC specifies the use of the graded approach in 10 CFR 71.101 and 10 CR 72.140, in RG 7.10 [3], and in NUREG/CR-6407, “Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety” [10]. DOE specifies the use of the graded approach for QA in DOE Order 414.1D. Parts I and II of the ASME NQA-1 standard [8] specify the use of a graded approach. The graded approach in QA is directly coupled to determining the importance to safety of each item (i.e., each SSC) and each activity.

For items and activities “important to safety,” §71, Subpart H, specifies the following:

- §71.101(a): *“This subpart describes quality assurance requirements applying to design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety.”*
- §71.103(b)(2): *“The quality assurance functions are—Verifying, by procedures such as checking, auditing, and inspection, that activities affecting the functions that are important to safety have been correctly performed.”*
- §71.107(a): *“Measures must be established for the selection and review for suitability of application of materials, parts, equipment, and processes that are essential to the functions of the materials, parts, and components of the packaging that are important to safety.”*

NUREG/CR-6407 [10] provides a detailed "roadmap" for classifying packaging components following a graded approach. Each component of a transportation packaging and spent fuel storage system is first identified as either important to safety or not important to safety. Components that are considered important to safety are then further categorized into one of three classification categories:

- **Category A** – Critical to safe operation: *Items whose failure or malfunction could directly result in an unacceptable condition of containment/confinement, shielding, or nuclear criticality*.
- **Category B** – Major impact on safety: *Items whose failure or malfunction could indirectly result in an unacceptable condition of containment/confinement, shielding, or nuclear criticality; an unsafe condition could result only if the failure of this item occurred in conjunction with the failure of another item in this category*.
- **Category C** – Minor impact on safety: *Items whose failure or malfunction would not reduce packaging effectiveness and would not result in an unacceptable condition of containment/confinement, shielding, or nuclear criticality, regardless of other failures in this category*.

Commercial-grade Dedication

Commercial-grade dedication (CGD) is a process by which a commercial-grade item (CGI) is designated for use as a basic component. This acceptance process is undertaken to provide reasonable assurance that a CGI to be used as a basic component will perform its intended safety function and, in this respect, is deemed equivalent to an item designed and manufactured under a 10 CFR Part 50, Appendix B, quality assurance program. This assurance is achieved by identifying the item's critical characteristic(s) and verifying their acceptability by inspections, tests, or analyses by the purchaser or third-party dedicating entity. A CGI may sometimes be identified as being commercial off-the-shelf or commercially available off-the-shelf (COTS). Examples of COTS from the NRC include:

- COTS software (NUREG/CR-6421)
- COTS systems (ML080590351)
- COTS commodity solutions (ML082070065)
- COTS items and related services (ML092580265)
- COTS products (ML040280585)

LESSONS LEARNEAD AND FUTURE COURSES

The QA for Radioactive Material Packaging courses have been conducted by Argonne staff annually for many years, covering initially only transportation packaging and later (since 2014) both transportation packaging and dry cask storage systems. The QA course and its companion course, "The ASME Pressure Vessel Code for Nuclear Transport and Storage" [11], are the required, foundational courses for the GCNP program, the educational objectives of which are to provide the necessary applied knowledge and skills that mechanical, materials, or nuclear engineers require to be successful as nuclear packaging designers, analysts, and users. More than 50 students have enrolled in the GCNP courses since 2015, with the first GCNP certificate awarded in 2017. Although the QA for Radioactive Material Packaging course has reached a level of maturity in terms of its content, we are continuously seeking improvement in its delivery, emphasizing class interactions, exercises, and use of videos and modern learning tools, such as an e-voting system with carefully designed questions to elicit participants' responses in a collective learning atmosphere. So far, feedback received from the course participants has been positive and encouraging.

ACKNOWLEDGMENTS

This work is supported by the U.S. Department of Energy, Office of Packaging and Transportation, Office of Environmental Management, under Contract No. DE-AC02-06CH11357. The submitted manuscript has been created by UChicago Argonne, LLC as operator of Argonne National Laboratory ("Argonne") under contract no. DE-AC02-06CH11357 with the U.S. Department of Energy. The U.S. government retains for

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