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ESTABLISHING QUALITY ASSURANCE PROGRAMS FOR PACKAGING USED IN TRANSPORT OF RADIOACTIVE MATERIAL

A. INTRODUCTION

This regulatory guide provides guidance for use in developing quality assurance (QA) programs for packaging to be used in shipping Type B and fissile radioactive materials. This guide also provides guidance for use in preparing and submitting QA program descriptions for review by the staff of the U.S. Nuclear Regulatory Commission (NRC). This guidance describes a method that is acceptable to the NRC staff for complying with the related regulatory requirements in Title 10, Part 71, of the *Code of Federal Regulations* (10 CFR Part 71), "Packaging and Transportation of Radioactive Material." Specifically, 10 CFR 71.37(a) requires that applicants requesting package design approval must describe, with respect to Subpart H of 10 CFR Part 71, the QA programs that they will apply in designing, fabricating, assembling, testing, maintaining, repairing, modifying, and using the proposed packaging. In addition, 10 CFR 71.101 requires that licensees, certificate holders, and applicants for a certificate of compliance must implement and use a QA program that the NRC staff has previously approved as satisfying the provisions of Subpart H of 10 CFR Part 71. Specifically, Subpart H requires, in part, that QA programs of licensees, certificate holders, and applicants for a certificate of compliance must satisfy each of the applicable criteria specified in 10 CFR 71.101 – 71.137 to an extent that is consistent with their respective importance to safety.

Terms used in this guide are consistent with those used in 10 CFR Part 71, as well as ANSI/ASME Standard NQA-1-1983, "Quality Assurance Requirements for Nuclear Power Facilities" (Ref. 1), promulgated by the American National Standards Institute (ANSI) and the American Society of Mechanical Engineers (ASME).

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This guide was issued after consideration of comments received from the public. The NRC staff encourages and welcomes comments and suggestions in connection with improvements to published regulatory guides, as well as items for inclusion in regulatory guides that are currently being developed. The NRC staff will revise existing guides, as appropriate, to accommodate comments and to reflect new information or experience. Written comments may be submitted to the Rules and Directives Branch, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001.

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This regulatory guide contains information collections that are covered by the requirements of 10 CFR Part 71, which the Office of Management and Budget (OMB) approved under OMB control number 3150-0008. The NRC may neither conduct nor sponsor, and a person is not required to respond to, an information collection request or requirement unless the requesting document displays a currently valid OMB control number.

B. DISCUSSION

REGULATORY FRAMEWORK FOR TRANSPORT OF RADIOACTIVE MATERIAL

The NRC's regulatory requirements for packaging and transporting radioactive materials are codified in 10 CFR Part 71. Those requirements state that the agency grants licenses to transport radioactive materials, under the provisions of 10 CFR Part 71, Subpart C, "General Licenses," only to licensees whose QA programs the NRC has previously approved as satisfying the provisions of 10 CFR Part 71, Subpart H, "Quality Assurance." The NRC also imposes QA requirements on those who submit applications for approval of package designs under the provisions of 10 CFR Part 71, Subpart D, "Application for Package Approval." Specifically, an application for an approval under Subpart D should include, for each proposed package design, a QA program description as required by Subpart H, or a reference to a QA program that the NRC has previously approved. If an applicant fails to include a QA program description or reference a previously approved description, the NRC staff considers the application incomplete and may return it to the applicant. As used in 10 CFR Part 71, "quality assurance" comprises all planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. As such, QA includes quality control (QC), which comprises those quality assurance actions that relate to controlling the physical characteristics and quality of the materials or components in accordance with predetermined requirements.

Subpart H of 10 CFR Part 71 establishes QA requirements that apply to designing, purchasing, fabricating, handling, shipping, storing, cleaning, assembling, inspecting, testing, operating, maintaining, repairing, and modifying packaging components that are important to safety. To meet those requirements, licensees should control the quality of each of the above activities using a graded approach; that is, the QA effort that a licensee expends on an activity should be consistent with the importance to safety of the associated structures, systems, and components. For the purposes of this regulatory guide, structures, systems, and components important to safety mean the features of a Type B or fissile material package that are intended to (1) maintain the conditions required to safely transport the package contents; (2) prevent damage to the package during transport; or (3) provide reasonable assurance that the radioactive contents can be received, handled, transported, and retrieved without undue risk to the health and safety of the public or the environment. Appendix A to this guide, "A Graded Approach to Developing Quality Assurance Programs for Packaging Radioactive Materials," describes a method for developing a QA program with a graded approach. Additional guidance is available in NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety" (Ref. 2).

The NRC explicitly requires that each licensee or package design applicant (hereinafter referred to as a "QA program user") must submit a description of its QA program, along with a discussion of which Subpart H requirements apply and how those requirements will be satisfied. Toward that end, QA program users should address the regulations delineated in Subpart H to the extent applicable to their respective operations.

The types of activities in which a given QA program user engages will determine which sections of the Subpart H regulations the QA program will need to address and which activities the NRC staff will review before approving the program. The activities covered by the QA program may be divided into two major areas. Specifically, the first area comprises activities associated with 10 CFR Part 71, Subpart D, "Application for Package Approval," which usually leads to issuance of a certificate of compliance (CoC) and fabrication of the approved packaging. The activities normally authorized by NRC approval of a QA program in this area are design, testing, repair, fabrication, procurement, modification, assembly, maintenance, and use. The second area comprises activities associated with 10 CFR Part 71, Subpart C, "General Licenses." The activities normally authorized by NRC approval of a QA program in this area are repair, procurement, maintenance, and use.

This regulatory guide includes information about commonly misinterpreted areas of 10 CFR Part 71, such as (1) the extent of detail required in QA program descriptions, (2) submittal of program descriptions based solely on other QA standards, and (3) requirements for initial and subsequent NRC approval of QA program descriptions.

LEVEL OF DETAIL IN QA PROGRAM DESCRIPTIONS

In their program description submittals, QA program users should identify how each regulation in 10 CFR Part 71, Subpart H applies to their particular situations and how those regulations will be satisfied. Thus, the information supplied for NRC review varies as a function of the nature of the activities in which a given QA program user will engage. For example, a QA program user who has a general license solely to transport radioactive materials in packages that are purchased or leased for that purpose would be expected to address criteria governing such activities as procurement, shipment, and handling. By contrast, a QA program user who designs and fabricates a packaging would be expected to address criteria for design and testing, as well as activities related to procuring the component materials. Elements that are common to all QA program descriptions include the quality organization and program, corrective actions, QA records, and audits (among others).

In defining what the NRC staff considers to be an acceptable QA program description submittal, it helps to define what the staff has determined to be unacceptable submittals. Generally, this focuses on the two extremes of providing either too little or too much information. With respect to providing too little information, the NRC has received and rejected QA program descriptions that basically restated the QA program requirements in Subpart H of 10 CFR Part 71, and failed to describe which elements of the NRC's QA program requirements applied to the QA program user's activities and/or how the QA program user would satisfy those requirements. At the other extreme, the NRC has received and rejected QA program submittals that were extremely detailed, to the point that they contained actual implementing procedures, which the staff does not review.

Thus, an acceptable QA program submittal is one that lies between the two extremes, in that it addresses each regulation in Subpart H of 10 CFR Part 71 that applies to the QA program user's activities, and describes how the QA program user will implement and satisfy each of those regulations. Keeping in mind the limitations described in the previous paragraph, the extent of detail is at the QA program user's discretion. However, while more detail may be desirable to a QA program user, it does have a potential downside. As discussed later in this regulatory guide, any proposed change to the content of an NRC-approved QA program requires NRC review and approval before implementing the change. Thus, a detailed QA program description allows the user less flexibility in the event that changes to activities described in the plan are needed quickly, as such changes will require NRC review and approval before they can be implemented and this will take time to accomplish.

QUALITY ASSURANCE PROGRAM SUBMITTALS BASED ON OTHER STANDARDS

The NRC staff occasionally receives QA program descriptions that are based on different QA standards, such as ANSI/ASME NQA-1-1983 (Ref. 1), or the ISO 9000 series promulgated by the International Organization for Standardization (Ref. 3). While the staff may find such submittals acceptable upon review, QA program users should be aware that the QA regulations in 10 CFR Part 71 include requirements that other standards may not fully address. In general, programs based on NQA-1 or the ISO 9000 standards will require supplementation in order to address all Subpart H regulations; the only exception is the 1983 revision of NQA-1, which the NRC has endorsed in its entirety. Without supplementation, the NRC may require the QA program user to submit additional information regarding how the applicable Subpart H regulations will be met. This may necessitate changes to the submitter's underlying QA program and delay NRC review and approval.

CHANGES TO APPROVED QA PROGRAM DESCRIPTIONS

Based on the applicable NRC regulations and the approved QA program, the QA program user should develop and implement lower-level (working-level) documents to govern the conduct of QA activities that are important to safety.

Any changes to an approved QA program description must be reviewed and approved by the NRC before being implemented. Therefore, to make a change in the QA program description that was the basis for NRC approval, the QA program user must submit the change for NRC review and approval before implementing the change. Because the NRC staff noted recurring misunderstanding of this requirement, the Commission issued NRC Information Notice 2002-35, "Changes to 10 CFR Parts 71 and 72 Quality Assurance Programs" (Ref. 4).

C. REGULATORY POSITION

To assess compliance with the QA requirements of Subpart H of 10 CFR Part 71, the NRC staff typically reviews elements of a QA program that involve activities related to the design, fabrication, procurement, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, modification, and use of radioactive material packaging. The applicability of each element depends on the activities in which the QA program user is involved, as well as the graded approach that the QA program user implements for items that are important to safety.

Individuals and organizations who are subject to Subpart H should submit their program descriptions to obtain NRC approval before engaging in any activity that is important to safety. Those who engage in activities important to safety before obtaining approval of their QA programs risk having to demonstrate that such activities were in compliance with QA requirements. After determining that a given QA program submittal is adequate, the NRC will issue a QA Program Approval. Such approvals expire on the last day of the month stated on the approval form and may be renewed (at the QA program user's request) prior to expiration.

Establishment of a QA program implies that all activities important to safety and applicable to the design, fabrication, procurement, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, modification, and use of packages are implemented with written procedures approved by appropriate levels of management.

To the NRC staff, a QA program that the agency approves under Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities") or Subpart G of Part 72, "Quality Assurance" is equivalent to a QA Program that the staff approves under 10 CFR Part 71. **The NRC has also endorsed the use of ANSI/ASME NQA-1-1983, "Quality Assurance Program Requirements for Nuclear Power Facilities,"** as a standard that, when properly applied and supplemented (as necessary) to meet all applicable criteria, should result in the development of a QA program that is acceptable to the NRC staff.

1. GUIDANCE ON §71.103, "QUALITY ASSURANCE ORGANIZATION"

1.1 Structure and Authority

For each function, the structure of the organization and the assignment of responsibility should ensure that the following requirements are fulfilled:

- The formal structure of the organization is documented by organization charts that identify each organizational element that functions under the QA program.
- The discussion specifies the required authority and organizational freedom, including sufficient independence from influences of cost and schedule.
- The specified quality requirements are achieved and maintained by those who have been assigned the responsibility for performing the work.
- The QA program user has established measures to provide adequate control over activities important to safety (e.g. inspecting, cleaning, purchasing, and preparing the packaging for delivery).
- Conformance to established requirements is verified by individuals and groups that are not directly responsible for performing the work.

Note: If, because of staffing limitations, the same individuals perform multiple functions (including QA), the QA program user should establish measures to ensure that when performing QA and QC functions, the designated individuals have the responsibility and authority to stop unsatisfactory work and/or delivery or installation of nonconforming material, and have direct access to management levels that can ensure that QA procedures important to safety have been accomplished.

In addition, the QA program user should establish and document the required duties and qualifications for (1) the individual who has overall authority and responsibility for the QA program, as well as (2) other personnel performing QA and QC functions, and those individuals should have the written endorsement of top management.

1.2 Top Management Endorsement of a QA Program

Top management should maintain a continuing involvement in QA matters in order to ensure that the QA program is effective. To ensure the commitment of top management, the company/corporate president or chief executive officer should establish a written policy stating that it is company/corporate policy to perform work on items important to safety in accordance with the requirements of Subpart H, as described in the QA program plan and implemented in the QA program implementing documents.

The policy statement should also identify the functions and positions who have delegated authority for the following tasks:

- Implement and revise the provisions of the described QA program.
- Regularly assess the scope, status, implementation, and effectiveness of the QA program.

2. GUIDANCE ON §71.105, "QUALITY ASSURANCE PROGRAM"

2.1 General Guidance on QA Programs

In its program description submittal, the QA program user should identify to the NRC how each of the regulations in Subpart H of 10 CFR Part 71 applies to its particular situation and how it will be satisfied. The information supplied for NRC review will vary as a function of the nature of activities in which the QA program user is involved. For example, an individual or organization using a general license solely for transportation of radioactive material in packages purchased or leased for that purpose would be expected to address regulations governing activities such as procurement, shipment, and handling. By contrast, someone who designs and fabricates packaging would be expected to address criteria for design and testing, as well as material procurement activities. Elements common to all QA program descriptions include the quality organization and program, corrective action, QA records, and audits.

In developing its programs, prospective QA program users can refer to the NRC's guidance in this regulatory guide, as well as the additional guidance on graded QA in NUREG/CR-6407 (Ref. 2). In developing its program, QA program users should apply each of the applicable Subpart H regulations in a graded approach (i.e., to an extent that is consistent with its importance to safety).

Following the NRC staff's technical review and determination that the QA program submittal meets regulatory requirements, the Commission issues a QA Program Approval. The approval expires on the last day of the month stated on the approval form and may be renewed (at the request of the QA program user and in accordance with 10 CFR 71.38) not less than 30 days prior to expiration.

All changes to the approved QA program description require NRC approval. Therefore, before implementing any change in the QA program description that was used as the basis for NRC approval, the QA program user should submit the proposed change for NRC review and approval. Requests for review and approval of such changes are handled through amendments to the QA Program Approvals and do not affect the renewal dates. The only exception to the requirement for NRC approval of any change relates to QA programs that the NRC staff approved under Appendix B to 10 CFR Part 50, which was subsequently accepted under 10 CFR 71.101(f). This exception allows a nuclear power plant licensee to change such a QA Program to the extent permitted under 10 CFR 50.54(a)(3).

Based on NRC approval of its QA program description submittals, a QA program user will translate the regulations discussed in its submittals into lower-level (working-level) implementing procedures that govern the conduct of QA activities that are important to safety.

If the NRC staff reviews a QA program submittal and finds that it inadequately describes how the requirements will be met or fails to specifically address some Subpart H regulation(s), the staff will ask the QA program user to submit additional information to correct the deficiencies.

2.2 Scope of QA Program

The QA program user should establish measures for identifying (1) the components, structures, and systems to be covered by the QA program, and (2) the approach for verifying that the applicable components, structures, and systems meet design objectives. Although 10 CFR Part 71 allows the development of a "graded" QA program, this does not preclude the alternative of defining a program based on maximum controls if such a program is deemed necessary to attain the confidence needed for meeting design objectives. In particular, the QA program user should establish measures to ensure that the following requirements are fulfilled:

- Activities important to safety are performed using specified equipment and under suitable environmental conditions.
- QA/QC manuals specify the designated QA and QC responsibilities for implementation of activities important to safety.
- The QA program user has established indoctrination and training programs to ensure that personnel performing activities important to safety are trained and qualified to perform those activities.

2.3 Applicability of QA Program

Measures covered by the QA program should be compatible with and emphasize characteristics identified in the manufacturer's QA program. The QA program user should establish the rationale to identify items that are classified as important to safety and subject to the user's QA program.

2.4 Documentation

The QA program user should ensure that (1) written procedures and instructions describe all activities that are important to safety and applicable to the design, procurement, fabrication, and testing of packaging, and (2) those procedures and instructions will be in place before the QA program user engages in those activities.

With respect to anticipated activities important to safety that the QA program user has not yet initiated, the user should identify the implementing procedures by title and procedure number, and should provide a brief description of the content of those procedures with an estimated date for their completion. The following table shows a suitable format for listing procedures to demonstrate implementation of a documented QA program.

Table 1. Format for Listing Implementing Procedures*

Implementing Document	Title	Regulatory Position	Description
Quality Assurance Manual (QAM), Quality Procedure (QP) 1	Organization	1	Identifies the QA organization, its relationship to other organizations within the company, and its responsibilities for activities affecting quality.
QAM, QP 2	QA Program	2	Describes basic methods for establishing a documented QA program that implements requirements of Subpart H to Part 71.
QAM, QP 3	Design Control	3	Describes design control measures established for structures, systems, and components.
QAM, QP 4	Procurement Document Control	4	Describes procedures for ensuring that applicable regulatory requirements, design bases, and other requirements necessary to ensure adequate quality are suitably included or referenced in documents for procurement of material, equipment, and services.
QAM, QP 18	Audits	18	Describes internal and external audit programs applicable to both in-house and major suppliers.

* This table shows examples only for Regulatory Positions 1, 2, 3, 4, and 18; however, the QA program user should provide the requested information for all 18 regulatory positions.

To demonstrate that written procedures fully implement and reflect the current status of the documented QA program, the QA program user should establish and maintain a master index of QA procedures related to all activities important to safety, as well as a matrix of the QA procedures that implement each section of Subpart H. These written procedures should also address the use, management, and storage of electronic records and data.

2.5 Controlled Conditions and Assignment of Responsibilities

The QA program user should establish measures to ensure that activities important to safety are accomplished using appropriate production and test equipment, suitable environmental conditions, applicable codes and standards, and proper work instructions. The QA program user should also document the assignment of responsibility for each task and method used to verify conformance to these quality requirements.

3. GUIDANCE ON §71.107, "PACKAGE DESIGN CONTROL"

Essential elements of adequate design control are (1) good relationships among those responsible for preparing design disclosures, (2) conducting independent design analyses, (3) coordinating interfaces, and (4) maintaining lines of communication. To ensure an adequate commitment to control of design activities, applicants should consider the three principal areas of (1) control of the design process, (2) control of design input, and (3) control of design verification, as defined in regulatory positions 3.1 – 3.3.

Since users of packaging do not normally perform design activities, this section of Subpart H should not be applicable to users of packaging. However, users should establish and verify that the packaging was designed under the control of an NRC-approved QA program.

Computer-aided design (CAD) is extensively used in current design applications. Designs developed using CAD methods are prepared and stored electronically. Thus, applicable QA procedures that address software verification/validation, management of electronic records, and quality control of electronic data should address the control of electronic data in design applications to ensure authenticity and technical accuracy. The Nuclear Information and Records Management Association (NIRMA), American National Standards Institute (ANSI), and the Electric Power Research Institute (EPRI) provide guidance for use in developing QA programs for managing electronic data. In addition, NRC Generic Letter 88-18, "Plant Record Storage on Optical Disks" (Ref. 5), and Regulatory Information Summary 00-18, "Guidance on Managing Quality Assurance Records in Electronic Media" (Ref. 6), provides guidance on the use of optical disc document imaging systems for retrieving record copies of QA records.

3.1 Control of the Design Process

The QA program user should establish measures such as "classification of characteristics" to ensure that packaging designs are reviewed to emphasize critical parameters that can be controlled by inspections or tests and to identify test and inspection criteria and quality standards.

To control the preparation of drawings and specifications, the QA program usershould establish recognized engineering practices, such as prescribing drafting room standards, checking methods, establishing review/approval and issuance/distribution requirements (including revisions to them), maintaining current "as-built" configurations, and storing and controlling original and master copies.

3.2 Control of Design Input

The QA program user should establish measures to ensure that appropriate codes and standards are used in the design of the packaging. In the absence of such codes and standards for formulation of the design activities, the QA program user should identify alternative approaches.

The QA program user should establish measures to ensure that (1) the responsible design organization has properly considered, reviewed, and approved all design parameters (e.g., criticality physics, cooling, and decontamination of an item); (2) the parameters are in accordance with the applicable performance codes, standards, and regulatory requirements; and (3) design documents specify the related maintenance, repair, inservice inspection, handling, storage, and cleaning requirements.

3.3 Control of Design Verification

The QA program user should establish methods for use in verifying the adequacy of the design (e.g., qualification testing, design review, or alternative calculations, including use of computer programs). Technically qualified individuals or groups responsible for design verification should not be in the administrative line of authority of the original designer, with the exception that the designer's immediate supervisor may perform the verification, provided that the following criteria are met:

- The supervisor is the only technically qualified individual.
- The supervisor's management documents and approves the need in advance.
- The QA audits cover the effectiveness of the use of supervisors as design verifiers to guard against abuse of this practice.

Changes to the final design may arise during the sequence of design verification. Consequently, the QA program user should establish measures to ensure that drawing and specification changes are reviewed and approved by the same individuals or organizations who reviewed and approved the original documents. Changes in design that could result in conditions different from those prescribed on the CoC should be approved by the NRC prior to implementation.

Design verification, if other than by qualification testing of a prototype or lead production unit, should be satisfactorily completed prior to (1) release for procurement or fabrication and (2) release to other organizations for use in other design activities except when this timing cannot be met. In such cases, design verification may be deferred, provided that the justification for this action is documented and the unverified portion of the design output documents are appropriately identified and controlled. When a test program is used to verify the adequacy of a design, the prototype should be subjected to the most adverse design conditions.

4. GUIDANCE ON §71.109, "PROCUREMENT DOCUMENT CONTROL"

The QA program user should establish measures to control the preparation, review, concurrence, and approval of all procurement documents.

4.1 Content of Procurement Documents

The QA program user should establish measures to ensure that procurement documents include the following information (as applicable):

- the scope of work to be performed by the prospective supplier
- the design-basis technical requirements (or references thereto), including applicable regulatory requirements, material and component identification requirements, drawings, specifications, codes and standards, special process instructions, and test and inspection requirements
- applicable Subpart H requirements that should be complied with and described in the supplier's QA program (Qualified QA personnel from the purchaser's organization should review and concur in the supplier's QA program or portions thereof before the purchaser initiates activities affected by the program. Also, if sub-tier suppliers are involved, the QA program user should specify the QA provisions appropriate to those procurements. The extent of the supplier's and sub-tier supplier's QA programs will depend on the particular item or service being procured.)
- permission to gain access to the supplier's and sub-tier supplier's plant facilities and records for inspection and audit purposes (Procurement documents should identify the type of verification activities required of any sub-tier suppliers for supplied materials, as well for any design, fabrication, assembly, testing, maintenance, and repair services or activities supplied.)

- identification of the documentation (e.g., drawings, specifications, procedures, inspection and fabrication plans, inspection and test records, personnel and procedure qualifications, results of chemical and physical tests on material) that the supplier(s) must prepare, maintain, and submit to the purchaser for approval
- requirements for reporting and approving disposition of nonconformances
- identification of records that the supplier must retain, control, and maintain, as well as those records that the supplier must deliver to the purchaser prior to installation of hardware [These records should include the pertinent documentation to be furnished with the procured materials or services (e.g., CoC, as-built drawings, photographs, sketches, use and maintenance manuals). If the pertinent documentation is in an electronic format, the QA program user should specify the software system that must be used to prepare and deliver the documentation.]

4.2 Replacement Part Procurement

Measures should be established to require that procurement of replacement parts important to safety be reviewed by QA personnel to ensure that appropriate technical and QA requirements are included in purchase orders and that the purchase orders are placed with suppliers previously qualified during fabrication of the packaging. If replacement parts are purchased from suppliers not previously identified as qualified sources, the QA program user must assure himself or herself that the replacement parts meet requirements at least as stringent as the original criteria.

4.3 Review and Changes to Procurement Documents

The QA program user should establish measures to ensure that review and approval of procurement documents are recorded prior to release, and that changes and revisions to those documents are subject to at least the same review and approval as the original documents.

5. GUIDANCE ON §71.111, "INSTRUCTIONS, PROCEDURES, AND DRAWINGS"

5.1 Quality Assurance Program Procedures

The QA program user should establish measures to ensure that the following requirements are fulfilled:

- Activities important to safety are prescribed and accomplished in accordance with current documented instructions, procedures, or drawings that have been approved by appropriate levels of management.
- Instructions, procedures, and drawings specify the methods for complying with each of the applicable sections of Subpart H of 10 CFR Part 71.
- All work activities are coordinated with QA personnel to ensure that the work controlling documents incorporate appropriate inspection and hold points to verify that initial work, planned work, effective repairs, or rework have been performed satisfactorily.
- Instructions, procedures, and drawings include quantitative acceptance criteria (e.g., dimensions, tolerances, and operating limits) and qualitative acceptance criteria (e.g. workmanship samples) to verify that activities important to safety have been satisfactorily accomplished.
- Written procedures address the use, management, storage, and protection of electronic records and data. The QA program user should also maintain information on the specific software applications and storage or computing hardware.

5.2 QA Review and Concurrence

The QA program user should establish measures to ensure that the QA organization reviews and concurs in inspection plans; test, calibration, and special process procedures; and specifications as well as any changes thereto. Prior to fabrication of an item, the QA organization should review and concur in the related manufacturing plans, as they relate to scheduled witness and hold points during fabrication.

6. GUIDANCE ON §71.113, "DOCUMENT CONTROL"

6.1 Controlled Documents

The QA program user should maintain each of the documents under the control of the QA program to reflect the current status. As a minimum, the QA program user should exercise control over the following:

- design documents (e.g., drawings, specifications, and computer codes)
- procurement documents
- QA and QC manuals
- operating, maintenance, and modification procedures
- inspection and test procedures
- nonconformance reports
- design change requests
- corrective action reports

6.2 Control of Document Generation and Issuance

The QA program user should establish controls to ensure that all documents and changes thereto are adequately reviewed and approved prior to their issuance. These controls should include measures (e.g., the use of a master document list) to ensure that current issues of applicable documents are available at the location where the activity is being performed to preclude use of obsolete or superseded documents. The QA program user should also check all packaging affected by design changes to verify that it is in accordance with the appropriate revision. In addition, the QA program user should identify (by function or position) the individuals or groups responsible for reviewing, approving, and issuing documents and revisions thereto.

6.3 Control of Document Changes

The QA program user should establish measures to ensure that changes to documents are reviewed and approved by the same organization that performed the original review and approval and the changes are in accordance with established configuration control procedures.

6.4 Control of Electronic Documents

If the documents are stored electronically, the QA program user should establish controls over access to the documents to ensure that the latest versions of the documents are available and changesto the documents are properly authorized and implemented. The software and hardware systems used to store electronic information should be reliable to avoid alteration or corruption of the information.

7. GUIDANCE ON §71.115, "CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES"

The QA program user should establish measures in the areas identified below to ensure that materials, equipment, and services conform to procurement documents.

7.1 Procurement Document Planning

The QA program user should establish procurement planning procedures that describe each procurement step leading to contract award for items and services. These procedures should identify the organizations responsible for each procurement step.

7.2 Selection of Procurement Sources

The QA program user should establish measures for evaluating and selecting procurement sources, including the extent of QA and engineering involvement. Specifically, the QA program user should consider establishing the following provisions (if applicable):

- the supplier's capability to comply with applicable sections of Subpart H
- results of the survey of the supplier's facility and QA program
- review of the supplier's previous records and performance

7.3 Bid Evaluation and Award

The QA program user should establish measures to ensure that designated individuals or organizations evaluate proposed suppliers, as applicable to the type of procurement, based on technical considerations, conformance to QA requirements, production capability, and past performance.

Prior to contract award, the QA program user should resolve (if possible) all unacceptable conditions identified during the bid evaluation. If any unacceptable conditions cannot be resolved prior to contract award, the QA program user should obtain the supplier's commitment that the conditions will be resolved at a mutually agreeable date during the contract period.

7.4 Supplier Performance Control

The QA program user should establish measures for pre- and post-award activities, such as meetings and other communications, to ensure that the supplier understands procurement requirements, including, if applicable, "hold points" (i.e., preestablished inspection points in the manufacturing process that require inspection approval and release by the QA organization prior to further processing) during manufacturing and testing and before shipment.

7.5 Verification Activities

The QA program user should establish the extent to which source surveillance will be performed during fabrication, assembly, maintenance, modification, repair, inspection, testing, and shipment to ensure conformance with the purchase order requirements. The source surveillance should cover the following aspects:

- instructions specifying characteristics or processes to be witnessed, inspected, or verified
- the documentation required
- identification of those responsible for implementing source surveillance

The QA program user should also establish the extent to which inspection will be performed upon receipt of supplier-furnished hardware to ensure that items are properly identified and correspond with procurement documentation. When acceptance of an item is contingent on tests after installation in the package, the QA program user and item supplier should mutually establish the relevant acceptance documentation prior to its use.

In addition, the QA program user should take appropriate measures (such as source surveillance and audits of records) to ensure that the supplier performed the design and fabrication of packaging under the control of an NRC-approved QA program.

7.6 Controlling Nonconformances

The QA program user should establish measures to ensure the proper disposition of items or services that do not meet procurement requirements. These measures should include evaluation of nonconforming items categorized by the supplier, along with technical justification and recommended disposition (e.g., "use as is" or "repair").

7.7 Records

The QA program user should establish measures to ensure that the supplier furnishes to the purchaser the following records (as a minimum):

- documentation that identifies material or equipment and the specific procurement requirements (e.g., codes, standards, and specifications met by the items)
- documentation that identifies any procurement requirements that have not been met, along with a description of those nonconformances designated "use as is" or "repair"
- documentation that the supplied material and equipment meets the applicable procurement requirements prior to installation or use
- appropriate documentation, as identified in the purchase order, that will accompany the NRC-approved packaging during transport and be received at the destination by the user

Such documents should (1) be referenced in the CoC, (2) relate to the use and maintenance of the packaging, and (3) identify necessary actions to be taken prior to delivery of the licensed material to a carrier for transport. If the pertinent documentation is in an electronic format, the QA program user should specify the software system that must be used to prepare and deliver the documentation.

The QA program user should retain the documentation at the facility or site of material or equipment use.

8. GUIDANCE ON §71.117, "IDENTIFICATION AND CONTROL OF MATERIALS, PARTS, AND COMPONENTS"

The QA program user should establish measures to ensure that materials, parts, and components, including partially fabricated assemblies, are adequately identified to preclude the use of incorrect or defective items. These measures should provide the means for physical identification (e.g., stamping, tags, labels, or lot-follower cards) and traceability to appropriate documentation (e.g., mill reports, drawings, or specifications) throughout fabrication, installation, and use. Also, when replacement of limited-life items is specified, the QA program user should establish measures to preclude use of items for which the shelf life or prescribed operation time has expired.

In addition, the QA program user should establish measures to facilitate continued processing when required inspections or tests have not been completed in order to maintain physical identity and control over affected materials.

9. GUIDANCE ON §71.119, "CONTROL OF SPECIAL PROCESSES"

Special processes are not normally performed by the user of packaging. However, if packaging maintenance requires the use of special processes (e.g., welding or heat treating) or nondestructive testing, or if special processes are required to meet CoC requirements, the QA program user should establish measures to ensure that the special processes are controlled in accordance with the following requirements:

- Procedures, equipment, and personnel are qualified in accordance with applicable codes, standards, and specifications.
- The operations are performed by qualified personnel and accomplished in accordance with written process or procedure sheets that direct the recording of evidence of verification.
- Qualification records of procedures, equipment, and personnel are established, filed, and kept current.

10. GUIDANCE ON §71.121, "INTERNAL INSPECTION"

10.1 The QA program user should establish measures to ensure that the following requirements are fulfilled:

- Inspection procedures, instructions, or checklists are available for each work operation, where necessary to ensure quality.
- Documents developed include methods for identifying characteristics and activities to be inspected, acceptance and rejection criteria, and the individuals or groups responsible for performing the inspection.
- Objective evidence of inspection results is recorded.
- Hold or witness points are identified.
- The appropriate personnel approve data to ensure that all inspection requirements have been satisfied.
- The prerequisites to be satisfied prior to inspection are identified, including operator qualification and equipment calibration. Where sampling is used to verify acceptability of a group of items, the standard used as the basis for acceptance should be identified.

10.2 Inspections

10.2.1 Receiving Inspections

The QA program user should establish measures to ensure that items that are important to safety (i.e., the features of a structure, component, or system under control of the QA program and necessary to ensure the integrity of the packaging and its capability to prevent or mitigate the consequences that could result from release of radioactive material) meet the requirements specified on the purchase order when the items are received at the plant.

The QA program user should establish the criteria for acceptance of each of these inspections, as well as the action to be taken if noncompliance is encountered. These visual inspections should include the following aspects:

- surface conditions
- weld and structural integrity
- the condition of flange faces or sealing areas, gaskets, seals, gauges, rupture disks, valves, and pressure relief devices
- the condition of tie-down members (if applicable)
- labeling and marking
- leak-tightness of the packaging

In addition, the QA program user should establish provisions to control accepted items until they are placed in stock or released for use, as well as provisions for the proper disposition of rejected items.

10.2.2 In-Process Inspections

The QA program user should establish measures to ensure that process specifications and their supporting documentation provide for indirect control by monitoring processing methods, equipment, and personnel if direct inspection is impractical.

10.2.3 Final Inspections

The QA program user should establish measures to ensure that (1) final inspections provide for resolution of nonconformances identified in earlier inspections, (2) the inspected item is identifiable and traceable to specific records and is adequately protected from physical or environmental damage, and (3) supervisors review inspection records to verify that all inspection requirements have been satisfied.

For packaging use, the QA program user should establish checklists to ensure that inspections are performed to verify the following:

- Packages are properly assembled.
- Moderators and neutron absorbers are present, if applicable.
- Valves through which primary coolant flows are protected against tampering.
- Valves are set to specifications.
- All shipping papers are properly completed.
- Packages are conspicuously and durably marked as required by the regulations set forth by the U.S. Department of Transportation (DOT).
- Measures are established to ensure that appropriate personnel designated by the package user sign the shipping tags or indicators prior to authorization for shipping.

10.2.4 Maintenance Inspections

The QA program user should establish measures for an inspection program to ensure adequate maintenance of packaging. This inspection program should identify the items to be maintained, criteria for acceptability or replacement, and the frequencies of inspection assigned to each item.

10.2.5 Inspectors

The QA program user should establish measures to ensure that (1) inspectors are qualified in accordance with applicable codes, standards, and company training programs; (2) such qualifications and certifications are kept current; and (3) inspection personnel are independent from all individuals performing the activity being inspected.

10.2.6 Inspection Documentation

The QA program user should maintain inspection records as QA records to document performance of inspection activities.

11. GUIDANCE ON §71.123, "TEST CONTROL"

11.1 Requirements

The QA program user should establish measures to ensure that applicable test programs, including prototype qualification tests, production tests, proof tests, and operational tests, are accomplished in accordance with written procedures. The QA program user should also establish measures to ensure that modifications, repairs, and replacements are tested in accordance with the original design and testing requirements.

11.2 Procedures

The QA program user should establish measures to ensure that test prerequisites identified in the appropriate design disclosures (e.g., instrument calibrations, monitoring to be performed, mandatory hold points, suitable environmental conditions to be maintained, condition of the test equipment, methods for physical identification of test specimen, methods for documenting or recording test data, and criteria for acceptance) are properly translated into test procedures.

11.3 Acceptance Tests

The QA program user should establish measures, as appropriate, to ensure that acceptance tests are conducted prior to delivering packages for transport to a carrier. These measures should identify the basis for acceptance criteria (e.g., CoC, maintenance and operational manuals furnished by the packaging manufacturers). Tests should typically include the following considerations:

- structural integrity
- leak-tightness (on containment vessel as well as auxiliary equipment and shield tanks)
- component performance for valves, gaskets, and fluid transport devices
- shielding integrity
- thermal integrity

11.4 Maintenance Tests

The QA program user should establish maintenance test programs to ensure that packages remain usable and free of excessive radiation and contamination. These test programs should include measures to ensure that qualified and responsible individuals document, evaluate, and assess the acceptability of all test results.

11.5 Results

The QA program user should establish measures to ensure that test results are documented, evaluated, and maintained as QA records. These records should be readily available if questions arise concerning operational aspects of the packages. In addition, a qualified individual or group should determine the acceptability of the records.

12. GUIDANCE ON §71.125, "CONTROL OF MEASURING AND TEST EQUIPMENT"

12.1 Calibration Control

The QA program user should establish measures to ensure that measurement and test equipment (e.g., gauges, fixtures, reference standards, and devices used to measure product characteristics) is calibrated, adjusted, and maintained at prescribed intervals or prior to use. Such equipment should be labeled or tagged to indicate the planned date of its next calibration, and the calibration records should be identified, traceable, and maintained as QA records. The QA program user should also establish measures to ensure that in-house reference or transfer standards used in calibrating measuring and test equipment are traceable to nationally recognized standards. Calibrating standards should have known valid relationships to nationally recognized standards. If no known recognized standard exists, the QA program user should document the basis for calibration.

12.2 Out-Of-Calibration Equipment

When test and measuring equipment is found to be out of calibration, the QA program user should take measures to validate previous inspection and test results up to the time of previous calibration. In addition, the QA program user should repair or replace any measuring equipment that is consistently out of calibration.

13. GUIDANCE ON §71.127, "HANDLING, STORAGE, AND SHIPPING CONTROL"

13.1 Preservation

The QA program user should establish measures to ensure that cleaning, handling, storage, and shipping are accomplished in accordance with design requirements to preclude damage or deterioration by environmental conditions such as temperature and humidity. When necessary, the QA program user should also establish provisions for the use of special handling, lifting, or storage devices (e.g. cranes, shock absorbers, or special markings) to adequately identify and preserve packaging components or assemblies. In addition, the QA program user should ensure that conditions identified in the CoC are adhered to when unloading packaging.

13.2 Preparation, Release, and Delivery to Purchaser

The QA program user should establish measures to ensure that a final pre-release review has been completed. This review should ensure that packaging (1) is prepared for delivery to the purchaser in accordance with approved drawings, specifications, and government regulations; (2) has passed all applicable inspections and tests; (3) is properly identified by physical markings or tags; and (4) contains operating manuals, maintenance manuals, and generic procedures relating to its use.

In addition, the QA program user should establish measures to ensure that the following requirements are fulfilled:

- Cavities within gas-cooled package containments have been adequately dried, and cavities within liquid-cooled packages have been drained to allow adequate void space.
- All conditions (including specified operations, inspections, and tests) have been completed prior to delivery to a carrier.
- All NRC and DOT requirements have been satisfied prior to delivery to a carrier.
- All necessary shipping papers have been prepared as required and reviewed by qualified personnel to verify completeness and accuracy.

14. GUIDANCE ON §71.129, "INSPECTION, TEST, AND OPERATING STATUS"

The QA program user should establish measures to ensure that the status of inspections, tests, and operating conditions (including maintenance of items) is known by organizations responsible for ensuring quality.

The QA program user should also establish measures to control the application and removal of status indicators (e.g., tags, markings, stamps) and to ensure that bypassing a required inspection or test or any other required operation is procedurally controlled under the cognizance of the QA organization.

15. GUIDANCE ON §71.131, "NONCONFORMING MATERIALS, PARTS, OR COMPONENTS"

An acceptable program for controlling nonconforming items should include the following principal elements:

- proper identification
- segregation of discrepant or nonconforming items
- disposition of the nonconforming items
- evaluation of the nonconforming items

16. GUIDANCE ON §71.133, "CORRECTIVE ACTION"

16.1 Reporting

The QA program user should establish measures to ensure that the causes of conditions detrimental to quality (e.g., those resulting from failures, malfunctions, deficiencies, deviations, or defective material and equipment) are promptly identified and reported to appropriate levels of management. In addition, the QA program user should establish measures to obtain corrective actions from suppliers and ensure that followup actions are documented to verify that the corrective actions were implemented and effective.

16.2 Closeout, Retrieval, and Disposition of Records

The QA program user should establish measures to ensure that corrective actions designated by cognizant individuals have been implemented to preclude recurrence. In addition, the QA program user should identify (by function or position) the individuals or organizations responsible for closing out corrective actions and documenting their resolution**.**

17. GUIDANCE ON §71.135, "QUALITY ASSURANCE RECORDS"

17.1 General

QA records should furnish documentary evidence of the activities that affect quality and should provide sufficient information to allow each record to be identified with the items or activities to which it applies. As a minimum, QA records should include the following information:

- design, procurement, manufacturing, and installation records
- supplier evaluations
- nonconformance reports
- results of inspections and tests
- failure analyses
- as-built drawings and specifications
- qualification of personnel, procedures, and equipment
- calibration procedures
- training and retraining records
- corrective action reports
- records demonstrating evidence of operational capability
- records verifying repair, rework, and replacement
- audit plans, audit reports, and corrective actions
- records that are used as a baseline for maintenance

In addition, the QA program user should retain records that show evidence of package delivery to a carrier and proof that all NRC and DOT requirements have been satisfied (with their retention times identified).

Where applicable, inspection and test records should contain the following information:

- a description of the observation
- evidence of completion of the inspection or test operation
- results of inspections or tests with appropriate data
- conditions that are detrimental to quality
- names of inspectors, testers, or data recorders
- evidence of acceptability

17.2 Generating Records

The QA program user should establish measures to ensure that methods employed to generate and manage documents that are designated as QA records result in information that is retrievable, intelligible, and reliable. Such records should reflect the work accomplished and should be stored in a manner that avoids unnecessary delay when the record is needed. In addition, procedures for generating QA records should address both hard copy records and electronic information.

17.3 lndexing and Classification Records

The QA program user should classify QA records as either "lifetime" or "nonpermanent":

- Lifetime records include those pertaining to package fabrication and those associated with a particular item while it is installed in the packaging or stored for future use. These records demonstrate the capability for safe operation; provide evidence of repair, rework, replacement, or modification; aid in determining the cause of an accident or malfunction of an item; and provide a baseline for inservice inspection.
- Nonpermanent records are those that show evidence that an activity has been performed but do not meet the criteria for lifetime records. Records pertaining to use of a package should be retained for a period of 3 years after the shipment.

17.4 Receipt, Retrieval, and Disposition of Records

The QA program user should establish measures to provide a receipt control system, including identification of functions or positions in each organization responsible for receiving records and assessing the current status of records in their possession. The QA program user should also establish measures to ensure that records that are maintained in-house or at other locations are identifiable and retrievable, and are not disposed of until prescribed conditions are satisfied. For electronic records the software systems employed to image and store information should be compatible with new hardware as current technologies are implemented. In addition, before installing any new hardware systems, the QA program user should have a procedure in place to ensure that the new systems can reliably store and retrieve information from existing software systems.

17.5 Storage, Preservation, and Safekeeping

The QA program user should establish measures to ensure that the following requirements are fulfilled:

- Facilities used to store records should be constructed to minimize the risk from damage or destruction by severe natural conditions, such as wind, flood, fire, temperature, humidity, mold, or infestation by insects or rodents.
- Records should be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets.
- Electronic records should be maintained in facilities that minimize or eliminate the potential for destruction of information as a result of demagnetization.
- Electronic records should be backed up daily to eliminate the potential for loss of information as a result of equipment failure or human error.
- If dual storage facilities are used to ensure the record integrity, the storage facilities should be sufficiently remote from each other to preclude a single event (such as a fire or flood) from damaging both facilities.
- The QA program user should take measures to protect special records (e.g., radiographs and microfilm) from excessive light, electromagnetic fields, and temperature.
- The QA program user should take measures to prevent unauthorized personnel from entering record storage areas.
- Electronic information storage systems should be accessible only through security measures such as passwords, and the number of personnel who have authorized access should be limited. In addition, personnel who have authorized access should have identified privileges, such as "read only" or "read and add only."
- The QA program user should establish measures to ensure prompt replacement of a record that is lost or damaged.

18. GUIDANCE ON §71.137, "AUDITS"

18.1 Elements of an Audit Program

A comprehensive audit program should include the following elements:

- assurance of the authority and organizational independence of the auditors
- a commitment to adequate manpower, funding, and facilities to implement the audit
- identification of audit personnel and their qualifications
- provisions for reasonable and timely access of audit personnel to facilities, documents, and qualified personnel necessary for performing audits
- use of established procedures and checklists
- methods for reporting audit findings to responsible management of both the audited and auditing organizations
- provisions for the audit team to gain access to levels of management that have responsibility and authority for corrective action
- methods for verifying that effective corrective action has been accomplished on a timely basis

The QA program user should also establish and maintain a list to reflect the current status of the activities important to safety that are to be audited and the frequency at which each quality criterion is to be audited. The frequency of audits should be based on each activity's importance to safety; however, each quality criterion should be audited at least once each year.

The QA program user should also establish measures to ensure that packaging manufacturers are audited to assess the extent of their compliance with purchase orders and to verify that their work is controlled under an NRC-approved QA program.

In addition, the QA program user should also identify (by function or position) the individuals or groups that have the responsibility and authority to ensure that corrective actions resulting from audit findings are accomplished on a timely basis. The QA program user should re-audit deficient areas on a timely basis to verify implementation of corrective actions.

18.2 Scheduling of Audits

The QA program user should establish schedules for internal audits, external audits, and audits performed by management. These schedules should ensure that key activities of the QA program (e.g., design, fabrication) receive priority consideration.

For audits performed by management, the schedules should identify the level of management (usually from the corporate office or another division) designated to assess the overall effectiveness of the implementation of the described inhouse QA program. The QA program user should also identify the activities important to safety (e.g., procurement, training of personnel) that should be included in the audit program. Management audits should be conducted at least once every 12 months.

For internal audits, the schedules should ensure that applicable elements of the QA program are audited annually or at least once within the life of the activity, whichever is shorter.

For external audits, the schedules should ensure that all elements of a major supplier's (or major contractor's) QA programs are audited on a triennial basis. The 3-year period should begin with performance of an audit when sufficient work is in progress to demonstrate implementation of a QA program that has the required scope for purchases placed during the 3-year period.

18.3 Team Selection

The QA program user should establish the qualifications of the lead auditor and audit team members and specify their respective responsibilities with respect to evaluating and issuing audit reports. The auditing organizations should have the responsibility to establish qualifications for prospective audit personnel and the requirements for use of technical specialists to accomplish auditing activities that are important to safety. The QA program user should select the lead auditor and audit team members from personnel who do not have direct responsibility in the areas being audited.

Specific guidance for determining qualifications for the lead auditor and individual audit team members may be obtained from ANSI/ASME NQA-1 (Ref. 1).

18.4 Pre-Audit Conference

Prior to an audit, the QA program user should specify the nature and scope of the pre-audit conference between management of the organizations being audited and the team conducting the audit. The purpose of the pre-audit conference should be to meet counterparts, confirm the audit scope and dates, establish channels of communication, discuss the sequence and duration of the audit, prepare an agreed-upon agenda for the audit, and set the time for the post-audit conference.

18.5 Post-Audit Conference

The QA program user should establish measures to conduct a post-audit conference between management of the organizations being audited and the team conducting the audit to present the results and clarify any misunderstandings that may arise.

18.6 Reporting and Response

The QA program user should establish measures to identify time constraints imposed for issuing audit reports and the requested date for a corrective action response by the audited organization. The response should clearly state the corrective action taken to prevent recurrence of nonconformances. If corrective action cannot be taken immediately, the response of the audited organization should include scheduled dates for initiation and completion of the corrective action.

18.7 Followup Action

The audit team leader should verify that (1) the audited organization provides a timely response to the audit report, (2) the response is adequate, and (3) the corrective action has been accomplished within the prescribed schedule.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants, certificate holders and licensees regarding the NRC staff's plans for using this guide. No backfitting is intended or approved in connection with the issuance of this guide.

Except when an applicant, certificate holders or licensee proposes or has previously established an acceptable alternative method for complying with specified portions of the NRC's regulations, the methods described in this guide will be used in evaluating QA program descriptions which relate to establishing QA programs for packages that are used to transport radioactive materials or assessing QA program users' performance with respect to developing, implementing, and maintaining such QA programs.

REFERENCES

1. ANSI/ASME-NQA 1-1983, "Quality Assurance Program Requirements for Nuclear Facilities," American National Standards Institute, American Society of Mechanical Engineering, New York, NY, 1983.

2. NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety," U.S. Nuclear Regulatory Commission, Washington, DC, February 1996.

3. ISO 9000, "Quality Management Systems," International Organization for Standardization, Geneva, Switzerland, 2000.

4. Information Notice 2002-35, "Changes to 10 CFR Parts 71 and 72 Quality Assurance Programs," U.S. Nuclear Regulatory Commission, Washington, DC, December 20, 2002.*

5. Generic Letter 88-18, "Plant Record Storage on Optical Disks" (provides guidance on optical disk document imaging systems for storage and retrieval of official copies of a plant's QA records), U.S. Nuclear Regulatory Commission, Washington, DC, October 20, 1988.*

6. Regulatory Issue Summary (RIS) 00-18, "Guidance on Managing Quality Assurance Records in Electronic Media," U.S. Nuclear Regulatory Commission, Washington, DC, October 23, 2000.*

* Available on the NRC's public Web site in the Generic Communications document collection of the Electronic Reading Room at http://www.nrc.gov/reading-rm/doc-collections/gen-comm/.

REGULATORY ANALYSIS

The NRC staff did not prepare a separate regulatory analysis for this regulatory guide. The staff found it necessary to revise this regulatory guide to provide additional clarity and definition, with regard to the guidance that applicants, licensees, and certificate holders commonly use in developing their QA programs to ensure the quality and control of transportation activities under 10 CFR Part 71. NUREG/CR-6713, "Draft Regulatory Analysis of Major Revision of 10 CFR Part 71," provides a related regulatory analysis. A summary of the analysis follows:

> The resulting rulemaking would modify 10 CFR Part 71 requirements pertaining to the packaging and transport of radioactive materials, including fissile materials. The rulemaking is intended to: (1) harmonize 10 CFR Part 71 with the most recent transportation standards established by the International Atomic Energy Agency (IAEA), and the U.S. Department of Transportation's (DOT) requirements at 49 CFR; and (2) address the Commission's goals for risk-informed regulations and eliminating inconsistencies between Part 71 and other parts of 10 CFR. Based on this analysis, none of the 19 potential changes evaluated are expected to result in significant impacts. In fact, the analysis indicates that most of the changes will have negligible impacts or result in slight increases in values.

A copy of NUREG/CR-6713 is available for inspection and copying (for a fee) at the NRC's Public Document Room (PDR), which is located at 11555 Rockville Pike, Rockville, Maryland. The PDR's mailing address is USNRC PDR, Washington, DC 20555-0001. The PDR can also be reached by telephone at (301) 415-4737 or (800) 397-4205, by fax at (301) 415-3548, and by email to PDR@nrc.gov. Copies of NUREG/CR-6713 are also available (at current prices) from the U.S. Government Printing Office (GPO) at P.O. Box 37082, Washington, DC 20402-9328; GPO can also be reached by telephone at (202) 512-1800. In addition, copies of NUREG/CR-6713 are available (at current prices) from the National Technical Information Service at 5285 Port Royal Road, Springfield, VA 22161, on the Internet at http://www.ntis.gov, or by telephone at (703) 487-4650.

APPENDIX A

A GRADED APPROACH TO DEVELOPING QUALITY ASSURANCE PROGRAMS FOR PACKAGING RADIOACTIVE MATERIAL

The design effort and requirements for a QA program are interrelated and should be developed simultaneously. Addressing them as independent functions may result in an overly stringent QA program (i.e., one that imposes unnecessary QA activities to verify attainment of design objectives) or an inadequate QA program (i.e., one that imposes too few QA activities to verify attainment of design objectives). To develop a QA program in which the application of QA requirements is commensurate with their safety significance, it is essential that engineering personnel perform a systematic analysis of each component, structure, and system of packages to assess the consequences to the health and safety of the public and the environment that would result from malfunction or failure of such items. This engineering assessment and development of the QA program should be initiated as early in the design process as practicable and should be in accordance with approved procedures. Establishment of an engineering basis for the formulation of a QA program early in the design process enables a uniform, consistent application of QA requirements during fabrication, use, and maintenance of packaging.

A logical sequence leading to identifying realistic QA requirements would involve (1) classifying each structure, system, and component as "important to safety" or "not important to safety" ("Q" or "non-Q"); (2) grouping items classified as important to safety into quality categories; and (3) specifying the applicable level of QA effort for each category. To ensure a better understanding of the process, the remaining sections of this appendix provide additional detail concerning each of these three steps.

1. CLASSIFYING STRUCTURES, SYSTEMS, AND COMPONENTS

To begin the process of identifying realistic QA requirements, the QA program user should first analyze all structures, systems, and components that appear on the latest packaging parts list to determine whether their functions or physical characteristics are essential to safety. Items identified as essential to safety (often referred to as "Q" items) should then be subjected to a QA program based on the requirements of Subpart H of 10 CFR Part 71.

2. GROUPING ITEMS INTO QUALITY CATEGORIES

After classifying the structures, systems, and components that appear on the latest packaging parts list, the QA program user should establish quality categories based on the relative safety significance of each Q item and, where appropriate, their subcomponent parts. In so doing, the QA program user could identify the categories as "A" for items that are critical to safe operation, "B" for items that have a major impact on safety, and "C" for items that have only a minor impact on safety. For example, Category A items could include structures, systems, and components for which a failure or malfunction could directly result in a condition that would adversely affect public health and safety. This would include such conditions as loss of primary containment with subsequent release of radioactive material, loss of shielding, or an unsafe geometry compromising criticality control. Category B items could include structures, systems, and components for which a failure or malfunction could indirectly result in a condition that would adversely affect public health and safety. However, an unsafe condition could result only if the primary event occurs in conjunction with a secondary event or other failure or environmental occurrence. Finally, Category C items could include the structures, systems,

and components for which a failure or malfunction would not significantly reduce packaging effectiveness and would be unlikely to create a condition that would adversely affect public health and safety such as the dunnage, packaging hardware, protective cover, security lockwire and seals, and skids or forklift channels for low specific activity (LSA) and Type A (fissile) shipments as well as all of the previously mentioned items and vent and drain port plug and pressure relief device outer seals, vent, drain and leak check port plug cover plates for Type B shipments.

3. SPECIFYING THE APPLICABLE LEVEL OF QA EFFORT

The last step in the process of identifying realistic QA requirements would be to assign an appropriate degree of QA effort to each quality category. For example, QA requirements for Category A items would include the following specifications:

- The design should be based on the most stringent industrial codes or standards, and design verification would be accomplished by prototype testing or formal design review.
- The procurement documentation for materials or services should specify that the QA program user should use only suppliers from qualified vendor lists.
- The suppliers and sub-tier suppliers should have QA programs based on the applicable criteria in Subpart H to 10 CFR Part 71.
- The manufacturing planning should specify complete traceability of raw materials and the use of certified welders and processes.
- The verification planning (test and inspection) should require use of qualified inspectors (i.e., personnel performing nondestructive examinations such as radiography and ultrasonic testing would be qualified in accordance with recommended practices described in such documents as ASNT-TC-1A* and Section IX of the ASME Boiler and Pressure Vessel Code or other industrial standards).
- Only qualified auditors and lead auditors should perform audits.
- A representative of the buyer would be present at a supplier's facility to approve the final acceptance test and to authorize shipment.

Category B quality requirements should include the following specifications:

- The design should be based on the most stringent industrial codes and standards, but design verification could be through use of calculations or computer codes.
- Materials need not be procured from a qualified vendor list.
- Manufacturing planning need not require traceability of materials, and only specified welds would be done by qualified welders.
- Verification activities would still require use of inspectors qualified to appropriate codes, standards, or other industrial specifications.
- Only the lead auditor need meet certain qualification requirements.

With respect to Category C items, the only enforced quality requirements include the following specifications:

- Items should be purchased from a catalog or "off the shelf."
- When the item is received, the material should be identified and checked for damage.

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* ASNT-SNT-TC-1A, "Recommended Practice for Personnel Qualification and Certification for Nondestructive Testing," American Society for Nondestructive Testing (ASNT), Columbus, Ohio, 2001.