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REGULATORY GUIDE

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REGULATORY GUIDE 7.10

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

A. INTRODUCTION

This revision of Regulatory Guide 7.10 is being developed to provide persons subject to the quality assurance (QA) requirements of Part 71, "Packaging and Transportation of Radioactive Material," of Title 10 of the Code of Federal Regulations (CFR) with current guidance on developing QA programs for implementation with respect to the transport of radioactive materials in Type B and fissile material packages. This guide also provides information on the submittal of QA program descriptions to the NRC staff for review and determination of acceptability. Terms used in this guide are consistent with terms used in 10 CFR Part 71 and ANSI/ASME NQA-1-1979, "Quality Assurance Requirements for Nuclear Power Plants" (Ref. 1).

Paragraph 71.37(a) of 10 CFR Part 71 requires applicants for package design approval to describe the quality assurance (QA) program, with respect to Subpart H of 10 CFR Part 71, to be applied to the design, fabrication, assembly, testing, maintenance, repair, modification, and use of the proposed packaging.

Licensees are required by 10 CFR 71.101 to have a QA program that has been submitted to and approved by NRC as satisfying the provisions of Subpart H of Part 71. Subpart H requires, in part, that licensees' QA programs satisfy each of the applicable criteria specified in Sections 71.101 through 71.137 to an extent consistent with their importance to safety.

Regulatory guides are issued to describe to the public methods acceptable to the NRC staff for implementing specific parts of the NRC's regulations, to explain techniques used by the staff in evaluating specific problems or postulated accidents, and to provide guidance to applicants. Regulatory guides are not substitutes for regulations, and compliance with regulatory guides is not required. Regulatory guides are issued in draft form for public comment to involve the public in developing the regulatory positions. Draft regulatory guides have not received complete staff review; they therefore do not represent official NRC staff positions.

The information collections contained in this regulatory guide are covered by the requirements of 10 CFR Part 71, which were approved by the Office of Management and Budget (OMB), approval number 3150-0008. The NRC may not conduct or sponsor, and a person is not required to respond to, a request for information or an information collection requirement unless the requesting document displays a currently valid OMB control number.

B. DISCUSSION

REGULATORY FRAMEWORK FOR TRANSPORT OF RADIOACTIVE MATERIAL

NRC's packaging and transportation requirements are codified in 10 CFR Part 71, "Packaging and Transportation of Radioactive Material." NRC's regulations state that a license to transport radioactive material is granted under the provisions of Subpart C, "General Licenses," of 10 CFR Part 71 only to a licensee who has a QA program approved by the NRC as satisfying the provisions of Subpart H, "Quality Assurance," of 10 CFR Part 71. QA requirements are also imposed on those who submit an application for approval of a package design under the provisions of Subpart D, "Application for Package Approval," of 10 CFR Part 71. Specifically, an application for an approval under Subpart D should include, for each proposed package design, a QA program description as required by Subpart H, or a reference to a QA program that has been approved by the NRC. If a QA program description is not included or a previously approved description not referenced, the application is incomplete and may be returned to the applicant. As used in 10 CFR Part 71, "quality assurance" comprises all those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. QA includes quality control, which comprises those quality assurance actions related to control of the physical characteristics and quality of the material or component to predetermined requirements.

Subpart H of Part 71 contains QA requirements that apply to the design, purchase, fabrication, handling, shipping, storing, cleaning, assembly, inspection, testing, operation, maintenance, repair, and modification of components of packaging that are important to safety. The control for each of the above activities should be applied in a graded approach, i.e., the QA effort expended 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 package or fissile material package that are (1) to maintain the conditions required to safely transport the package's contents, (2) to prevent damage to the package during transport, or (3) to provide reasonable assurance that the radioactive material contents can be received, handled, transported, and retrieved without undue risk to public health and safety and the environment. Appendix A, "A Graded Approach to Developing Quality Assurance Programs for Packaging of Radioactive Material," to this guide 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).

Each licensee or package design applicant (hereinafter referred to as QA program user) is required to file a description of its QA program with the NRC, along with a discussion of which requirements of Subpart H are applicable and how they will be satisfied. The regulations delineated in Subpart H should be addressed by QA program users to the extent applicable to their operation.

The type of activities that the QA program user engages in will determine which of the sections of the regulations in Subpart H will need to be addressed in the QA program and what activities will be reviewed by NRC for approval of the program. The activities covered by the QA program may be divided into two major areas. The first area consists of activities associated with an application for package approval (Subpart D, "Application for Package Approval," of 10 CFR Part 71), 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 consists of activities associated only with the use of approved packages (Subpart C, "General Licenses," of 10 CFR Part 71). 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, the QA program users should identify to the NRC how each of the regulations of Part 71 apply to their particular situations and how the regulations will be satisfied. Thus, the information supplied to the NRC for review varies as a function of the nature of the activity the QA program user will be engaged in. For example, someone using a general license solely for the transportation of radioactive material in packages purchased or leased for that purpose would be expected to address criteria governing activities such as procurement, shipping, and handling; whereas someone who designs and fabricates packagings would be expected to address criteria on design and testing as well as material procurement activities. Examples of elements common to all QA program descriptions include the quality organization and program, corrective action, QA records, and audits.

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

An acceptable QA program submittal, therefore, is one that lies between these two extremes. An acceptable submittal is one that addresses each of the regulations stated in Section H of Part 71, if they are applicable to the QA program user's activities, and that provides a description of how each of the applicable regulations will be implemented. Keeping in mind the limitations described in the previous paragraph, the extent of detail is left up to the applicant. However, while more detail may be desirable to a QA program user, it does have a potential downside. As discussed further in a subsequent paragraph, any proposed change to the contents of an NRC-approved QA program requires subsequent NRC review and approval prior to implementing such change. The more detailed a QA program, the less flexibility the user will

have in the event changes to activities described in the plan are needed quickly, as the changes will require NRC review and approval before they can be implemented and this will take time to accomplish.

In developing a QA program, the QA program user is required to apply each of the applicable regulations in a graded approach, i.e., to an extent that is consistent with its importance to safety. Guidance on graded QA is provided by the NRC in NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety" (Ref. 2).

QUALITY ASSURANCE PROGRAM SUBMITTALS BASED ON OTHER STANDARDS

Occasionally the NRC staff receives a QA program description based upon a different QA standard such as the American Society of Mechanical Engineering (ASME) NQA-1-1979, "Quality Assurance Program Requirements for Nuclear Facilities" (Ref. 1), or the International Organization for Standardization 9000 series standards (ISO 9000). While these submittals may be found to be acceptable upon staff review, QA program users should be sensitive to the fact that the 10 CFR Part 71 QA regulations contain requirements that may not be fully addressed by another standard. In general, programs based on the NQA-1 or ISO-9000 standards will require supplementation in order to address all the Subpart H regulations; the only exception is the 1979 revision to NQA-1 that the NRC has endorsed in its entirety. Without supplementation, the NRC may require the submittal of additional information regarding how all the applicable Subpart H regulations will be met. This may necessitate that the QA program user make changes to the underlying QA program and delay the NRC approval review.

CHANGES TO APPROVED QA PROGRAM DESCRIPTIONS

Based on NRC regulations determined to apply and the associated approved QA program, the QA program holder should develop and implement lower level (working level) documents governing the conduct of QA activities that are important to safety.

A QA Program Approval expires five years from the month of issuance and may be renewed prior to expiration at the QA program user's request. Any changes to the approved QA program description require NRC approval prior to implementation. Therefore, if a QA program user desires to make a change in the QA program description that was used as the basis for NRC approval, the change should be submitted for review and approval by the NRC before the change can be implemented. Because the NRC staff noted recurring misunderstanding of this requirement, they issued NRC Information Notice 2002-35, "Changes to 10 CFR Parts 71 and 72 Quality Assurance Programs" (Ref. 4).

C. REGULATORY POSITION

The elements of a QA program reviewed by NRC staff for determining compliance with the QA requirements of Subpart H of 10 CFR Part 71 should include activities related to the design, procurement, fabrication, 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 the QA program user is involved in and the use of a graded approach for items important to safety.

Persons subject to Subpart H should submit their program descriptions to obtain approval from the NRC prior to engaging in any activity important to safety. Persons who engage in activities important to safety prior to obtaining approval of the established QA program risk

having to demonstrate that such activities were in compliance with QA requirements. Following a determination that the QA program submittal is adequate, the NRC will issue a Quality Assurance Program Approval. The approval expires on the last day of the month stated on the approval form and may be renewed prior to expiration at the QA program user's request.

Establishment of a QA program implies that all activities important to safety applicable to the design, procurement, fabrication, 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.

The NRC recognizes a QA program approved by NRC under Part 50 (Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," of 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities") as equivalent to an NRC-approved Part 71 QA Program. The NRC also has endorsed the use of ANSI/ASME NQA-1-1979, "Quality Assurance Program Requirements for Nuclear Power Plants," as a standard that, when applied properly and supplemented as necessary to meet all the applicable criteria, should result in the development of a QA program that is acceptable to the NRC.

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

Note: If, because of limited personnel, multiple functions including QA are performed by the same individuals, measures should be established to ensure that the designated individuals when performing QA and QC functions have the responsibility and authority to stop unsatisfactory work, stop 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.

The duties and qualifications required for (1) the individual who has overall authority and responsibility for the QA program and (2) the other personnel performing QA and QC functions should be established and documented and should have the written endorsement of top management.

1.2 Top Management Endorsement of a QA Program

Top management needs to maintain a continuing involvement in QA matters if the QA program is going to be effective. To ensure the commitment of top management, written policy should be established by the company or corporate president or by the chief executive officer stating that it is company or 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 been delegated authority for

- Implementing and revising the provisions of the described QA program and
- Regularly assessing 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 apply to its particular situation and how they will be satisfied. The information supplied to the NRC for review will vary as a function of the nature of the activities of the QA program user. For example, someone using a general license solely for the transportation of radioactive material in packages purchased or leased for that purpose would be expected to address regulations governing activities such as procurement, shipping, and handling; whereas someone who designs and fabricates packagings would be expected to address criteria on design and testing as well as material procurement activities. Elements common to all QA program descriptions include the quality organization and program, corrective action, QA records, and audits.

In developing their QA programs, the proposed QA program users can refer to the NRC guidance in this regulatory guide and the additional guidance on graded QA in NUREG/CR-6407 (Ref. 2). In developing its program, the QA program user is to 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 a technical review and a determination by the NRC staff that the QA program submittal meets regulatory requirements, NRC issues a QA Program Approval. The approval expires on the last day of the month and year stated on the approval form and may be renewed, according to
10 CFR 71.38, not less than 30 days prior to expiration by the request of the QA program user.

All changes to the approved QA program description require NRC approval. Therefore, if a QA program user desires to make a change in the QA program description that was used as the basis for NRC approval, the change should be submitted for review and approval by the NRC before the change can by implemented. Requests for review and approval of such changes are handled through an amendment of the QA Program Approval and do not affect the five-year renewal date. The only exception to the need for NRC approval of any change is with respect to an NRC-approved Appendix B to 10 CFR Part 50 QA Program that has been accepted under 10

CFR 71.101(f). This exception allows a nuclear power plant licensee to change an NRC-approved Appendix B to Part 50 QA Program to the extent permitted under 10 CFR 50.54(a)(3).

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

If a QA program submittal has been reviewed by the NRC and a description of how the requirements will be met is either lacking or some NRC regulations are not specifically addressed, the NRC will request the submittal of additional information regarding how all the applicable Subpart H regulations will be met.

2.2 Scope of QA Program

Measures should be established for identifying (1) the components, structures, and systems to be covered by the QA program and (2) the approach used for verifying that the applicable components, structures, and systems meet design objectives. Although 10 CFR Part 71 allows for 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. Measures should be established to ensure that:

- Activities important to safety are performed with specified equipment and under suitable environmental conditions,
- Designated QA and QC responsibilities for implementation of activities important to safety are contained in QA/QC manuals, and
- Indoctrination and training programs are established so that personnel performing activities important to safety are trained and qualified to perform these 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 rationale used to identify items classified as important to safety and subject to the users QA program should be established.

2.4 Documentation

The QA program should ensure that activities important to safety applicable to the design, purchase, fabrication, and testing of packaging are described by written procedures and instructions and will be in place prior to engaging in these activities.

With respect to anticipated activities important to safety that have not yet been initiated, the implementing procedures should be identified by title and procedure number. A brief description of the content of the procedures with an estimated date for completion should be included. The following table shows a suitable format for listing procedures to demonstrate implementation of a documented QA program.

Table 1

FORMAT FOR LISTING OF IMPLEMENTING PROCEDURES*

Implementing Document	Title	Regulatory Position	Description
QAM, QP 1 Quality Assurance Manual (QAM),	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.

***The information requested for all 18 regulatory positions would be listed; the table shows examples only for Regulatory Positions 1, 2, 3, 4, and 18.

To demonstrate that a documented QA program has been fully implemented by written procedures, a master index of QA procedures related to all activities important to safety and a matrix of the QA procedures that implement each section of Subpart H should be established and maintained to reflect the current status of the QA program. The use, management, and storage of electronic records and data should also be addressed in these written procedures.

2.5 Controlled Conditions and Assignment of Responsibilities

Measures should be established 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 assignment of responsibility for each task and method used to verify conformance to these quality requirements should be documented.

3. GUIDANCE ON § 71.107, PACKAGE DESIGN CONTROL

Good relationships among those responsible for preparing design disclosures, conducting independent design analyses, coordinating interfaces, and maintaining lines of communication are essential for adequate design control. To ensure an adequate commitment to control of design activities, three principal areas need to be considered: control of the design process, control of design input, and control of design verification.

Since design activities are not normally performed by users of packaging, this section of Subpart H should not be applicable to users of packaging. However, it should be established by the user of the packaging that the design was accomplished under control of an NRC-approved QA program.

Computer-aided design (CAD) is used extensively for current design applications. Designs developed using CAD methods will be prepared and stored electronically. The control of electronic data in design applications to ensure authenticity and technical accuracy should be

addressed in applicable QA procedures that address software verification/validation, management of electronic records, and quality control of electronic data. Guidance for the development of QA programs for the management of electronic data are available from the Nuclear Information and Records Management Association (NIRMA), American National Standards Institute (ANSI), and the Electric Power Research Institute (EPRI). 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 the retrieval of record copies of QA records.

3.1 Control of Design Process

Measures such as "classification of characteristics" should be established 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.

Recognized engineering practices such as prescribing drafting room standards, checking methods, review and approval requirements, issuance and distribution requirements (including revisions to them), maintaining current "as-built" configurations, and storage and control of original and master copies should be established to control the preparation of drawings and specifications.

3.2 Control of Design Input

Measures should be established 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, alternative approaches should be identified.

Measures should be established to ensure (1) that all design parameters, e.g., criticality physics, cooling, and decontamination of an item, have been properly considered, reviewed, and approved by the responsible design organization and that the parameters are in accordance with the applicable performance codes, standards, and regulatory requirements and (2) that maintenance, repair, in-service inspection, handling, storage, and cleaning requirements are specified in design documents.

3.3 Control of Design Verification

Methods to be used in verifying the adequacy of the design (e.g., qualification testing, design review, or alternative calculations, including use of computer programs) should be established. Technically qualified individuals or groups responsible for design verification should not be in the administrative line of authority of the original designer. The designer's immediate supervisor may perform the verification provided:

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

During the sequence of design verification, changes to the final design may result; consequently, measures should be established for ensuring 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 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 these cases, design verification may be deferred provided 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

Measures should be established to control the preparation, reviews, concurrences, and approvals of procurement documents.

4.1 Content of Procurement Documents

Measures should be established to ensure that procurement documents include the following information as applicable:

- A statement of the scope of work to be performed by the prospective supplier.

- The design basis technical requirements (or references thereto), including the 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. This QA program or portions thereof should be reviewed and concurred in by qualified QA personnel from the purchaser's organization prior to initiation of activities affected by the program. Also, if sub-tier suppliers are involved, the QA provisions appropriate to those procurements should be specified. (The extent of the supplier's or sub-tier supplier's QA program will depend on the particular item or service being procured.)

- Permission to gain access to the supplier's or sub-tier suppliers plant facilities and records for inspection or audit purposes. Procurement documents should identify the type of verification activities required from 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) to be prepared, maintained, and submitted to purchaser for approval.

- Requirements for reporting and approving disposition of nonconformances.

- Identification of records to be retained, controlled, and maintained by the supplier and of those records delivered 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 software system the documentation is to be delivered in should be specified.

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

Measures should be established to ensure that review and approval of procurement documents are recorded prior to release and that changes and revisions to procurement 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

Measures should be established to ensure that:

- 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.

- Methods for complying with each of the applicable sections of Subpart H of 10 CFR Part 71 are specified in instructions, procedures, and drawings.

- All work activities are coordinated with QA personnel to ensure that appropriate inspection and hold points are incorporated into the work controlling documents to verify that initial work, planned work, effective repairs or rework have been performed satisfactorily.

- Instructions, procedures, and drawings include quantitative (e.g., dimensions, tolerances, and operating limits) and qualitative (e.g. workmanship samples) acceptance criteria to verify that activities important to safety have been satisfactorily accomplished.

- The use, management, storage, and protection of electronic records and data are addressed in written procedures. Information on the specific software applications and storage or computing hardware should also be maintained.

5.2 QA Review and Concurrence

Measures should be established to ensure that the QA organization reviews and concurs in inspection plans; test, calibration, and special process procedures; and specifications and any

changes thereto. Prior to fabrication of an item, manufacturing plans should be reviewed to obtain concurrence by QA of scheduled witness and hold points during fabrication.

6. GUIDANCE ON § 71.113, DOCUMENT CONTROL

6.1 Controlled Documents

Each of the documents under the control of the QA program should be maintained to reflect current status. As a minimum, control should be exercised over the following items:

- 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, and
- Corrective action reports.

6.2 Control of Document Generation and Issuance

Controls should be established to ensure that all documents and changes thereto are adequately reviewed and approved prior to their issuance. Measures (e.g., the use of a master document list) should be included 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. All packaging affected by design changes should be checked to verify that it is in accordance with the appropriate revision. The individuals or groups responsible for reviewing, approving, and issuing documents and revisions thereto should be identified by function or position.

6.3 Control of Document Changes

Measures should be established to ensure that changes to documents are reviewed and approved by the same organization that performed the original review and approval and that the changes are in accordance with configuration control procedures.

6.4 Control of Electronic Documents

If the documents are stored electronically, controls should be established over access to the documents to ensure that the latest versions of the documents are available and that changes to the documents are properly authorized and implemented. The software and hardware systems used for storing 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

Measures should be established in the areas identified below to ensure that materials, equipment, and services conform to procurement documents.

7.1 Procurement Document Planning

Procurement planning procedures should be established to describe each procurement step leading to contract award for items and services. Responsible organizations for each procurement step should be identified.

7.2 Selection of Procurement Sources

Measures should be established for evaluating and selecting procurement sources, including the extent of QA and engineering involvement. Provisions that should be considered, if applicable, include:

- The supplier's capability to comply with applicable sections of Subpart H,
- Results of the survey of the supplier's facility and QA program, and
- Review of the supplier's previous records and performance.

7.3 Bid Evaluation and Award

Measures should be established 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, all unacceptable conditions identified during the bid evaluation should be resolved if possible. If any unacceptable conditions cannot be resolved prior to contract award, a commitment from the supplier should be obtained indicating that resolution will be made at a mutually agreeable date during the contract period.

7.4 Supplier Performance Control

Measures should be established 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 extent to which source surveillance during fabrication, assembly, maintenance, modification, repair, inspection, testing, and shipment is performed to ensure conformance with the purchase order requirements should be established. The measures should cover:

- Instructions specifying characteristics or processes to be witnessed, inspected, or verified;

- The documentation required, and

- Identification of those responsible for implementing source surveillance.

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

Measures such as source surveillance and audits of records should be taken as appropriate to ensure that the design and fabrication of packaging were performed under the control of an NRC-approved QA program.

7.6 Controlling Nonconformances

Measures should be established 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

Measures should be established 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 packing during transport and be received at the destination by the user.

Such documents should be referenced in the CoC, should relate to the use and maintenance of the packaging, and should 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 software system the documentation is to be delivered in should be specified.

Documentation is to be retained at the facility or site of material or equipment use.

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

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

Measures should be established to facilitate continued processing when required inspections or tests have not been completed in order to maintain physical identity and control over affected material.

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 non-destructive testing, or if special processes are required to meet CoC requirements, measures should be established to ensure that the special processes are controlled in accordance with the following:

9.1 Procedures, equipment, and personnel are qualified in accordance with applicable codes, standards, and specifications.

9.2 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.

9.3 Qualification records of procedures, equipment, and personnel are established, filed, and kept current.

10. GUIDANCE ON § 71.121, INTERNAL INSPECTION

10.1 Measures should be established to ensure that:

10.1.1 Inspection procedures, instructions, or checklists are available for each work operation where necessary to assure quality,

10.1.2 Documents developed include methods for identification of characteristics and activities to be inspected, acceptance and rejection criteria, and identification of the individuals or groups responsible for performing the inspection operation,

10.1.3 Objective evidence of inspection results is recorded,

10.1.4 Hold or witness points are identified,

10.1.5 Approval of data by the appropriate personnel to ensure that all inspection requirements have been satisfied, and

10.1.6 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

Measures should be established to ensure that items 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 or its capability to prevent or mitigate the consequences that could result from release of radioactive material) received at the plant meet the requirements specified on the purchase order.

The criteria for acceptance of each of these inspections and the action to be taken if noncompliance is encountered should be established. These visual inspections should include inspection of:

- 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, and
- Leak-tightness of the packaging.

Provisions should be established for the control of accepted items until they are placed in stock or released for use, and provisions should be established for the proper disposition of rejected items.

10.2.2 In-Process Inspections

Measures should be established 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

Measures should be established to ensure that final inspections provide for resolution of nonconformances identified in earlier inspections, that the inspected item is identifiable and traceable to specific records and is adequately protected from physical or environmental damage, and that supervisors review inspection records to verify that all inspection requirements have been satisfied.

For packaging use, checklists should be established 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 DOT regulations,
- Measures are established to ensure that appropriate personnel designated by the user of packages signs the shipping tags or indicators prior to authorization for shipping.

10.2.4 Maintenance Inspections

Measures should be established for an inspection program to ensure adequate maintenance of packaging. The 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

Measures should be established to ensure that inspectors are qualified in accordance with applicable codes, standards, and company training programs; that such qualifications and certifications are kept current; and that inspection personnel are independent from individuals performing the activity being inspected.

10.2.6 Inspection Documentation

Inspection records should be maintained as QA records to document performance of inspection activities.

11. GUIDANCE ON § 71.123, TEST CONTROL

11.1 Requirements

Measures should be established to ensure that applicable test programs, including prototype qualification tests, production tests, proof tests, and operational tests, are accomplished in accordance with written procedures. Measures should be established to ensure that modifications, repairs, and replacements are tested in accordance with the original design and testing requirements.

11.2 Procedures

Measures should be established for ensuring 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

Measures should be established, as appropriate, to ensure that acceptance tests are conducted prior to delivering packages for transport to a carrier. The basis for acceptance criteria (e.g., CoC, maintenance and operational manuals furnished by the packaging manufacturers) should be identified. The following items should be included in typical tests:

- 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, and
- Thermal integrity.

11.4 Maintenance Tests

Maintenance test programs should be established to ensure that packages remain usable and free of excessive radiation and contamination.

The test program should include measures to ensure that test results are documented, evaluated, and determined to be acceptable by qualified responsible individuals.

11.5 Results

Measures should be established 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. The acceptability of records should be determined by a qualified individual or group.

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

12.1 Calibration Control

Measures should be established for ensuring that measurement and test equipment (e.g., gauges, fixtures, reference standards, and devices used to measure product characteristics) are calibrated, adjusted, and maintained at prescribed intervals or prior to use. The measuring and test equipment should be labeled or tagged to indicate the planned date of its next calibration, and the calibration records should be identified and traceable and maintained as QA records. Measures should be established 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 basis for calibration should be documented.

12.2 Out-Of-Calibration Equipment

Measures should be taken to validate previous inspection and test results up to the time of previous calibration when test and measuring equipment is found to be out of calibration. If any measuring equipment is consistently out of calibration, it should be repaired or replaced.

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

13.1 Preservation

Measures should be established 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, provisions should be established for the use of special handling, lifting, or storage provisions (e.g. cranes, shock absorbers, or special markings) to adequately identify and preserve packaging components or assemblies. QA program users should determine that conditions identified in a CoC are adhered to when unloading packaging.

13.2 Preparation, Release, and Delivery to Purchaser

Measures should be established to ensure that a final pre-release review has been completed. This pre-release review should ensure that packaging is prepared for delivery to the purchaser in accordance with approved drawings, specifications, and government regulations; has passed all applicable inspections and tests; is properly identified by physical markings or tags; and contains operating manuals, maintenance manuals, and generic procedures relating to its use.

Measures should be established to ensure that:

- 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

Measures should be established to ensure that the status of inspections, tests, and operating conditions, including maintenance of items is known by organizations responsible for assurance of quality.

Measures should be established for controlling the application and removal of status indicators (e.g., tags, markings, stamps) and for ensuring that the bypassing of a required inspection or test or any other required operation is procedurally controlled and 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 items of nonconformance, and
- Evaluation of the items of nonconformance.

16. GUIDANCE ON § 71.133, CORRECTIVE ACTION

16.1 Reporting

Measures should be established to ensure that the causes of conditions detrimental to quality (e.g., those resulting from failures, malfunctions, deficiencies, deviations, and defective material and equipment) are promptly identified and reported to appropriate levels of management. Measures should be established for obtaining corrective actions from suppliers and for ensuring that follow-up is documented to verify that corrective actions were implemented and effective.

16.2 Closeout, Retrieval, and Disposition of Records

Measures should be established to ensure that corrective actions designated by cognizant individuals have been implemented to preclude recurrence. Individuals or organizations responsible for closing out corrective actions and documenting their resolution should be identified by function or position**.**

17. GUIDANCE ON § 71.135, QUALITY ASSURANCE RECORDS

17.1 General

QA records should furnish documentary evidence of the activities affecting quality and should provide sufficient information to permit identification of the record with the items or activities to which it applies. QA records should include, as a minimum:

- 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, corrective actions and
- Records that are used as a baseline for maintenance.

Records that show evidence of delivery of packages to a carrier and proof that all NRC and DOT requirements have been satisfied should also be retained with their retention times identified.

Where applicable, inspection and test records should contain:

- A description of the observation,
- Evidence of completion of the inspection or test operation,
- Results of inspections or tests with appropriate data,
- Conditions detrimental to quality,
- Names of inspectors, testers, or data recorders, and
- Evidence of acceptability.

17.2 Generating Records

Measures should be established to ensure that methods employed for the generation and management of documents designated as QA records result in information that is retrievable, intelligible, understandable, and reliable. The records should reflect the work accomplished and be stored in a manner that avoids unnecessary delay when the record is needed. Procedures for the generation of QA records should address hard copy records as well as electronic information.

17.3 Indexing and Classification Records

Quality assurance records should be classified as either "lifetime" or "nonpermanent."

Lifetime records include records pertaining to fabrication of the package and those of a particular item while it is installed in the packaging or stored for future use. These are the records that demonstrate the capability for safe operation; provide evidence of repair, rework, replacement, or modification; aid in determining the cause for an accident or malfunction of an item; or provide a baseline for in-service inspection.

Nonpermanent records are those that show evidence that an activity has been performed but do not meet 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

Measures should be established 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. Measures should be established to ensure that records maintained inhouse 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 for imaging and storing of information should be compatible with new hardware as current technologies are implemented. A procedure should be in place to ensure that new hardware systems can reliably store and retrieve information from existing software systems prior to the installation of the new hardware systems.

17.5 Storage, Preservation, and Safekeeping

17.5.1 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 and humidity, or infestation of insects, rodents, or mold.

17.5.2 Records should be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets.

17.5.3 Electronic records should be maintained in facilities that minimize or eliminate the potential for destruction of information due to demagnetization.

17.5.4 Electronic records should be backed up daily to eliminate the potential for loss of information by equipment failure or human error.

17.5.5 If dual storage facilities are used to ensure the integrity of records, they should be sufficiently remote from each other to preclude damage to both facilities from a single event such as a fire or flood.

17.5.6 Measures should be taken to preserve special records (e.g., radiographs and microfilm) from excessive light, electromagnetic fields, and temperature.

17.5.7 Measures should be taken to preclude the entry of unauthorized personnel into record storage areas.

17.5.8 Electronic information storage systems should be accessible only through security measures such as passwords, and the number of personnel with authorized access should be limited. Personnel with authorized access should have identified privileges, such as read only, or read and add only.

17.5.9 Measures should be established for 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:

- 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 access by the audit team to levels of management that have responsibility and authority for corrective action, and
- Methods for verification that effective corrective action has been accomplished on a timely basis.

A list of the activities important to safety to be audited and the frequency at which each quality criterion is to be audited should be established and maintained to reflect current status. The frequency of audits should be based on the importance of the activity to safety; however, each quality criterion should be audited at least once each year.

Measures should be established to ensure that audits are made of the manufacturers of packaging to determine the extent of compliance with the purchase order and to verify that the work is being controlled by a QA program approved by the NRC.

Individuals or groups that have responsibility and authority for ensuring that corrective actions resulting from findings during audits are accomplished on a timely basis should be identified. Deficient areas should be re-audited on a timely basis to verify implementation of corrective action.

18.2 Scheduling of Audits

Schedules for internal audits, external audits, and audits performed by management should be established. Measures should be established to ensure that key activities of the QA program (e.g., design, fabrication) are given priority consideration. For audits performed by management, the schedules should identify the level of management (usually from corporate office or another division) designated to assess the overall effectiveness of the implementation of the described in-house QA program. The activities important to safety (e.g., procurement, training of personnel) to be included in the audit program should be identified.

Internal audits of the applicable elements of the QA program should be audited annually or at least once within the life of the activity, whichever is shorter.

External audits of the elements of a major supplier's or major contractor's QA programs should be 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. Management audits should be conducted at least once every 12 months.

18.3 Team Selection

Qualifications of auditing personnel, including the lead auditor, should be established. The responsibilities of the audit team members and the lead auditor with respect to evaluation and issuance of audit reports should be specified. It is the responsibility of the auditing organizations to establish qualifications for prospective audit personnel and the requirement for

the use of technical specialists to accomplish auditing activities important to safety. The lead auditor and the team members should be selected from personnel who do not having direct responsibility in the areas being audited.

Specific guidance for determining qualifications for individual auditors and lead auditors may be obtained by referring to ANSI/ASME NQA-1 (Ref. 1) for the qualification of quality assurance program audit personnel.

18.4 Pre-audit Conference

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

18.5 Post-Audit Conference

Measures should be established to conduct a post-audit conference between the audit team and the management of the audited organization to present the results and clarify misunderstandings.

18.6 Reporting and Response

Measures should be established that 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 Follow-Up Action

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

D. IMPLEMENTATION

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

This guide has been released to encourage public participation in its development. Except when an applicant or licensee proposes an acceptable alternative method for complying with the specified portions of the NRC's regulations, the methods to be described in the active guide reflecting public comments will be used in the evaluation of submittals by applicants for establishing QA programs for packages that transport radioactive materials and in the assessment of QA program users' performance with respect to developing, implementing, and maintaining such QA programs.

REFERENCES

1. American National Standards Institute (ANSI), American Society of Mechanical Engineering (ASME) ANSI/ASME NQA-1-1979, "Quality Assurance Program Requirements for Nuclear Power Plants," 1979.

2. NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety," USNRC, February 1996.

3. ISO 9000, "Quality Management Systems," International Organization for Standardization, Case Postale 56, CH-1211, Geneva 20, Switzerland, 2000.

4. NRC Information Notice 2002-35, "Changes to 10 CFR Parts 71 and 72 Quality Assurance Programs," USNRC, December 20, 2002.*

5. NRC Generic Letter 88-18, "Plant Record Storage on Optical Disks" (Provides guidance on optical disc document imaging systems for the retrieval of record copies of QA records), USNRC, October 20, 1988.*

6. Regulatory Information Summary 00-18, "Guidance on Managing Quality Assurance Records in Electronic Media," USNRC, October 23, 2000.*

* Available on the NRC web site, www.nrc.gov, in the Electronic Reading Room in Document Collections, under Generic Communications.

APPENDIX A

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

The design effort and the 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 consequence to public health and safety 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 be by (1) classifying each component, structure, and system 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 a level of QA effort applicable to each category. To ensure a better understanding of the process, each step is further detailed below:

1. CLASSIFICATION

All components, structures, and systems that appear on the latest list of packaging parts would first be analyzed to determine whether their functions or physical characteristics are essential to safety. Items identified as essential to safety (often referred to as "Q" items) are then subject to a QA program based on the requirements of Subpart H of 10 CFR Part 71.

2. QUALITY CATEGORIES

Quality categories would then be established based on the relative safety significance of each Q item and, where appropriate, their sub-component parts. Categories could be identified as A for items that are critical to safe operation, B for items with a major impact on safety, and C for items with a minor impact on safety. For example, Category A items could be structures, components, and systems whose failure or malfunction could result directly in a condition adversely affecting 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 be structures, components, and systems whose failure or malfunction could indirectly result in a condition adversely affecting pubic health and safety. An unsafe condition could result only if the primary event occurs in conjunction with a secondary event or other failure or environmental occurrence. Category C items could be the structures, components, and systems whose failure or malfunction would not significantly reduce the packaging effectiveness and would be unlikely to create a condition adversely affecting public health and safety.

3. LEVEL OF QA EFFORT

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

- The design would 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 would specify that only suppliers from qualified vendor lists be used,
- The suppliers and sub-tier suppliers would have a QA program based on applicable criteria in Subpart H to Part 71,
- The manufacturing planning would specify complete traceability of raw materials and the use of certified welders and processes,
- The verification planning (test and inspection) would 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 would perform audits, and
- 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 would include the following:

- The design would be based on the most stringent industrial codes and standards, but design verification could be through use of calculations or computer codes,
- The procurement of materials need not be from a qualified vendor list,
- The 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, and
- Only the lead auditor need meet certain qualification requirements.

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

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

* ASNT-SNT-TC-1A, "Standard for Qualification and Certification of Non-Destructive Personnel," American Society for Nondestructive Testing (ASNT), Recommended Practice No. SNT-TC-1A, 2001. Published by the American Society for Nondestructive Testing, 1711 Arlingate Lane, Columbus, Ohio 43228.

VALUE/IMPACT STATEMENT

A separate regulatory analysis was not prepared for this regulatory guide. However, revision of this regulatory guide was necessary to provide additional clarity and definition to guidance commonly used by applicants and QA Program Approval Holders in the development of QA programs to be used for the control of transportation activities under 10 CFR Part 71. NUREG/CR-6713, "Draft Regulatory Analysis of Major Revision of 10 CFR Part 71," provides the regulatory analysis for this regulatory guide. A copy of NUREG/CR-6713 is available for inspection and copying for a fee at the U.S. Nuclear Regulatory Commission Public Document Room, 11555 Rockville Pike, Rockville, MD; the PDR's mailing address is US NRC PDR, Washington, D.C. 20555; telephone (301) 415-4737 or (800)397-4209; fax (301)415-3548; e-mail <PDR@NRC.GOV>. Copies are available at current rates from the U.S. Government Printing Office, P.O. Box 37082, Washington, D.C. 20402-9328 (telephone (202)512-1800); or from the National Technical Information Service by writing NTIS at 5285 Port Royal Road, Springfield, VA 22161: <http://www.ntis.gov/ordernow>; telephone (703)4874650.