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REGULATORY GUIDE

OFFICE OF NUCLEAR REGULATORY RESEARCH

REGULATORY GUIDE 7.10

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

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A. INTRODUCTION

Paragraph 71.37(a) of 10 CFR Part 71, "Packaging and Transportation of Radioactive Material," requires applicants for package design approval to identify the NRC-approved quality assurance (QA) program to be applied to the design, fabrication, assembly, testing, maintenance, repair, modification, and use of the proposed packaging.

Section 71.101, "Quality Assurance Requirements," requires that licensees have a quality assurance 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' quality assurance programs satisfy each of the applicable criteria specified in Section 71.101 to an extent consistent with their importance to safety.

This regulatory guide provides persons subject to the QA requirements of Part 71 with information on the essential elements needed to develop, establish, and maintain a quality assurance program acceptable to the NRC staff for packages to transport radioactive materials. 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."**

Any information collection activities mentioned in this regulatory guide are contained as requirements in 10 CFR Part 71, which provides the regulatory basis for this guide. The information collection requirements in 10 CFR Part 71 have been cleared under OMB Clearance No. 3150-0008.

B. DISCUSSION

The quality assurance program is intended to provide control over all activities important to safety that are applicable to the design, fabrication, assembly, testing, maintenance, repair, modification, and use of packaging for transporting specified types of radioactive materials. This control should be applied to the various activities in a graded approach, i.e., the QA effort expended on an activity should be consistent with its importance to safety. 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.

The activities covered by the QA program may be divided into two major groups: those activities culminating in completed packaging and those activities associated with procurement and use of the completed packaging. Annex 1 provides guidance on the essential elements needed to develop, establish, and maintain a quality assurance program for the design, fabrication, assembly, and testing of packaging. Similar guidance for procurement, use, maintenance, and repair of all types of completed packaging is presented in Annex 2. In recognition of the fact that the QA program derived from Annex 2 would be unnecessarily complicated for users of packages designed to transport radiographic exposure devices, the staff developed simplified guidance specifically for this application. Annex 3 provides guidance on QA programs for procurement, use, maintenance, and repair of packages designed to transport radiographic exposure devices. In developing the guidance in Annex 3, the staff took into account the elements of a QA program specifically required for radiography licensees by 10 CFR Part 34, "Licenses for Radiography and Radiation Safety Requirements for Radiographic Operations."

C. REGULATORY POSITION

The essential elements of a quality assurance program acceptable to the NRC staff for complying with the quality assurance requirements of Subpart H of 10 CFR Part 71 are contained in Annex 1 of this guide for activities related to design, fabrication, assembly, and testing of packaging and in Annex 2 for activities related to procurement, use, maintenance, and repair of completed packaging.

Annex 3 contains simplified guidance specifically applicable to users of radiographic exposure devices for activities related to procurement, use, maintenance, and repair of packages designed to transport such devices.

The recommendations of this guide apply to the general QA criteria contained in Subpart H of 10 CFR Part 71. Subpart G, "Operating Controls and Procedures" of 10 CFR Part 71 and NRC certificates of compliance applicable to particular packages contain specific criteria and requirements that should be incorporated into the QA program.

Persons subject to Subpart H should submit their programs to and obtain approval from the NRC prior to engaging in any activity important to safety. Those engaging 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 after their QA program has been approved.

Establishment of a QA program implies that all activities important to safety applicable to the design, fabrication, inspection, testing, purchase, use, maintenance, repair, and modification of packages are implemented with written procedures approved by appropriate levels of management and are contained in quality assurance/quality control (QC) manuals.

*Lines indicate substantive changes from previous issue.

**Copies may be obtained from the American Society of Mechanical Engineers, United Engineering Center, 345 East 47th Street, New York, NY 10017.

D. IMPLEMENTATION

This section provides information to applicants and licensees regarding the NRC staff's plan for using this regulatory guide.

Except in those cases in which an applicant proposes an acceptable alternative method for complying with specified portions of the Commission's regulations, the method described in the guide will be used (1) to evaluate submittals by applicants for establishing quality assurance programs for packages that transport radioactive materials and (2) to assess licensees' performance with respect to developing, establishing, and maintaining such QA programs.

ANNEX 1

Quality Assurance Programs Applicable to Design, Fabrication, Assembly, and Testing of Packaging Used in Transport of Radioactive Material

This annex provides guidance in formulating quality assurance (QA) programs applicable to design, fabrication, assembly, and testing of packaging used in the transport of radioactive material. This guidance is presented in the same order as the criteria in Subpart H of 10 CFR Part 71.

1.1 Organization

1.1.1 Structure and Authority

The structure of the organization and the assignment of responsibility for each function should ensure that (1) specified quality requirements are achieved and maintained by those who have been assigned the responsibility for performing the work and (2) conformance to established requirements is verified by individuals and groups not directly responsible for performing the work. The persons or organizations responsible for verifying quality should report through a management hierarchy so that required authority and organizational freedom, including sufficient independence from influences of cost and schedule, are provided. Where more than one organization is involved in the execution of activities important to safety, including major contractors, the authority of each organization should be clearly established. The QA and quality control (QC) functions retained by the QA organization or delegated to other organizations should be identified to ensure that all the appropriate elements of Subpart H will be implemented.

A formal organization structure should be established, and organization charts identifying each organizational element that functions under the QA program (e.g., engineering, procurement, inspection, testing, quality assurance) should be prepared. The interface relationships and QA responsibilities of each organizational element, including those of principal contractors, should be identified to demonstrate assignment of responsibilities that meet Subpart H requirements. In addition, qualification requirements for principal QA and QC management positions should be identified to demonstrate competence commensurate with the responsibilities of these positions. Measures should be established to ensure that designated QA individuals have the responsibility and authority to stop unsatisfactory work and the processing, delivery, or installation of nonconforming material; this authority should be delineated in writing.

1.1.2 Top Management Endorsement of a Quality Assurance 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 a company or corporate president or by a 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 QA manuals. The policy statement should also identify those individuals delegated authority for (1) implementing and revising the provisions of the described QA program and (2) regularly assessing the scope, status, implementation, and effectiveness of the QA program.

1.2 Quality Assurance 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 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. Three major factors are necessary for an acceptable quality assurance program: appropriate documentation, proficient personnel, and assurance that activities important to safety are performed under suitably controlled conditions.

1.2.1 Documentation

The quality assurance 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.

To demonstrate that a documented QA program has been fully implemented by written procedures and is contained in QA/QC manuals, a master index of QA procedures related to all activities important to safety and a matrix of those QA procedures that implement each criterion of Subpart H should be established and maintained to reflect the current status of the QA program. With respect to those anticipated activities important to safety not yet 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. Table 1 of this annex shows a suitable format for listing procedures to demonstrate implementation of a documented QA program.

1.2.2 Personnel

The QA program should provide measures for ensuring (1) that personnel performing activities important to

Table 1

FORMAT FOR LISTING OF IMPLEMENTING PROCEDURES*

Implementing Document	Title	10 CFR Part 71 Subpart H Criteria	Description
Quality Assurance Manual (QAM), Quality Procedure (QP) 1	Organization	1	Identifies organizations and their relationships in performance of 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 procedure 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 criteria would be listed; the table shows examples for Criteria 1, 2, 3, 4, and 18 only.

safety receive indoctrination and training commensurate with the skill levels needed and (2) that qualified personnel within the organization be assigned to determine that functions delegated to principal contractors are properly accomplished. The required training should be completed before the personnel engage in such activities. The program should identify the scope and objective of the training and the method for implementing it. The proficiency of the personnel should be maintained by retraining, reexamining, and recertifying. Personnel performing functions important to safety, e.g., inspecting and testing, should be qualified based on their abilities gained through education, training, and experience. Records of persons performing functions important to safety should include the bases on which an individual is qualified to perform a required function.

For personnel performing special processes, e.g., nondestructive examinations or welding, measures should be established for obtaining proof of their certification to perform the process, the period their certification remains in effect, and the conditions under which recertification would be required. Qualification and certification of nondestructive testing personnel should be accomplished based on guidelines established by such recognized authorities as the American Society for Nondestructive Testing (ASNT), American Society of Mechanical Engineers (ASME), or American National Standards Institute (ANSI).

Provisions should be established for resolving disputes involving quality that arise from a difference of opinion between QA/QC personnel and personnel from other departments (e.g., engineering, procurement, manufacturing).

1.2.3 Controlled Conditions

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.

1.3 Design Control

Good interrelationships 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.

1.3.1 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.

1.3.2 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, inservice inspection, handling, storage, and cleaning requirements are specified in design documents.

1.3.3 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. Individuals or groups responsible for design verification should be other than the original designer. The designer's immediate supervisor may perform the verification provided (1) the supervisor is the only technically qualified individual, (2) the need is documented and approved in advance by the supervisor's management, and (3) the QA audits cover the effectiveness of 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 that reviewed and approved the original documents. Changes in design that could result in conditions differing from those prescribed on the certificate of compliance 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.

1.4 Procurement Document Control

1.4.1 Preparation and Issuance of Procurement Documents

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

1.4.2 Content of Procurement Documents

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

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

2. 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.

3. Applicable Subpart H requirements that must 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, where subtier suppliers are involved, the QA provisions appropriate to those procurements should be specified. (The extent of the supplier's or subtier supplier's QA program will depend on the particular item or service being procured.)

4. Permission to gain access to the supplier's or subtier supplier's plant facilities and records for inspection or audit purposes.

5. 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.

6. Identification of those records to be retained, controlled, and maintained by the supplier and of those records delivered to the purchaser prior to installation of hardware.

7. Requirements for reporting and approving disposition of nonconformances.

1.4.3 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.

1.5 Instructions, Procedures, and Drawings

1.5.1 Quality Assurance Program Procedures

Measures should be established to ensure that:

1. Activities important to safety are prescribed and accomplished in accordance with documented instructions, procedures, or drawings.

2. Methods for complying with each of the applicable 18 criteria of Subpart H of 10 CFR Part 71 are specified in instructions, procedures, and drawings.

3. 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.

1.5.2 Quality Assurance 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.

1.6 Document Control

1.6.1 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:

1. Design documents (e.g., drawings, specifications, and computer codes),

2. Procurement documents,

3. QA and QC manuals,

4. Operating, maintenance, and modification procedures,

5. Inspection and test procedures,

6. Nonconformance reports,

7. Design change requests, and

8. Corrective action reports.

1.6.2 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. Those individuals or groups responsible for reviewing, approving, and issuing documents and revisions thereto should be identified.

1.6.3 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.

1.7 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.

1.7.1 Procurement Document Planning

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

1.7.2 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 (1) the supplier's capability to comply with applicable criteria of Subpart H, (2) results of the survey of the supplier's facility and QA program, and (3) review of the supplier's previous records and performance.

1.7.3 Bid Evaluation and Award

Measures should be established to ensure that designated individuals or organizations evaluate proposed suppliers based on the following criteria as applicable to the type of procurement: (1) technical considerations, (2) conformance to QA requirements, (3) production capability, and (4) 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.

1.7.4 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 quality assurance organization prior to further processing) during manufacturing and testing and prior to shipment.

1.7.5 Verification Activities

The extent to which source surveillance during fabrication, 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 receipt inspection 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.

1.7.6 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).

1.7.7 Records

Measures should be established to ensure that the supplier furnishes to the purchaser the following records as a minimum:

1. Documentation that identifies material or equipment and the specific procurement requirements (e.g., codes, standards, and specifications met by the items).

2. Documentation that identifies any procurement requirements that have not been met along with a description of those nonconformances designated "use as is" or "repair."

1.8 Identification and Control of Materials, Parts, and Components

1.8.1 Identification and Control

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, where 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.

1.8.2 Conditional Releases

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.

1.9 Control of Special Processes

Measures should be established to ensure that special processes (e.g., welding, radiography, heat treating) are controlled in accordance with the following criteria:

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

2. The operations are performed by qualified personnel and accomplished in accordance with recorded evidence of verification.

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

1.10 Inspection Control

1.10.1 Inspection Planning

Measures should be established to ensure that inspection procedures, instructions, or checklists include identification of characteristics and activities to be inspected, acceptance and rejection criteria, identification of the individuals or groups responsible for performing the inspection operation, recording of objective evidence of inspection results, identification of hold or witness points, approval of data by the supervisor to ensure that all inspection requirements have been satisfied, and the prerequisites to be satisfied prior to inspection, 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.

1.10.2 Inspections

1.10.2.1 Receiving. Measures should be established to ensure that items important to safety (i.e., those 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. Also provisions for the control of accepted items until they are placed in stock or released for use and provisions for the proper disposition of rejected items should be established.

1.10.2.2 In-Process. 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.

1.10.2.3 Final. Measures should be established to ensure that final inspection provides 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.

1.10.3 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.

1.11 Test Control

1.11.1 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.

1.11.2 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.

1.11.3 Results

Measures should be established to ensure that test results are documented and evaluated and that their acceptability is determined by a qualified individual or group.

1.12 Control of Measuring and Test Equipment

1.12.1 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) should be 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. 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.

1.12.2 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.

1.13 Handling, Storage, and Shipping

1.13.1 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.

1.13.2 Preparation, Release, and Delivery to Purchaser

Measures should be established to ensure that a final prerelease review has been completed. This prerelease 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.

1.14 Inspection, Test, and Operating Status

Measures should be established to ensure that the identification of the inspection, test, and operating status of items is known by organizations responsible for assurance of quality.

Also, 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 quality assurance organization.

1.15 Control of Nonconforming Materials, Parts, or Components

An acceptable program for controlling nonconforming items should include the following principal elements: (1) proper identification, (2) segregation of discrepant or nonconforming items, (3) disposition of the items of nonconformance, and (4) evaluation of the items of nonconformance.

1.15.1 Identification

Measures should be established to identify nonconformances (e.g., Deviating Material Reports that identify detailed processing steps leading to item disposition, inspection requirements, and corrective action) along with the individuals or groups responsible for approval of the disposition of nonconforming items.

1.15.2 Segregation

Measures should be established to ensure that nonconforming items are quarantined or placed in controlled hold areas until proper disposition is completed.

1.15.3 Disposition

Measures should be established to ensure that the acceptability of nonconforming items is verified by reinspecting or retesting the item against the original requirements after designated repair or rework. Final disposition of nonconformances should be identified and documented.

1.15.4 Evaluation

Nonconformance reports should be analyzed by QA personnel to determine quality trends for appropriate management review and assessment.

1.16 Corrective Action

1.16.1 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 followup is documented to verify that corrective actions were implemented and effective.

1.16.2 Closeout

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.

1.17 Quality Assurance Records

1.17.1 General

Quality assurance 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. Quality assurance records should include, as a minimum, design, procurement, manufacturing, and installation records; supplier evaluations; nonconformance reports; results of inspections, tests, and audits; failure analyses; as-built drawings and specifications; qualification of personnel, procedures, and equipment; calibration procedures; training and retraining records; and corrective action reports.

Where applicable, inspection and test records should contain (1) description of the observation, (2) evidence of completion of the inspection or test operation, (3) results of inspections or tests with appropriate data, (4) conditions detrimental to quality, (5) names of inspectors, testers, or data recorders, and (6) evidence of acceptability.

1.17.2 Generating Records

Measures should be established to ensure that documents designated as QA records are legible and completed to reflect the work accomplished and are processed quickly to avoid unnecessary delay when the record is needed.

1.17.3 Indexing and Classification of 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 inservice 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 must be retained for a period of 2 years after the shipment.

1.17.4 Receipt, Retrieval, and Disposition of Records

Measures should be established to provide a receipt control system, including identification of individuals 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 in house or at other locations are identifiable and retrievable and are not disposed of until prescribed conditions are satisfied.

1.17.5 Storage, Preservation, and Safekeeping

Facilities used to store records should be constructed to minimize the risk from damage or destruction by severe natural conditions such as wind, flood, or fire; temperature and humidity; and infestation of insects, rodents, or mold. Records should be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets. If dual 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. Measures should be taken to preserve special records (e.g., radiographs and microfilm) from excessive light, electromagnetic fields, and temperature. Measures should also be taken to preclude the entry of unauthorized personnel into record storage areas. Measures should be established for prompt replacement of a record that is lost or damaged.

1.18 Audits

1.18.1 Elements of Audit Program

A comprehensive audit program should include assurance of the authority and organizational independence of the auditors; 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 personnel necessary for performing audits; use of 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.

1.18.2 Scheduling of Audits

Schedules for internal, external, and management audits 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 management audits, 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 quality assurance program should be audited at least 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 quality assurance 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 quality assurance program having the required scope for purchases placed during the 3-year period. Management audits should be conducted at least once every 12 months.

1.18.3 Team Selection

Qualifications of auditing personnel, including the lead auditor, should be established, and 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.

Sp[illegible] guidance for determining qualifications for indivi[illegible] auditors and lead auditors may be obtained by referring to Supplement 2S-3, "Supplementary Requirements for the Qualification of Quality Assurance Program Audit Personnel," to ANSI/ASME NQA-1-1979.*

*Copies may be obtained from the American Society of Mechanical Engineers, United Engineering Center, 345 East 47th Street, New York, NY 10017.

1.18.4 Preaudit Conference

The nature and scope of the preaudit 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 postaudit conference, establish channels of communication, and prepare an agreed-to agenda for the audit.

1.18.5 Postaudit Conference

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

1.18.6 Reporting and Response

Measures should be established identifying time constraints imposed for issuing audit reports and the requested date for corrective-action response by the audited organization. The response should clearly state the corrective action taken to prevent recurrence of nonconformances. In the event that corrective action cannot be taken immediately, the response of the audited organization should include scheduled dates for initiation and completion of the corrective action.

1.18.7 Followup 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.

ANNEX 2

Quality Assurance Programs Applicable to Procurement, Use, Maintenance, and Repair of Packaging Used in Transport of Radioactive Material

Paragraphs 71.12(b), 71.14(b), and 71.16(c)(2) provide users with a general license to deliver packaged licensed material to a carrier for transport provided certain conditions are met. One of these conditions is that the user must provide for the establishment and execution of a quality assurance (QA) program consistent with the provisions of Subpart H of 10 CFR Part 71. The user may delegate to other organizations the work of establishing or executing the QA program or any part thereof but retains the responsibility for its overall effectiveness. Therefore, the user must (1) determine that during design and fabrication all quality assurance provisions applicable to packaging have been followed, (2) describe to the NRC how this determination has been made, and (3) submit to the NRC for evaluation and approval the established QA program applicable to procurement, use, maintenance, and repair of packaging.

This annex provides guidance on the essential elements needed to develop, establish, and maintain a QA program applicable to procurement, use, maintenance, and repair of packages that must meet the requirements of Subpart H of 10 CFR Part 71.

2.1 Organization

A formal organization structure should be established and documented by organization charts identifying each organizational element that functions under the QA program. Measures should be established to provide adequate control over activities important to safety (e.g., inspecting, cleaning, purchasing, preparing the packaging for delivery). 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 principal personnel performing QA and QC functions should be established and documented and should have the written endorsement of top management.

2.2 Quality Assurance Program

2.2.1 Scope of Quality Assurance Program

Measures should be established to ensure that (1) activities important to safety are performed with specified equipment and under suitable environmental conditions, (2) designated QA and QC responsibilities for implementation of activities important to safety are contained in QA/QC manuals, and (3) indoctrination and training programs are established so that personnel performing activities important to safety are trained and qualified to perform these activities.

2.2.2 Applicability of Quality Assurance Program

Measures should be established to ensure that items covered by the QA program are 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 user's QA program should be established.

2.3 Design Control

Design activities are not normally performed by users of packaging; consequently, this criterion of Subpart H should not be applicable. However, it should be established that the design was accomplished under control of an NRC-approved QA program (see Sections 2.4.1 and 2.7 of this annex).

2.4 Procurement Document Control

2.4.1 Packaging Procurement

Measures should be established to ensure that procurement documentation (1) requires the manufacturers of packaging to supply appropriate certifications verifying that the designated (model and serial number) packaging was manufactured under the control of an NRC-approved QA program, (2) identifies the type of verification activities required during use and maintenance, and (3) designates other pertinent documentation to be furnished with the packaging (e.g., certificate of compliance, as-built drawings, photographs, sketches, use and maintenance manuals).

2.4.2 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 user must assure himself or herself that the replacement parts meet requirements at least as stringent as the original criteria.

2.5 Instructions, Procedures, and Drawings

2.5.1 Preparation of Packaging for Use

Procedures for meeting the requirements of § 71.87 of 10 CFR Part 71 for placing the packaging in use should be established and approved by appropriate levels of management. A listing of these procedures should be maintained to always reflect current status.

2.5.2 Repair, Rework, and Maintenance

Measures should be established to ensure that plans for necessary repairs or rework of packaging are prescribed before the work begins. These plans should be coordinated with quality assurance personnel to ensure that appropriate inspection and hold points are incorporated into the plans to verify that effective repairs or rework have been satisfactorily performed. Also, measures should be established to ensure that plans for maintenance are reviewed by quality assurance personnel to verify that the plans emphasize those characteristics that are important to safety.

2.5.3 Loading and Unloading Contents

Measures should be established to ensure that loading radioactive material into packaging and unloading radioactive material from packages are controlled (e.g., surveys for contamination and radiation; measurements of pressure, temperature, and coolant radioactivity; adequate venting of the package; preparation for immersion; rigging and hoisting the package; and proper level of antifreeze).

2.5.4 Transport of Package

Measures should be established to ensure that packages are in good condition, adequately secured within or on the transport vehicle, properly sealed, marked per DOT regulations, and identified by model and license registration numbers.

2.6 Document Control

Each of the documents under the control of the QA program should be identified. As a minimum, control should be exercised over the following documents:

1. QA and QC Manuals,
2. Operating Procedures,
3. Maintenance Procedures,
4. Inspection and Test Procedures,
5. Loading and Unloading Procedures,
6. Packaging for Transport Procedures,
7. Repair Procedures, and
8. Procurement Documentation.

Measures should be established to ensure that the most recent revision to an instruction, procedure, specification, or drawing is available to those persons responsible for using these documents and to ensure that changes to documents are reviewed and approved by the same organization that performed the original review and approval.

2.7 Control of Purchased Material, Equipment, and Services

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.

Measures should be established to ensure that packaging when received at the destination designated by the user is accompanied by appropriate documentation as identified in the purchase order. Such documents should be referenced in the certificate of compliance, 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.

2.8 Identification and Control of Materials, Parts, and Components

Measures should be established to ensure that materials, parts, and components used for repair or rework for maintenance purposes are adequately identified to preclude use of incorrect or defective items. Also, where replacement of limited-life items is specified, measures should be established to preclude use of items whose shelf life or operation times have expired.

2.9 Control of Special Processes

Special processes such as welding or nondestructive testing are not normally performed by the users of packaging. However, if packaging requires major repairs necessitating use of special processes, e.g., welding or heat treating, measures should be established to ensure that the special processes are controlled in accordance with the following criteria:

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

2. The operations are performed by qualified personnel and accomplished in accordance with written process sheets with recorded evidence of verification.

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

2.10 Inspection Control

2.10.1 Receipt Inspection

Visual inspections should be performed upon receipt of packaging to ensure compliance with procurement documents. 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 tiedown members (if applicable); labeling and marking; and leaktightness of the packaging.

2.10.2 Maintenance

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.

2.10.3 Final Inspection

Checklists should be established to ensure that inspections are performed to verify that the following items have been complied with:

1. Packages are properly assembled.

2. Moderators and neutron absorbers are present, if applicable.

3. Valves through which primary coolant flows are protected against tampering.

4. Valves are set to specifications.

5. All shipping papers are properly completed.

6. Packages are conspicuously and durably marked as required by DOT regulations.

7. Measures are established to ensure that an individual designated by the user of packages signs the shipping tags or indicators prior to authorization for shipping.

For all the inspections identified above, the inspection personnel should be independent from the individual performing the activity being inspected.

2.11 Test Control

2.11.1 Use of Packages

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., certificate of compliance, maintenance and operational manuals furnished by the packaging manufacturers) should be identified. The following items should be included in typical tests:

1. Structural integrity,

2. Leaktightness (on containment vessel as well as auxiliary equipment and shield tanks),

3. Component performance for the following:

   a. Valves,
   b. Gaskets, and
   c. Fluid transport devices,

4. Shielding integrity, and

5. Thermal integrity.

2.11.2 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 by qualified responsible individuals to be acceptable.

2.12 Control of Measuring and Test Equipment

2.12.1 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) should be 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. 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.

2.12.2 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.

2.13 Handling, Storage, and Shipping

2.13.1 Handling and Storage

Measures should be established to ensure that:

1. Special handling and lifting equipment to move packaging from one station to another is used.

2. Special handling or storage provisions for packaging (e.g., shock absorbers, tags, or markings to adequately protect and identify critical components) are used.

3. Proper environmental conditions to preserve packaging are maintained.

4. All conditions identified in a certificate of compliance when unloading packaging are adhered to.

2.13.2 Preparation for Release and Shipment

Measures should be established to ensure that:

1. Cavities within gas-cooled package containments have been adequately dried and cavities within liquid-cooled packages have been drained to allow adequate void space.

2. All conditions, including specified operations, inspections, and tests, have been completed prior to delivery to a carrier.

3. All NRC and DOT requirements have been satisfied prior to delivery to a carrier.

4. All necessary shipping papers have been prepared as required.

2.14 Inspection, Test, and Operating Status

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

Measures should be established to indicate by use of tags, markings, stamps, etc., that individual items of the packaging procedurally controlled by the QA program have not inadvertently bypassed required inspections and tests.

2.15 Control of Nonconforming Materials, Parts, or Components

The following guidance for controlling nonconforming items for completed packaging, replacement parts, or components should include the following principal elements: (1) proper identification, (2) segregation of discrepant or nonconforming items, (3) disposition of the items of nonconformance, and (4) evaluation of the items of nonconformance.

2.15.1 Identification

Measures should be established to identify nonconformances (e.g., Deviating Material Reports that identify detailed processing steps leading to item disposition, inspection requirements, and corrective action) and the individuals or groups responsible for approval of the disposition of nonconforming items.

2.15.2 Segregation

Measures should be established to ensure that nonconforming items are quarantined or placed in controlled hold areas until proper disposition is completed.

2.15.3 Disposition

Measures should be established to ensure that the acceptability of nonconforming items is verified by reinspecting or retesting the item against the original requirements after designated repair or rework. Final disposition of nonconformances should be identified and documented.

2.15.4 Evaluation

Nonconformance reports should be analyzed by QA personnel to determine quality trends for appropriate management review and assessment.

2.16 Corrective Action

2.16.1 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 for activities important to safety concerning use, maintenance, and repair of packages. Measures should be established for obtaining corrective actions from suppliers and for ensuring that followup is documented to verify that corrective actions were implemented and effective.

2.16.2 Closeout

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.

2.17 Quality Assurance Records

2.17.1 General

The QA records that are to be retained for the lifetime of packaging should include appropriate design- and production-related records that are generated throughout manufacturing and furnished with packaging; records demonstrating evidence of operational capability; records verifying repair, rework, and replacement; and audit plans, audit reports, corrective actions, and records that are used as a baseline for maintenance. Records showing 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.

2.17.2 Generating Records

Measures should be established to ensure that documents designated as QA records are legible and completed to reflect the work accomplished and are processed quickly to avoid unnecessary delay when the record is needed.

2.17.3 Receipt, Retrieval, and Disposition of Records

Measures should be established to provide a receipt control system, including identification of the individuals 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 in house or at other locations are identifiable and retrievable and are not disposed of until prescribed conditions are satisfied.

2.17.4 Storage, Preservation, and Safekeeping

Facilities used to store records should be constructed to minimize the risk from damage or destruction by severe natural conditions such as wind, flood, or fire; temperature and humidity; and infestation of insects, rodents, or mold. Records should be firmly attached in binders or placed in folders or envelopes for storage in steel file cabinets. If dual 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. Measures should be taken to preserve special records (e.g., radiographs and microfilm) from excessive light, electromagnetic fields, and temperature. Measures should also be taken to preclude the entry of unauthorized personnel into record storage areas. Measures should be established for prompt replacement of a record that is lost or damaged.

2.18 Audits

Measures should be established to ensure that audits are performed in accordance with preestablished written procedures or checklists and are conducted by qualified personnel not having direct responsibility in the areas being audited.

A listing of the activities important to safety to be audited and the frequency at which each activity 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 activity 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 NRC.

Individuals or groups having 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 reaudited on a timely basis to verify implementation of corrective action.

ANNEX 3

Quality Assurance Programs Applicable to Procurement, Use, Maintenance, and Repair of Packages Designed to Transport Radiographic Exposure Devices

3.1 Organization

Organization charts identifying each organizational element (e.g., purchasing, engineering, quality assurance) functioning under the QA program, including principal contractors, should be established. Because limited staff may be devoted to QA/QC activities, certain individuals may be performing multiple duties. If this is the case, measures should be established to ensure that designated individuals performing QA/QC functions have written delegated authority to stop unsatisfactory work, unsatisfactory processing, or the installation of nonconforming material and that they have direct access to management levels that can ensure the accomplishment of activities important to safety.

Duties and qualifications should be identified for the positions with responsibility for (1) establishment of the QA program, (2) overall execution of the QA program, and (3) assessing the scope, status, and effectiveness of the QA program. (Typically this responsibility is vested in the Radiation Safety Officer.) The duties and qualifications of other key personnel performing QA/QC functions should also be identified.

3.2 Quality Assurance Program

Measures should be established to ensure that items designated to be controlled by the QA program are compatible with and emphasize the characteristics that are identified in the manufacturer's QA program.

Measures should be established to ensure that items important to safety requiring periodic replacement because of limited operating or shelf life are identified.

Measures should be established to provide for indoctrination and training to ensure that personnel engaged in use, maintenance, and repair activities important to safety are knowledgeable before they engage in such activities.

Measures should be established to ensure that procedures implementing QA/QC activities important to safety are contained in QA/QC manuals. A matrix of instructions and procedures should be provided that cross-references each applicable QA program requirement of Subpart H. Identify each procedure or instruction by number and title and provide a brief description of the content.

3.3 Procurement Document Control

3.3.1 Package Procurement

Measures should be established to ensure that procurement documentation (1) requires the manufacturers of packages to supply appropriate certifications verifying that the designated (model and serial number) package was manufactured under the control of an NRC-approved QA program, (2) identifies types of inspections and tests required during use and maintenance, and (3) designates other pertinent documentation to be furnished with the package (e.g., certificate of compliance, as-built drawings, use and maintenance manuals, and all other documents referred to in the certificate of compliance).

3.3.2 Replacement Parts Procurement (If Applicable)

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

3.4 Instructions, Procedures, and Drawings

Measures should be established to ensure that loading radioactive material into or unloading radioactive material from a package is controlled to protect the public health and safety and the environment.

3.5 Document Control

Controls should be established to ensure that all documents and changes thereto are adequately reviewed and approved prior to their issuance. Measures 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 packages affected by design or manufacturing changes should be checked to verify that they are in accordance with the appropriate revision.

Documents under the control of the QA program should include at least the following:

1. QA and QC Manuals,
2. Operating Procedures,
3. Maintenance Procedures,
4. Inspection and Test Procedures,
5. Loading and Unloading Procedures,

6. Packaging for Transport Procedures, and

7. Repair Procedures.

3.6 Handling, Storage, and Shipping

3.6.1 Handling and Storage

Measures should be established to ensure that procedures provide for any special handling required of the package while in storage or when moving from one station to another. Particular attention should be given to precautions required for ensuring radiation safety of the package.

3.6.2 Preparation for Shipment

Measures such as use of checklists should be established to ensure that all conditions have been met, including specified operations, inspections and tests, and NRC and DOT shipping requirements, and that all necessary shipping papers have been completed prior to delivery to a carrier.

3.7 Inspection, Test, and Operating Status

Subpart B of Part 34 identifies specific inspections and certain tests to be conducted during use and maintenance of radiographic devices. Measures should be established to ensure that identification of the status of these inspections and tests through use of tags, labels, markings, etc., is known by organizations responsible for assurance of quality.

3.8 Quality Assurance Records

A list of records to be controlled under the QA program and identification of retention times for each record should be established. These records should include, as a minimum, procurement documentation; inspection, test, and audit results; nonconformance and corrective reports; personnel training and certification; evidence of operational capability; and verification of repair, replacement, and maintenance.

Measures should be established to store records, provide for their safekeeping, and prevent their deterioration.

3.9 Audit

Elements of the QA audit program, including work areas, activities, and processes to be audited to ensure the objective evaluation of practices, procedures, and instructions important to safety and the effectiveness of their implementation should be established. (If the organization is so small that independence of the auditing personnel is impractical, a checklist of the activities to be audited should be prepared.)

Frequencies for the audits listed in the paragraph above should be established.

Individuals or organizations responsible for performing external audits of the QA program to determine its overall effectiveness and compliance with management policies and procedures should have no responsibility in the areas being audited.

APPENDIX A

A Graded Approach to Developing Quality Assurance Programs for Packaging of Radioactive Material

The design effort and the requirements for a quality assurance 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 the development of an inadequate quality assurance program (i.e., one that imposes too few QA activities to verify attainment of design objectives). To develop a quality assurance 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 the public health and safety and the environment resulting from malfunction or failure of such items. This engineering assessment and quality assurance program development 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 quality assurance 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 quality assurance 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 quality assurance 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 appearing on the latest list of packaging parts would first be analyzed to determine whether their functions or physical characteristics are essential to safety. Those 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 to 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 subcomponent 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 public 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 those 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 Quality Assurance Effort

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

a. 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;

b. The procurement documentation for materials or services would specify that only suppliers from qualified vendor lists be used;

c. The suppliers and subtier suppliers would have a QA program based on applicable criteria in Subpart H to Part 71;

d. The manufacturing planning would specify complete traceability of raw materials and the use of certified welders and processes;

e. 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 SNT-TC-1A,* Section IX of the ASME Boiler and Pressure Vessel Code,** or other industrial standards);

*Copies of "Personnel Qualification and Certification for Nondestructive Examination, Recommended Practice No. SNT-TC-1A," are available from the American Society for Nondestructive Testing, 3200 Riverside Drive, Columbus, OH 43221.

**Copies of Section IX, "Qualification Standard for Welding and Brazing Procedures, Welders, Brazers and Welding and Brazing Operators," are available from the American Society of Mechanical Engineers, 345 East 47th Street, New York, NY 10017.

f. Only qualified auditors and lead auditors would perform audits; and

g. 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:

a. 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;

b. The procurement of materials need not be from a qualified vendor list;

c. The manufacturing planning need not require traceability of materials, and only specified welds would be done by qualified welders;

d. Verification activities would still require use of inspectors qualified to appropriate codes, standards, or other industrial specifications; and

e. Only the lead auditor need meet certain qualification requirements.

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

a. Items would be purchased from a catalog or "off the shelf"; and

b. When the item is received, the material would be identified and checked for damage.

1. BACKGROUND

Assurance that packaging used to transport radioactive materials will not be hazardous to public health and safety depends greatly on the integrity of the features of the container that are important to safety.

To increase confidence that designated features important to safety of particular packaging are designed, built, and used so as to minimize the risk to the public from exposure to radioactivity, prescribed systematic management and administrative controls need to be invoked during each phase of their design, production, and use.

These management controls are embodied in the 18 criteria of Subpart H, "Quality Assurance," of 10 CFR Part 71.

Prior to October 1977, when Appendix E (now Subpart H) became effective, quality assurance (QA) programs were required by approval condition (1972) only for packaging designed to transport plutonium, high-level waste, and irradiated fuel. The description of the quality assurance program was to be included in the application for package approval and was reviewed against the criteria identified in Appendix E to Part 71.

After Appendix E (now Subpart H) became effective and pursuant to paragraph 71.24(a) (now paragraph 71.37(a)) and § 71.51 (now § 71.101), "Establishment and Maintenance of a Quality Assurance Program," all applicants for and holders of licenses to use, possess, design, or build packages to transport radioactive material in excess of Type A quantities as defined in paragraph 71.4(g) have been required to provide documented evidence of a QA program acceptable to the NRC. A special provision of the rule allows any licensee with an NRC-approved QA program covering activities under 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," as delineated in Appendix B to Part 50 to apply it without further approvals to activities covered by Part 71.

An NRC licensee cannot use packaging subject to 10 CFR Part 71 if its use is not covered by an NRC-approved QA program. Also, the rule clarified NRC's position as to responsibility for quality assurance by stating that it was the licensee who delivers a package to a carrier for transport who must ensure that all quality assurance provisions for the package have been followed.

2. PROPOSED ACTION

2.1 Description

The proposed action provides guidance to persons needing information on the essential elements needed to develop, establish, and maintain quality assurance programs in accordance with the requirements of Appendix E (now Subpart H) to 10 CFR Part 71 for packaging used to transport radioactive materials.

The NRC revised 10 CFR Part 71 on September 6, 1983, to be consistent with the International Atomic Energy Agency regulations (Safety Series No. 6) in effect at that time. In addition, the format of 10 CFR Part 71 was changed to be compatible with new guidelines issued by the Office of Federal Regulations concerning use of appendices. These format changes resulted in a nonsubstantive incorporation of Appendix E into the regulation as a new Subpart H. Consequently, for compatability, all references in Regulatory Guide 7.10 to Appendix E have been changed to Subpart H.

2.2 Need

According to paragraph 71.37(a), applicants for package approval are required to identify their quality assurance programs, and, according to Subpart H, licensees are required to establish and maintain a quality assurance program.

Guidance is needed by persons establishing QA programs and by persons having NRC-approved QA programs who need to maintain them. Guidance is also needed by the NRC staff to develop inspection plans and procedures.

Furthermore, because there is a wide disparity of applicability of the requirements of Subpart H, specific guidance concerning grading of a particular QA program to fit its potential impact on safety is needed. The economic penalties for overcommitment to QA requirements resulting from uniform application of quality assurance without regard to its specific impact on safety can be as severe as not applying any quality requirements at all to achieve design objectives.

The revision to Regulatory Guide 7.10 is needed to provide consistency between the guide and 10 CFR Part 71.

2.3 Value/Impact Assessment

2.3.1 NRC

Staff time required for evaluation and inspection should be reduced because standardized QA programs should allow the use of standard review plans and uniform inspection plans and procedures.

Other than the allocation of staff resources to developing, reviewing, and issuing this guide, no impact on the NRC is anticipated.

2.3.2 Other Government Agencies

Impact on other government agencies would be essentially the same as that on industry to the extent that these agencies are regulated by NRC.

2.3.3 Industry

Specific guidance on QA criteria applicable to particular packaging should aid in developing, establishing, and maintaining a QA program that meets the spirit and intent of the so-called "graded approach." Formulating a program in which the QA effort expended on an activity is consistent with its importance to safety can be interpreted quite differently by different licensees. Spelling out only the applicable criteria as well as the specific applicable safety elements will result in a graded approach. Proliferation of documentation prevalent in industry should be reduced.

2.3.4 Public

No impact on the public is foreseen.

2.3.5 Worker

No impact on the worker is foreseen.

2.4 Decision

The proposed action, developing and issuing a revised regulatory guide, should be completed because of the benefits previously discussed.

3. PROCEDURAL APPROACH

3.1 Alternatives

No meaningful alternative exists. Use of the general description of the QA criteria of Subpart H without further amplification would place too much responsibility on licensees for judging what constitutes an acceptable commitment. The ANSI N14.4 Subcommittee is chartered to produce a standard based on Subpart H, but its ongoing effort is not expected to be completed in the near future.

3.2 Discussion

A regulatory guide is the most efficient way to transmit information about the subject QA programs that would be acceptable to the NRC. In addition, this regulatory guide exists, and updating to changes in 10 CFR Part 71 is a relatively simple procedure.

4. STATUTORY CONSIDERATIONS

4.1 NRC Authority

The proposed guide provides guidance for the implementation of regulations promulgated in paragraph 71.101 and described in Subpart H to 10 CFR Part 71. Authority for these regulations is derived from the Atomic Energy Act of 1954, as amended, and from the Energy Reorganization Act of 1974.

4.2 Need for NEPA Assessment

Issuance or amendment of guides for the implementation of regulations in Title 10, Chapter I, of the Code of Federal Regulations is a categorical exclusion under paragraph 51.22(c)(16) of 10 CFR Part 51. Thus, an environmental impact statement or assessment is not required for this action.

5. RELATIONSHIP TO OTHER EXISTING OR PROPROSED REGULATIONS OR POLICIES

The structure of Subpart H to 10 CFR Part 71 is identical to that of Appendix B to 10 CFR Part 50, which describes quality assurance criteria now in effect for nuclear power plants and certain fuel cycle facilities; the only changes were made to accommodate terminology specific to transportation.

6. SUMMARY AND CONCLUSIONS

The proposed action will provide persons involved in activities related to the packaging for transportation of radioactive material much needed information on the essential elements of QA programs acceptable to the NRC. The revised regulatory guide discussed herein should be prepared and issued.