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ESTABLISHING QUALITY ASSURANCE PROGRAMS FOR PACKAGING USED IN THE TRANSPORT OF SPENT FUEL, HIGH-LEVEL WASTE, AND PLUTONIUM

A. INTRODUCTION

Paragraph 71.24(a) of 10 CFR Part 71, "Packaging of Radioactive Material for Transport and Transportation of Radioactive Material Under Certain Conditions," 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 71.12 of Part 71 requires that certain licensees have a quality assurance program that has been submitted to and approved by NRC as satisfying the provisions of paragraph 71.51(a) of Part 71. Paragraph 71.51(a) requires, in part, that licensees' quality assurance programs satisfy each of the applicable criteria specified in Appendix E, "Quality Assurance Criteria for Shipping Packages for Radioactive Material," to 10 CFR Part 71 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 spent fuel, high-level waste, and plutonium.

B. DISCUSSION

The quality assurance program is intended to provide control over all quality-related activities 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

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This regulatory guide and the associated value/impact statement are being issued in draft form to involve the public in the early stages of the development of a regulatory position in this area. They have not received complete staff review and do not represent an official NRC staff position.

Public comments are being solicited on both drafts, the guide (including any implementation schedule) and the value/impact statement. Comments on the value/impact statement should be accompanied by supporting data. Comments on both drafts should be sent to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, Attention: Docketing and Service Branch, by JUN 22 1981

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activities in a graded approach, i.e., the QA effort expended on an activity should be consistent with its importance to safety. The appendix 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. Accordingly, the regulatory position of this guide contains two annexes. 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. Annex 2 provides similar guidance for procurement, use, maintenance, and repair of packaging.

The recommendations of this guide apply to the general QA criteria contained in Appendix E to 10 CFR Part 71. Subpart D 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.

C. REGULATORY POSITION

The essential elements of a quality assurance program acceptable to the NRC staff for complying with the quality assurance requirements of paragraph 71.51(a) of 10 CFR Part 71 are contained in Annex 1 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 packaging.

Persons subject to paragraph 71.51(a) should submit their programs to and obtain approval from the NRC prior to engaging in any quality-related activity. Those engaging in quality-related activities 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 quality-related activities 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.

D. IMPLEMENTATION

The purpose of this section is to provide information to applicants regarding the NRC staff's plan for using this regulatory guide.

The proposed guide has been released to encourage public participation in its development. 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 to be described in the active guide reflecting public comments will be used in (1) the evaluation of submittals by applicants for establishing quality assurance programs for packages that transport spent fuel, high-level waste, and plutonium and (2) in assessing 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 TO TRANSPORT SPENT FUEL, HIGH-LEVEL WASTE, AND PLUTONIUM

This annex provides guidance in formulating QA programs applicable to design, fabrication, assembly, and testing of packaging used in the transport of spent fuel, high-level waste, and plutonium and is presented in the same order as the criteria in Appendix E to 10 CFR Part 71.

1.1. Organization

1.1.1 Structure and Authority

The organizational structure and the functional responsibility assignments should ensure that (a) specified quality requirements are achieved and maintained by those who have been assigned the responsibility for performing the work and (b) verification of conformance to established requirements is accomplished 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 quality-related activities, including major contractors, the authority of each organization should be clearly established. The QA and QC functions retained by the QA organization or delegated to other organizations should be identified to ensure that all of the appropriate elements of Appendix E 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 Appendix E 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

It is important that top management 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 safety-related items in accordance with the requirements of Appendix E as described in the QA program plan and implemented in QA manuals. The policy statement should also identify those individuals delegated authority for (a) implementing and revising the provisions of the described QA program and (b) regularly assessing the scope, status, implementation, and effectiveness of the QA program.

1.2 Quality Assurance Program

Measures should be established for identifying (a) the components, structures, and systems to be covered by the QA program and (b) 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 compose an acceptable quality assurance program: appropriate documentation, proficient personnel, and assurance that activities affecting quality are performed under suitably controlled conditions.

1.2.1 Documentation

The quality assurance program should ensure that quality-related activities 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 quality-related activities and a matrix of those QA procedures that implement each criterion of Appendix E should be established and maintained to reflect the current status of the QA program. With respect to those quality-related activities not yet initiated, but anticipated, 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 to 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 (a) that personnel performing quality-related activities receive indoctrination and training commensurate with the skill levels needed and (b) 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.

For personnel performing special processes (e.g., nondestructive examinations, 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.

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

1.2.3 Controlled Conditions

Measures should be established to ensure that quality-related activities 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.

A listing of the safety-related items (structures, systems, and components) to be controlled by the QA program should be established along with the rationale for their selection.

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 for design activities, three principal areas need to be considered: control of design disclosures, control of design input, and control of design verification.

1.3.1 Control of Design Disclosures

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.

Good 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, 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 can perform the verification provided that (1) the supervisor is the only technically qualified individual, (2) the review 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 variance with conditions prescribed on the certificate of compliance should be approved by NRC prior to implementation.

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:

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

b. 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.

c. Applicable Appendix E 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 personnel in QA 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.)

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

e. Identification of the documentation (e.g., drawings, specifications, procedures, inspection and fabrication plans, inspection and test records, personnel and procedure qualifications, chemical and physical test results of material) to be prepared, maintained, and submitted to purchaser for approval.

f. 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.

g. 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 the following occurs:

a. Activities affecting quality are prescribed and accomplished in accordance with documented instructions, procedures, or drawings.

b. Methods for complying with each of the applicable 18 criteria of Appendix E to 10 CFR Part 71 are specified in instructions, procedures, and drawings.

c. Instructions, procedures, and drawings include quantitative (e.g., dimensions, tolerances, and operating limits), and qualitative (e.g., workmanship samples) acceptance criteria to verify that important activities 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 drawings and specifications and any changes thereto.

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:

a. Design documents (e.g., calculations, drawings, specifications, and computer codes),
b. Procurement documents,
c. QA and QC manuals,
d. Operating, maintenance, and modification procedures,
e. Inspection and test procedures,
f. Nonconformance reports,
g. Design change requests, and
h. Corrective action reports.

1.6.2 Control of Document Generation and Issuance

Controls should be established to ensure that documents, including 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 and that configurations of all packages affected by design changes are controlled. 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 Materials, Equipment, and Services

Measures should be established to ensure that materials, equipment, and services conform to procurement documents. The following should be included: (a) procurement document planning, (b) selection of procurement sources, (c) bid evaluation and award, (d) supplier performance, (e) verification activities by purchaser, (f) disposition of nonconformances, and (g) acceptance of the item or service. These measures are amplified below.

a. 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.

b. 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 Appendix E, (2) results of the survey of the supplier's facility and QA program, and (3) review of the supplier's previous records and performance.

c. 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.

d. 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., a pre-established inspection point in the manufacturing process that requires

inspection approval and release by the quality assurance organization prior to further processing) during manufacturing and testing and prior to shipment.

e. 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.

f. Controlling Nonconformances

Measures should be established to ensure the proper disposition of items or services that do not meet procurement requirements.

g. 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 "accept 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, lot-follower cards) and traceability to appropriate documentation (e.g., drawings, specifications, 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 controls over special processes (e.g., welding, radiography, heat treating) are subject to the following criteria:

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

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

c. 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, and 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.

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* For further information on qualification of nondestructive examination personnel, see "Personnel Qualification and Certification for Nondestructive Examination, Recommended Practice No. SNT-TC-1A," available from the American Society for Nondestructive Testing, 3200 Riverside Drive, Columbus, Ohio 43221.

1.10.2 Inspections

1.10.2.1 Receiving. Measures should be established to ensure that safety-related items (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 and that supervisors review inspection records to verify that the item being inspected meets drawing and specification requirements, is identifiable or traceable to specific records, and is adequately protected from physical or environmental damage.

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) have proper calibration status. 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 an uncertainty (error) requirement of no more than one-fourth of the tolerance of the equipment being calibrated. A greater uncertainty may be acceptable when limited by the state of the art.

1.12.2 Out-Of-Calibration Equipment

Measures should be taken to validate previous inspection and test results when test and measuring equipment is found to be out of calibration.

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 Release for Shipment

Measures should be established to ensure that a final QA certification has been completed, including verification that all required NRC and DOT shipping papers have been prepared, and that departure and arrival times, and destination have been established and approved by the authorized agent of the shipper prior to delivery to the carrier. This certification should ensure that packaging is prepared for delivery 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 appropriate documents (e.g., certificate of compliance) as evidence that the packaging was fabricated under the control of an NRC-approved QA program.

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: (a) proper identification, (b) segregation of discrepant or nonconforming items, (c) disposition of the items of nonconformance, and (d) evaluation of the items of nonconformance.

1.15.1 Identification of Noncomformance

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.

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; nonconformance reports; results of inspections, test, and audits; failure analyses; as-built drawings and specifications; operating logs; qualification of personnel, procedures, and equipment; training and retraining records; and corrective action reports.

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 are those required to be maintained for the life 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. The retention times for nonpermanent records should be specified; however, those records identified in paragraphs 71.62(a)(1) and (a)(2) must be maintained for a period of at least 2 years.

1.17.4 Receipt, Retrieval, and Disposition of Records

Measures should be established to provide a receipt control system, including identification of individuals of 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. 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.

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 quality-related activities (e.g., procurement, training of personnel) to be included in the audit program should be identified.

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.

1.18.4 Pre-Audit Conferences

The nature and scope of preaudit meetings between management of the organizations being audited and the team conducting the audit should be specified prior to an audit.

1.18.5 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.

Table 1

FORMAT FOR LISTING OF IMPLEMENTING PROCEDURES*

Implementing Document	Title	10 CFR Part 71 Appendix E 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 Appendix E 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.
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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; examples for only criteria 1, 2, 3, 4, and 18 are shown.

ANNEX 2

QUALITY ASSURANCE PROGRAMS APPLICABLE TO PROCUREMENT, USE, MAINTENANCE, AND REPAIR OF PACKAGING USED TO TRANSPORT SPENT FUEL, HIGH-LEVEL WASTE, AND PLUTONIUM

Section 71.12 provides for a general license to use (deliver licensed material to a carrier for transport) packages provided certain conditions are met. One of these conditions is that the licensee-user must provide for the establishment and execution of a quality assurance (QA) program consistent with the provisions of Appendix E to 10 CFR Part 71. The licensee-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 licensee-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 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 containing spent fuel, high-level waste, or plutonium that would meet the requirements of Appendix E to 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 quality-related activities (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 and delivery or installation of nonconforming material and have direct access to management levels that can ensure accomplishment of quality-related activities.

The duties and qualifications required for (a) the individual who has overall authority and responsibility for the QA program and (b) the other principal personnel performing QA and QC functions should be established and documented.

2.2 Quality Assurance Program

2.2.1 Scope of the Quality Assurance Program

Measures should be established to ensure that (a) quality-related activities are performed with specified equipment and under suitable environmental conditions, (b) designated QA and QC responsibilities for implementation of quality-related activities are contained in QA/QC manuals, and (c) indoctrination and training programs are established so that personnel performing quality-related activities are trained and qualified to perform these activities.

2.2.2 Applicability of the 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 safety-related 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 Appendix E should not be applicable. However, assurance that design was accomplished under control of an NRC-approved QA program is required.

2.4 Procurement Document Control

2.4.1 Packaging Procurement

Measures should be established to ensure that procurement documentation (a) 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, (b) identifies the type of verification activities required during use and maintenance, and (c) 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 safety-related replacement parts 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.

2.5 Instructions, Procedures, and Drawings

2.5.1 Preparation of Packaging for Use

Procedures as required by § 71.54 of 10 CFR Part 71 should be established and approved by appropriate levels of management for placing the packaging in use. 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 test 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 most significant 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:

a. QA and QC manuals,
b. Operating procedures,
c. Maintenance procedures,
d. Inspection and test procedures,
e. Loading and unloading procedures,
f. Packaging for transport procedures, and
g. Repair procedures.

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 are 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 controls over special processes (e.g., welding, radiography, heat treating) are subject to the following criteria:

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

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

c. 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 documentation. 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 the following: surface conditions; weld and structural integrity; the condition of flange faces or sealing areas, gaskets, seals, gauges, rupture disks, valves,

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* For further information on qualification of nondestructive examination personnel, see "Personnel Qualification and Certification for Nondestructive Examination, Recommended Practice No. SNT-TC-1A," available from the American Society for Nondestructive Testing, 3200 Riverside Drive, Columbus, Ohio 43221.

and pressure relief devices; the condition of tiedown members (if applicable); the labeling and marking; and leak tightness 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 Inspections

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

a. Packages are properly assembled.
b. Moderators and/or neutron absorbers are present.
c. Valves through which primary coolant flows are protected against tampering.
d. Valves are set to specifications.
e. All shipping papers are properly completed.
f. Packages are conspicuously and durably marked as required by DOT regulations.
g. Measures are established to ensure that an individual designated by the owner or 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:

a. Structural integrity,

b. Leak tightness (on containment vessel as well as auxiliary equipment and shield tanks)

c. Component performance for the following:

(1) valves,

(2) gaskets, and

(3) fluid transport devices,

d. Shielding integrity, and

e. 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

Measures should be established for ensuring that instruments used in tests and inspections, including maintenance of safety-related items, have proper calibration status. Inspection and test equipment should be labeled or tagged to indicate the date of the next planned calibration and traceability of the calibration test data. The calibration intervals should be prescribed along with the rationale for the designated calibration frequencies.

Measures should be established to ensure that in-house reference or transfer standards are used in calibrating measuring equipment and are traceable to a nationally recognized standard.

2.13 Handling, Storage, and Shipping

2.13.1 Handling and Storage

Measures should be established to ensure that the following occurs:

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

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

c. Proper environmental conditions to preserve packaging is maintained.

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

2.13.2 Preparation for Shipment

Measures should be established to ensure that the following has been done:

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

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

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

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

e. Departure and arrival times will be recorded, and, if required, transport of package will be under surveillance until delivered to the carrier.

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: (a) proper identification, (b) segregation of discrepant or nonconforming items, (c) disposition of the items of nonconformance, and (d) evaluation of the items of nonconformance.

2.15.1 Identification of Noncomformance

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.

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.

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 quality-related activities 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

The QA records that are to be retained for the lifetime of packaging should include appropriate design- and production-related records, which are generated throughout manufacturing and furnished with packaging; records demonstrating evidence of operational capability; and records verifying repair, rework, and replacement 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.

Measures should be established to ensure that QA records are adequately stored to prevent loss or deterioration and that the records are readily identifiable and retrievable.

2.18 Audits

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

A listing of the quality-related activities to be audited and the frequency at which each activity is to be audited should be established and maintained to reflect current status.

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 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.

APPENDIX A

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

If the design effort for a quality assurance program and the quality assurance program itself are addressed as independent functions, either an overcommitment to quality assurance activities that impose unnecessary requirements for verifying design objectives, or, conversely, inadequate quality assurance program requirements could result. To develop a quality assurance program in which application of quality requirements are 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 through (1) classification of each component, structure, and system, (2) grouping of safety-related items into quality categories, and (3) specifying a level of quality assurance effort applicable to each category. To gain 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 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 Appendix E to 10 CFR Part 71.

2. Quality Categories

Quality categories would be established based upon the relative safety significance of each Q-item and, where appropriate, their subcomponent parts. Categories could be identified as A, B, and C with the first letter of the alphabet corresponding to whether the item is critical to safe operation, the next to a major impact on safety, and the next letter to 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 unlikely pose 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 that design verification would be accomplished by prototype testing or formal design review;

b. The procurement documentation for materials or services would specify use of suppliers only from qualified vendors lists;

c. The suppliers and subtier suppliers would have a QA program based on applicable Appendix E to Part 71 criteria;

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 only qualified inspectors (e.g., personnel performing nondestructive examinations such as radiographics and ultrasonic testing would be qualified to Level 3 of SNT-TC-1A*);

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

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 vendors 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 not require use of qualified inspectors (e.g., NDE personnel could be qualified to Level 1 or 2 of SNT-TC-1A*),

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. Packaging would be purchased from a catalog or "off the shelf."

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

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* 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, Ohio 43221.