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ESTABLISHING QUALITY ASSURANCE PROGRAMS FOR PACKAGING USED IN THE TRANSPORT OF SPECIAL FORM AND CERTAIN NORMAL FORM RADIOACTIVE MATERIAL

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. Section 71.54, "Routine Determinations," requires, in part, that prior to shipping a package, the package and packaging comply with the standards set forth in Subpart C, "Package Standards," of 10 CFR Part 71.

This regulatory guide provides persons subject to the QA requirements of 10 CFR Part 71 with information on the essential elements needed to develop, establish, and maintain a quality assurance program for packaging to transport special form and certain normal form radioactive material. Examples of special form material (defined in paragraph 71.4(o) of 10 CFR Part 71) covered by this guide include certain sealed sources containing byproduct material such as cobalt-60, iridium-192, and plutonium-beryllium neutron sources commonly used for radiographic, medical-teletherapy, and industrial purposes. Examples of

normal form material (radioactive material that has not been demonstrated to be special form material) include sealed sources not meeting special form requirements, contaminated reactor components, bulk oxides used in fabrication of reactor fuel, and enriched uranium hexafluoride. Also within the scope of this guide is special and normal form material classified as fissile owing to the presence of plutonium, uranium-233, uranium enriched in the 235 isotope, and fuel rods or plates containing plutonium or uranium-233.

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 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 and licensees 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 special form and certain normal form radioactive material 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 SPECIAL FORM AND CERTAIN NORMAL FORM RADIOACTIVE MATERIAL

This annex provides guidance in formulating quality assurance (QA) programs applicable to design, fabrication, assembly, and testing of packaging used to transport special form and certain normal form radioactive material 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

A formal organization structure should be established, and organization charts identifying each organizational element that functions under the QA program (e.g., procurement, inspection, testing, design, quality assurance) should be prepared. The organization charts should show interrelationships of the QA functions with other management functions, including principal contractors, and should differentiate between lines of direct reporting and lines for coordination/communication purposes to demonstrate assignment of responsibilities that meet Appendix E requirements.

Measures should be established to ensure that the quality assurance/quality control (QC) functions performed by the QA organization and functions delegated to other organizations (e.g., engineering, procurement) are identified. Where more than one organization, including major contractors, is involved in the execution of quality-related activities, the authority of each organization should be clearly established.

Those positions responsible for (a) establishment of the QA program, (b) execution of the QA program, and (c) regular assessment of its overall effectiveness should be identified.

Qualification requirements for principal QA/QC management positions should be identified. Measures should be established to ensure that designated QA individuals have organizational freedom and independence from cost and schedule

pressures and have written delegated authority to stop unsatisfactory work and to control further processing, delivery, or installation of nonconforming material until proper disposition of the material is made.

1.1.2 Top Management Endorsement of a Quality Assurance Program

Measures should be established to ensure that management (above or outside the QA organization) (1) regularly assesses the scope, status, implementation, and effectiveness of the QA program, (2) communicates to all responsible organizations and individuals that implementing and enforcing QA policies and establishing and maintaining QA procedures and manuals are mandatory requirements that should be met, and (3) resolves disputes involving quality that arise from a difference of opinion between QA/QC personnel and personnel from other departments (e.g., engineering, procurement).

1.2 Quality Assurance Program

Measures should be established for specifying the safety-related items to be controlled by the QA program, classifying them relative to their importance to safety, and designating the appropriate level of QA effort corresponding to the identified level of safety. Although Criterion 2 of 10 CFR Part 71 permits the development of a "graded" QA program based upon safety significance, this does not preclude the alternative of establishing a program based upon more stringent controls if it is felt necessary to attain the confidence needed for protecting the public health and safety.

1.2.1 Personnel

The QA program should provide measures for ensuring that indoctrination and training programs are established for personnel performing quality-related activities (e.g., welding, nondestructive testing) to ensure proficiency in the use of QA procedures and knowledge of QA requirements. Also measures should be established for retraining, reexamining, or recertifying these persons to ensure maintainance of the skills needed to perform the assigned tasks.

1.2.2 Controlled Conditions

Measures should be established to ensure that quality-related activities are accomplished under controlled conditions (e.g., appropriate production

and test equipment, suitable environmental controls, completion of prerequisites prior to engaging in the activity).

1.3 Design Control

Measures should be established to ensure that specified design requirements (e.g., applicable codes, standards, regulatory requirements, inspection and test criteria, QA requirements, operational and maintenance requirements, handling, storage and cleaning requirements) are translated into specifications, drawings, and procedures.

Measures should be established for controlling the preparation of appropriate reviews, approvals, design releases, and the issuance of, distribution of, and revisions to drawings and specifications.

Measures (e.g., qualification test of a prototype, design review, or an engineering analysis, including computer programs) should be established to verify or check design adequacy. When a test program is used to verify the adequacy of a design, the prototype should be subjected to the most adverse design conditions.

Individuals or groups responsible for design verification should be other than the original designer or the designer's immediate supervisor.

1.4 Procurement Document Control

Measures should be established to ensure that procurement documents and changes thereto for safety-related items and services are correctly stated, inspectable, and controllable and that the documents have been prepared and approved in accordance with QA requirements and include the following information:

a. A statement of work,

b. Delineation of technical requirements, including the applicable regulatory requirements, material identification requirements, and test and inspection requirements,

c. Identification of the applicable Appendix E to 10 CFR Part 71 QA requirements that must be addressed in the supplier's QA program,

d. Right of access to the supplier's facilities and records for inspection/audit purposes,

e. Identification of requirements for acceptance and delivery, including documentation (e.g., drawings, specifications, material certifications to be submitted to the purchaser),

f. Requirements for reporting and approving dispositions of nonconformances,

g. Instructions on record retention and disposition and provision for extending applicable requirements to lower tier subcontractors.

1.5 Instructions, Procedures, and Drawings

Measures should be established to ensure (1) that activities affecting quality are prescribed and accomplished by documented instructions, procedures, or drawings and changes thereto and (2) that the QA organization reviews and concurs with test plans, inspection plans, calibration procedures, special process procedures, procurement documents, and engineering specifications and drawings.

1.6 Document Control

Measures should be established to ensure that the following controls on documents are applied:

a. Prior to release of any documents, they should be reviewed and determined to be adequate for their purpose, including specification of quality requirements.

b. Changes to documents, including instructions, procedures, and drawings, should be reviewed and approved by the same organization that performed the original review and approval and should be in accordance with configuration control procedures.

c. Current issues of applicable documents, including configurations of all packages affected by design changes, should be available at the locations where the activity is being performed to preclude use of obsolete or superseded documents. Use of a master document list may help achieve this control.

d. Individuals or organizations responsible for preparing, reviewing, approving, and issuing documents or revisions thereto and establishing current and updated distribution lists should be identified.

e. Documents to be controlled by the QA program should be identified. As a minimum, this should include design specifications, design and manufacturing drawings, procurement documents, QA manuals, test and inspection procedures, design change requests, nonconformance reports, and audit and corrective action reports.

1.7 Control of Purchased Materials, Equipment, and Services

Measures should be established to ensure that purchased materials, equipment, and services, whether purchased directly or through suppliers, conform to the procurement documents.

The measures should include provisions as appropriate for source evaluation and selection (e.g., capability to comply with applicable elements of Appendix E to 10 CFR Part 71, survey of prospective supplier's facilities, and assessment of the supplier's QA program), objective evidence of quality furnished by the supplier, inspection at the source, and examination of products upon delivery.

Measures should be established to ensure that the receiving inspection is performed to verify that the material received corresponds with its identification on the purchase order, specified inspections are completed, acceptance tests are conducted prior to installation, required documentation is available, and the readiness of the material for use is known prior to forwarding the material for storage, installation, or use in other work areas. In addition, measures should be established to ensure that the effectiveness of the supplier's QA program in meeting purchase order requirements is assessed at regular intervals.

1.8 Identification and Control of Materials, Parts, and Components

Measures should be established to ensure that identification of an item is maintained by part number, serial number, or other appropriate means, either on the item or on records traceable to the item throughout fabrication and installation.

1.9 Control of Special Processes

Measures should be established to ensure that special processes (e.g., welding, heat-treating, cleaning, and nondestructive testing*) are controlled and accomplished by qualified personnel, using qualified procedures in accordance with applicable codes, standards, specifications, criteria, or other special requirements, and that qualification records of procedures, equipment, and personnel are filed and kept current.

1.10 Inspection Control

1.10.1 Inspection Planning

Measures should be established to ensure that inspection procedures provide for identification of characteristics and activities to be inspected, acceptance and rejection criteria, a description of the method of inspection, recorded evidence of completed inspections, and review and approval of inspection results by appropriate supervisors.

1.10.2 Inspections

If inspection hold points (i.e., a preestablished inspection point in the manufacturing process that requires inspection, approval, and release by QA personnel prior to further processing) are mandatory, provisions should be established to ensure that work does not proceed until designated witnessing or inspection is performed.

If inspection of processed material by direct methods is impractical, indirect methods should be established for inspecting or monitoring.

Measures should be established to ensure that modifications, repairs, and replacements are inspected in accordance with the original design and inspection requirements or acceptable alternatives.

*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.

1.10.3 Inspectors

Measures should be established to ensure (1) that inspection is performed by individuals independent of the activity being inspected, (2) that inspectors are qualified in accordance with applicable codes, standards, and company training programs, and (3) that inspectors' qualifications are kept current.

1.11 Test Control

Measures should be established to ensure that the following conditions are met:

a. Test requirements and acceptance criteria are provided or approved by the organization responsible for the design of the item under test.

b. Test results are documented and evaluated by qualified persons to ensure that the test requirements have been satisfied.

c. Test procedures include provisions specifying that all prerequisites for the given test have been met, that adequate test instrumentation has been used, and that the test has been performed under suitable environmental conditions.

d. Modifications, repairs, and replacements are tested in accordance with the original design and testing requirements or acceptable alternatives.

1.12 Control of Measuring and Test Equipment

Measures should be established to ensure that the following conditions are met:

a. Tools, gauges, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified periods, based upon the degree of usage, inherent stability, or other conditions affecting measurement that maintain accuracy within prescribed limits.

b. Inspection, measuring, and test equipment is calibrated, adjusted, and maintained against standards for certified equipment traceable to nationally recognized standards.

c. When inspection, measuring, and test equipment is found to be out of calibration, an evaluation should be made and the validity of previous inspections or tests should be documented.

d. Records are maintained and equipment suitably labeled or tagged to indicate calibration status and the planned date of its next calibration.

e. Measuring and test equipment is identified and traceable to the calibration data.

1.13 Handling, Storage, and Shipping

Measures should be established to ensure that the following conditions are met:

a. Handling, storage, shipping, cleaning, and preservation of material and equipment are accomplished in accordance with work and inspection instructions and by qualified personnel to prevent damage to or deterioration of the material and equipment.

b. Special handling tools and equipment (if applicable) are inspected or tested in accordance with written procedures and on a regularly scheduled basis.

c. Adequate instructions exist for marking or labeling the material for packaging, shipping, and storing to preclude damage or deterioration by environmental conditions such as temperature and humidity.

d. A final QA certification is made to verify compliance with purchase order requirements. This certification should include verification that all required NRC and DOT shipping papers are available, that the packages are properly identified and contain appropriate documents (e.g., operating manuals, certificate of compliance), and that evidence exists that the packaging was fabricated under control of an NRC-approved QA program.

e. Departure and arrival times and destination of packages are established and monitored to a degree consistent with the safe transport of packages.

1.14 Inspection, Test, and Operating Status

Measures (e.g., stamps, tags, labels, routing cards, or other suitable means) should be established to indicate the status of inspections and tests and to ensure control of the application and removal of the status indicators

to preclude inadvertent bypassing of required inspections, tests, or other required operations.

1.15 Control of Nonconforming Materials, Parts, or Components

Measures should be established to ensure that the following conditions are met:

a. Parts, components, or assemblies that do not conform to requirements are segregated from acceptable items and controlled to prevent their inadvertent use or installation.

b. Nonconforming items are reviewed and either accepted, rejected, repaired, or reworked in accordance with documented procedures.

c. The responsibility and authority for individuals or organizations designated to dispose of nonconforming items is defined.

d. The acceptability of nonconforming items that have the disposition of "repair" or "use as is" is verified by reinspection, retest, or engineering analysis.

e. Nonconformance reports identify nonconformances, disposition of the nonconformances, inspection requirements for nonconformances, and the signature of the individual authorized to approve disposition of nonconformances.

1.16 Corrective Action

Measures should be established to ensure that the following conditions are met:

a. Conditions detrimental to quality such as malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified, reported to appropriate levels of management, and corrected.

b. Followup reviews are conducted to verify that specified corrective actions have been taken and that documentation has been closed out.

1.17 Quality Assurance Records

Records controlled by the QA program should be identified. As a minimum, QA records should include the qualifications of personnel, evidence of training of personnel, supplier evaluations, as-built drawings, operating logs, equipment

calibration procedures, qualification of procedures and equipment, material and failure analyses, lists of nonconformances, corrective-action reports for nonconformances, and results of design reviews, inspections, tests, and audits. Also, a list of records should be established identifying those records required to be kept on file as long as a particular item is installed in packaging and those records to be kept only until shipping packaging is transferred to another authority.

Measures should be established to ensure (1) that records are identifiable and retrievable and (2) that requirements for record storage, transmittal, retention, and maintenance are identified.

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

a. A description of the observation,

b. Evidence of completing and verifying manufacture, inspection, and test operations,

c. Results of inspections and tests, with appropriate dates,

d. Conditions detrimental to quality,

e. Names of inspectors/testors or data recorders, and

f. Evidence of acceptability.

1.18 Audits

Measures should be established to ensure that the following conditions are met:

a. A comprehensive system of planned and periodic audits is established.

b. Audits are performed at least annually to verify compliance with all aspects of the QA program, including those of principal contractors.

c. Audits are performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibilities in the areas being audited. Additionally, the qualifications for the audit team and the team leader should be established and the responsibilities of the audit team and the level of management to which results are reported should be specified.

d. Audit results are documented and reviewed by management having responsibility in the area audited.

e. Responsible management takes necessary action to correct the deficiencies revealed by the audit.

f. Followup action, including reaudit of deficient areas, is taken where indicated.

ANNEX 2

QUALITY ASSURANCE PROGRAMS APPLICABLE TO PROCUREMENT, USE, MAINTENANCE, AND REPAIR OF PACKAGING USED TO TRANSPORT SPECIAL FORM AND CERTAIN NORMAL FORM RADIOACTIVE MATERIAL

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 coditions 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 special form and certain normal form radioactive material that would meet the requirements of Appendix E to 10 CFR Part 71.

QA programs should be essentially the same for all users of packages subject to this guide; however, the QA program should be designed to control the safety-related items that are unique to the particular normal form or special form types of packages being transported.

2.1 Organization

2.1.1 Structure and Authority

A formal organization structure should be established and verified by organization charts identifying each organizational element that functions under the QA program. Because limited staff may be devoted to Quality Assurance/ Quality Control (QC) activities during operations, certain individuals may be performing multiple duties. If this is the case, 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 of the individuals responsible for overall administration of the QA program should be established. (Typically for industrial radiography or medical therapy QA programs, this responsibility is vested in the Radiation Safety Officer.) Also other key personnel performing QA/QC functions should be identified.

2.1.2 Top Management Involvement and Assessment of a Quality Assurance Program

Measures should be established to ensure that management above or outside the QA organization regularly assesses the scope, status, implementation, and effectiveness of the QA program.

2.2 Quality Assurance Program

2.2.1 Personnel

Measures should be established for indoctrinating and training personnel engaged in quality-related use, maintenance, and repair activities to ensure that they are knowledgeable in the areas of work they must perform prior to their engaging in such activities.

2.2.2 Controlled Conditions

Measures should be established to ensure that the following conditions are met:

a. Items designated to be controlled by the QA program are compatible with and emphasize the same characteristics identified in the manufacturer's QA program.

b. Maintenance procedures specify the criteria and parts or equipment that should be periodically replaced because of their limited operating or shelf life.

c. QA/QC quality-related activities are contained in QA/QC manuals.

d. Quality-related activities are performed with specified equipment under suitable environmental conditions and prerequisites are completed prior to inspection or test.

2.3 Design Control

Design activities are not normally performed by "users," consequently this criterion should not be applicable. However, the users of packaging must have documented evidence that design of designated packaging was accomplished under the control of an NRC-approved QA program.

2.4 Procurement Document Control

2.4.1 Packaging Procurement

Measures should be established to ensure that procurement documentation (a) requires manufacturers of packaging to supply appropriate certifications verifying that the designated (model/serial number) packaging was manufactured under the control of an NRC-approved QA program, (b) identifies the type of inspections and tests 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, use and maintenance manuals, and all documents referenced in the certificate of compliance).

2.4.2 Replacement Parts Procurement

Measures should be established to require that procurement documentation 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. Measures should be established to grant QA personnel right of access to supplier's facilities and records to perform source inspections and audits.

2.5 Instructions, Procedures, and Drawings

2.5.1 Preparation of Packaging for Use

Procedures as required by § 71.54, "Routine Determinations," of 10 CFR Part 71 should be established and approved by the appropriate levels of management prior to placing the package in use (e.g., surveys for contamination and radiation, measurements of pressure and temperature).

2.5.2 Loading and Unloading Contents

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

2.5.3 Transfer of Package to Consignee (Carrier)

Measures, including procedures/instructions or checklists to ensure that a final preshipment review verifying that all required inspections and tests have been conducted, should be established to ensure that applicable documentation required by DOT and NRC accompanies packages and that packages are properly sealed and conspicuously marked with the correct 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 (e.g., use of a master document list) to ensure that current issues of applicable documents are available at the location where the activity is being performed to preclude use of obsolete or superseded documents and to ensure 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.

2.7 Control of Purchased Materials, Equipment, and Services

Measures such as source surveillance and audits of manufacturer's 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 location designated by the user is accompanied by the documentation that is identified in the purchase order. Such documents should be referenced in the certificate of compliance and should relate to the use and maintenance and repair of packaging.

2.8 Identification and Control of Materials, Parts, and Components

Measures should be established to ensure that prior to delivery of a package to a carrier, packages are conspicuously and durably marked with the proper model and serial numbers. Additionally, measures should be established to ensure that identification of safety-related items can be traced to appropriate documentation (e.g., drawings, purchase orders, nonconformance reports, inspection reports).

2.9 Control of Special Processes

Special processes, such as welding or nondestructive testing,* are not normally performed by users of packaging. However, if a special process is performed because of repair or modification of packaging, measures should be established to ensure that these special processes are controlled and accomplished by qualified personnel, using qualified procedures in accordance with applicable codes, standards, specifications, criteria, or other special requirements, and that qualification records of procedures, equipment, and personnel are filed and kept current. Routine-type processes, such as decontamination of a package, leak testing, etc., are covered below in Sections 2.10 and 2.11.

*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.

2.10 Inspections

2.10.1 Receipt

Visual inspections should be performed upon receipt of packages to ensure that they comply 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.

2.10.2 Maintenance

Measures should be established to ensure that those items (e.g., surface conditions of package, critical welds, gaskets, seals, and o-rings) designated in the QA program for periodic inspection and preventive maintenance are identified.

2.10.3 Inspection Personnel

Measures should be established to ensure that inspection personnel are independent from individuals performing the activity being inspected.

2.11 Test Control

2.11.1 Routine Use

Test programs, including identification of acceptance criteria prior to each use of the packaging and assurance that test results are documented and evaluated by qualified individuals, should be established.

2.11.2 Maintenance Tests

Maintenance test programs should be established to ensure that packages remain usable and free of excessive radiation and contamination. Test results should be documented, evaluated, and determined to be acceptable by qualified individuals.

2.12 Control of Measuring and Test Equipment

Measures should be established to ensure that instruments used in tests and inspections, including maintenance of safety-related items, have been properly calibrated against nationally recognized standards.

2.13 Handling, Storage, and Shipping

2.13.1 Handling and Storage

Measures should be established to provide for any special hoisting, rigging, positioning, and tiedowns for major components of the package while in storage or when moving from one station to another. Particular attention should be given to precautions required for ensuring the safety of the contents of the package.

2.13.2 Preparation for Shipment

Measures should be established to ensure that any special limitations or requirements (e.g., loading limits, special package handling of quantities of radioactive materials authorized, mode of shipment) are specified in approved procedures. Also, measures, such as the use of checklists, should be established to ensure that all conditions, including completion of specified operations, inspections and tests, NRC and DOT shipping requirements, and all necessary shipping papers, have been met prior to delivery to a carrier.

2.14 Inspection, Test, and Operating Status

Measures should be established to ensure that identification (e.g., stamps, tags, labels, routing cards, or other suitable means) of the status of inspections, tests, and operating conditions, including maintenance, is known by organizations responsible for assurance of quality.

Measures should be established to ensure that required inspections, tests, and other critical operations are procedurally controlled to prevent their being inadvertently bypassed and that nonconforming, inoperative, or malfunctioning components are identified to prevent their inadvertent use.

2.15 Control of Nonconforming Materials, Parts, or Components

Measures should be established to ensure that the following conditions are met:

a. Parts, components, or assemblies that do not conform to requirements are segregated from acceptable items and controlled to prevent their inadvertent use or installation.

b. Nonconforming items are reviewed and either accepted, rejected, repaired, or reworked in accordance with documented procedures.

c. The responsibility and authority for individuals or organizations designated to dispose of nonconforming items is defined.

d. The acceptability of nonconforming items that have the disposition of "repair" or "use as is" is verified by reinspection, retest, or engineering analysis.

e. Nonconformance reports identify nonconformances, dispositions of the nonconformances, inspection requirements for nonconformances, and the signature of the individual authorized to approve disposition of nonconformances.

2.16 Corrective Action

Measures should be established to ensure that the following conditions are met:

a. Conditions adverse to quality such as malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified, reported to appropriate levels of management, and corrected.

b. Followup reviews are conducted to verify that specified corrective actions have been taken and that documentation has been closed out.

2.17 Quality Assurance Records

Records to be controlled under the QA program should be identified. These records should include, as a minimum, procurement documentation, results of inspections, tests, and audits, evidence of personnel training and certification, evidence of operational capability, verification of repair, replacement, and maintenance, and nonconformance and corrective action reports.

Measures should be established to ensure that QA records are identifiable and retrievable and that a current list of the records and their storage locations is available.

2.18 Audits

2.18.1 Elements of Audit Program

Elements of the QA audit program should be established to include work areas, activities, and processes to be audited that will ensure the objective evaluation of quality-related practices, procedures, and instructions and the effectiveness of their implementation. (In cases where the organization is so small that independence of the auditing personnel is impractical, a checklist of the activities to be audited should be included in the appropriate QA/QC manual).

Measures should be established to ensure that audits are performed in accordance with preestablished written procedures or checklists.

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 design and fabrication activities are controlled by an NRC-approved QA program.

2.18.2 Scheduling

Frequencies of established audits listed in Section 2.18.1 should be identified.

Measures should be established to ensure that audits of a QA program are performed at least annually and that the frequency of audit is based on the safety significance of the activity being audited.

2.18.3 Personnel

Individuals or organizations responsible for performing management audits of the QA program to determine its overall effectiveness and compliance with management policies and procedures should be identified. Personnel performing audits should not have direct responsibilities in the areas being audited.

2.18.4 Reporting and Response

Measures should be established to ensure that the audit results are documented and that the documentation is reviewed with management having responsibility in the area audited.

Measures should be established to ensure that deficient areas are reaudited on a timely basis to verify implementation or corrective action.

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 packages.

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 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 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 owing to system insensitivity to the structure, component, or system performance.

3. Level of Quality Assurance Effort

The final step would be to assign an appropriate degree of quality assurance effort to each quality category.

For example, the quality assurance effort for Category A items would require that the following items be complied with:

a. A formalized design review would be conducted by representatives from design other than those responsible for the design, manufacturing, quality assurance, etc., before permitting release of the design;

b. Procurement of safety-related items would be permitted only with suppliers from qualified vendors lists; and

*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.

c. Manufacturing and inspection planning would specify that critical welds and nondestructure examinations,* such as radiography, could be accomplished only by certified personnel and that the welds must be inspected by qualified inspectors.

Quality assurance effort for Category B items would require that the following items be complied with:

a. The design should be informally reviewed by design personnel who could be from the same organization as the designer;

b. Procurement of materials need not be from suppliers who appear on qualified vendors lists, and

c. Manufacturing and inspection planning could be accomplished without requiring qualified nondestructive examination or inspection personnel.

Quality assurance effort for Category C items would require that the following items be complied with:

a. The design would be checked only by the designers' supervisors;

b. Procurements could be from a catalog or off-the-shelf; and

c. When the item is received, it would only be visually inspected to confirm proper identity and physical condition.

DRAFT VALUE/IMPACT STATEMENT

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 safety-related features of the container.

To increase confidence that designated safety-related features of particular packagings 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 18 criteria identified as Appendix E to 10 CFR Part 71, "Quality Assurance (QA) Criteria For Shipping Packages for Radioactive Material."

Prior to October 1977 when Appendix E became an effective rule, quality assurance programs were required 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 reviewed against the criteria identified in Appendix E to Part 71.

Subsequent to Appendix E becoming an effective rule and pursuant to paragraph 71.24(a) and § 71.51, "Establishment and Maintenance of a Quality Assurance Program," all applicants and licensees authorized to use, possess, design, or build packages to transport radioactive material in excess of Type A quantities, as defined in paragraph 71.4(g), had to provide documented evidence of a QA program acceptable to the NRC. A special provision of the rule allowed any licensee in possession of 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.

The effective date to submit to the NRC the QA program descriptions was initially set as July 1, 1978, but because of large numbers of inquiries, primarily from radiographers, the date was extended to January 1, 1979. Licensees filing their QA program descriptions by January 1, 1979, were authorized continued use of their packages contingent upon the determination of acceptability by the NRC.

2. THE PROPOSED ACTION

2.1 Description

The proposed action provides guidance to persons desiring information on the essential elements needed to develop, establish, and maintain quality assurance programs in accordance with the requirements of Appendix E to Part 71 for packaging used to transport special form and certain normal form radioactive material. The guide will include two annexes: (1) Quality Assurance Programs Applicable to Design, Fabrication, Assembly, and Testing of Packaging Used To Transport Special Form and Certain Normal Form Radioactive Material and (2) Quality Assurance Programs Applicable to Procurement, Use, Maintenance, and Repair of Packaging Used To Transport Special Form and Certain Normal Form Radioactive Material.

2.2 Need for the Proposed Action

According to § 71.24, applicants for package approval are required to identify their quality assurance program, and, according to § 71.51, licensees are required to establish and maintain a quality assurance program.

Guidance is needed by (a) persons establishing QA programs and (b) 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 to the requirements of Appendix E, specific guidance concerning grading of a particular QA program to fit its potential impact on safety is needed. The economic penalties for overcommitment resulting from uniform application of quality assurance without regard to specifics can be as severe as not applying any quality requirements at all to achieve design objectives.

2.3 Value/Impact of the Proposed Actions

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 about 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

Development of this regulatory guide should be initiated 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 in Appendix E 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 Appendix E, but their 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 what would be acceptable to the NRC. In addition, a regulatory guide will ensure uniform transmission of information and responses from applicants and licensees.

4. STATUTORY CONSIDERATIONS

4.1 NRC Authority

The proposed guide provides guidance for the implementation of regulations promulgated in paragraph 71.24(a) and § 71.51 and described in Appendix E 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

The proposed action is not a major action as defined in § 51.5 of 10 CFR Part 51 and, therefore, does not require an environmental impact statement.

5. RELATIONSHIP TO OTHER EXISTING OR PROPOSED REGULATIONS OR POLICIES

Appendix E to 10 CFR Part 71 is structured identically to Appendix B to 10 CFR Part 50 describing quality assurance criteria now in effect for nuclear power plants and certain fuel cycle facilities but changed essentially only to accommodate terminology specific to transportation.

6. SUMMARY AND CONCLUSIONS

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

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