10 QUALITY ASSURANCE EVALUATION

10.1 Review Objective

The objective of the U.S. Nuclear Regulatory Commission's (NRC's) quality assurance (QA) review is to verify that an application for a transportation package for radioactive material certificate includes a quality assurance program description (QAPD) or references a previously approved QA program. The QAPD must demonstrate that the applicant's QA program complies with the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71, "Packaging and Transportation of Radioactive Material," Subpart H, "Quality Assurance."

The basis for that determination is developed from an evaluation of the applicant's high-level QAPD against the 18 criteria provided in Section 10.4 of this standard review plan (SRP) chapter, 10 CFR Part 71, and any associated information found in the *Federal Register* since the last rulemaking has been completed, as applicable. (Note: The scope of review does not include actual procedures and instructions that implement the QA program, although they may be described in the QAPD.)

The determination that the applicant's QA program is in compliance occurs during the NRC inspection activities that evaluate implementation of the QA plan. (Note: The scope of an inspection does include the actual procedures and instructions that implement the QA program.)

10.2 Areas of Review

This chapter addresses the following areas of review:

- QA organization
- QA program
- package design control
- procurement document control
- instructions, procedures, and drawings
- document control
- control of purchased material, equipment, and services
- identification and control of materials, parts, and components
- control of special processes
- internal inspection
- test control
- control of measuring and test equipment
- handling, storage, and shipping control
- inspection, test, and operation status
- nonconforming materials, parts, or components
- corrective action
- QA records
- Audits

10.3 Regulatory Requirements and Acceptance Criteria

The NRC staff reviewer should refer to the exact language in 10 CFR Part 71, Subpart H. The acceptance criteria in Section 10.4 reflect the 18 quality criteria in 10 CFR Part 71, Subpart H, and

describe the information to be included in the applicant's QAPD. Examples of measures are provided for each criterion to assist the reviewer in determining whether the QAPD meets the applicable criterion. For each of the activities and items identified as important to safety, the applicant should identify the applicable QA programmatic elements and include, as applicable, provisions for meeting each of the quality criteria listed in Section 10.4 of this SRP chapter.

10.4 Review Procedures

The purpose of the QA review is to obtain reasonable assurance that the applicant has developed and described a QA program for activities associated with transportation packaging components important to safety. Those activities include design, procurement, fabrication, assembly, testing, modification, maintenance, repair, and use. An application for QA program approval or reference to a previously approved QA program will be included in the application. In the case that a reference to a previously approved program is submitted, the reviewer should verify that the referenced program is applicable to the applicant and NRC approved.

In the case that a QAPD is submitted with the package application, it is important that the applicant's QAPD provide sufficient detail to enable the reviewer to assess whether the applicant has committed to comply with the program and that the QA program complies with the applicable requirements in 10 CFR Part 71, Subpart H. Section 10.5 of this SRP describes the course of action if the reviewer determines that sufficient detail does not exist in the QAPD. If the QAPD indicates a commitment to follow certain standards or codes, then the reviewer should consider the commitments as an integral part of the QA program.

The applicant's QA program may be structured to apply QA measures and controls to all activities and items in proportion to their importance to safety, commonly referred to as a graded approach. The QAPD should address the use of a graded approach for the application of QA by adequately assigning appropriate grading classifications and providing an associated justification. However, an applicant may instead choose to apply the highest level of QA and control to all activities and items. The QA program should identify the items and attributes that are important to safety and the degree or category, as applicable, of their importance. For application of a graded approach, the highly important-to-safety activities and items must have a high level of quality control, whereas those less important may have a lower level of quality control. If the QA program is graded, the staff should be able to conclude that the structure of the graded program is acceptable and that the highest levels of QA are applied to those components that are most important to safety. In making determinations about the application of QA to those packaging components important to safety, coordinate with the appropriate NRC project manager and associated technical staff to possibly evaluate other sections or portions of the application. In evaluating the QA program, the QA reviewer may also use NUREG/CR-6314, "Quality Assurance Inspections for Shipping and Storage Containers," and Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material," as additional sources of information in determining the program's compliance with regulatory requirements.

If the reviewer finds the QAPD submitted as part of an application to be acceptable, this should be documented in the safety evaluation report (SER). The documentation of the review should include the basis for acceptance as noted in Section 10.5 of this SRP. Section 10.5 also describes the process for making any recommendations (requests for additional information process) for modifications to the application that are required before the application can be accepted. If a reference to a previously approved QAPD is submitted with the application, the verification of its applicability to the applicant and current NRC approval should also be documented in the SER.

10.4.1 Quality Assurance Organization

Ensure that the QAPD describes the structure, interrelationships, and areas of functional responsibility and authority for all organizational elements that will perform activities related to quality and safety. The following are examples of areas and items that may be addressed to support implementation of the quality criteria:

- measures to retain and exercise responsibility for the QA program; the assignment of responsibility for the overall QA program in no degree relieves line management of its responsibility for the achievement of quality

- measures to identify and describe the QA functions the applicant's QA organization performed or delegated to other organizations that will provide controls to ensure implementation of the applicable elements of the QA criteria

- measures to provide clear management controls and effective lines of communication between the applicant's QA organizations and suppliers to ensure proper direction of the QA program and resolution of QA-related problems

- measures to identify onsite and offsite organizational elements that will function under the purview of the QA program and the lines of responsibility

- measures to designate a position that retains overall authority and responsibility for the QA program (e.g., manager or director of QA) and independently reports to at least the same organizational level authority as the highest line manager directly responsible for performing activities affecting quality

- measures to ensure that high-level management is responsible for documenting and promulgating the applicant's QA policies, goals, and objectives, and that this management level maintains a continuing involvement in QA matters; the application should also describe the lines of communication between intermediate levels of management and between high-level management and the manager (or director) of QA

- measures to provide authority and independence of the individual responsible for managing the QA program such that he or she can direct and control the organization's QA program, effectively ensure conformance to quality requirements, and remain sufficiently independent of undue influences and responsibilities of schedules and costs

- measures for individuals or groups responsible for defining and controlling the content of the QA program and related manuals to have appropriate organizational position and authority, as should the management level responsible for final review and approval

- measures describing the qualification requirements for the principal QA management positions so as to demonstrate management and technical competence commensurate with the responsibilities of these positions

- measures to ensure that conformance to established requirements will be verified by individuals or groups who do not have direct responsibility for performing the work being verified; the quality control function may be part of the line organization, provided the QA organization performs periodic surveillance to confirm sufficient independence from the individuals who performed the activities

- measures to ensure that persons and organizations performing QA functions have direct access to management levels that will ensure accomplishment of quality-affecting activities; these individuals should have sufficient authority and organizational freedom to perform their QA functions effectively and without reservation and should be able to identify quality problems; initiate, recommend, or provide solutions through designated channels; and verify implementation of solutions

- measures to ensure that designated QA individuals or organizations have the responsibility and authority, delineated in writing, to stop unsatisfactory work and control further processing, delivery, or installation of nonconforming material; the application should describe how stop-work requests will be initiated and completed

- measures to determine the extent of QA controls to be identified by the QA staff in combination with the line staff and to depend on the specific activity or item complexity and level of importance to safety

10.4.2 Quality Assurance Program

Ensure that the QAPD provides acceptable evidence that the applicant's proposed QA program will be well documented, planned, implemented, and maintained to provide the appropriate level of control over activities and packaging components consistent with their relative importance to safety. The following are examples of areas and items that may be addressed to support implementation of the quality criteria:

- measures used to ensure that the QA program meets applicable acceptance criteria

- measures for management to regularly assess the effectiveness of the QA program; measures for management (above and beyond the QA organization) to regularly assess the scope, status, adequacy, and compliance of the QA program to the requirements of 10 CFR Part 71; measures to provide for management's frequent appraisal of program status through reports, meetings, and audits as well as performance of a periodic assessment that is planned and documented with corrective actions identified and tracked

- measures to ensure that activities important to safety are accomplished using appropriate production and test equipment, suitable environmental conditions, applicable codes and standards, and proper work instructions

- measures used to ensure that trained, qualified personnel within the organization will be assigned to determine that functions delegated to contractors are properly accomplished

- summaries of the corporate QA policies, goals, and objectives and establishment of a meaningful channel for transmittal of these policies, goals, and objectives down through the levels of management

- measures to designate responsibilities for implementing the major activities addressed in the QA manuals

- measures to control the distribution of the QA manuals and revisions

- measures for communicating to all responsible organizations and individuals that policies, QA manuals, and procedures are mandatory requirements

- measures to provide a comprehensive listing of QA procedures, as well as a matrix of these procedures cross-referenced to each of the QA criteria, to demonstrate that the QA program will be fully implemented by documented procedures

- identification of packaging components, items, and attributes important to safety and how the QA program will control them

- measures for the applicant to review supplier documents for agreement with QA program provisions and ensure implementation of a program meeting the QA criteria

- measures for the resolution of disputes involving quality arising from a difference of opinion between QA personnel and personnel from other departments (e.g., engineering, procurement, manufacturing)

- measures for indoctrination, training, and qualification programs that fulfill the following criteria:

    — instruction of personnel responsible for performing activities affecting quality as to the purpose, scope, and implementation of the quality-related manuals, instructions, and procedures

    — training and qualification in the principles and techniques of the activities being performed for personnel performing activities affecting quality

    — maintenance of the proficiency of personnel performing quality-affecting activities by retraining, reexamining, and recertifying

    — preparation and maintenance of documentation of completed training and qualification

    — qualification of personnel in accordance with accepted codes and standards

10.4.3 Package Design Control

Ensure that the QAPD describes the approach the applicant will use to define, control, and verify the design and development of the transportation packaging. The following are examples of areas and items that may be addressed to support implementation of the quality criteria:

- measures to carry out design activities in a planned, controlled, and orderly manner

- measures to correctly translate the applicable regulatory requirements and design bases into specifications, drawings, written procedures, and instructions

- measures to describe how the applicant will specify quality standards in the design documents and control deviations and changes from these quality standards

- measures to describe how the applicant will review designs to ensure that design characteristics can be controlled, inspected, and tested and that inspection and test criteria are identified

- measures to describe how the applicant will establish both internal and external design-interface controls; these controls should include review, approval, release, distribution, and revision of documents involving design interfaces with participating design organizations

- measures to describe how the applicant will properly select and perform design verification processes such as design reviews, alternative calculations, or qualification testing; when a test program is to be used to verify the adequacy of a design, measures to describe how the applicant will use a qualification test of a prototype unit under adverse design conditions

- measures to ensure that design verifications (i.e., confirmation that the design of the packaging component is suitable for its intended purpose) are completed by an individual with a level of skill at least equal to that of the original designer; measures to ensure design checking is also performed, recognizing design checking can be performed by a less-experienced person (as an example, confirmation that the correct computer code has been used is part of design verification. Design checking includes confirmation of the numerical accuracy of computations and the accuracy of data input to computer codes); measures to describe how design verification will be performed by persons other than those performing design checking; measures to include how individuals or groups responsible for design verification will not include the original designer and normally not include the designer's immediate supervisor

- measures to ensure that design and specification changes are subject to the same design controls and the same or equivalent approvals that were applicable to the original design

- measures to ensure the documentation of all errors and deficiencies in the design or the design process that could adversely affect packaging components, items, and attributes important to safety; measures for adequate corrective action, including root cause evaluation of significant errors and deficiencies, to preclude repetition

- measures to review the suitability of any materials, parts, and equipment for the intended application before selecting such items that are standard, commercial (off-the-shelf), or have been previously approved for a different application

- measures to provide written procedures to identify and control the authority and responsibilities of all individuals or groups responsible for design reviews and other design-verification activities

- measures that include the use of valid industry standards and specifications for the selection of suitable materials, parts, equipment, and processes for packaging components important to safety

10.4.4 Procurement Document Control

Ensure that documents used to procure packaging components or services include or reference applicable design bases and other requirements necessary to ensure adequate quality. The following are examples of areas and items that may be addressed to support implementation of the quality criteria:

- measures to establish procedures that clearly delineate the sequence of actions to be accomplished in the preparation, review, approval, and control of procurement documents

- measures to ensure that qualified personnel review and concur with the adequacy of quality requirements stated in procurement documents and ensure that the quality requirements are correctly stated, inspectable, and controllable; there are adequate acceptance and rejection criteria; and the procurement document has been prepared, reviewed, and approved in accordance with QA program requirements

- measures to document the review and approval of procurement documents before they are released, with the documentation available for verification

- measures to ensure that procurement documents identify the applicable QA requirements that should be compiled and described in the supplier's QA program and to ensure that the applicant reviews and concurs with the supplier's QA program; if subtier suppliers are also used, measures to ensure that the supplier's QA program applies to the subtier suppliers

- measures to ensure that procurement documents contain or reference the regulatory requirements, design bases, and other technical requirements

- measures to ensure that procurement documents identify the documentation (e.g., drawings, specifications, procedures, inspection and fabrication plans, inspection and test records, personnel and procedure qualifications, and chemical and physical test results of material) to be prepared, maintained, and submitted to the purchaser for review and approval

- measures to ensure that procurement documents identify records to be retained, controlled, and maintained by the supplier and those records to be delivered to the purchaser before use or installation of the hardware

- measures to ensure that procurement documents specify the procuring agency's right of access to the supplier's facilities and records for source inspection and audit

- measures to ensure that changes and revisions to procurement documents are subject to the same or equivalent review and approval as the original documents

10.4.5 Instructions, Procedures, and Drawings

Ensure that the QAPD defines the applicant's proposed procedures for ensuring that activities affecting quality will be prescribed by, and performed in accordance with, documented instructions, procedures, or drawings of a type appropriate for the circumstances. The following are examples of areas and items that may be addressed to support implementation of the quality criteria:

- measures to ensure that activities affecting quality are prescribed and accomplished in accordance with documented instructions, procedures, or drawings

- measures to establish provisions that clearly delineate the sequence of actions to be accomplished in the preparation, review, approval, and control of instructions, procedures, and drawings

- measures to ensure that instructions, procedures, and drawings specify the methods for complying with each of the applicable QA criteria

- measures to ensure that instructions, procedures, and drawings include quantitative acceptance criteria (such as dimensions, tolerances, and operating limits) as well as qualitative acceptance criteria (such as workmanship samples) as verification that activities important to safety have been satisfactorily accomplished

- measures to ensure that the QA organization reviews and concurs with the procedures, drawings, and specifications related to inspection plans, tests, calibrations, and special processes, as well as any subsequent changes to these documents

10.4.6 Document Control

Ensure that the QAPD defines the applicant's proposed procedures for preparing, issuing, and revising documents that specify quality requirements or prescribe activities affecting quality. The following are examples of areas and items that may be addressed to support implementation of the quality criteria:

- identification of all documents to be controlled under this subsection, including, as a minimum, design specifications; design and fabrication drawings; procurement documents; QA manuals; design-criteria documents; fabrication, inspection, and testing instructions; and test procedures

- measures to ensure the establishment of procedures to control the review, approval, and issuance of documents, and any subsequent changes, before release to ensure that the documents are adequate and applicable quality requirements are stated

- measures to ensure the establishment of provisions to identify individuals or groups responsible for reviewing, approving, and issuing documents and subsequent revisions to the documents

- measures to ensure that document revisions receive review and approval by the same organizations that performed the original review and approval or by other qualified responsible organizations the applicant designated

- measures to ensure that approved changes are included in instructions, procedures, drawings, and other documents before the change is implemented

- measures to ensure the control of obsolete or superseded documents to prevent inadvertent use

- measures to ensure that documents are available at the location where the activity is performed

- measures to ensure the establishment of a master list (or equivalent) to identify the current revision number of instructions, procedures, specifications, drawings, and procurement documents; measures to ensure the updating and distribution of the list to predetermined, responsible personnel to avoid the use of superseded documents

10.4.7 Control of Purchased Material, Equipment, and Services

Ensure that the QAPD defines the applicant's proposed procedures for controlling purchased material, equipment, and services to ensure conformance with specified requirements. The

following are examples of areas and items that may be addressed to support implementation of the quality criteria:

- measures to ensure that qualified personnel evaluate the supplier's capability to provide services and products of acceptable quality before the award of the procurement order or contract; measures to ensure that QA and engineering groups participate in the evaluation of those suppliers providing critical items and services important to safety, including a definition of the responsibilities for each participating group

- measures to ensure the evaluation of suppliers should consider establishing the following provisions (if applicable):

  — the supplier's capability to comply with the elements of the QA criteria that are applicable to the type of material, equipment, or service being procured

  — review of previous records and performance of suppliers that have provided similar articles or services of the type being procured

  — a survey of the supplier's facilities and QA program to assess the capability to supply a product that meets applicable design, manufacturing, and quality requirements

- measures to ensure the documentation and filing of the results of supplier evaluations

- measures to ensure the planning and performance of adequate surveillance of suppliers during fabrication, inspection, testing, and shipment of materials, equipment, and components in accordance with written procedures to ensure conformance to the purchase-order requirements; the measures should ensure that the procedures provide the following information:

  — instructions that specify the characteristics or processes to be witnessed, inspected or verified, and accepted; the method of surveillance and the extent of documentation required; and those responsible for implementing these instructions

  — procedures for audits and surveillance to ensure that the supplier complies with the quality requirements (surveillance should be performed for packaging components for which verification of procurement requirements cannot be determined upon receipt)

- measures to ensure that the supplier furnishes the following records to the purchaser:

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

  — documentation that identifies any procurement requirements that have not been met and a description of any nonconformances designated "accept as is" or "repair"

- measures to describe the proposed procedures for reviewing and accepting these documents and, as a minimum, to ensure that this review and acceptance will be undertaken by a responsible QA individual

- measures to ensure the performance of periodic audits, independent inspections, or tests to ensure the validity of the suppliers' certificates of conformance

- measures to ensure the performance of a receiving inspection of supplier-furnished material, equipment, and services to ensure fulfillment of the following criteria:

  — proper identification of the material, component, or equipment in a manner that corresponds with the identification on the purchasing and receiving documentation

  — inspection of material, components, equipment, and acceptance records and judgment of their acceptability in accordance with predetermined inspection instructions before installation or use

  — availability of inspection records or certificates of conformance attesting to the acceptance of material, components, and equipment before installation or use

  — identification of the inspection status for accepted items and ensuring associated markings are attached before the accepted items are forwarded to a controlled storage area or released for installation or further work

- measures to assess the effectiveness of suppliers' quality controls at intervals consistent with the importance to safety, complexity, and quantity of the packaging components procured

10.4.8 Identification and Control of Materials, Parts, and Components

Ensure that the QAPD defines the applicant's proposed provisions for identifying and controlling materials, parts, and components to ensure that incorrect or defective packaging components are not used. The following are examples of areas and items that may be addressed to support implementation of the quality criteria:

- measures to establish procedures to identify and control materials, parts, and components (including partially fabricated subassemblies)

- measures to determine identification requirements during the generation of specifications and design drawings

- measures to ensure that identification will be maintained either on the item or on records traceable to the item to preclude the use of incorrect or defective items

- measures to ensure that the identification of materials and parts for items important to safety is traceable to the appropriate documentation (such as drawings, specifications, purchase orders, manufacturing and inspection documents, deviation reports, and physical and chemical mill test reports)

- measures to ensure that the location and method of identification do not affect the fit, function, or quality of the item being identified

- measures to verify and document the correct identification of all materials, parts, and components before releasing them for fabrication, assembly, shipping, and installation

10.4.9 Control of Special Processes

Ensure that the QAPD describes the controls the applicant will establish to ensure the acceptability of special processes (such as welding, heat treatment, nondestructive testing, and chemical cleaning) and that the proposed controls are performed by qualified personnel using qualified procedures and equipment. The following are examples of areas and items that may be addressed to support implementation of the quality criteria:

- measures to establish procedures to control special processes (such as welding, heat treating, nondestructive testing, and cleaning) for which direct inspection is generally impossible or disadvantageous, as well as providing a listing of these special processes
- measures to qualify procedures, equipment, and personnel connected with special processes in accordance with applicable codes, standards, and specifications
- measures to ensure that qualified personnel perform special processes in accordance with written process sheets (or the equivalent) with recorded evidence of verification
- measures to establish, file, and keep current qualification records of procedures, equipment, and personnel associated with special processes

10.4.10 Internal Inspection

Ensure that the QAPD defines the applicant's proposed provisions for the inspection of activities affecting quality to verify conformance with instructions, procedures, and drawings. The following are examples of areas and items that may be addressed to support implementation of the quality criteria:

- measures to establish, document, and conduct an inspection program that effectively verifies the conformance of quality-affecting activities with requirements in accordance with written, controlled procedures
- measures to ensure that inspection personnel are sufficiently independent from the individuals performing the activities being inspected
- measures to ensure that inspection procedures, instructions, and checklists provide the following details:
    - — identification of characteristics and activities to be inspected
    - — identification of the individuals or groups responsible for performing the inspection operation
    - — acceptance and rejection criteria
    - — a description of the method of inspection
    - — procedures for recording evidence of completing and verifying a manufacturing, inspection, or test operation

— identification of the recording inspector or data recorder and the results of the inspection operation

- measures to ensure the use of inspection procedures or instructions with the necessary drawings and specifications when performing inspection operations
- measures to qualify inspectors in accordance with applicable codes, standards, and company training programs and to keep inspector qualifications and certifications current
- measures to inspect modifications, repairs, and replacements in accordance with the original design and inspection requirements or acceptable alternatives
- measures to establish provisions that identify mandatory inspection hold points for witnessing by a designated inspector
- measures to identify the individuals or groups who will perform receiving and process verification inspections, demonstrating that these individuals or groups have sufficient independence and qualifications
- measures to establish provisions for indirect control by monitoring processing methods, equipment, and personnel if direct inspection is not possible

10.4.11 Test Control

Ensure that the QAPD defines the applicant's proposed provisions for tests to verify that packaging components important to safety conform to specified requirements and will perform satisfactorily in service. The following are examples of areas and items that may be addressed to support implementation of the quality criteria:

- measures to establish, document, and conduct a test program to demonstrate that the item will perform satisfactorily in service in accordance with written, controlled procedures
- measures to ensure that written test procedures incorporate or reference the following information:
  - — requirements and acceptance limits contained in applicable design and procurement documents
  - — instructions for performing the test
  - — test prerequisites
  - — mandatory inspection hold points
  - — acceptance and rejection criteria
  - — methods of documenting or recording test data results
- measures to ensure a qualified, responsible individual or group documents test results and evaluates their acceptability; when practicable, the measures should ensure that testing of the packaging component occurs under suitable environmental conditions.

10.4.12 Control of Measuring and Test Equipment

Ensure that the QAPD defines the applicant's proposed provisions to ensure that tools, gauges, instruments, and other measuring and testing devices are properly identified, controlled, calibrated, and adjusted at specified intervals. The following are examples of areas and items that may be addressed to support implementation of the quality criteria:

- measures to ensure that documented procedures describe the calibration technique and frequency, maintenance, and control of all measuring and test equipment (instruments, tools, gauges, fixtures, reference and transfer standards, and nondestructive test equipment) that will be used in the measurement, inspection, and monitoring of packaging components important to safety

- measures to ensure that measuring and test equipment are identified and traceable to the calibration test data

- measures to ensure the use of labels, tags, or documents for measuring and test equipment to indicate the date of the next scheduled calibration and to provide traceability to calibration test data

- measures to calibrate measuring and test instruments at specified intervals on the basis of the required accuracy, precision, purpose, degree of usage, stability characteristics, and other conditions that could affect the accuracy of the measurements

- measures to assess the validity of previous inspections when measuring and test equipment is found to be out of calibration, and measures to document the assessment and to take control of the equipment that is out of calibration

- measures to document and maintain the complete status of all items under the calibration system

- measures to ensure that reference and transfer standards are traceable to nationally recognized standards, or to document the basis for calibration where national standards do not exist

10.4.13 Handling, Storage, and Shipping Control

Ensure that the QAPD defines the applicant's proposed provisions to control the handling, storage, shipping, cleaning, and preservation of packaging components important to safety in accordance with work and inspection instructions to prevent damage, loss, and deterioration. The following are examples of areas and items that may be addressed to support implementation of the quality criteria:

- measures to establish and accomplish special handling, preservation, storage, cleaning, packaging, and shipping requirements in accordance with predetermined work and inspection instructions

- measures to control the cleaning, handling, storage, packaging, shipping, and preservation of materials, components, and systems in accordance with design and specification requirements to preclude damage, loss, or deterioration by environmental conditions (such as temperature or humidity)

10.4.14 Inspection, Test, and Operating Status

Ensure that the QAPD defines the applicant's proposed provisions to control the inspection, test, and operating status of packaging components important to safety to prevent the inadvertent use of components or bypassing of inspections and tests. The following are examples of areas and items that may be addressed to support implementation of the quality criteria:

- measures to know the inspection and test status of items throughout fabrication and use
- measures to establish procedures to control the application and removal of inspection and welding stamps and operating status indicators (such as tags, markings, labels, and stamps)
- measures to ensure that procedures under the cognizance of the QA organization control the bypassing of required inspections, tests, and other critical operations
- measures to specify the organization responsible for documenting the status of nonconforming, inoperative, or malfunctioning packaging components and for identifying the item to prevent inadvertent use

10.4.15 Nonconforming Materials, Parts, or Components

Ensure that the QAPD defines the applicant's proposed provisions to control the use or disposition of nonconforming materials, parts, or components. The following are examples of areas and items that may be addressed to support implementation of the quality criteria:

- measures to establish procedures to control the identification, documentation, tracking, segregation, review, disposition, and notification of affected organizations regarding nonconforming materials, parts, components, services, or activities
- measures to provide for adequate documentation to identify nonconforming items and describe the nonconformance, its disposition, and the related inspection requirements; such measures should also provide for adequate documentation and include signature approval of the disposition
- measures to establish provisions to identify those individuals or groups with the responsibility and authority for the disposition and closeout of nonconformance
- measures to ensure that nonconforming items are segregated from acceptable items and identified as discrepant until properly dispositioned and closed out
- measures to verify the acceptability of reworked or repaired materials, parts, and components by reinspecting and retesting the item as originally inspected and tested or by using a method that is at least equal to the original inspection and testing method; the measures should provide for documentation of the relevant inspection, testing, rework, and repair procedures
- measures to ensure that nonconformance reports designated "accept as is" or "repair" are made part of the inspection records and forwarded with the hardware to the customer for review and assessment

- measures to periodically analyze nonconformance reports to show quality trends and help identify root causes of nonconformance. Significant results should be reported to responsible management for review and assessment

10.4.16 Corrective Action

Ensure that the QAPD defines the applicant's proposed provisions to ensure that conditions adverse to quality are promptly identified and corrected, and for significant conditions adverse to quality, that measures are taken to preclude recurrence. The following are examples of areas and items that may be addressed to support implementation of the quality criteria:

- measures to evaluate conditions adverse to quality (such as nonconformance, failures, malfunctions, deficiencies, deviations, and defective material and equipment) in accordance with established procedures to assess the need for corrective action

- measures to initiate corrective action to preclude the recurrence of a condition identified as adverse to quality

- measures to conduct follow-up activities to verify proper implementation of corrective actions and close out the corrective action documentation in a timely manner

- measures to document significant conditions adverse to quality, as well as the root causes of the conditions, and the corrective actions taken to remedy and preclude recurrence of the conditions; this information should be reported to cognizant levels of management for review and assessment

10.4.17 Quality Assurance Records

Ensure that the QAPD defines the applicant's proposed provisions for identifying, retaining, retrieving, and maintaining records that document evidence of the control of quality for activities and packaging components important to safety. The following are examples of areas and items that may be addressed to support implementation of the quality criteria:

- measures to define the scope of the records program such that sufficient records will be maintained to provide documentary evidence of the quality of items and activities affecting quality; to minimize the retention of unnecessary records, the records program should list records to be retained by type of data rather than by record title

- measures to ensure that QA records include operating logs; results of reviews, inspections, tests, audits, and material analyses; monitoring of work performance; qualification of personnel, procedures, and equipment; and other documentation such as drawings, specifications, procurement documents, calibration procedures and reports, design review and peer review reports, nonconformance reports, and corrective action reports

- measures to ensure that records are identified and retrievable

- Measures to ensure that requirements and responsibilities for record creation, transmittal, retention (such as duration, location, fire protection, and assigned responsibilities), and maintenance subsequent to completion of work are consistent with applicable codes, standards, and procurement documents

- measures to ensure that inspection and test records contain the following information, where applicable:

  — a description of the type of observation
  — the date and results of the inspection or test
  — information related to conditions adverse to quality
  — identification of the inspector or data recorder
  — evidence as to the acceptability of the results
  — action taken to resolve any noted discrepancies

- measures to ensure that record storage facilities are constructed, located, and secured to prevent destruction of the records by fire, flood, theft, and deterioration by environmental conditions (such as temperature or humidity); measures to ensure that the facilities are maintained by, or under the control of, the certificate holder throughout the life of the packaging(s)

10.4.18 Audits

Ensure that the QAPD defines the applicant's proposed provisions for planning and scheduling audits to verify compliance with all aspects of the QA program and to determine the effectiveness of the overall program. The following are examples of areas and items that may be addressed to support implementation of the quality criteria:

- measures to perform audits in accordance with written procedures or checklists such that qualified personnel tasked with performing these audits do not have direct responsibility for the achievement of quality in the areas being audited

- measures to ensure that audit results are documented and reviewed by management with responsibility in the area audited

- measures to establish provisions for responsible management to undertake appropriate corrective action as a follow up to audit reports; the measures should ensure that auditing organizations schedule and conduct appropriate follow up to ensure that the corrective action is effectively accomplished

- measures to perform both technical and QA programmatic audits to achieve the following objectives:

  — comprehensive, independent verification and evaluation of procedures and activities affecting quality

  — verification and evaluation of the suppliers' QA programs, procedures, and activities

- measures to ensure that appropriately qualified and certified audit personnel from the QA organization lead the audits; measures to ensure that the audit team membership includes personnel (not necessarily QA organization personnel) with technical expertise in the areas being audited

- measures to schedule regular audits on the basis of the status and importance to safety of the activities being audited; measures to provide that audits are initiated early enough to ensure effective QA during design, procurement, and contracting activities

- measures to analyze and trend audit deficiency data as well as ensure that the resulting reports, indicating quality trends and the effectiveness of the QA program, are given to management for review, assessment, corrective action, and follow up

- measures to ensure that audits objectively assess the effectiveness and proper implementation of the QA program and address the technical adequacy of the activities being conducted

- measures to establish provisions requiring the performance of audits in all areas to which the requirements of the QA program apply

10.5 Evaluation Findings

If the package application included the QAPD, the NRC reviewer should prepare evaluation findings upon satisfaction of the regulatory requirements in Section 10.3 of this SRP. If the reviewer determines that the applicant's QAPD does not adequately address the requirements in 10 CFR Part 71, a request for additional information (RAI) must be prepared and submitted to the NRC project manager to be forwarded to the applicant for resolution and response to the NRC. If the reviewer concludes that information provided with the application, along with additional information provided in response to the NRC's RAI, shows that the QAPD meets the requirements, statements of finding similar to the following should be included in the staff's SER:

F10.1 The staff has reviewed the applicant's description of the QA program and concludes that the requirements, procedures, and controls, when properly implemented, should comply with the requirements of 10 CFR Part 71, Subpart H.

F10.2 The staff has reviewed the applicant's description of the QA program and concludes that it covers activities affecting packaging components, items, and attributes important to safety, as identified in the application.

F10.3 The staff has reviewed the applicant's description of the QA program and concludes that it covers activities affecting other packaging components, items, and attributes with consideration of their relative importance to safety, as identified in the application.

F10.4 The staff has reviewed the applicant's description of the QA program and concludes that it describes organizations and persons performing QA functions, indicating that sufficient independence and authority should exist to perform their functions without undue influence from those directly responsible for costs and schedules.

F10.5 The staff has reviewed the applicant's description of the QA program and concludes that it is in compliance with applicable NRC regulations and industry standards, and the acceptance of the QA program description by NRC allows implementation of the associated QA program for the design, procurement, fabrication, assembly, testing, modification, maintenance, repair, and use of transportation packagings.

The reviewer should provide a summary statement similar to the following when providing input to the SER:

- The staff finds, with reasonable assurance, that the QA program for transportation packaging meets the requirements in 10 CFR Part 71 and addresses all 18 criteria as required in Subpart H to 10 CFR Part 71. The staff also finds, with reasonable assurance,

that the QA program encompasses design controls, materials and services procurement controls, records and document controls, fabrication controls, nonconformance and corrective actions controls, an audit program, and operations or programs controls, as appropriate, adequate to ensure that the package will allow safe transport of the radioactive material authorized in this approval. The staff reached this finding based on a review that considered applicable NRC regulations and regulatory guides and the statements and representations contained in the application.

If the package application included a reference to a previously approved QAPD, the NRC reviewer should document in the SER, upon satisfaction of a referenced QAPD, that it is applicable to the applicant and approved by the NRC.

10.6 References

10 CFR Part 71, “Packaging and Transportation of Radioactive Material.”

NUREG/CR-6314, “Quality Assurance Inspections for Shipping and Storage Containers,” INEL95-0061, Idaho National Engineering Laboratory, Idaho Falls, ID, April 1996.

Regulatory Guide 7.10, “Establishing Quality Assurance Programs for Packaging Used in Transport of Radioactive Material,” Revision 3, June 2015.