



July 31, 2007

ATTN: Document Control Desk
Director, Spent Fuel Project Office
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

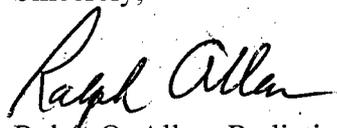
SUBJECT: QUALITY ASSURANCE PROGRAM APPROVAL FOR RADIOACTIVE
MATERIAL PACKAGES NO. 0460, REVISION 6

Dear Mr. Pstrak:

The University of Virginia wishes to renew its Quality Assurance Program Approval for Radioactive Material Packages No. 0460. As the University's Research Reactor no longer exists, we wish to amend certain wording in the Program description to reflect this. Please find attached an amended description of our Quality Assurance Program.

If you have any questions regarding this request, please contact Ms. Deborah Steva at 434-982-4917.

Sincerely,



Ralph O. Allen, Radiation Safety Officer

Revision 7
July, 2007

University of Virginia

QUALITY ASSURANCE PROGRAM FOR RADIOACTIVE MATERIAL PACKAGES

QUALITY ASSURANCE PROGRAM

Quality Assurance Program Applicable to Procurement, Use, Maintenance, and Repair of Packaging Used to Transport Spent Fuel, Radioactive Material, and Plutonium

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Quality Assurance Program Applicable to Procurement, Use, Maintenance, and Repair of Packaging Used to Transport Spent Fuel, Radioactive Material, and Plutonium

A. Introduction

This part of the Quality Assurance Program is applicable to procurement, use, maintenance, and repair of packaging used to transport spent fuel, greater than Type A quantities of radioactive material, and plutonium. It is designed to assure the safety of the general public during packaging and transportation of the above mentioned materials. This program applies to items 30 days subsequent to the date of NRC approval of this program and to those activities related to the procurement of packaging and shipment of the above mentioned materials.

B. Quality Assurance Program

1. Scope

The description of the QA program, contained within, will include a discussion of which requirements of 10 CFR, Part 71, Subpart H are applicable and how they will be satisfied. Establishment of the QA program deems that all quality related activities applicable to the design, fabrication, inspection, testing, purchase, use, maintenance and repair of packages are implemented with written procedures approved by appropriate levels of management and are contained in quality assurance (QA) files.

The licensee-user retains the responsibility for the overall effectiveness of the QA program. The licensee-user must determine that during design and fabrication of the shipping package all quality assurance provisions applicable to packaging have been followed and will submit to the Nuclear Regulatory Commission for evaluation how this determination has been made.

Indoctrination and training will be included as part of an existing re-qualification program so that personnel performing quality related activities are trained and qualified to perform these activities. Upgrading of personnel performing quality related work will be on a continuing basis as changes are implemented in quality assurance procedures.

2. Responsibilities

The Radiation Safety Committee is responsible for reviewing the University's quality assurance policies, goals, and objectives. The Radiation Safety Officer retains overall authority and responsibility for the quality assurance program.

3. Organization (10 CFR 71.103)

Radiation Safety staff may perform functions under this QA program as designated by the Radiation Safety Officer or higher-level management. The Radiation Safety Officer will insure that measures are established to provide adequate control over any designated quality-related activities. Individuals performing QA functions have the responsibility and authority to stop unsatisfactory work and the delivery or installation of nonconforming materials and have direct access to the Radiation Safety Officer or higher-level management that can ensure accomplishment of quality-related activities.

The duties and qualifications required for the Radiation Safety Officer, who retains overall authority and responsibility for the QA program, and other principal personnel performing quality related functions will be established and documented in the QA files.

4. Design Control (10 CFR 71.107)

As a user of packaging: design activities will not normally be performed by this facility. Consequently, this criterion of 10 CFR Part 71.107 is not applicable. Assurance that the design of packaging used was accomplished under control of an NRC approved QA program is required. This will be accomplished by requiring the supplier of packaging to submit documented proof of package design under an NRC approved QA plan. Documented proof will be kept on file.

5. Procurement Document Control (10 CFR 71.109)

The licensee-user when procuring packaging will require manufacturers of packaging to supply appropriate certifications verifying that the designated (model and serial number) packaging was manufactured under an approved NRC QA program. Other pertinent documentation (as built drawings, photographs, sketches, use and maintenance manuals, etc.) are to be furnished by the manufacturer with the packaging. The Radiation Safety Officer will determine all pertinent documentation required. Also to be supplied with the procurement of the package will be identification of the type of verification activities required during use and maintenance of packaging.

If safety related replacement parts are required to be procured for the packaging, the Radiation Safety Officer will designate QA personnel to ensure that appropriate technical and QA requirements are included in purchase orders and that the purchase orders are placed with suppliers which have been previously qualified to supply the parts required.

6. Instructions, Procedures and Drawings (10 CFR 71.111)

In the preparation of packaging for use the licensee-user shall ascertain that the package with its contents satisfies the applicable requirements of 10 CFR 71.111 and of the licensee. The Reactor Supervisor or higher-level management must approve for placing the package in use.

The licensee-user shall prescribe activities affecting quality by documented instructions or procedures of a type appropriate to the circumstances and shall require that these instructions or procedures be followed.

If repair, rework, or maintenance is required to be performed on packaging, a written procedure will be used and coordinated with quality assurance personnel to ensure that appropriate inspection and test points are incorporated in the procedure and that effective repairs or rework have been satisfactorily performed. Any plans for maintenance will be reviewed by designated QA personnel to verify that the plans emphasize those characteristics that are most significant to safety.

7. Document Control (10 CFR 71.113)

Each of the shipping and packaging documents under control of the QA program for radioactive material packages will be identified in the QA files. Documents will be reviewed biennially by appropriate personnel not directly associated with radioactive material shipping. Changes to documents shall be reviewed and approved by the Radiation Safety Committee.

Control shall be exercised over the following transportation/shipping documents:

- a) Operating Procedures
- b) Maintenance procedures
- c) Inspection and test procedures
- d) Loading and unloading procedures
- e) Packaging and transport procedures
- f) Repair procedures

8. Control of Purchased Material, Equipment, and Services (10 CFR 71.115)

Designated QA personnel will take the necessary measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement requirements. Documentary evidence that the package conforms to the procurement specifications shall be supplied with the package. Such documentation should be referenced in the certificate of compliance and should relate to the use and maintenance of the packaging and should identify the necessary actions to be taken prior to delivery of the packaging to a carrier for transportation. This documentary evidence shall be retained and shall be sufficient to identify the specific requirements met by the purchased material or equipment.

9. Identification and Control of Materials, Parts and Components (10 CFR 71.117)

To prevent the use of incorrect or defective materials, parts and components, identification and control measures shall be established. The identification of the item must be maintained by heat number, part number, or other appropriate means, either on the item or on records directly

traceable to the item. Where replacement of limited life items are specified, measures will be taken to preclude use of items whose shelf life or operation times have expired.

10. Control of Special Processes (10 CFR 71.119)

Special processes are not normally performed by the users of packaging. However, if packaging requires major repairs necessitating the use of these processes, measures will be taken to ensure that controls over special processes are subject to the following criteria:

- a) Procedures, equipment, and personnel are qualified in accordance with applicable codes, standards and specifications.
- b) The operations are performed by qualified personnel and accomplished in accordance with written procedures with recorded evidence of verification.
- c) Qualification records of procedures, equipment, and personnel are established, filed, and kept current.

11. Inspection Control (10 CFR 71.121)

Visual inspections by designated QA personnel will be performed upon receipt of packaging to ensure compliance with procurement documentation. The criteria for acceptance of each of these inspections and action to be taken if non-compliance is encountered will be determined by the Radiation Safety Officer.

These visual inspections should include an inspection of the following:

- a) Surface conditions
- b) Weld and structural integrity
- c) Condition of flange or sealing faces
- d) Gaskets and seals
- e) Gauges, rupture disks, valves, pressure relief devices
- f) Condition of tied own members
- g) Labeling and marking
- h) Leak tightness of the packaging

The inspection program should ensure adequate maintenance of packaging. The manufacturer of the packaging should identify all items to be maintained, criteria for acceptability or replacement, and the frequencies of inspection assigned to each item during use of the package.

Final inspections will be performed with a checklist to verify as a minimum that the following items are complied with:

- a) Packages are properly assembled
- b) Moderators and/or neutron absorbers are present
- c) Valves through which primary coolant flows are protected against tampering.
- d) Valves are set to specifications
- e) All shipping papers are properly completed
- f) Packages are conspicuously and durably marked as required by DOT regulations.
- g) Individual designated by the owner or user of the package has given authorization for shipment of the package.

12. Test Control (10 CFR 71.123)

A test program or verification of completed testing shall be established to assure that all testing required to demonstrate that packaging components will perform satisfactorily in service, will be identified and performed in accordance with written test procedures. These written procedures will incorporate the acceptance limits contained in the package approval, provisions for assuring that all prerequisites for a given test have been met, that adequate test instrumentation is available and used and that the test is performed under suitable environmental conditions. Test results shall be documented and evaluated to assure that test requirements have been satisfied prior to delivering packages for transport to a carrier. The following items shall be included in typical tests:

- a) Structural integrity
- b) Leak tightness
- c) Component performance for the following:
 - 1) Valves
 - 2) Gaskets
 - 3) Fluid transport devices
- d) Shielding integrity
- e) Thermal integrity

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

13. Control of Measuring and Test Equipment (10 CFR 71.125)

All instruments, gages, and other measuring and testing devices used in activities affecting quality shall be properly controlled, calibrated (if necessary), and adjusted at specific times to maintain accuracy within necessary limits. This includes measuring and test equipment used for maintenance of safety related items. Inspection and test equipment will be tagged or labeled to indicate the date of the next planned calibration. All calibration test data shall be maintained with facility records or be readily traceable.

14. Handling, Storage, and Shipping (10 CFR 71.127)

Measures will be taken to control the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to prevent damage or deterioration. The following actions will be taken when handling or storing packages:

- a) If packaging requires special handling and lifting equipment it will be used to move packaging from one station to another.
- b) Special handling or storage provisions for packaging (e.g., shock absorbers, tags or markings to adequately protect and identify critical components) will be identified and used.
- c) Special protective environments (e.g., inert gas atmosphere, specific moisture content levels, and temperature levels) shall be specified and provided where required.
- d) All conditions identified in a certificate of compliance when unloading packaging will be adhered to.

When preparing a package for shipment the following applicable measures will be taken:

- a) Cavities within gas-cooled package containments have been adequately dried and cavities within liquid cooled packages have been drained to allow adequate void space.
- b) Specified operations, inspections, and testes have been completed prior to delivery to a carrier.
- c) NRC and DOT requirements have been satisfied prior to delivery to a carrier.
- d) Necessary shipping papers have been prepared as required.
- e) Departure and arrival times will be recorded, and, if required, transport of package will be under surveillance until delivered to the carrier.

15. Inspection, Test and Operating Status (10 CFR 71.129)

The status of inspections and tests performed on individual items of packaging will be indicated by the use of markings such as stamps, tags, labels, or other suitable means. These markings shall provide for the identification of items that have satisfactorily passed required inspections and tests, where necessary to preclude inadvertent by-passing of such inspections and tests. The operating status of components of the packaging will be identified (e.g., tagging valves and switches) to prevent inadvertent operation.

16. Control of Nonconforming Materials. Parts or Components (10 CFR 71.131)

Measures shall be established to control materials, parts, or components which do not conform to specified requirements in order to prevent their inadvertent use or installation. All materials, parts, or components for use by this facility which must be quality controlled will be inspected upon receipt by designated QA personnel. This inspection will include as a minimum:

- a) Proper identification
- b) Identification of any nonconformances
- c) Segregation of nonconforming items
- d) Disposition
- e) Evaluation

All nonconforming items will be placed in designated control hold areas until disposition is completed. Nonconforming items shall be reviewed and accepted, rejected, repaired or reworked in accordance with documented procedures. The acceptability of nonconforming items after designated repair or rework will be verified by QA personnel by re-inspecting or retesting the item against the original requirements. All information that is found out concerning a nonconforming item will be recorded and kept with QA records such that it can be analyzed by QA personnel to determine quality trends for appropriate management review and assessment.

17. Corrective Action (10 CFR 71.133)

Conditions that are adverse to quality, such as deficiencies, deviations, defective material and equipment nonconformances shall be promptly identified. These conditions shall be reported to the Radiation Safety Officer or other appropriate levels of management. In the case of a significant condition adverse to quality, the cause of the condition shall be determined and prompt corrective action taken to preclude repetition. The Radiation Safety Officer shall be responsible for obtaining corrective actions from suppliers. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented to verify that corrective actions were implemented and effective. Individuals or organizations responsible for closing out corrective actions and documenting their resolution shall be identified.

18. Quality Assurance Records (10 CFR 71.135)

Sufficient written records shall be maintained to furnish evidence of activities affecting quality. The records shall include the following:

- a) Design records
- b) Records of use and results of reviews
- c) Inspections
- d) Tests
- e) Audits
- f) Monitoring of work performance
- g) Material analysis
- h) Qualifications of personnel
- i) Maintenance
- j) Delivery of package to a carrier (including proof that applicable NRC and DOT requirements have been satisfied).

All shipments of radioactive material must be reviewed and approved by Health Physics personnel. Shipping records for radioactive material will be maintained in the Radiation Safety Office. Records of fuel shipments utilizing a leased cask shall be kept for at least three years from the date of the last shipment (as per 10 CFR 71.135). Records that are to be retained for the lifetime of the packaging should include appropriate design and production-related records, which are generated throughout manufacturing and furnished with packaging; records demonstrating evidence of operational capability and records verifying repair, rework, and replacement that are used as a baseline for maintenance. QA records shall be adequately stored to prevent loss or deterioration and marked so as to be readily identifiable and retrievable.

Inspection and test records shall include (as required):

- a) Identity of the inspector or data recorder
- b) Completion of DOT/49 QA Checklist for Fissile Radioactive Material Shipments
- c) Completion of Radioactive Material Shipment QA Checklist
- d) Acceptance criteria
- e) Results
- f) Actions taken in connection with any deficiencies noted

19. Audits (10 CFR 71.137)

Audits of each safety related activity shall be completed at least biennially to verify compliance with all aspects of the QA program for radioactive packaging covered under this program and to determine the effectiveness of the program. The audit shall be performed by qualified personnel not having direct responsibility in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited. Follow-up action, including re-audit of deficient areas, shall be taken where indicated.