UNITED STATES DEPARTMENT OF COMMERCE
National Institute of Standards and Technology
Gaithersburg, Maryland 20899-

March 6, 2007

U. S. Nuclear Regulatory Commission
Document Control Desk
Washington DC 20555

Subject: NIST Packing and Shipping Quality Assurance Program

Docket Number: 50-184

Gentlemen,
In response to the finding of the NRC Quality Assurance Visit, please find attached the revised NIST Packaging and Shipping Quality Assurance Program For 10CFR 71 Transport of Radioactive Materials.
Further questions concerning this program should be directed to Dr. Wade J. Richards at (301)-975-6260 or wade.richards@nist.gov.

Sincerely,
Wade J. Richards
Chief, Reactor Operations and Engineering

I certify under penalty of perjury that the following is true and correct.

Executed on 3/6/07 by: Wade J. Richards

cc.
Marvin Mendonca
Project Manager

NIST
Q004

NIST PACKAGING AND SHIPPING QUALITY ASSURANCE PROGRAM FOR 10 CFR 71 – TRANSPORT OF RADIOACTIVE MATERIALS

Revision 2

March 2007

RECORD OF REVISIONS
NIST PACKAGING AND SHIPPING QA PROGRAM FOR 10 CFR 71

REVISION	DATE	DESCRIPTION	ORGINATOR	REVIEWER	APPROVER
0	6/25/80	Initial Issue	T. G. Hobbs	N/A	L. Pevey
1	10/13/81	Insert (after 1st paragraph)	T. G. Hobbs	N/A	L. Pevey
2	3/2/2007	All pages; clarify requirements per 10 CFR 71, Subpart H	C. Drewry C. Drewry 3/7/07	T. Mengers 3/2/2007	W. Richards 3/16/07

NIST PACKAGING AND SHIPPING QUALITY ASSURANCE PROGRAM FOR 10 CFR 71 – TRANSPORT OF RADIOACTIVE MATERIALS

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Introduction

With this document, the National Institute of Standards and Technology (NIST) establishes a Shipping Quality Assurance (QA) Program in accordance with 10 CFR 71, Subpart H. It is designed to ensure the safety of the general public during packaging and transportation of radioactive material. Shipping containers regulated by 10 CFR 71 will be released for shipping from NIST only after they have satisfactorily met the requirements of the NIST Shipping QA Program. This QA Program applies to those activities affecting the packages and their components which are significant to safety. Quality assurance comprises those planned and systematic actions necessary to provide adequate confidence that a system or component will perform satisfactorily in service. The degree of control over a radioactive materials shipment is governed by the activity and form of the radioactive materials involved. Typically, the control categories are: "Exempt," "Type A," "Type B," and "Large Quantity." This program concerns shipments other than "Exempt" and provides criteria for the QA factors that shall be addressed for packages of radioactive material used for transport to or from NIST and/or the National Bureau of Standards Reactor (NBSR). The criteria specified herein are consistent with the categories of 10 CFR 50, Appendix B and ASME NQA-1-2004 "Basic Requirements and Practices."

1. Scope and Responsibilities (10 CFR 71.101)

The description of the NIST Shipping QA Program, contained within, includes a discussion of which requirements of 10 CFR 71, Subpart H are applicable and how they will be satisfied. The NIST Shipping QA Program establishes requirements applicable to the procurement, use, maintenance, modification, and repair of packaging used to transport licensed radioactive material (reference to 10 CFR 71.4 and Appendix A of 10 CFR 71). The program includes the purchase, handling, shipping, storing, cleaning, inspection, operation, maintenance, and repair of Type A and Type B (reference 10 CFR 71.4 and

Appendix A of 10 CFR 71) shipping containers subject to a Certificate of Compliance (COC) as regulated by 10 CFR 71. The Chief, Reactor Operations and Engineering of the NIST NBSR retains the overall authority and responsibility for the NIST Shipping QA Program and its effectiveness. Independent oversight of the NIST Shipping QA Program shall be performed by the Chief, Health Physics, or his designee, on a regular basis to assure that the program is adequate and meets regulatory requirements. Quality Assurance and Quality Control (QC) functions are typically performed by designated Health Physics staff members. These individuals have the authority and responsibility to stop any unsatisfactory work and control over further processing, delivery, or installation of nonconforming materials. All NIST personnel involved with the shipment of licensed radioactive material requiring packaging covered by a COC (e.g., receipt or shipment of nuclear fuel) shall follow this QA Program. Additionally, NIST possesses and maintains non-Type A shipping materials and packages, including Type B containers and fissile material packages. This QA Program shall require vendor-supplied documentation of quality related activities applicable to the inspection, purchase, use, maintenance, modification, and repair of packages used and provided by the vendor (or organization) for transportation of licensed material in excess of a Type A quantity to or from NIST facilities. Establishment of this QA Program deems that all quality related activities applicable to the inspection, purchase, use, maintenance and repair of packages are implemented with written procedures approved by appropriate levels of management and are contained in NIST Shipping QA files.

2. <u>Quality Assurance Program Organization</u> (10 CFR 71.103)

The NIST facility organization chart for the NBSR can be found in the NIST NBSR Technical Specifications, Figure 6.1. Responsibility for the NIST Shipping QA Program lies within the Chief, Reactor Operations and Engineering, or his designee, as QA Program Manager (QAPM). Any or all of the personnel on the NBSR of Health Physics staff may perform functions under this QA Program as designated by the QAPM. The Chief, Reactor Operations and Engineering will ensure that measures are established to provide adequate control over any designated quality-related activities. Health Physics staff members performing QA functions have the responsibility and authority to stop unsatisfactory work, the delivery or installation of nonconforming materials, and have direct access to the Chief, Reactor Operations and Engineering, or higher-level management that can ensure accomplishment of quality-related activities. The duties and qualifications required for the NIST QAPM and other principal personnel performing quality related functions will be established and documented in the QA files. Typically, the QAPM should have some experience in a field that includes oversight of radioactive material shipments. Retraining of personnel performing quality related work will be on a continuing basis as changes are implemented in QA procedures. Indoctrination and training will be included as part of an existing re-qualification program so that personnel performing quality-related activities important to safety are trained on a regular basis and qualified to perform these activities. Retraining shall be performed at least biennially.

A graded approach to quality assurance and procedures training will be applied at such time as when specific containers are acquired or contracted for a specific radioactive material shipment activity. The extent of applied safety considerations will be based on their importance to safety as determined by the specific radioactive material involved. For

instance, more restrictive considerations would apply for spent fuel or high-level waste than for plutonium standard reference material, which, depending on quantity, may require more restrictions than non-irradiated "new" fuel or radiography-type sources.

3. Package Design Control (10 CFR 71.107)

The NIST facilities involved with radioactive material shipments requiring NRC-approved COC packages will only be a user of radioactive material packaging, not a designer or fabricator of the packaging for the radioactive material. Thus, design, fabrication, assembly and testing activities for packages requiring an NRC-approved COC will not be performed by any NIST facility and the criterion of 10 CFR 71.107 would not be applicable. For all packaging requiring a COC used to transport radioactive material, NIST shall assure that the design of the packaging was accomplished under the control of a Nuclear Regulatory Commission (NRC) approved QA Program as required. For supplier-provided packages, the supplier of the radioactive material packaging will be required to submit documented proof (e.g. drawings, manuals, etc.) of package design under an NRC-approved QA plan as required. The documented proof, including the issued COC, or equivalent, for each package to be used will be kept on file at the appropriate NIST facility.

4. Procurement Document Control (10 CFR 71.109)

NIST, when procuring packaging requiring a COC, shall require the suppliers of radioactive material packaging to provide appropriate certifications verifying that the designated (model and serial number) packaging was manufactured under an NRC-approved QA Program as required. Other pertinent documentation (e.g., as-built drawings, photographs, sketches, use and maintenance manuals, identification of safety-related features or components, etc.) are to be furnished by the package supplier with the packaging to be used for transport of the radioactive material. The QAPM, or his designee, will determine all pertinent documentation required for the shipment. If any safety-related replacement parts are required to be procured for the packaging, the Chief, Reactor Operations and Engineering, or his designee, 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 that are or have been previously qualified to supply the parts or the package required. Procurement shall be made in consultation with the package owner. Procedures will be established to delineate the sequence of actions for preparation, review, approval, and control of procurement documents, including review and concurrence on the adequacy of quality requirements by the QAPM in order to ensure the safety of the shipment.

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

In the preparation of packaging for use to transport radioactive materials, the QAPM, or his designee, shall ascertain that the package with its contents satisfies the applicable requirements of 10 CFR 71 and those contained in the COC. The Chief, Reactor Operations and Engineering, or his designee, must approve placing the package "in-use" for transporting radioactive material from any NIST facility. The Chief, Reactor Operations and Engineering, or his designee, shall prescribe activities affecting quality by documented instructions or procedures of a type appropriate to the particular circumstance(s) and shall require that these instructions or procedures be followed. Any plans for maintenance or repairs will be reviewed by designated QA personnel to verify that the maintenance or repair plans emphasize those characteristics that are most important to safety; safety is, therefore, paramount. If a repair or

maintenance is required to be performed on packaging, a written procedure will be followed and coordinated with the package owner/supplier and Quality Assurance personnel to ensure that appropriate inspection and test points are incorporated in the procedure and that effective repairs have been satisfactorily performed. The QAPM will provide for QA review and concurrence regarding inspection plans; test calibration, and special process procedures; and drawings and specifications as necessary.

6. Document Control (10 CFR 71.113)

Each of the shipping and packaging documents under control of the Shipping QA Program will be identified and maintained in the QA files associated with the NBSR Engineering Manual in accordance with NBSR facility configuration management (CM). The shipping and packaging documents shall be reviewed annually by appropriate Reactor Operations and Engineering or Health Physics personnel not directly associated with a specific radioactive material shipment. Control shall be exercised over the following documents, including the changes thereunto, used in the procurement, use, maintenance, modification and repair of NRC-licensed shipping packages (including Type A and B):

1. Operating procedures
2. Maintenance procedures
3. Inspection procedures
4. Loading and unloading procedures
5. Packaging and transport procedures
6. Modification and repair procedures
7. Audits
8. Drawings, sketches, manuals, and specifications
9. Training records

Revisions to these documents shall be reviewed by the appropriate Health Physics personnel having direct responsibility for shipment of radioactive material and approved by the QAPM, or his designee. Controlled copies of approved procedures will be made available to persons responsible for using those documents. In accordance with CM, the QAPM will establish a master listing (or equivalent) that identifies the current revision level of instructions, procedures, specifications, drawings and procurement documents.

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

Designated QA personnel shall take the necessary measures to assure that purchased material, equipment, and/or services, whether purchased directly or through contractors and subcontractors, conform to the procurement requirements. Documentary evidence that the package conforms to the particular procurement specification(s) shall be supplied with the package. This documentary evidence shall be retained and shall be sufficient to identify the specific requirements met by the purchased material or equipment.

The QAPM shall establish measures to ensure the proper disposition of items or services that do not meet procurement requirements. The measures established shall include evaluation(s) of nonconforming items categorized by the supplier, along with a justified recommended disposition (e.g., "use as-is").

Appropriate documentation, as identified in the purchase order, shall accompany the NRC-approved packaging during transport and can be received at the destination by the user.

8. Identification and Control of Materials, Parts and Components (10 CFR 71.117)
Designated QA personnel shall ensure that materials, parts, and components used for repair or modification of packaging in excess of Type A are adequately identified and controlled to prevent use of incorrect or defective items. Where replacement of limited-life items is specified, measures will be taken to preclude the use of items whose shelf- life or operation times have expired. Also, the physical identity of the item shall be maintained.

9. 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, designated QA personnel shall ensure that controls are followed for special processes subject to the following criteria:
1. Procedures, equipment, and personnel are qualified in accordance with applicable codes, standards and specifications.
2. The operations are performed by qualified personnel and accomplished in accordance with written procedures with recorded evidence of verification.
3. Qualification records of procedures, equipment, and personnel are established, filed, and kept current.

No special process will be undertaken without consultation with the package owner and those processes will be performed in accordance with an NRC-approved QA plan with appropriate procedures established by the package owner.

10. Internal Inspections (10 CFR 71.121)
Visual inspections by designated QA personnel will be performed upon receipt of packaging to ensure compliance with procurement documentation and QA procedures. The criteria for acceptance of each of these inspections, and actions to be taken if noncompliance is encountered, will be determined in accordance with approved procedures. These visual inspections should include an inspection of the following:
1. Surface conditions.
2. Weld and structural integrity.
3. Condition of flange or sealing faces.
4. Gaskets and seals.
5. Gauges, rupture disks, valves, pressure relief devices.
6. Condition of tie-down members and impact limiters, if used.
7. Labeling, marking, and placarding.
8. Leak tightness of the packaging.

The inspection program should ensure adequate maintenance of packaging. The manufacturer/owner/supplier of the packaging should identify all safety-related items to be maintained, criteria for acceptability or replacement, and the frequencies of inspection assigned to each item during use of the package. Hold or witness points shall be identified in the use and inspection procedures. Additional tests and inspections may also be performed by designated QA personnel, including contractor personnel, as required in accordance with package-specific COC requirements. Prior to shipment, final inspections will be performed with a checklist to verify that all the following items are complied with:
1. Packages are properly assembled.
2. Valves are set to specifications.

3. Shipping papers are properly completed, including the Bill of Lading.
4. Packages are conspicuously and durably marked and labeled as required by DOT regulations.
5. Individual designated by the owner or user of the package has given authorization for shipment of the package.
6. Authorized individuals shall sign the shipping paperwork prior to release for shipment.

Inspection records shall be maintained as QA records to document performance of inspection activities.

11. Test Control (10 CFR 71.123)
Documentation of a test program shall be established or provided to ensure that all the required testing of packaging components will perform satisfactorily in service. These written procedures will incorporate the acceptance limits contained in the package approval, provisions for assuring that all prerequisites for a given test were met, that adequate test instrumentation was used, and that the test was performed under suitable environmental conditions. For vendor-supplied packaging, the test results shall be made available as appropriate. For modifications, repair, and replacements of a package, testing shall be documented by designated QA personnel and evaluated by the Chief, Reactor Operations and Engineering, or his designee, to ensure that acceptance test requirements have been satisfied prior to delivering packages for transport to a carrier. For those cases, tests may include the following considerations:
1. Structural integrity.
2. Leak tightness.
3. Component performance (e.g. valves, gaskets, fluid transport devices, etc.).
4. Shielding integrity.
5. Thermal integrity.

During the loading process, periodic maintenance test programs shall be established to ensure that packages remain usable and free of excessive radiation and contamination.

12. Control of Measuring and Test Equipment (10 CFR 71.125)
Designated QA Personnel shall ensure that all instruments, gauges, 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 to nationally recognized standards. If no known recognized standard exists (for calibration), the basis for calibration shall be documented. When measuring and test equipment are found to be out-of-calibration, measures will be taken to validate previous inspection and test results up to the time of previous calibration.

13. Handling, Storage and Shipping Control (10 CFR 71.127)
The handling, storage, and shipping of Type B packaging will be controlled to assure safety and minimize degradation, damage and/or loss. 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 performed when handling or storing packages of radioactive material for shipment:
1. If packaging requires special handling and lifting equipment (as identified in the COC), then such equipment will be used to move packaging from one station to another.
2. As required, special handling or storage provisions for packaging (e.g. impact limiters, tags or markings to adequately protect and identify critical components, etc.) will be used.
3. As required, special protective environments (e.g. inert gas atmosphere, specific moisture content levels, and temperature levels, etc.) shall be specified and provided.
4. All conditions identified in a COC will be adhered to when unloading packaging.

When preparing a package for shipment the following measures will be taken, as appropriate:
1. Cavities within gas-cooled package containments have been adequately dried and cavities within liquid cooled packages have been drained to allow adequate void space.
2. Specified operations, inspections, and tests have been completed prior to delivery to a carrier.
3. NRC (10 CFR 71) and DOT (49 CFR 173) requirements have been satisfied prior to delivery to a carrier. When necessary, departure and arrival times will be established and monitored to a degree consistent with safe transportation of the package.
4. Necessary shipping papers, including Bill of Ladings, have been prepared as required.

14. Inspection, Test and Operating Status (10 CFR 71.129)
Procedures will be established to control application and removal of inspection and welding stamps and status indicators. A tag, label, marking, log entry, or other documentation will indicate the inspection, test, or operating status of Type B shipping containers. The records will indicate when periodic surveillance tests have been performed and if any nonconforming, inoperative, or malfunctioning structures, systems, or components have been identified. No deviation from the required inspection, test or other critical operations is authorized without the review and approval of the QAPM, or his designee.

15. Nonconforming Materials, Parts or Components (10 CFR 71.131)
Designated QA personnel will ensure established measures are followed to control safety-related materials, parts, or components that do not conform to specified requirements in order to prevent their inadvertent use or installation. All safety-related materials, parts, or components for use by any NIST facility which must be quality controlled will be inspected upon receipt or prior to use by designated QA personnel. This inspection will include, as a minimum:
1. Proper identification of item and any nonconformance(s).
2. Segregation of nonconforming items.
3. Disposition.
4. Evaluation.

Procedures will be developed for the identification, documentation, segregation, disposition, and notification to affected organizations of nonconforming materials, parts, or services. Nonconforming items will be placed in designated control hold areas until proper disposition is completed. Nonconforming items shall be dispositioned as follows: 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 designated QA personnel by re-inspecting or retesting the item against the original

requirements. All information that is discovered concerning a nonconforming item will be recorded and kept with QA records such that it can be analyzed by designated QA personnel.

16. Corrective Action (10 CFR 71.133)

For activities important to safety concerning use, maintenance, modification, and repair of Type B packages, the Chief, Reactor Operations and Engineering, or his designee, shall ensure that conditions adverse to quality (e.g., those resulting from failures, malfunctions, deficiencies, deviations, and defective material and equipment, etc.) are promptly identified and reported to appropriate levels of management and, as necessary, the appropriate regulatory authorities. In the case of a significant condition adverse to quality, a 'root cause analysis' of the condition will be performed and corrective actions taken to preclude recurrence. Lessons learned shall be utilized.

17. Quality Assurance Records (10 CFR 71.135)

Sufficient identifiable and retrievable written records shall be maintained in the NIST Shipping QA files to furnish evidence of activities affecting quality. The records shall include the following:

1. Instructions, procedures, drawings, and specifications required by 10 CFR 71.111.
2. Design records, as appropriate, including results of reviews.
3. Inspections (and Tests), as appropriate.
4. Audits.
5. Material Analyses.
6. Procurement Documents.
7. Maintenance and repair(s) of packages.
8. Calibration procedures and reports.
9. Nonconformance reports.
10. Training (and retraining) records and certifications.

All shipments of licensed radioactive material shall be reviewed and approved by designated Health Physics personnel. Shipping records for licensed radioactive material requiring COC packaging will be kept on file by the NIST Health Physics Office. Records of licensed radioactive material shipments, including superseded records, utilizing a leased shipping container shall be kept for at least three years from the date of the last shipment. Records that are to be retained for the lifetime of the packaging should include:

1. Appropriate design and production-related records, which are generated throughout manufacturing and furnished with the packaging.
2. Records demonstrating evidence of operational capability of the packaging.
3. Records verifying repair, rework, modification, and replacement that are used as a baseline for maintenance.

18. Audits (10 CFR 71.137)

Audits of each safety related activity shall be completed at least annually 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 the Chief, Health Physics, or his designee, but not by staff having direct responsibility in the areas being audited. Audit results shall be documented and reviewed by the Chief, Reactor Operations and Engineering, or his designee. Follow-up or corrective action, including the re-audit of deficient areas, shall be taken as necessary.