



May 1, 2007

U.S. Nuclear Regulatory Commission
Attn: Document Control Desk
Washington DC20555-0001

Attn: Robert J Lewis
Chief Rules, Inspections, and Operations Branch
Licensing and Inspection Directorate
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety and Safeguards

Response to the NOV for the Shipping QA Program Docket # 71-0390

NIST accepts the findings of the NRC Inspection 71-0390/2007-201 conducted February 20-21, 2007 which state that:

NIST failed to establish maintain and execute a quality assurance program satisfying the applicable criteria of 10CFR part 71, subpart H.

It should be noted that the NRC Inspectors stated that this NOV did not have any safety consequences nor have there been any safety events associated with the use for the last fifteen (15) years of these shipping containers.

Corrective action has been taken to address each of the items listed below.

1. NIST Quality Assurance plan incorrectly stated that certain QA criteria of 10CFR part 71 were not applicable to the NIST program.

Response: The QA program cited was written in 1980. The authors did not expect that NIST would normally participate in design, testing, manufacture, or repair of shipping containers. Presently the NIST Center for Neutron Research (NCNR) is the User of the DOT (7A) approved shipping containers and does not hold the Certificate of Compliance (COC) for the shipping containers. The NIST User QA plan was approved by the NRC on March 29, 2007.

2. NIST did not establish adequate procedures to prescribe activities affecting the quality such as resolving non-conformances and ensuring appropriated corrective action.

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Response: As was noted by the inspectors the containers were stored and maintained in appropriate conditions and there was no indication of degradation of the packages that would impact safety of the material. The new NIST QA plan that has been approved by the NRC does address the item of concern.

3. NIST did not execute independent QA Audits, e.g., the QA Program Manager performed an audit of shipping activities while having responsibility for the shipping activities being audited.

Response: The new NRC approved NIST QA Program is being administered by a new QA Program Manager. The QA Program Manager is independent of the shipping organization activities and should provide the independent oversight needed for this function.

4. NIST did not execute a comprehensive system of audits to verify compliance with all aspects of the QA program and determine the effectiveness of the QA program.

Response: NIST has rewritten the QA program and assigned QA Program Manager responsibility to the NCNR Reactor Engineering section, which is independent from the operational groups involved with shipping responsibilities. This plan was reviewed and approved by the NRC on March 29, 2007. The new NRC approved NIST QA program and new program manager are dedicated to ensuring all NRC requirements will be met.

5. NIST failed to obtain NRC approval of its QA Program description for design and fabrication activities.

Response: Prior to 1989 the NIST used a commercially supplied seven (7) element shipping container. The COC for this container was discontinued in 1989. NIST then designed, manufactured, and tested the Type A fissile single element shipping containers (designated "ST") and applied for a COC to the NRC in 1992. It was NIST understanding through the approval process and the subsequent renewals of the COC that the NRC has endorsed this approach.

Presently, the NCNR has contracted with a licensed shipper to transport the fuel to the NCNR. The ST model packages used in the past have been decommissioned and are no longer used.

6. NIST could not find the design and fabrication procedures and records for the model ST package.

Response: The original fifteen year old documentation was found after the inspection, but, that documentation does exist does not meet today's requirements. A much improved configuration management system is in-place today and will ensure that documents are kept in an auditable state.

Commitments to Corrective Actions:

1. NIST has discontinued the use of the ST fresh fuel shipping containers.
2. NIST has contracted for services of fresh fuel shipping containers and verified that they have a DOT (7A) approved program for Quality Assurance that includes all the services provided.
3. NIST has rewritten the QA program and placed responsibility as the QA PM for all required shipments in the NCNR Reactor Engineering section, which is independent from the operational groups involved with shipping responsibilities. This plan was reviewed and approved by the NRC on March 29, 2007.
4. The new NIST QA program requires that the Health Physics staff perform a comprehensive independent audit of the QA program annually. Procedures are being drafted and will be completed in a timely manner.
5. NIST is reviewing, updating existing shipping related procedures and writing additional internal procedures necessary to implement the new QA program. These will be completed in a timely manner to assure all future shipments are handled appropriately.

For further information please contact Tim Mengers, Chief of Health Physics, NIST Building 245 Room C125, 100 Bureau Drive Gaithersburg, Maryland 20899, (301) 975- 5800, Fax (301) 975- 4893 or E-mail at Timothy.Mengers@NIST.GOV

Sincerely:



Timothy F. Mengers, CHP, PE,
Chief of Health Physics
(301) 975- 5800

cc:

Rosamond Rutledge-Burns, NIST

Patrick Gallagher, NIST

Wade Richards, NIST

Mathew Heyman, NIST

Gail Porter, NIST

Michael Rubin, NIST

Mary Adams, US NRC