

April, 2, 2007

Ms. Rosamond A. Rutledge-Burns
Chief, Safety, Health and Environment Division
U.S. Department of Commerce
National Institute of Standards and Technology
100 Bureau Drive, Stop 1731
Gaithersburg, MD 20899

SUBJECT: NRC INSPECTION REPORT NO. 71-0390/2007-201 AND NOTICE OF VIOLATION

Dear Ms. Rutledge-Burns:

This refers to the announced inspection conducted on February 20-21, 2007, at the National Institute of Standards and Technology (NIST) facility in Gaithersburg, MD. The inspection was conducted to determine if activities associated with the transportation of radioactive material were being performed in accordance with the requirements of 10 CFR Part 71, applicable certificates of compliance, and your NRC-approved quality assurance program. The team reviewed your management, design, fabrication, and maintenance activities. The enclosed report presents the results of this inspection.

Based on the results of this inspection, the NRC has determined that a Severity Level IV violation of NRC requirements occurred. The violation was evaluated in accordance with the NRC Enforcement Policy included on the NRC's Web site at www.nrc.gov; select **Public Meetings and Involvement**, then **Enforcement**, then from the left menu, select **Policy**.

The violation is cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding it are described in detail in the subject inspection report. The violation is being cited in the Notice because it was identified by the NRC. The issues observed in the selected areas reviewed by the inspection team were not isolated instances of noncompliance, but rather indicated a general failure to adequately implement and maintain a quality assurance program satisfying the applicable requirements of 10 CFR Part 71. The NRC considers that you should assess your future radioactive material transportation activities with respect to the requirements of 10 CFR Part 71. A quality assurance program satisfying each of the applicable criteria of 10 CFR Part 71 is necessary for compliant shipment activities.

You are required to respond to this letter and should follow the instructions specified in the enclosed Notice when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response, will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from

the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

Sincerely,

/RA/ by L. R. Wharton for

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

Docket No. 71-0390

Enclosures:

1. NRC Inspection Report No. 71-0390/2007-201
2. Notice of Violation

the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction.

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NAME:	FJacobs		MDeBose		GMorell		RLewis -LRW for					
DATE:	3/21/07		3/21/07		3/21/07		4/2/07					

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**U.S. NUCLEAR REGULATORY COMMISSION
Office of Nuclear Material Safety and Safeguards
Division of Spent Fuel Storage and Transportation**

Inspection Report

Docket: 71-0390

Report: 71-0390/2007-201

Certificate Holder: National Institute of Standards and Technology (NIST)
100 Bureau Drive
Gaithersburg, MD 20899

Inspection Dates: February 20-21, 2007

Inspection Team: Frank Jacobs, Team Leader, Division of Spent Fuel Storage and
Transportation (SFST)
James Pearson, Inspector, SFST
Nancy Osgood, Senior Project Manager, SFST
Jessica Glenny, Project Manager, SFST

Approved by: Robert J. Lewis, Chief
Rules, Inspections and Operations Branch
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety
and Safeguards

EXECUTIVE SUMMARY

National Institute of Standards and Technology
Nuclear Regulatory Commission (NRC) Inspection Report 71-0390/2007-201

From February 20 through February 21, 2007, the NRC conducted an announced inspection at the National Institute of Standards and Technology (NIST) facilities in Gaithersburg, MD. The purpose of the inspection was to determine if NIST's activities associated with the transportation of radioactive material were being performed in accordance with the requirements of 10 CFR Part 71, applicable certificates of compliance, and NIST's NRC-approved quality assurance program. The team reviewed selected management, design, fabrication, and maintenance controls. The results of the inspection are summarized below and in Table 1.

This inspection did not identify any immediate safety concerns. However, a sampling of activities indicated significant compliance issues with respect to the requirements of 10 CFR Part 71:

- The NIST Quality Assurance (QA) Plan stated certain QA criteria of 10 CFR Part 71 were not applicable to the program, which was not consistent with the activities being performed.
- NIST did not adequately prescribe activities affecting quality, such as resolving nonconformances and ensuring appropriate corrective action, using documented procedures.
- A lack of independence of the QA function was identified while reviewing audit records which indicated the QA Program Manager performed an audit of shipping activities while having responsibility for the shipping activities being audited.
- NIST did not carry out a comprehensive system of audits to verify compliance with all aspects of the quality assurance program and determine the effectiveness of the quality assurance program.
- The NIST QA program description was not approved by NRC for design or fabrication activities, although such approval is required for a certificate holder.
- Design and fabrication procedures and records were not available for the Model No. ST package.

The issues observed in the selected areas reviewed by the inspection team were not isolated instances of noncompliance, but rather indicated a general failure to adequately implement and maintain a quality assurance program satisfying the applicable requirements of 10 CFR Part 71. A violation of subpart H of 10 CFR Part 71 was identified for failure to implement and maintain a quality assurance program satisfying the applicable requirements of 10 CFR Part 71.

Table 1
Summary of Inspection Findings

Regulatory Requirement 10 CFR Section	Subject of Violation or Noncompliance	Number of Findings	Type of Finding	Report Section
71.101(b)	Establishment of program	1	Violation	3.9

INSPECTION PROCEDURES USED

IP 86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packagings"
NUREG/CR 6314, "Quality Assurance Inspections for Shipping and Storage Containers"

LIST OF ACRONYMS USED

BWXT BWX Technologies, Inc.
CFR Code of Federal Regulations
CoC Certificate of Compliance
NBS National Bureau of Standards
NIST National Institute of Standards and Technology
NRC U.S. Nuclear Regulatory Commission
QA Quality Assurance
QAPM Quality Assurance Program Manager
SFST Division of Spent Fuel Storage and Transportation

PERSONS CONTACTED

The team held an entrance meeting on February 20, 2007, to present the scope and objectives of the NRC inspection. On February 21, 2007, the team held an exit meeting to present the preliminary results of the inspection. The individuals present at the entrance and exit meetings are listed below in Table 2.

Table 2
Entrance and Exit Meetings Attendance

NAME	AFFILIATION	ENTRANCE	EXIT
Frank Jacobs	NRC	X	X
James Pearson	NRC	X	
Nancy Osgood	NRC	X	
Jessica Glenny	NRC	X	
Robert Lewis	NRC		X
David Brown	NIST	X	X
Jim Tracy	NIST	X	X
Janna Shupe	NIST	X	X
Wade Richards	NIST		X
Tim Mengers	NIST		X

REPORT DETAILS

1. Inspection Purpose

The purpose of the inspection was to determine if transportation activities were being performed in accordance with the requirements of 10 CFR Part 71, applicable certificates of compliance, and the NRC-approved quality assurance (QA) program.

2. Background

NIST ships Type B quantities of radioactive material and is a registered user in accordance with 10 CFR 71.17 for six Type B transportation packages. NIST's QA program was approved June 12, 1980, for user-only activities, and has been renewed by NRC every five years for user-only activities.

NIST holds Certificate of Compliance (CoC) No. 9246, Revision No. 5, for the Model No. ST package (USA/9246/AF), currently used by BWX Technologies, Inc. (BWXT) for shipping fresh fuel to NIST. NIST submitted its application to NRC for approval of package Model No. ST on February 7, 1992, and CoC No. 9246, Revision No. 0, was issued on February 26, 1992. On August 7, 1996, NIST requested a change in the description of the package that affected the internal device that positions the fuel element, and Revision No. 2 was issued by NRC October 1, 1996. Since 1992, two other revisions were initiated by NRC for consistency with new standards for fissile material transport packages and to include minor administrative changes, and two more revisions were issued for routine renewal of the certificate. Prior to this inspection, NIST had never been inspected for 10 CFR Part 71 certificate holder activities.

Recently, NRC staff identified that NIST did not have NRC approval for a broad-scope quality assurance program satisfying all the requirements of 10 CFR Part 71 applicable to a certificate holder.

3. Inspection Details

The team reviewed selected procedures; examined documents, records, and drawings; and interviewed personnel.

3.1 Quality Assurance Program

The inspector reviewed NIST's QA Plan, "Quality Assurance Program for 10CFR71, Appendix E Requirements for Procurement, Maintenance, Repair, and Use of Transportation Packages for Radioactive Materials." The approval date on the copy reviewed was 6/25/80. The document included a revision sheet that indicated a Revision No. 1 was issued on 10/13/81. The revision provided a change in the review of purchase documents for QA specification containers. This change had not been submitted to NRC for approval prior to implementation, and had not been made known to NRC in subsequent requests for renewal of the QA program approval. Implementation of changes to the approved QA program prior to NRC approval of the changes is not permitted by 10 CFR Part 71.

The QA Plan was not being maintained current. The QA Plan refers to Appendix E of 10 CFR Part 71, which has changed to Subpart H, and contains the name National Bureau of Standards (NBS), which has changed to NIST.

The QA Plan, as indicated in the title and the introduction of the document, applies to the use of containers for the shipment of radioactive material. The document stated NBS (now NIST) will not normally engage in container design activities and that portions of the plan relating to design provide a contingency to be implemented at the time design functions are necessary. The document further stated that procedures will be established at the time design services are required to carry out design activities in a planned, controlled, and orderly manner. NBS's QA program was submitted to NRC for approval on May 30, 1980, and was approved June 12, 1980, for specified user-only activities. Quality Assurance Program Approval No. 0390, Revision No. 0, states that the shipping activities authorized by the approval are procurement, maintenance, repair, and use. It further states, "All other shipping activities (i.e., design, fabrication, assembly, testing, and modification) shall be satisfied by obtaining certifications from package suppliers that these activities were conducted in accordance with an NRC-approved QA program." NIST has not indicated, or requested approval of, any changes to the QA program since the initial approval. The approval for user-only activities has been renewed by NRC every five years, but had not been subject to a previous NMSS inspection.

The QA Plan stated that certain QA criteria of 10 CFR Part 71 were not applicable to the program, including control of purchased material, equipment, or services; identification and control of materials, parts, and components; and test control conditions. This is not consistent with other parts of the QA Plan which address procurement and other user activities. The QA Plan also stated "no corrective actions are required in this program," and did not address measures to assure conditions adverse to quality, such as deficiencies, deviations, defective material and equipment, and nonconformances, are promptly identified and corrected, and did not address appropriate actions for significant conditions adverse to quality.

3.2 Procedures

In the various areas reviewed by the inspectors, NIST staff stated that written and controlled procedures did not exist, with one exception. The inspector was provided HPI 4-12, "QA for Type B and NRC Approved Packages," dated 5/96. The scope of the procedure was receipt and shipment of Type B, NRC-approved, and fissile material packages. The procedure did not

appear to be current in that all six expiration dates of authorized packages listed in the procedure had passed, and the three container checklists in the procedure did not include the receipt inspection sheet reviewed by an inspector for the most recent container receipt.

In the area of procedures, NIST did not adequately prescribe activities affecting quality by documented procedures appropriate to the circumstances and require that these procedures be followed.

3.3 Audit Program

The QA program description states that audits of the QA program will be performed at least annually by trained personnel not having direct responsibilities in the area being audited. The inspector requested to review the last two annual audits of the QA program. The QA Program Manager (QAPM) referred to the audit as “the Type B QA program audit.” The documentation provided to the inspector consisted of two single-sheet forms titled “QA 4.11 - Audits,” one signed 1/24/06 and one signed 1/31/07, which appeared to serve as the audit plans. The form QA 4.11 stated that a copy of the audit report will be submitted to the Chief, Occupational Health and Safety Division. There were no obvious audit reports and no other documentation that indicated the depth of the audit, objective evidence of the areas reviewed, and the findings and results of the audits. The Health Physicist in the QAPM position performed one of the audits and acknowledged she was in charge of shipping activities that she audited. The QAPM stated there was no written procedure governing the conduct of audits.

In the area of audits, NIST did not carry out a comprehensive system of audits to verify compliance with all aspects of the QA program and to determine the effectiveness of the program. The QAPM performed an annual audit and was responsible for the area being audited.

3.4 Corrective Action

The inspector interviewed a Health Physicist that performed shipping and receiving activities regarding documentation and correction of nonconformances. The Health Physicist indicated that a discrepancy would probably be documented on the inspection checklist, but NIST did not have a controlled procedure or formal process for resolving nonconformances and ensuring appropriate corrective action.

3.5 Design Control

The inspector interviewed NIST staff regarding the design development of the Model No. ST package. The design work and package testing was performed by NIST personnel. The inspector requested design and testing procedures, records, and drawings associated with the Model No. ST package. NIST was unable to provide design procedures or records of the design process. The drawings provided were the same drawings submitted to NRC in the application for package approval and the subsequent revision. No fabrication or more detailed drawings were available, and there were no material specification details other than provided on the drawings. There was no approved test procedure available.

Although the QA Plan contained a design “contingency” to be implemented at the time design functions became necessary, there is no evidence that those requirements were implemented for the design of the Model No. ST package. The QA Plan stated specifically that test control conditions were not applicable to the program. Further, the QA Plan was not approved by NRC for design activities.

3.6 Fabrication Control

The inspector interviewed NIST staff regarding the fabrication of the Model No. ST packagings. The fabrication was performed by NIST personnel. The inspector requested fabrication procedures, records, and drawings associated with the Model No. ST packagings. NIST was unable to provide fabrication procedures, records, or drawings other than the application drawings. There were no material specification details other than those provided on the application drawings, and no material procurement, inspection, or certification records. The QA Plan stated that control of purchased material, equipment, or services was not applicable to the program. NIST was unable to provide evidence that the requirements of the QA Plan were implemented for the fabrication of the Model No. ST packagings. While the applicability of the Part 71 QA criteria to fabrication activities would be dependent on an assessment of the importance to safety of the packaging system, structures, and components, there is no documentation that such an assessment was performed in the design process. Further, the QA Plan was not approved by NRC for fabrication activities.

3.7 Package Operations

NIST does not act as shipper for the Model No. ST packages. BWXT is the shipper of the fresh fuel, which NIST receives. NIST does act as shipper for other NRC-approved packages. The Model No. ST package application includes a document regarding the procedures to be used to receive and unload the package. The document is entitled "NIST ST Series Shipping Container - Loading, Unloading and Quality Assurance Procedure." The inspector reviewed the most recent completed receipt inspection sheet. The inspection sheet was entitled "HP Surveys and Inspections - Incoming Unirradiated Fuel Elements," and was dated February 15, 2007. The form was appropriately filled out, and included signatures where needed. The form appeared to include all the appropriate elements specified in the package application, as referenced in the CoC (Condition No. 6). Despite the above-mentioned issues with the QA program, the limited package operations reviewed by the inspector appeared to be safe.

3.8 Packagings

The inspector observed two packagings, S/N 1 and S/N 2, fabricated to the Model No. ST design (CoC No. 9246). The packagings are stored inside the Center for Neutron Research, Building No. 235, in the basement. The building is access controlled (via manned security desk). The packagings were stored in a locked cage area. The key to the cage area was controlled (limited staff had the key). The packagings were stored on a gurney that is used to move the packages in both the NIST facility as well as the BWXT facility. The licensee explained that during transport the gurney is tied down within the truck. The packages are positioned within steel cradles that are bolted to the top of the gurney. A strap is used to tie the packagings down to the gurney.

The packagings appeared to be in very good condition. The packagings were painted inside and out, and the paint was in fairly good condition. The fasteners were all present and in good condition. For one packaging, all socket head screws were removed and they threaded and unthreaded freely from the package flange. A black gasket was present and appeared in good condition. The packaging drawing specifies neoprene as the gasket material. The gasket material was not confirmed. The inspector examined two wood nozzle support pieces from one packaging. The wood pieces looked to be in good condition with no rotting, discoloration, softness, or other obvious damage. The nozzle support pieces had been cracked but were repaired with a clear glue.

The inspector took several “gross” measurements of the packaging component dimensions, and compared them to the drawing referenced in the Certificate of Compliance (NIST Drawing No. D-04-048, Sheets 1 and 2, Rev. 3). In general it appeared that the packaging dimensions were in accordance with the drawings. For the wood pieces, the following were noted: The nozzle support length was 4-3/8 inches per the drawing, but measured closer to 4-1/2 inches. The top support diameter was 5-1/16 inches per the drawing, but measured closer to 5 inches.

As the certificate holder, NIST may want to consider: (1) Revising the drawing to include appropriate tolerances. No tolerances are shown on the drawing, and some dimensions are given to the 64th of an inch. Such precision is not needed for this design, and may cause non-compliance due to wear of the wooden components, or addition of coats of paint. (2) Reviewing the as-built packagings and revising the drawing to reflect the actual physical features. For example, the drawing does not specify that the packaging is painted. The optional use of paint or coatings should be indicated on the drawing. The top and bottom square flanges have holes that are filled with weld material. These present a physical feature that is not indicated in the drawing. The optional presence of these filled holes should be shown. The drawings and packagings should be carefully reviewed to assure that other potential discrepancies are identified. Optional configurations that do not affect safety may be included on the drawing.

3.9 Conclusions

This inspection did not identify any immediate safety concerns. However, in a sampling of selected activities, significant and extensive compliance issues with respect to the requirements of 10 CFR Part 71 were observed by the inspection team:

- The NIST Quality Assurance (QA) Plan stated certain QA criteria of 10 CFR Part 71 were not applicable to the program, which was not consistent with the activities being performed.
- NIST did not adequately use documented procedures to prescribe activities affecting quality, such as resolving nonconformances and ensuring appropriate corrective action.
- A lack of independence of the QA function was identified while reviewing audit records which indicated the QA Program Manager performed an audit of shipping activities while having responsibility for the shipping activities being audited.
- NIST did not carry out a comprehensive system of audits to verify compliance with all aspects of the quality assurance program and determine the effectiveness of the quality assurance program.
- The NIST QA program description was not approved by NRC for design or fabrication activities, although such approval is required for a certificate holder.
- Design and fabrication procedures and records were not available for the Model No. ST package.

The issues observed in the selected areas reviewed by the inspection team were not isolated instances of noncompliance, but rather indicated a general failure to adequately implement and maintain a quality assurance program satisfying the applicable requirements of 10 CFR Part 71.

10 CFR 71.101(b), "Establishment of program," requires, in part, that each licensee, certificate holder, and applicant for a CoC shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of subpart H.

NIST's failure to implement and maintain a quality assurance program satisfying the applicable criteria of subpart H of 10 CFR Part 71 is a violation of NRC requirements.

4. Exit Meeting

An exit meeting was conducted by the inspection team on February 21, 2007. The team's preliminary findings and assessments were presented at the meeting. NIST personnel at the meeting acknowledged the team's findings and did not state any disagreement with the preliminary findings and their characterization.

NOTICE OF VIOLATION

National Institute of Standards and Technology
Gaithersburg, MD

Docket No. 71-0390

During an NRC inspection conducted on February 20-21, 2007, violations of NRC requirements were identified. In accordance with the NRC Enforcement Policy, the violations are listed below:

10 CFR 71.101(b), "Establishment of program," requires, in part, that each licensee, certificate holder, and applicant for a CoC shall establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of Subpart H, "Quality Assurance."

Contrary to the above, the National Institute of Standards and Technology (NIST) failed to establish, maintain, and execute a quality assurance program satisfying the applicable criteria of Subpart H of 10 CFR Part 71, as demonstrated by the following examples:

1. The NIST Quality Assurance (QA) Plan incorrectly stated that certain QA criteria of 10 CFR Part 71 were not applicable to the NIST program.
2. NIST did not establish adequate procedures to prescribe activities affecting quality, such as resolving nonconformances and ensuring appropriate corrective action.
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.
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.
5. NIST failed to obtain NRC approval of its QA program description for design and fabrication activities.
6. NIST could not find design and fabrication procedures and records for the Model No. ST package.

This is a Severity Level IV violation (Supplement V).

Pursuant to the provisions of 10 CFR 2.201, NIST is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to 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 within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violation" and should include: (1) the reason for the violation, or if contested, the basis for disputing the violation or severity level, (2) the corrective steps that have been taken and the results achieved, (3) the corrective steps that will be taken to avoid further violations, and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. If an adequate reply is not received within the time specified

in this Notice, an order or a Demand for Information may be issued as to why the license should not be modified, suspended, or revoked, or why such other action as may be proper should not be taken. Where good cause is shown, consideration will be given to extending the response time.

If you contest this enforcement action, you should also provide a copy of your response, with the basis for your denial, to the Director, Office of Enforcement, United States Nuclear Regulatory Commission, Washington, DC 20555-0001.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>, to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

In accordance with 10 CFR 19.11, you may be required to post the Notice within two working days.

Dated this 2nd day of April 2007.