

71-0249



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Spent Fuel Project Office, NMSS  
U. S. Nuclear Regulatory Commission  
Washington, DC 20555-0001

June 30, 2005

Attention: Robert Lewis, Section Chief, MS 013 D13  
Transportation and Storage Safety and Inspection Section

Reference: Docket No. 71-0249, Quality Assurance Program for Shipping Packages  
for Radioactive Material

Dear Mr. Lewis:

Nuclear Fuel Services, Inc. (NFS) requests renewal of the attached Quality Assurance Program for Shipping Packages for Radioactive Material (Revision 10). The Plan has been revised to reflect the recent transfer of responsibility for the Quality Assurance of Shipping Packages for Radioactive Material from the Safety Department to the Quality Assurance Department. The Organization Chart, Figure 1, has been updated to reflect this change. Changes are shown by a line in the margin.

If you or your staff have any questions, require additional information, or wish to discuss this, please contact me or Ms. Marcy Shope, Quality Assurance Manager, at 423-743-9141, extension 1059. Please reference our unique document identification number (56G-05-0005) in any correspondence concerning this letter.

Sincerely,

**NUCLEAR FUEL SERVICES, INC.**

B. Marie Moore  
Vice President  
Safety and Regulatory

Attachment

BMM/MWS/mag

cc: Daniel Rich – Sr. Resident NRC Inspector

Regional Administrator  
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NMSS01

**ATTACHMENT**

**NUCLEAR FUEL SERVICES, INC.  
ERWIN, TENNESSEE**

**QUALITY ASSURANCE PROGRAM  
FOR SHIPPING PACKAGES  
FOR RADIOACTIVE MATERIAL**

**REVISION 10**

**June 30, 2005**

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**QUALITY ASSURANCE PROGRAM FOR SHIPPING  
PACKAGES FOR RADIOACTIVE MATERIAL**

**Purpose and Scope**

The purpose of this document is to describe the Nuclear Fuel Services, Inc. (NFS) Quality Assurance Program applicable to the design, fabrication, assembly, testing, procurement, use, maintenance, and repair of packaging used in the transport of radioactive material. The requirements for this document are contained in Title 10, Code of Federal Regulations, Part 71, Subpart H. This Quality Assurance Program was developed in accordance with Regulatory Guide 7.10, *Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material*, dated March 2005.

This program applies to radioactive material shipping packages used for fissile and Type B quantities of radioactive materials. It does not apply to DOT specification packages procured only to assure a quality package or to transport a Type A quantity, or less, of radioactive materials not classed as Fissile. Type A and Type B quantities of material are defined in 10 CFR 71.4. Fissile material is defined in 10 CFR 71.4 and Fissile Excepted material is defined in 10 CFR 71.53.

This quality assurance program for shipping packages for radioactive material is referred to in the remainder of this document as the "Transportation QA Program".

**1.0 Organization**

The Quality Assurance function has primary responsibility for ensuring the implementation of the Transportation QA Program is compliant with regulations. This function enforces the policies set forth in this document, and reports at a management level that will permit the freedom of action to do so. Figure 1 shows the functional organization as it pertains to this program.

The Quality Assurance function is responsible for:

- Ensuring that the Transportation QA Program is carried out in accordance with this document, and
- Reviewing the status and adequacy of the Transportation QA Program through planned audits.

As shown in Figure 1, the Quality Assurance function does not have direct responsibility for performing the work and is organizationally separate from groups having responsibilities in the Transportation QA Program.

The Quality Assurance function has the responsibility and authority to stop

unsatisfactory work, stop delivery or installation of non-conforming material, and/or has direct access to management levels that can ensure that procedures important to safety and quality have been effectively implemented. The NFS Quality Assurance function is responsible for determining that vendors who manufacture packages used in the transportation of radioactive material are qualified and for initiating audits of quality assurance programs both internally and externally. They are also responsible for the submittal of the various documents and requests to keep the Transportation QA Program up-to-date.

The Transportation and Waste Management (T&WM) function has primary responsibility for implementation of the Transportation QA Program, and is responsible for scheduling shipments, maintaining programs to assure the contents of packages conform to the requirements of regulations or applicable certificates of compliance, and preparing the Bills of Lading. The T&WM function is also responsible for the physical movement of both empty and loaded packages, and for placing these packages on vehicles for transport.

The Decommissioning, Blended Low Enriched Uranium & High Enriched Uranium (BLEU & HEU) Projects, and Fuel Manufacturing functions are the most frequent users of shipping packages. The users are responsible for verifying the contents and proper use of inner containers. This verification is usually achieved by adhering to written procedures or other documents which have been appropriately approved. They may also rely on material analysis results provided by the Analytical Services function.

The BLEU & HEU Projects are conducted by both NFS and Framatome ANP, Inc. Framatome ANP, Inc. operates the portion of the process in which low enrichment uranyl nitrate is converted to an oxide powder. NFS performs the enrichment down-blending portion of the process and holds the NRC license under which all of these activities are conducted.

The Engineering function provides engineering support by reviewing vendor's calculations and specifications of package designs.

The Purchasing function is responsible for the procurement of complete packages, repair parts, consumable materials used in these packages, and vendor repairs in accordance with specifications provided by the requisitioner. Such requisitions are reviewed and approved by the Quality Assurance and T&WM functions for compliance and conformance before a purchase order is developed.

The New & Offsite Projects function may rent or lease NFS-owned packagings to other organizations for their use. This function is responsible for the repair and maintenance of these packages and for instructing non-NFS users in the proper use of the packages.

Personnel responsible for performing activities which can affect safety and quality of shipping packages are trained in accordance with established training procedures. The training procedures require the instruction of personnel on the Standard Operating Procedures (SOP) for these packages.

## **2.0 Quality Assurance Program**

The purpose of the Transportation QA Program is to outline a framework of controls for safety-related program activities associated with the design, fabrication, assembly, testing, procurement, use, maintenance, and repair of packages used under NRC approval for the shipment of radioactive materials. These activities are detailed in implementing procedures to ensure that appropriate controls are effectual. Personnel performing work affecting quality and/or safety of radioactive materials packages shall maintain strict compliance with the requirements of this program and the implementing documents.

The program is compatible with, and emphasizes requirements identified in, the package Certificate of Compliance. These requirements are also reflected in the applicable procedures for using these packages.

The individual assigned the primary responsibility as the Quality Assurance Manager is responsible for:

- Meeting the requirements for that position of having a Bachelor of Science degree and at least five years experience;
- Approving requisitions for procurement, repair and maintenance of shipping containers;
- Ensuring proper documentation that program requirements are being met; and
- Reporting the results of the Transportation QA Program audits to senior and appropriate management.

The individual assigned the primary responsibility for the Transportation and Waste Management function is responsible for:

- Ensuring that proper indoctrination and training of personnel performing activities affecting quality is achieved and maintained;
- Identifying the material and components to be covered by the program;
- Ensuring that applicable regulatory requirements are correctly translated into written procedures and instructions

- Ensuring the implementation of the Transportation Quality Assurance Program in written procedures or instructions;
- Implementing the program approved for each licensed package;
- Ensuring proper identification of containers;
- Initiating requisitions for procurement, repair and maintenance of shipping containers;
- Reviewing and approving shipping documents, procedures, and other authorizations; and
- Maintaining the records of package approvals and other official documents associated with the shipment of radioactive material.

The individual assigned primary responsibility for the Framatome ANP, Inc. function is responsible for:

- Ensuring that proper indoctrination and training of personnel performing activities affecting quality is achieved and maintained;
- Identifying the material and components to be covered by the program;
- Ensuring that applicable regulatory requirements are correctly translated into written procedures and instructions
- Ensuring the implementation of the Transportation Quality Assurance Program in written procedures or instructions;
- Implementing the program approved for each licensed package;
- Ensuring proper identification of containers;
- Initiating requisitions for procurement, repair and maintenance of shipping containers in accordance with the NRC approved Framatome ANP, Inc. Quality Assurance program;
- Reviewing and approving shipping documents, procedures, and other authorizations; and
- Maintaining the records of package approvals and other official documents associated with the shipment of radioactive material in accordance with the Framatome ANP, Inc, NRC approved Quality Assurance program .

### **3.0 Design Control**

Shipping packages are fabricated only in accordance with designs previously certified by the NRC or as specified by DOT regulations. The T&WM function is responsible for maintaining current files of packages certified by the NRC, the Certificates of Competent Authority issued by the DOT, and maintaining an up-to-date copy of the DOT regulations which contain the specifications of packages utilized by NFS. Modifications to packages are performed only in accordance with changes issued by the NRC and/or DOT.

Contractors and sub-contractors employed to fabricate a shipping package are required to submit a copy of their quality assurance program to NFS for review by the Quality Assurance function. NFS Quality Assurance will determine if their program is satisfactory and whether a vendor audit is needed to qualify for use under this Transportation QA Program.

The following are design control requirements:

- a. Quality standards are specified in the design documents, and deviations and changes from these quality standards are controlled.
- b. Designs are reviewed to assure that: (1) design characteristics can be controlled, inspected, and tested; and (2) inspection and test criteria are identified.
- c. Proper selection and accomplishment of design verification or checking processes, such as by design reviews, alternate calculations, or qualification testing are performed. When a test program is used to verify the adequacy of a design, a qualification test of a prototype unit under design conditions will be used.
- d. Individuals or groups responsible for design verification are other than the original designer and designer's immediate supervisor.
- e. Design and specification changes are subject to the same design controls and approvals that were applicable to the original design, unless NFS designates another qualified responsible organization.

### **4.0 Procurement Document Control**

Shipping container procurement documentation must:

- Require the manufacturers to supply appropriate verification that the packaging was manufactured in accordance with the applicable requirements of 10CFR71 Subpart H, including flowdown to sub-tier

vendors;

- Designate other pertinent documentation to be furnished with the packaging, such as certificate of compliance, as-built drawings, material and component identification requirements, photographs, sketches, identify the type of verification activities required during use and maintenance, use and maintenance manuals, as appropriate;
- Include directions for the reporting and dispositioning of nonconformances; and
- Contain the statement: "The provisions of 10CFR21 apply" (or similar statement of applicability).

Procurement of replacement parts and services important to safety are reviewed by the individual(s) assigned responsibility for the Transportation QA Program. The purpose of this review is to ensure that:

- Appropriate technical and quality assurance requirements are included in purchase orders;
- The purchase orders are placed with approved vendors; and,
- Replacement parts and services meet requirements at least as stringent as the original criteria.

## **5.0 Instructions, Procedures, and Drawings**

Procedures, or SOPs, for placing packages in use are required to be in place before use of the particular package. These documents are approved by the user and/or the T&WM function as a minimum.

Approval of plans for necessary repair or rework of packages is required prior to beginning the work. These plans may be in the form of a procedure, or other authorization, which emphasizes those characteristics that are important to safety. This document must be approved by the using group and/or the T&WM function, as a minimum.

Procedures are established to ensure that loading and unloading radioactive material packages are controlled. These documents specify the requirements identified in the regulations, the applicable Certificate of Compliance, and/or use documents.

Procedures require the inspection of packages before loading, after loading, and after placement on the transporting vehicle to ensure that packages are in good condition, adequately secured within, or on, the transporting vehicle, properly

sealed, marked in accordance with regulatory requirements, and identified by model and license registration numbers. These procedures must be approved by the using group and/or the T&WM function, as a minimum.

## **6.0 Document Control**

Procedures and instructions which implement this program are available in the work area.

Obsolete or superseded documents are controlled or destroyed to prevent inadvertent use. The initiator is responsible for having the revised documents distributed. Outdated documents are removed from use.

Documents controlled include as a minimum:

- Purchase Orders;
- Operating, maintenance and repair procedures or SOPs;
- Inspection and test procedures or SOPs; and,
- Packaging for transport, loading, and unloading procedures or SOPs.

Revised procedures and SOPs are approved by the using and/or the Transportation and Waste Management function, as a minimum.

## **7.0 Control of Purchased Material, Equipment, and Services**

Prior to the use of purchased material, equipment, or services, a receipt inspection will be conducted to ensure conformance with the purchase requisitions. Receipt inspections will be documented and signed by the inspector.

Qualified personnel evaluate the supplier's capability to provide acceptable quality services and products before the award of the purchase order or contract. Prior to award of a contract, NFS will evaluate the capability of a supplier to provide items or services in accordance with the requirements included in the applicable procurement documents. NFS Quality Assurance will evaluate a supplier's capability to comply with the elements of 10 CFR Part 71, Subpart H that are applicable to the type of material, equipment, or service being procured based on one or more of the following criteria:

- ISO accreditation or equivalent board certification.
- evaluation of third-party audit reports (dated within past two years) of the vendor, including the vendor's corrective actions when applicable.

- evaluation of the vendor's current quality records, supported by documented qualitative and/or quantitative information that can be objectively evaluated.
- direct evaluation or audit of the vendor's quality program and technical capabilities.
- evaluation of the vendor's history of providing an identical or similar product which performs satisfactorily in actual use, and remains within the vendor's current capability.

Suppliers who successfully pass this evaluation are placed on the NFS Approved Vendor List. The Supplier Evaluation form will note the elements of 10CFR71 Subpart H the vendor is qualified to perform. Results of supplier evaluations are documented and retained.

Surveillance of suppliers during fabrication, inspection, testing, and shipment of materials, equipment, and components may be required. If so, the following provisions are implemented:

- 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.
- Surveillance is performed on those items where verification of procurement requirements cannot be determined upon receipt.

The supplier furnishes the following records as a minimum to NFS:

- 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 which have not been met together with a description of those non-conformances dispositioned "accept as is" or "repair".

The receiving inspection of the supplier furnished material, equipment, and services are performed to assure:

- The material, component, or equipment is properly identified and corresponds with the identification on receiving documentation.
- Inspection records or certificates of conformance attesting to the acceptance

of material, components, and equipment are available at NFS prior to installation or use.

- Items accepted and released are identified as to their inspection status prior to forwarding them to a controlled storage area or releasing them for installation or further work.

The effectiveness of the control of quality by suppliers is assessed by NFS at intervals consistent with the importance, complexity, quantity, and/or quality history of the item.

Framatome ANP, Inc has the responsibility, in accordance with the NRC approved Fuel Sector Quality Management Manual, for the procurement of shipping containers, spare parts, or maintenance services for BLEU Project shipping containers. Receipt inspection and control of containers and parts shall be in accordance with the requirements provided above.

## **8.0 Identification and Control of Materials, Parts, and Components**

Procedures implementing the quality assurance program require that materials, parts, and components used for repair or rework for maintenance purposes are adequately identified to preclude the use of incorrect or defective items. Also, where the replacement of limited-life items is required, these procedures are used to preclude the use of items whose shelf life or operation times have expired.

## **9.0 Control of Special Processes**

Special processes, such as welding or non-destructive testing (with the exception of certain leak testing controlled by approved procedures) of radioactive material shipping packages are not performed by NFS. The Quality Assurance function reviews the supplier's or contractor's QA Program to insure that:

- Applicable codes, standards, or specifications are utilized for welding, heat treating, and non-destructive testing that affect quality. The qualifications of personnel performing the activities are documented.
- Special processes, such as welding, heat treating, non-destructive testing, and cleaning are procedurally controlled. Procedures, equipment, and personnel connected with special processes are qualified in accordance with applicable codes, standards, and specifications.
- Special processes are performed by qualified personnel and accomplished in accordance with written procedures or instructions with recorded evidence of verification. Qualification records of procedures,

equipment, and personnel associated with special processes are established, filed and kept current.

## **10.0 Inspection Control**

Visual inspections are performed upon initial receipt of purchased or leased packaging to ensure compliance with procurement documents. The requirement for these inspections and criteria for acceptance of each type of package are contained in procedures implementing this quality assurance program. These procedures also specify the action to be taken if an item of non-compliance is found.

This visual inspection includes inspection of surface conditions, weld and structural integrity, the condition of flange faces or sealing areas, gaskets, seals, gauges, rupture disks, valves, pressure relief devices, tie-down members, labeling and marking, and apparent leak-tightness of the packaging, as appropriate.

Procedures also specify the inspection of packaging to ensure adequate maintenance. These procedures identify the items to be maintained, criteria for acceptability or replacement, and the frequency of these inspections for each type of package.

Checklists are used to ensure and document that inspections are performed and to verify that the required items have been accomplished, including:

- Documentation from the vendor that packages are properly assembled;
- Documentation from the vendor that moderators and neutron absorbers are present if required;
- There are no visual defects; and
- Packages are conspicuously and durably marked as required by DOT regulations.

Prior to the approval for shipment of any radioactive material in packages used under NRC approval, the shipping papers are reviewed and approved by the T&WM function (or designee), at a minimum. This review is performed to ensure that the papers are properly completed and that the required signatures are present.

The inspections identified in this section are performed by trained and qualified personnel.

## **11.0 Test Control**

Testing is required for compliance verification and is performed prior to delivery of packages to a carrier for transport. Test procedures are written to include test objectives and provision for assuring that the prerequisites for testing are complete. These tests are performed as required by the Certificate of Compliance for the package or by the manufacturer or lessor of the package. Documentation of results is required by these procedures.

For packages used by NFS, these procedures for testing are reviewed, evaluated, and approved by the Transportation and Waste Management function, at a minimum.

## **12.0 Control of Measuring and Test Equipment**

Measuring and test equipment used as a part of this quality assurance program are included in NFS' Equipment Calibration Program. This program is operated by the Quality Control function of NFS and requires that equipment be calibrated, adjusted, and maintained at prescribed intervals, generally that recommended by the manufacturer, prior to use. The calibration program also requires that this equipment be identified with a unique identifier, and be tagged or labeled to show the due date of the next calibration. All standards used in this program are traceable to nationally recognized standards, and the traceability of this calibration is documented.

If test equipment is discovered to be out of calibration, all measurements made since the last calibration are suspect, unless an event which caused the failure can be identified. Should a piece of equipment be consistently out of calibration, it is repaired or replaced.

## **13.0 Handling, Storage, and Shipping**

Written procedures define the handling practices and lifting equipment that is to be used for the radioactive material packaging. Special handling, storage provisions, environmental conditions, and/or unloading conditions for packaging are also used as defined by these documents, if appropriate.

These procedures also establish that the requirements for release of the package, such as specified operations, inspections, tests, and shipping papers be completed prior to delivery to a carrier.

## **14.0 Inspection, Test, and Operating Status**

Release of each new package for shipment is required by a procedure. This procedure contains a checklist of the required tests and inspections for each authorized package. This assures that an inspection required for the item has not been bypassed before delivery of a package(s) to a carrier. As appropriate,

procedures will be established to control the application and removal of status indicators (e.g., tags, inspection sheets, markings, stamps).

#### **15.0 Control of Nonconforming Materials, Parts, or Components**

Nonconforming items are identified, segregated, evaluated, and promptly dispositioned. This is accomplished by specifying the criteria for acceptance for materials, parts, and components. Material not meeting these criteria is treated as nonconforming, and is placed in a controlled holding area until appropriate disposition is made. A nonconformance report is made to management. These reports are used, as appropriate, to determine quality trends. Identified trends are submitted for management review and assessment.

#### **16.0 Corrective Action**

Conditions adverse to quality are reported to management, responsibility for corrective action assigned, and steps toward resolution tracked until the cause is identified and corrected. Follow-up evaluations are conducted to ensure corrective actions are appropriately implemented and effective. NFS has a corrective action program to implement these actions.

#### **17.0 Quality Assurance Records**

The records that are retained for radioactive material shipping packages include:

- Design, procurement, and production-related records that are generated throughout manufacturing and are furnished with the package.
- Records verifying repair, rework, and replacement of parts.
- Audit reports, supplier evaluations, nonconformance reports, corrective actions, and maintenance work orders.
- Records showing evidence of delivery to a carrier and that all applicable regulatory requirements have been satisfied are retained for at least three (3) years after this delivery.
- Records of personnel qualification and personnel training/retraining.

Implementing procedures require that documents are legible and completed to reflect the work accomplished.

These documents are included in NFS' Vital Records Program to ensure the proper retention of these documents and placement in the appropriate file classification for easy retrieval. Documents in this system are routinely microfilmed to provide a second set of these records in a different location

remote from the first location. Steps are taken to prevent the presence of environmental conditions, such as excessive light, electromagnetic fields, and temperature which could damage these records.

## **18.0 Audits**

The Transportation QA Program is reviewed annually to assess the implementation and effectiveness of the program to assure that the program is adequate and complies with 10CFR71, Subpart H criteria. This audit is performed by the Quality Assurance function, and will include all elements of Subpart H.

The QA audit program requires that audit personnel are trained and qualified in accordance with written procedures. QA audit schedules are developed on an annual basis, and include audit drivers and audit team assignments. QA audits are conducted and reported under the direction of a qualified lead auditor, and in accordance with QA procedures. Audits are performed in accordance with written procedures using a checklist of items which are important to safety. This checklist is prepared by the audit team prior to performing the audit. Nonconformances are reported to the Vice President, Safety and Regulatory and other responsible management. A response to any nonconformance identified by the audit is required, and must identify the cause of the nonconformance and include a plan of corrective actions. These corrective actions are tracked by the NFS corrective action program and closed only after verification that corrective actions are adequately implemented and effective in correcting the nonconformance.

Figure 1. NFS Organization

