Nuclear Fuel Services, Inc.

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21G-20-0081
GOV-01-55-04
ACF-20-0216

August 13, 2020

U.S. Nuclear Regulatory Commission
Attention: Document Control Desk
Washington, DC 20555-0001

Subject: **Revised Quality Assurance Program for Shipping Packages for Radioactive Material**

Pursuant to the regulations in 10 CFR 71.106 that allow changes to be made and implemented that do not reduce commitments to the Nuclear Regulatory Commission, Nuclear Fuel Services, Inc., (NFS) hereby reports such changes made within the last 12 months to its *Quality Assurance Program for Shipping Packages for Radioactive Material (the Program)*. The Program text has been revised to describe title and organizational changes and to better align with NFS' Quality Manual.

If you or your staff have any questions, require additional information, or wish to discuss this further, please contact me, or Mr. James Hutton, Quality Assurance Unit Manager at (423) 735-5497. Please reference our unique document identification number (21G-20-0081) in any correspondence concerning this letter.

Sincerely,

NUCLEAR FUEL SERVICES, INC.

Richard J. Freudenberger, Director
Safety and Safeguards

AAM/pj

Attachment: *Quality Assurance Program for Shipping Packages for Radioactive Material, Revision 19 (56T-20-0100)*

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NUCLEAR FUEL SERVICES, INC.

ERWIN, TENNESSEE

56T-20-0100

QUALITY ASSURANCE PROGRAM

FOR SHIPPING PACKAGES

FOR RADIOACTIVE MATERIAL

REVISION 19

August 3, 2020

TABLE OF CONTENTS

QUALITY ASSURANCE PROGRAM FOR SHIPPING PACKAGES FOR RADIOACTIVE MATERIAL

NFS Quality Assurance Policy and Authority

The policy of Nuclear Fuel Services, Inc., (NFS) is to provide products, processes, and services that meet the customer's needs and to perform those functions reliably, safely, and in an environmentally responsible manner. We will strive to continuously improve the quality of our products, processes, and services.

The plant-wide Quality Assurance Program (QAP) describes the policies and practices that constitute the NFS Quality Assurance Program for achieving or exceeding the required quality requirements for all activities.

The President has the responsibility for the overall NFS Quality Assurance Program. All NFS employees are responsible for the execution of the Quality Assurance Program in their specific activities, jobs, and work assignments. All levels of management are responsible for contributing to the achievement of quality and taking a leadership role in ensuring that NFS' Quality Assurance Program is executed. Quality Assurance (QA) is an interdisciplinary function involving many organizational components and not regarded as the sole domain of a single quality assurance group. Management shall regularly assess the adequacy and effective implementation of the Quality Assurance Program. Specifically, senior management will establish the expectations for effective implementation of the QAP.

Management, at all levels, promotes a "no-fault" attitude to encourage everyone to identify nonconforming items/processes and to identify and suggest improvements. Every NFS employee is charged to fully support the Quality Assurance Program. This support is essential to ensure a sustained leadership position in the quality of our products and services.

Purpose and Scope

The purpose of this document is to describe the Nuclear Fuel Services, Inc., (NFS) Quality Assurance Program applicable to the 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 June 2015.

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 also defined in 10 CFR 71.4.

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 and the independence of the Quality Assurance function from Operations.

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 independent from groups having responsibilities in the Transportation QA Program.

Each employee has the responsibility and authority to stop unsatisfactory work and/or stop delivery or installation of non-conforming material. The NFS Quality Assurance function 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 Safety and Safeguards organization provides general oversight and counsel regarding nuclear safety and related regulatory matters to all levels of NFS management and to all areas of NFS operations.

The Radiation Protection and Health Physics function has responsibility for performing radioactive material receipt and shipment surveys.

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

The Calibration function is responsible for calibration of selected measuring and testing equipment used for testing and inspecting shipping packages. The calibration program is operated by the Quality function and requires that equipment be calibrated, adjusted, and maintained at prescribed intervals, generally that recommended by the manufacturer, prior to use.

The Corrective Action Program (CAP) is responsible for providing and administering a program which enables NFS to report, investigate, correct, and track events and conditions adverse to safety and quality.

The Downblending and Fuel Manufacturing functions are the most frequent users of shipping packages, with Decommissioning function use occurring intermittently. 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 Engineering function provides engineering support by reviewing vendor's calculations and specifications of package designs.

The Purchasing Services 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 and T&WM functions for compliance and conformance before a purchase order is developed.

The Contracts Manager for Corporate Services may sign agreements to rent or lease NFS-owned packages to other organizations for their use. This function would coordinate with other functions the appropriate requirements for rentals and use by any other third parties.

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 (SOPs) 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 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 NFS safety culture policy encourages all personnel to immediately report any concern relating to safety or noncompliance with federal, state, local, or NFS regulatory requirements. The policy states a lack of tolerance for harassment, intimidation, retaliation, or discrimination for personnel who communicate safety or regulatory compliance issues.

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 Section Manager or chosen delegate is responsible for:

- 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 T&WM 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.

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.

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 10 CFR 71 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 resolution of nonconformances; and,

- Contain the statement: "The provisions of 10 CFR 21 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 function and/or the T&WM 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 by utilizing one or more of the following methods:

- Evaluation of the vendor's history of providing a product/service that has performed satisfactorily in actual use;
- Evaluation of the vendor's current quality records supported by documented qualitative and quantitative information;

- Evaluation of the vendor's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and the implementation of the vendor's quality assurance program.

For Important-to-Safety (ITS), Category A components (as defined in NUREG/CR-6407, February 1996), 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 by utilizing, at a minimum, the following method:

- Evaluation of the vendor's technical and quality capability as determined by a direct evaluation of the facilities, personnel, and the implementation of the vendor's quality assurance program.

Suppliers who successfully pass this evaluation are placed on the NFS Shipping Approved Vendors List (AVL). The supplier evaluation form will note the elements of 10 CFR 71; 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.

The prime contractor for HEU Downblending projects has the responsibility for procurement, maintenance, and repair of the LR-230 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 assure 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, 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 and documented as required by the Certificate of Compliance for the package, or by the manufacturer or leaser of the package.

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. The calibration program 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. An evaluation shall be performed and documented of the validity of previous inspection or test results and the acceptability of items previously inspected or tested. Out-of-calibration test equipment shall be tagged or segregated from production until it has been recalibrated. 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 resolved.

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:

- 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 10 CFR 71, 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. Audit results are reported to the President 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