UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

May 25, 2018

Mr. Richard J. Freudenberger
Quality, Safety, & Safeguards Director
Nuclear Fuel Services, Inc.
1205 Banner Hill Road
Erwin, Tennessee 37650

SUBJECT: NRC INSPECTION REPORT 71-0249/2017-201

Dear Mr. Freudenberger:

From July 24 through 27, 2017, the U.S. Nuclear Regulatory Commission (NRC) performed an announced inspection of Nuclear Fuel Services, Inc. (NFS) at its facility in Erwin, Tennessee. The inspection continued in NRC headquarters with further review of documents supplied by NFS until a final exit meeting was conducted with NFS by teleconference on April 26, 2018. The team inspected NFS' activities associated with transportation of radioactive material to determine if they were executed in accordance with the requirements of 10 CFR Parts 21 and 71, Certificates of Compliances (CoCs), Safety Analysis Reports, and NFS' NRC-approved Quality Assurance Program (QAP). The team inspected NFS' management and maintenance controls. Inspection results are detailed in Enclosure 1 to this letter.

With respect to the inspection results, the NRC inspection team assessed that, overall, as presently developed and implemented, NFS' QAP and procedures are adequate in meeting the QA requirements of 10 CFR Part 71 and 10 CFR Part 21 with the exception of one unresolved item. The unresolved item is discussed in detail in the inspection report. The team also identified examples where records were not properly maintained and measuring and testing equipment used in activities affecting quality were not properly calibrated.

Based on the results of this inspection, the NRC has determined that one non-cited Severity Level IV violation and one minor violation of NRC requirements occurred, in addition to the unresolved item. The violation and minor violation are non-cited because NFS placed the items in their corrective action program, the issues were of low safety significance, not willful on NFS' part, and actions were taken to address the immediate issue.

In accordance with 10 CFR 2.390, “Public inspections, exemptions, requests for withholding,” a copy of this letter, and its enclosure will be made available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records System (PARS) component of NRC’s Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web site at https://www.nrc.gov/reading-rm/adams.html.

Sincerely,

/RA/

Meraj Rahimi, Acting Branch Chief
Inspections and Operations Branch
Division of Spent Fuel Management
Office of Nuclear Material Safety
and Safeguards

Docket No. 71-0249

Enclosures:
1. NRC Inspection Report No. 71-0249/2017-201

SUBJECT: NRC INSPECTION REPORT 71-0249/2017-201 DOCUMENT
DATE: MAY 25, 2018

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Office of Nuclear Material Safety and Safeguards
Division of Spent Fuel Management

Inspection Report

Docket No.	71-0249
Report No.	71-0249/2017-201
User of Certificates:	Nuclear Fuel Services, Inc. 1205 Banner Hill Road Erwin, Tennessee 37650
Inspection Location:	Nuclear Fuel Services, Inc. 1205 Banner Hill Road Erwin, Tennessee 37650
Inspection Dates:	July 24-27, 2017 at NFS Facility and in NRC Headquarters until Exit Meeting by Teleconference on April 26, 2018
Inspection Team:	Jon Woodfield, Team Leader, Safety Inspector, DSFM, IOB Carla Roque-Cruz, Safety Inspector Engineer, DSFM, IOB
Approved by:	Meraj Rahimi, Acting Branch Chief Inspections and Operations Branch Division of Spent Fuel Management Office of Nuclear Material Safety and Safeguards

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

EXECUTIVE SUMMARY

Nuclear Fuel Services, Inc.
NRC Inspection Report 71-0249/2017-201

From July 24 through July 27, 2018, the U.S. Nuclear Regulatory Commission (NRC) performed an announced inspection of Nuclear Fuel Services, Inc. (NFS), at its facility in Erwin, Tennessee. The inspection continued in the NRC's Headquarters Office until the final exit meeting on April 26, 2018, which was held by teleconference. The team inspected NFS' activities associated with transportation of radioactive material to determine if they were executed in accordance with the requirements of 10 CFR Parts 21 and 71, Certificates of Compliances (CoCs), Safety Analysis Reports (SARs), and NFS' NRC-approved quality assurance program (QAP). The team inspected NFS' management and maintenance controls. The results of the inspection are as follows:

Management Controls

The team interviewed NFS personnel and reviewed and verified documented aspects of quality assurance, nonconformance controls, documentation controls, as well as various audit activities. The team determined that NFS' implementation in this area was adequate with one finding and one unresolved item.

The finding was against 10 CFR 71.135, "Quality assurance records." The team requested NFS to provide the original qualification records for Rainier Rubber, a commercial supplier of O-rings that were used in an important-to-safety (ITS) Category A application on the ES-3100 packaging. NFS was unable to locate the original qualification records and initiated Problem Identification, Resolution and Correction System (PIRCS) report 61250 to place the issue in its corrective action program. The team determined this violation to be of minor safety significance and not subject to formal enforcement action because other audits had been performed since the original audit and it appeared to be an isolated incident.

The unresolved item is associated with 10 CFR 71.115, "Control of purchased material, equipment, and services." The following instance was identified by the team where NFS vendor qualification records did not provide adequate evaluations and at intervals consistent with the importance of the material being procured. NFS' Vendor Qualification Procedure NFS-Q-224, Revision 1, Method I, (to evaluate a vendor's history of providing a product/service that has performed satisfactorily in actual use) was used in 2017 and 2014 to qualify a commercial grade vendor to supply ITS Category A O-rings for use in the ES-3100 packaging. This level of quality assessment of the commercial grade O-ring vendor performed at three year intervals is not consistent with the significance of an ITS Category A component. However, it should be noted that NFS Procedure NFS-Q-224 was developed from an NRC-approved QAP. NFS also took immediate corrective action to procure the ITS Category A O-rings directly from the ES-3100 packaging CoC holder. The inspection team evaluated the violation in accordance with Section

2.3 of the NRC Enforcement Policy and dispositioned it as a potential non-cited Severity Level IV violation since it was of low safety significance due to NFS leak testing the O-rings once installed and NFS' decision to procure the O-rings directly from the ES-3100 CoC holder going forward. However, this item is unresolved.

As a generic implication of the unresolved O-ring item, the team has determined that Section 7.0, Control of Purchased Material, Equipment, and Services, of NFS' QAP is inadequate as currently written to evaluate a supplier's capability to comply with the elements of 10 CFR 71.115, "Control of purchased material, equipment, and services." NFS has stated that it plans to revise and correct Section 7.0 of its QAP and submit it to the NRC for re-approval as part of the resolution of the unresolved item.

Maintenance

The team reviewed maintenance documents associated with maintenance controls for activities affecting quality and interviewed NFS personnel involved with maintenance. The team determined that NFS' implementation in this area was adequate with one finding against 10 CFR 71.125, "Control of measuring and test equipment."

NFS Procedure NFS-WST-026 Revision 12 for handling/shipping ES-3100 packagings requires the ES-3100 containment vessel (CV) closure nut to be tightened to 120 ft-lbs +/- 5 ft-lbs torque using a calibrated torque wrench.

Contrary to this requirement, the calibrated torque wrench dedicated to the task of tightening the CV closure nut had been set/calibrated at a value of 125 ft-lbs +/- 5 ft-lbs and used in the field at this setting for at least four years.

Overall

The team assessed that NFS' overall implementation of its NRC-approved QAP was adequate, with the one unresolved item associated with NFS' QAP as noted above. A summary of inspection findings is presented in Table 1 below.

Table 1

Summary of Inspection Findings

Regulatory Requirement 10 CFR Section	Subject of Violation or Noncompliance	No. of Findings	Type of Finding	Report Section
71.115	Control of purchased material, equipment, and services	1	Potential Non-cited Level IV Violation – Unresolved Item (URI)	2.5.2
71.125	Control of measuring and test equipment	1	Non-cited Level IV Violation	5.3.2
71.135	Quality assurance records	1	Minor Violation	2.4.2

REPORT DETAILS

1.0 Inspection Scope

The team inspected NFS' management and maintenance controls to determine whether they were executed in accordance with the requirements of 10 CFR Parts 21 and 71, applicable CoCs, related SARs, and NFS' NRC-approved QAP. The team reviewed documentation, interviewed personnel, and observed activities in various facility areas. The team focused its review on the following transportation packagings for which NFS is a user only.

Model	Package ID#	Certificate	Revision	Expiration Date
Liqui-Rad (LR-230)	USA/9291/B(U)F-96	9291	9	7/31/2019
ES-3100	USA/9315/B(U)F-96	9315	15	4/30/2021
Versa-Pac, VP-110	USA/9342/AF-96	9342	12	8/31/2020

1.1 Inspection Procedures/Guidance Documents Used

IP 86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packagings"
NUREG/CR-6314, "Quality Assurance Inspections for Shipping and Storage Containers"
NUREG/CR-6407, "Classification of Transportation Packaging and Dry Spent Fuel Storage System Components According to Importance to Safety"
Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material"

1.2 List of Acronyms Used

CAP	Corrective Action Program
CAR	Corrective Actions Report
CFR	Code of Federal Regulations
CoC	Certificate of Compliance
CV	Containment Vessel
ITS	Important-to-Safety
M&TE	Measuring and Test Equipment
NCR	Nonconformance Report
NFS	Nuclear Fuel Services
NRC	U.S. Nuclear Regulatory Commission
PIRCS	Problem Identification, Resolution and Correction System
QA	Quality Assurance
QAP	Quality Assurance Program
QC	Quality Control
RA	Records Administrator
SAR	Safety Analysis Report
TWM	Transportation Waste Management

URI Unresolved Item
WMS Waste Management Specialist

1.3 Persons Contacted

The team held an entrance meeting with NFS on the afternoon of July 24, 2017, to present the scope and objectives of the NRC inspection. On the afternoon of July 27, 2017, the team held a preliminary exit meeting with NFS to present the preliminary results of the inspection. On April 26, 2018 the team held the final exit meeting by teleconference with NFS. Individuals present at the entrance, preliminary exit meeting, and final exit meeting are listed in Table 2.

Table 2

Entrance and Exit Meeting Attendees

Name	Affiliation	Entrance	Preliminary Exit	Final Exit
Jon Woodfield	NRC	X	X	X
Carla Roque-Cruz	NRC	X	X	
Richard Gibson	NRC (Region II)	X	X	
Larry Harris	NRC (Resident)	X	X	X
Joel Duling	NFS	X		
Rich Freudenberger	NFS	X	X	X
Marie Moore	NFS	X	X	
Amaryl Morie	NFS	X	X	X
Dave Deming	NFS	X	X	
Robert Dotson	NFS	X	X	X
Rebecca Lind	NFS	X	X	X
Carol Anderson	NFS	X	X	
Brad McKeehan	NFS	X		
Natalie Willis	NFS	X		
Jim Hutton	NFS	X		
Jerry May	NFS	X	X	
Tim Knowles	NFS			X
Randy Shackelford	NFS		X	X
Jon Hagemann	NFS		X	
Jeffery Eidens	NFS		X	
Tom Holly	NFS		X	
Danielle Rogers	NFS		X	
Ron Rice	NFS		X	

2.0 Management Controls

2.1 General

The team assessed the adequacy of management controls in the areas of NFS' QAP implementation, nonconformance controls, documentation controls, and audit program. The team reviewed NFS' practices and procedures, and their implementation, to determine the effectiveness of management controls.

2.2 Quality Assurance Program

2.2.1 Scope

The team reviewed NFS' QAP to determine the effectiveness of instructions and procedures that implement its program. The team inspected NFS' QAP goals, objectives and practices, personnel responsibilities, QA organizational independence, management involvement, and staffing levels.

2.2.2 Observations and Findings

The team reviewed NFS' "Quality Assurance Program for Shipping Packages for Radioactive Material," Revision 16, dated 8/11/2016; and NFS procedures NFS-M-48, "Quality Assurance Program," Revision 5, dated 3/18/2013; and NFS-GH-49, "Implementing Procedure for the Transportation Quality Assurance Program," Revision 7, dated 9/22/2015.

The team verified that the Quality Assurance Program as written, (with the exception of vendor audits, reference section 2.5 and URI) adequately addresses the applicable Quality Assurance criteria of 10 CFR Part 71 used for the activities performed at NFS. As stated in the NFS QAP Quality Assurance Policy and Authority section, the company President has the responsibility for the overall NFS QAP. All NFS employees are responsible for the execution of the QAP in their specific activities, jobs, and work assignments. Each employee is responsible for Quality Assurance as it applies to his or her work assignments. However, the responsibility for evaluating the effectiveness of the QAP is delegated to the Deputy Quality Assurance Director. The team noted that the Quality Assurance function is independent and does not have direct responsibility for performing work and is independent from groups having production responsibilities in the Transportation Program. The team also noted that the NFS Transportation QA Program as outlined is an adequate framework of controls for the ITS activities (with the exception of vendor audits associated with the procurement URI) associated with the use, maintenance, and minor repair of packages used under NRC's approval for the shipment of radioactive materials.

2.2.3 Conclusion

Overall, the team determined that responsibilities were identified in quality procedures and controls for quality activities. Other than the URI for vendor audits associated with procurement, no concerns were identified with NFS' QAP.

2.3 Nonconformance and Corrective Action Controls

2.3.1 Scope

The team reviewed NFS' nonconformance control program to assess the effectiveness of measures established to control materials, parts, or components that did not conform to requirements. The team evaluated how NFS identified, segregated, tracked, and controlled, any nonconforming items and any program deficiencies. The team inspected nonconformance reports (NCR), nonconforming items, and measures used to keep track of the status of nonconforming items. In addition, the team reviewed NFS' corrective action program.

The team also reviewed training and implementing procedures, internal postings, supplier notifications, reporting processes, and program controls in accordance with the provisions of 10 CFR Part 21, "Reporting of Defects and Noncompliance."

2.3.2 Observations and Findings

The team reviewed NFS' nonconformance program to assess the effectiveness of controls established for the processing of nonconforming materials, parts, or components. The requirements for NFS' nonconformance program are contained in NFS procedure NFS-Q-185, "Control of Nonconforming Items," Revision 9, dated 11/14/2016. This procedure describes the control system for nonconforming and suspected nonconforming items at NFS. This control system provides the requirements for identifying, segregating, controlling, and dispositioning of suspected nonconforming items.

NFS-Q-185 requires that nonconforming items be tagged, segregated and classified. The Quality Department maintains a log of nonconformance reports. This log is located on the NFS intranet and allows access to NCR status information. Once the quality staff is notified of the nonconformance, an entry in the PIRCS is generated. PIRCS is the software program used to document plant wide corrective action activities. The Respondent, the individual to whom the NCR was written, will evaluate the nonconformance and determine the appropriate disposition, document the factors supporting the proposed disposition, and obtain approval from the responsible manager. Dispositions of "Use-As-Is," "Rework," or "Repair," and "Reject" can be assigned to the nonconforming item. Once the disposition has been proposed, approved, and corresponding activities completed, Quality will verify each nonconforming item was processed in accordance with the approved disposition and record the verification of the disposition in the NCR log.

The team interviewed NFS Quality Control (QC) and QA personnel on the NCR process and found them all knowledgeable with an understanding of the process as described in the procedures. The team also reviewed a sample of NCRs from the last year that involved ITS items. The team confirmed that the NCRs received the required review, evaluation, and approvals by NFS personnel as evidenced by the entries into the PIRCS

system. The team assessed that the NCRs reviewed had been appropriately dispositioned and closed in a timely manner. No concerns were identified by the team in the processing of NCRs by NFS.

The team reviewed NFS' corrective action program (CAP) to assess the effectiveness of controls established for the processing of programmatic issues or hardware non-conformances. The objective of NFS' corrective action program is to provide and administer a program which enables NFS to report, investigate, correct, and track events and conditions adverse to safety. The requirements for NFS' corrective action program are contained in NFS procedure NFS-CAP-009, "The NFS Corrective Action Program," Revision 7, dated 12/12/2016. As stated in Section 2.0, "Scope," the Corrective Action Program at NFS is to provide for accurate and timely notification, ensure rapid and risk-graded investigations, tracking of the investigative process to closure, as well as the resultant corrective actions; and provide for trending analysis of problems through a database of problems information and causes.

All NFS employees and contractor employees are required to identify and report events and conditions adverse to safety through their management and/or the PIRCS. NFS procedure NFS-GH-65, "Problem Identification," Revision 9, dated 3/20/2015, defines the types of problems/adverse conditions that should be identified (or reported) through the CAP. This procedure also provides guidance on how to document items into PIRCS.

The team interviewed NFS QC and QA personnel on the Corrective Action process and Corrective Action software used by NFS. The team determined the NFS personnel were all knowledgeable and understood the process as described in the applicable procedures. The team reviewed a sample of Corrective Actions Reports (CARs) generated in the prior year before the inspection on issues identified at NFS. The corresponding CAR response and evaluation documented by NFS was also reviewed. For the majority of the CARs and corresponding response, the team found that the corrective actions proposed and taken by NFS were adequate and closed out in a timeframe commensurate with the safety significance of the issue. The team found a few instances where complete documentation or evidence of completion of activities were missing from the Problem Reports generated by PIRCS. The staff discussed these instances with NFS staff and in all cases the activities had been completed but the information not entered in PIRCS.

The team also assessed how the requirements of 10 CFR Part 21 were being implemented for activities being performed at NFS. NFS procedure NFS-MGT-058, "Nuclear Fuel Services 10 CFR Part 21.21 Program," Revision 0, dated 9/30/2015 provides the process for notifying management of any condition potentially reportable to a regulatory authority and for tracking the condition to ensure that reportability determinations, and reports, if necessary; are filed within a timely fashion. The team verified that for each NCR and CAR reviewed, the assessment for reportability was performed. The team noted that this is one of the entries required in PIRCS. The team also reviewed Part 21 evaluations from the last five years and verified that the required Part 21 postings were posted and accessible in the NFS main entrance building.

2.3.3 Conclusion

Overall, the team assessed that NFS' implementation of its nonconformance, corrective action, and Part 21 programs was adequate with no concerns identified.

2.4 Documentation Controls

2.4.1 Scope

The team reviewed NFS' documentation control program to determine the effectiveness of the QAP in controlling quality-related documentation and records. The team reviewed instructions, procedures, and drawings for adequacy, approval signatures, document releases by authorized personnel, and document availability to personnel. The team reviewed the control of such documents as inspection work orders, QA procedures, and packaging drawings. The team reviewed quality records to assure that they were properly identified, retrievable, controlled, and maintained.

2.4.2 Observations and Findings

The team reviewed the section of the NFS QAP, Revision 16 and the NFS procedures specifically related to documentation controls. The team also had discussions with the NFS staff responsible for document control and quality records.

The team specifically reviewed the following procedures associated with document controls and records:

- NFS-GH-49, Implementing Procedure for the Transportation Quality Assurance (QA) Program, Revision 7
- NFS-DOC-001, Procedure Implementation Process, Revision 8
- NFS-DOC-002, Procedure Development Standards, Revision 8
- NFS-RM-002, Vital Records Protection Procedure, Revision 12

The team focused its review of document controls on procedures that were written for addressing purchase orders, operations, maintenance, repair, inspection, testing, transportation, loading, and unloading of the transportation packagings for which NFS is a user.

Obsolete or superseded hard copies of procedures are removed from work areas to prevent inadvertent use. The initiator of new revisions is responsible for removal of the superseded document.

Procedure NFS-DOC-001 goes into great detail describing the approval, distribution, revision, and deletion process that establishes NFS' formal document control process. The team had extensive discussions with the NFS personnel responsible for the NFS electronic document control system. NFS personnel demonstrated to the team how the NFS electronic document control system worked at their computer stations.

The team requested to see NFS' copies of all the Certificate of Compliances (CoC) and Safety Analysis Reports (SAR) for the transportation packages for which NFS is an NRC

registered user. An NFS transportation and waste management specialist was able to demonstrate that the documents could be quickly found and retrieved through NFS' computer/electronic controlled document system.

The team reviewed two examples of form FM-DOC-005, "Unclassified Document Distribution Sheets," Revision 3, which is a return receipt for controlled document holders to acknowledge their receipt of a revised document. These two forms were used to distribute hard copies of NFS procedures NFS-WST-036, "Handling and Packaging of the Versa-Pac," Revision 2 and NFS-WST-026, "Handling/Shipping Instructions for the ES-3100 Drum," Revision 12.A. Each form listed several areas of the facility, or persons, which were to receive a numbered controlled copy of the revised procedure. The team gained access to secured areas where loading of the ES-3100 and Versa-Pac packaging occurred to verify the correct/current revision of procedure NFS-WST-036 and NFS-WST-026 were being used in the secured loading areas. The team verified that the controlled documents in the ES-3100 and Versa-Pac secured loading areas were current.

The quality records retained for the transportation packagings used by NFS are records verifying replacement of parts, supplier evaluations, maintenance work orders, procurement and receipt inspection records for both new packagings and repair parts if needed; and records of personnel qualification and personnel training/retraining. It should be noted that the scope of this inspection did not include the review of records for the contents of the transportation packagings when used.

NFS personnel demonstrated how all the records associated with an individual transportation package during its use and maintenance were collected and reviewed by a Waste Management Specialist (WMS) in the Transportation and Waste Management Technical Services Organization. The WMS logs all the documents/records on form FM-DOC-017, "Document Management Log," with the records attached, for delivery to the quality records department and administrator for retention. Each individual transportation packaging is uniquely labeled with a sticker containing a number and bar code prior to each use to trace it back to packaging document records at NFS. The identifying number provides traceability back to the packaging contents, fabrication records, and maintenance records.

The team interviewed the records administrator (RA) in a standalone building dedicated to records storage that had a controlled environment. The RA stated that documents included in NFS' Vital Records Program are routinely microfilmed or scanned to provide a second set of the records in a different location. The RA demonstrated to the team how quality records for a particular transportation packaging could be easily retrieved. The RA also discussed how NFS procedure NFS-RM-006, "Uniform Classification System Outline," Revision 23 was used to classify quality records and their retention period.

As part of an unresolved item involving external audits of commercial grade vendors supplying ITS Category A components, (Reference Section 2.5 below, Audit Program) the team requested NFS to provide the original qualification records for Rainier Rubber, a commercial supplier of O-rings that were used in an ITS Category A application on the ES-3100 packaging. This request to NFS was made by the team after the inspection continued back in NRC headquarters. NFS was unable to locate the original qualification records and initialed PIRCS 61250 to place the issue in its corrective action program.

The team determined the missing original qualification records to be a violation of 10 CFR 71.135, “Quality assurance records,” which states, in part, that the licensee shall maintain sufficient written records to describe the activities affecting quality. The licensee shall retain these records for 3 years beyond the date when the licensee last engage in the activity for which the QAP was developed. The team determined this to be a minor violation with minor safety significance and not subject to formal enforcement action because other audits had been performed since the original audit and it appeared to be an isolated incident.

2.4.3 Conclusion

The team assessed that document controls and records management at NFS were adequate and effective for the transportation packagings for which NFS is an NRC registered user. However, there was one minor violation of minor safety significance identified for missing records.

2.5 Audit Program

2.5.1 Scope

The team reviewed NFS’ audit program to determine whether audit plans, procedures, and records were developed and maintained. The team evaluated whether NFS scheduled and performed internal QA audits and vendor audits in accordance with approved procedures or checklists; whether qualified and independent personnel performed the audits; whether NFS management reviewed audit results; and whether NFS took appropriate follow up actions in those areas found to be deficient.

2.5.2 Observations and Findings

Internal Audits

The team reviewed NFS-Q-178, “Quality Assurance Audit Process,” Revision 8, dated 7/7/2014. This procedure describes the methods for planning, scheduling, conducting, documenting, and follow up of Internal Audits. In addition, the team reviewed the results of two audits performed at NFS by the U.S. Department of Energy on June 2016 and by BWXT Fluor – BWXT Portsmouth on April 2017. The team noted that the audit reports contained findings and observations with adequate supporting details. The audits were also conducted and documented using a checklist tailored specifically to NFS' quality program. The team determined that the audits were adequate in there scope. The team noted that CARs were initiated for the findings documented in the audit reports. The team reviewed these CARs and determined that for the findings reviewed, all were adequately evaluated and corrective actions implemented in a timely manner. No concerns were identified by the team regarding NFS’ internal audit process.

External Audits

Additionally, the team reviewed NFS-Q-224, “Quality Assurance Shipping Vendor Qualification Procedure”, Revision 001, dated 4/1/13, attachment A: “Quality Assurance Shipping Vendor Evaluation Form” and the training records for NFS’ auditors and lead

auditors. The team reviewed NFS' vendor evaluations for three suppliers, Accurate Machine Products performed on 2/1/2017, Duncan Machine Inc. performed on 10/19/15 and Rainier Rubber in 2014 and 2017. The team determined the Accurate Machine Products and Duncan Machine vendor evaluations to be adequate.

The team noted that Rainier Rubber was a commercial vendor of O-rings. NFS stated that they procured the inner and outer CV O-rings from Rainier for the ES-3100 packaging. The team asked NFS if the inner O-ring was an ITS Category A component and after consulting with the ES-3100 CoC holder, NFS confirmed the inner O-ring was an ITS Category A component.

The team assessed that the method used by NFS to evaluate Rainier to supply an ITS Category A component was not adequate and a violation of 10 CFR 71.115, "Control of purchased materials, equipment and services."

Title 10 CFR 71.115, "Control of purchased material, equipment, and services," states in part, that the licensee shall establish measures to assure that purchased material, equipment, and services, whether purchased directly or through contractors and subcontractors, conform to the procurement documents. These measures must include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by the contractor or subcontractor, inspection at the contractor or subcontractor source, and examination of products on delivery. The licensee shall assess the effectiveness of the control of quality by contractors and subcontractors at intervals consistent with the importance, complexity, and quantity of the product or services.

Contrary to the requirements of 10 CFR 71.115, the following instance was identified by the NRC where NFS vendor qualification records did not provide adequate evaluations and at intervals consistent with the importance of the material being procured. NFS' Vendor Qualification Procedure NFS-Q-224, revision 1, Method I, (to evaluate a vendor's history of providing a product/service that has performed satisfactorily in actual use) was used in 2017 and 2014 to qualify a commercial grade vendor to supply ITS Category A O-rings for use in the ES-3100 packaging. This level of quality assessment of the commercial grade O-ring vendor performed at three year intervals is not consistent with the importance of an ITS Category A component.

This violation was entered into NFS' corrective action program as PIRCS 61300. The team determined that there was no immediate safety issue because the CV is leak tested before each shipment, which verifies that the O-rings are adequately performing their containment function. As part of the corrective action, NFS stated that it was no longer going to procure the ITS Category A O-rings directly from Rainier but procure them from the ES-3100 CoC holder. Therefore, the inadequate NFS evaluation of Rainier as an ITS Category A supplier concern was eliminated.

Although the issue of procurement of O-rings for the ES-3100 CV has been addressed, there is a generic procurement issue not addressed by PIRCS 61300. The team has determined that Section 7.0, Control of Purchased Material, Equipment, and Services, of NFS' QAP is inadequate as currently written to evaluate a supplier's capability to comply with the elements of 10 CFR 71.115, "Control of purchased material, equipment, and

services." However, it should be noted that NFS submitted its QAP with section 7.0 as currently written for NRC approval and the NRC approved it. This QAP programmatic failure and prior procurement of ITS Category A O-rings from commercial grade vendor Rainier is an URI. NFS has stated that it plans to revise and correct Section 7.0 of its QAP and submit it to the NRC for re-approval as part of the resolution of the unresolved item. In resolution of the URI, this is one factor which will be considered in making the issue a potential non-cited Level IV violation.

2.5.3 Conclusion

Overall, the team assessed that NFS was marginally adequate in implementing its audit program, with the team identifying this as an area needing improvement with a URI. A potential non-cited Severity Level IV violation was identified by the team and a generic issue with Section 7.0 of the NFS QAP was also identified which are part of a URI.

3.0 Design Controls

3.1 General

NFS' NRC approved QAP is for a transportation packaging user only and not for a packaging CoC holder. As a user only, NFS is not responsible for the design of any packagings it uses. Therefore, this section was not inspected by the team.

4.0 Fabrication Controls

4.1 General

NFS' NRC approved QAP is for a transportation packaging user only and not for a packaging CoC holder. As a user only, NFS is not responsible for the fabrication of any packagings it uses. Therefore, this section was not inspected by the team.

5.0 Maintenance Controls

5.1 General

The team assessed the adequacy of maintenance controls in the areas of maintenance activities and maintenance tools and equipment to ensure: 1) that each packaging will meet its design task throughout its useful life; 2) suitable spare parts are used and; 3) that adequate tool and equipment controls are established. The team reviewed NFS' practices and procedures, and their implementation to determine the effectiveness of maintenance controls.

5.2 Maintenance Activities

5.2.1 Scope

The team evaluated the maintenance process to ensure that it was controlled and verifiable from the onset of placing packagings into service. The team verified that the maintenance procedures required the performance of packaging inspections to identify

the need for maintenance and also the performance of routine package maintenance. Documents reviewed included maintenance procedures, SAR Chapter 8 requirements, maintenance checklists, and completed maintenance records.

5.2.2 Observations and Findings

The team reviewed NFS' transportation packaging maintenance program which involves routine inspections prior to packaging use and annual packaging inspections. The team specifically reviewed NFS' procedure NFS-WST-026, "Handling/Shipping Instructions for the ES-3100 Drum," Revision 12.A. The ES-3100 is a reusable transportation packaging and procedure NFS-WST-026 addresses the operations of opening, loading or unloading, closing, leak testing, inspection, routine maintenance, and annual maintenance for the ES-3100.

Each ES-3100 is required to be inspected prior to every loading. Form FM-WST-011, "ES-3100 Inspection Checklist," is a checklist associated with NFS-WST-026 for performing the inspection and documenting the results. Any deficiencies discovered during the inspection are to be corrected before that particular ES-3100 can be used. The form is a quality record associated with each ES-3100 packaging identification number and retained.

The team toured the NFS warehouse of empty ES-3100 packagings and randomly selected two ES-3100s to review their maintenance records and verify compliance with procedure NFS-WST-026. The team reviewed the maintenance records for ES-3100 packaging serial numbers 2007-11-059 and 2007-33-121. Being a procedure, NFS-WST-026 provides detailed instructions on how to inspect ES-3100s. The team reviewed the latest FM-WST-011 form for each of the ES-3100s sampled and compared the checklists to all the detailed written instructions in the procedure and found the correlation adequate. The team found both FM-WST-011 checklists to be completely filled out and each itemized step checked off and initialed by the inspector. It should be noted that the form FW-WST-011 is used as a material loading checklist also. The loader verification section of the forms were also found to be properly filled out and each step checked and initialed by the loader. Both forms reviewed also had a transportation waste management (TWM) supervisor review signature. For the ES-3100 to ship material, a leak test is required to be performed on the containment vessel. The team also reviewed the leak test record of performance for each of the sampled ES-3100s. The team found that the CVs passed the leak testing and the documentation of the testing acceptable.

Procedure NFS-WST-026 requires that a "Runsheet 33D" (Form FM-WST-013) be completed for each ES-3100 containing product material for shipment. The procedure states that the material handlers are to initial all the checklist line items on the Runsheet form and when completed, sign and date it. The TWM supervisor also signs as reviewer of the form and dates it. The team reviewed the latest Runsheet for each of the two ES-3100s sampled and found them to be completely filled out, checklist items initialed, Measuring & Test Equipment calibration due dates provided, and having all three required signatures and dates.

As stated above, procedure NFS-WST-026 also addresses ES-3100 annual maintenance. Each ES-3100 shall be inspected once per year during its time of service.

Form FM-WST-012, “ES-3100 Annual Inspection/Maintenance Checklist,” is used to document the annual maintenance and any deficiencies are to be corrected before an ES-3100 is placed back into service. The FM-WST-012 is to be completed by two material handlers and reviewed by a TWM supervisor. A package certifier is to be present during the inspection process; concur with the handlers inspections; and sign the inspection checklist. Annually both of the O-rings of the CV are replaced by an approved vendor and the packaging leak tested by the same vendor. Inspection stickers on the side of the ES-3100 drum assembly and the lid of the CV are applied by the approved vendor. The annual NFS inspections and checklist are completed after the O-rings are replaced and Helium leak testing completed by the approved vendor.

The team reviewed the 2016 annual inspection documentation for the two sample ES-3100s. The outside vendor provided recertification documentation for each of the two sample ES-3100s with leak test performance records for the ES-3100 lid, nut assembly, and vessel body. The team then reviewed the NFS annual inspection/maintenance checklists for the two ES-3100s which were completed after the leak testing was performed. The checklists followed the described inspection criteria in the NFS-WST-026 procedure. The team found the inspection forms to be completely filled out with checkoffs and the inspector’s initials; and also with the TWM supervisor’s signature, package certifier concurrence signature, and dates. One of the inspector checks is to verify that the drum and CV have an annual leak test certification sticker with the correct expiration date applied by the approved vendor.

The team reviewed the requirements for ES-3100 packaging operations and maintenance in NFS procedure NFS-WST-026 against the requirements in Section 7, “Package Operations,” and Section 8, “Acceptance Tests and Maintenance Program,” of revision 5 of the ES-3100 SAR listed as a reference on ES-3100 CoC 9315, Revision 15. The team determined the requirements in Sections 7 and 8 of the SAR were adequately transferred as requirements in the NFS NFS-WST-026 procedure.

It should be noted that in NFS-WST-026, as users only, it is stated that NFS personnel are not authorized to perform welding and structural repairs to the ES-3100 drum body or CV assembly. At the time of the inspection, all spare parts for the ES-3100 were supplied by the ES-3100 CoC holder to NFS except for the CV inner and outer O-rings.

The team reviewed the NFS training department lesson plan for ES-3100 Shipping Container Training which required an objective test and on the job training. The training covered NFS-WST-026 and the ES-3100 SAR sections 7 and 8. The team assessed the training plan to be thorough and adequate.

The team also toured the NFS warehouse for new and empty Versa-Pac packagings and randomly selected four Versa-Pac’s to review their documentation. Two of the Versa-Pac’s were fabricated by one vendor and two fabricated by another. The Versa-Pac is a one-time use transportation packaging and therefore does not have any maintenance. The team therefore focused on the NFS receipt inspection of the four Versa-Pac’s. The team reviewed the manufacturer’s (fabricator’s) certification documentation provided with the four Versa-Pac’s. The team also reviewed NFS form FM-WST-019, “Versa-Pac Inspection Checklist,” for each of the four packagings and the associated form NFS-SCM-003, “Category 2 and Category 3 Inspection Documentation Form.” The team

determined the receipt inspection forms to be thorough and properly filled out for each of the four packagings.

The team reviewed NFS procedure NFS-WST-036, “Handling and Packaging of the Versa-Pac,” Revision 2. The procedure provides instructions for opening, closing, pre-load inspection, and packaging (loading) of Versa-Pac’s. NFS forms NFS-WST-017 (Load Sheet for the Versa-Pac) and NFS-WST-050 (Pre-Load Inspection Checklist for the Versa-Pac) are used with the procedure. Although receipt inspected for initial placement in the NFS warehouse, each Versa-Pac is again pre-loaded inspected using form FM-WST-050. The checklist is completed by two material handlers and reviewed by a TWM supervisor. The team reviewed blank FM-WST-050 and NFS-WST-017 forms and determined the checklist and load sheet to be appropriate, thorough, and adequate. Due to time constraints, the team was not able to review completed forms NFS-WST-017 and FM-WST-050 for loaded and shipped Versa-Pac’s. However, the team was able to review the training records for several individuals qualified on handling and packaging of the Versa-Pac. The team determined the training was in-depth, thorough, and well documented for the material handlers using and loading the Versa-Pac’s.

5.2.3 Conclusion

Although only a small sampling was performed by the team; overall, the team found the packaging periodic and annual maintenance program for re-usable packagings at NFS to be comprehensive with detailed guidance on inspection acceptance criteria. The team identified no concerns with the general operations, pre-loading inspections, periodic maintenance, and annual maintenance of either one time use or re-usable transportation packagings.

5.3 Measuring and Test Equipment

5.3.1 Scope

The team reviewed the controls for the calibration of measuring, testing, and inspection tools/equipment and verified the procedural controls for tool traceability, as well as out of calibration controls.

5.3.2 Observations and Findings

The team reviewed NFS procedure NFS-M-17, “Calibration System Manual,” Revision 27 for the QA requirements for maintenance of measuring and test equipment (M&TE) and to verify that it was being properly implemented. M&TE that are in service are to be labeled to indicate the calibration status. For calibrated instruments in service the label shall include:

- Instrument identification
- Date of calibration
- Calibration due date
- Technician’s or Supplier’s initials

The team focused on the loading operations for the ES-3100 and Versa-Pac packagings. Since these packagings utilize bolted/nut closure devices, the M&TE used on these packagings are torque wrenches. NFS-M-17 in Attachment B shows torque wrenches to be calibrated annually using calibration procedure NFS-EC-33, “Calibration of Torque Wrenches Using an Electronic Torque Tester.”

From NFS procedures NFS-WST-036 (Versa-Pac) and NFS-WST-026 (ES-3100), a torque wrench set at 60 ft-lbs is used to tighten closure devices on the Versa-Pac and two torque wrenches set at 30 ft-lbs and 120 ft-lbs +/- 5 ft-lbs are used on the ES-3100 to tighten its closure devices.

NFS stated that it uses dedicated torque wrenches to specifically use on the two packagings at specific locations in the NFS facility. The team requested to see the listing of the three torque wrenches in the NFS master calibration M&TE database. The database identified the 30 ft-lb torque wrench as TW-156, the 60 ft-lb torque wrench as TW-173, and the 120 ft-lb torque wrench as TW-152 (although the database showed it as a 125 ft-lb torque wrench). The database also showed the location of use in the NFS facility and calibration due date for each wrench.

Since an Electronic Torque Tester is used to calibrate the torque wrenches, the team requested the last calibration record for the tester. The tester calibration is performed by an outside calibration laboratory at an interval of 12 months. The team reviewed the latest calibration certificate from the vendor and found it adequate.

The team requested and reviewed the calibration records for the three torque wrenches. A review of the records showed that the three wrenches have been calibrated at three month intervals instead of annually. However, the calibration records for the torque wrench which by procedure NFS-WST-026 required a 120 ft-lb +/- 5 ft-lbs torque wrench, had actually been historically calibrated to 125 ft-lbs +/- 5 ft-lbs.

The team walked down the three torque wrenches in the secured areas of the facility to check the calibration label sticker information on the actual torque wrenches in service. The calibration labels for all three torque wrenches had information that agreed with the database, calibration logs, and M&TE procedures. The torque wrench that was supposed to be set at 120 ft-lbs +/- 5 ft-lbs per procedure NFS-WST-026 was found to be currently and historically calibrated to 125 ft-lbs +/- 5 ft-lbs.

The team determined that based on the calibration records provided, torque wrench TW-152 had been used on all ES-3100 packagings for tightening closure devices with an incorrect torque value of 125 ft-lbs +/- 5 ft-lbs since 10/29/2012, instead of the required 120 ft-lbs +/- 5 ft-lbs torque value. NFS Procedure NFS-WST-026 Revision 12.A for handling/shipping ES-3100 packagings requires the ES-3100 containment vessel closure nut to be tightened to 120 ft-lbs +/- 5 ft-lbs torque using a calibrated torque wrench.

The team determined this failure to be a violation of 10 CFR 71.125, "Control of measuring and test equipment," which states, in part, that the licensee shall establish measures to assure that tools, gauges, instruments, and other measuring and testing devices used in activities affecting quality are properly controlled, calibrated, and adjusted at specified times to maintain accuracy within necessary limits. Contrary to the

requirements of 10 CFR 71.125, the calibrated torque wrench dedicated to the task of tightening the CV closure nut had been set/calibrated at a value of 125 ft-lbs +/- 5 ft-lbs and used in the field at that setting for at least four years.
This violation was entered into NFS' corrective action program PIRCS as Problem Report 59151, dated July 27, 2017. The inspection team evaluated the violation in accordance with Section 2.3 of the NRC Enforcement Policy and dispositioned it as a non-cited Severity Level IV violation.

The team determined that there was no immediate safety issue because the CV is leak tested before each shipment, which verifies that the O-rings are adequately performing their containment function.

5.3.3 Conclusion

Overall, the team found that the control of measuring and test equipment was adequate, with the one non-cited violation described above.

6.0 Other Issues Reviewed By The Inspection Team

6.1 Corrective Action Follow-up to 2006 NFS Inspection Notice of Violation

6.1.1 Notice of Violation

The team reviewed NFS' corrective actions associated with the violation identified during the September 11-13, 2006 inspection (Inspection Report 71-0249/2006-201, NRC ADAMS ML062710015) to verify the corrective actions had been completed as described in NFS' response to the violation on October 12, 2006 (ADAMS ML062960383). In 2006 NFS procedure NFS-RM-008, "Document Control Procedure," Revision 6, Section 6.b stated, in part, that a distribution sheet is prepared and maintained identifying the document being distributed, number of copies made, to whom issued, and date of issuance. Section 6.c stated, in part, that the copy number is written in red ink on the front of each copy. Section 6.e stated, in part, that a master file of the current original document and the distribution sheet is maintained for each controlled document in the controlling department, and that these documents may be entered into the vital records systems for microfilming as instructed by the area manager/director. 10 CFR 71.111 states, in part, that a licensee or certificate holder shall prescribe activities affecting quality by documented procedures and shall require that these procedures be followed. Contrary to this requirement, the requirements from NFS-RM-008 were not implemented by NFS when Revision 4 to NFS-GH-49, "Implementing Procedure for Transportation QA Program," was issued and thus being in violation of 71.111.

The team tried to verify the following actions described in the NFS response letter were taken: 1) a document distribution sheet for Revision 4 of NFS-GH-49, was prepared and maintained with the original copy; and 2) the employee responsible for issuance of procedures by the controlling department involved in the violation was informed of the non-conformance and read procedure NFS-RM-008, "Document Control Procedure," again.

Due to the age of this violation, the document distribution sheet for Revision 4 of NFS-GH-49 and the original procedure had been discarded. NFS provided to the team their procedure NFS-RM-006 Revision 24, "Uniform File Classification Outline," which shows how long records are to be retained. Records such as the document distribution sheet for revision 4 and the original procedure were discarded after two years in compliance with the procedure and therefore could not be verified by the team.

NFS was able to provide the training records for the employee that did not follow the procedure NFS-RM-008 requirements and caused the violation. The team verified that the training records recorded that the individual had read NFS-RM-008, Revision 6 and later revisions also. It should be noted that NFS-RM-008 was superseded by NFS-DOC-001, "Document Standards and Control," Revision 0 in 2012 and is currently at revision 8 and now titled, "Procedure Implementation Process."

6.1.2 Conclusion

The team determined the corrective actions in response to the violation were adequate and the violation is closed.

7.0 Exit Meeting

On July 27, 2017, the NRC inspection team presented the preliminary inspection results and observations during an on-site preliminary exit meeting. On April 26, 2018, the NRC inspection team conducted the final exit meeting with NFS by teleconference. The team exited with one Non-cited Level IV Violation, one Minor Violation, and one Unresolved Item. Table 2 of this report shows the attendance for the entrance, preliminary exit, and final exit meetings.