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REPORT NUMBER(S)	71-0254/2	2014-201	Washington, DC	20555-0001	
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QAP 71-0254		Wilmington, N		02/03-07/2014	25
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INSPECTOR NOTES COVER SHEET

Licensee/Certificate Holder	Global Nuclear Fuel – Americas, LLC (GNF)		
Licensee/Certificate Holder contact/address	Scott P. Murray Manager, Facility Licensing 3901 Castle Hayne Road P.O. Box 780 Wilmington, NC 28402		
Docket No.	71-0254		
Inspection Report No.	71-0254/2014-201		
Inspection Dates	February 3-7, 2014		
Inspection Location	Wilmington, NC Facility		
Inspectors	Rob Temps, Team Leader, Senior Safety Inspector Earl Love, Safety Inspector Jon Woodfield, Safety Inspector Shadi Ghrayeb, Observer		
Summary of Findings and Actions	This inspection involved a review of GNF's Quality Assurance (QA) Program implementation at their location in Wilmington, NC. Inspection activities focused on management controls, design activities, and maintenance controls, and how these activities are being controlled under GNF's NRC-approved QA Program.		
	Overall, GNF's activities were assessed to be in compliance with 10 CFR Part 71 regulations and with GNF's NRC approved QA Program. A Violation regarding procedural non-compliances was identified by the NRC and is described in these inspector notes and cited in the attached Form 591S.		
Lead Inspector Signature/Date	Jon M. Woodfield Robert Temps 3/6/2014		
Inspector Notes Approval Branch Chief Signature/Date	15 Cyl 3/14/2014		

INSPECTOR NOTES: IP 86001 WAS USED IN CONJUNCTION WITH APPLICABLE PARTS OF NUREG/CR 6314. INSPECTION RESULTS USING THE NUREG/CR 6314 FORMAT ARE DOCUMENTED BELOW:

Background

Global Nuclear Fuel – Americas, LLC (GNF), based in Wilmington, NC, holds Part 71 Quality Assurance Program (QAP) Approval No. 71-0254, Revision 9. The QAP authorizes activities at the GNF fuel fabrication facility in Wilmington, NC, with regard to the design and use of transportation packagings.

GNF was last inspected for Part 71 QAP activities in December 2006. The inspection was a full QAP implementation inspection at the Wilmington location. Inspection results were documented using a Form 591S with Inspector Notes and can be accessed through ADAMS accession number ML063630172.

Inspection Purpose

This inspection involved a review of GNF's QAP implementation at the Wilmington, NC, location. Inspection activities focused on management controls, design activities, and maintenance controls, and how these activities are being controlled under GNF's NRC-approved QAP. Follow-up to corrective actions from two Notice of Violations cited in the previous 2006 NRC inspection was also performed.

The inspection team assessed GNF's compliance with 10 CFR Parts 21 and 71, and verified that the transportation packagings for which GNF holds an NRC Certificate of Compliance (CoC) comply with the quality assurance requirements of 10 CFR Part 71, Subpart H, in the areas of management, design, procurement, nonconformance, maintenance, and audit program activities. The primary focus in the design and maintenance areas involved a systematic review of the Safety Analysis Report (SAR) Chapters 7 and 8 for two packaging CoCs that GNF holds and uses for transportation of NRC licensed material from the Wilmington facility.

Inspection Procedures/Guidance Documents

IP 86001, "Design, Fabrication, Testing, and Maintenance of Transportation Packagings"

NUREG-6314, "Quality Assurance Inspections for Shipping and Storage Containers"

Regulatory Guide 7.10, "Establishing Quality Assurance Programs for Packaging Used in the Transport of Radioactive Material"

Inspection Results

4.1.1 Quality Assurance Policy

The team reviewed NEDO-11209-A, "GE Hitachi Nuclear Energy Quality Assurance Program

Description," Revision 10, dated December 20, 2012. The document is written to satisfy the quality assurance (QA) requirements of 10 CFR 50, Appendix B. GNF applies NEDO-11209-A to Part 71 activities as allowed by 10 CFR 71.101(f). The team verified that QA personnel at GNF have appropriate independence and lines of authority for QA activities subject to Part 71. No concerns were noted in the implementation of NEDO-11209-A for Part 71 activities at the GNF Wilmington facility.

4.1.2 Nonconformance and Corrective Action Controls

The team reviewed the various GNF implementing procedures that address the documentation, tracking and resolution of nonconforming conditions and conditions adverse to quality. The team reviewed the following procedures:

- CP-16-108, "Corrective Action Program," Revision 5.0, 12/31/13
- CP-15-104, "Material Review Process," Revision 0.1, 01/23/14
- WI-15-100-02, "GNF-A Nonconforming Material Control," Revision 0.0, 03/12/13

The team reviewed the nonconformance controls implemented by GNF for transportation packaging maintenance operations and related procurement activities. WI-15-100-02, together with CP-15-104, provides guidance on the identification and quarantine of nonconforming items and their resolution through use of Inspection Reports (IRs), Nonconformance Reports (NCRs) or other administrative controls. The team reviewed Part 71 related IRs issued over a several year period. The team noted that most IRs were closed and that their resolution was appropriate to the identified nonconforming condition; however, some IRs were still open after several years. These IRs involved damaged transportation containers (removed from service) for which GNF final resolution as to repair or scrap was still to be decided.

The team identified two findings during its review of the IRs, specifically:

- 1. WI-15-100-02, step 4.3.4, states "Provide disposition for NCM (Nonconforming Material) per CP-15-104," and step 4.3.5.3, states "Acquire required IR, NCR approvals and technical justification per CP-15-104." CP-15-104, step 4.3.13, requires documentation of the acceptance rationale for "Use-As-Is" and "Repair" dispositions. Once these actions are completed, step 4.4.1 of WI-15-100-02 states to implement nonconforming material disposition detail as specified. The team identified that GNF's processing of NCM was not in accordance with the above sequence in that approvals and technical justification for "Use-As-Is" and "Repair" dispositions were obtained at IR closure instead of prior to implementation of disposition actions.
- 2. WI-15-100-02, Attachment 3, "FMO Nonconforming Material Handling and Storage," states that fuel shipping containers and radioactive material shipping containers dispositioned as scrap must be clearly marked as "scrap." The team identified two instances in which nonconforming shipping containers were dispositioned as scrap and were not clearly marked as "scrap." The team noted that the two shipping containers did have blue hold tags on them; however, as noted, the IR disposition of marking them as scrap had not been implemented.

10 CFR 71.111, "Instructions, procedures, and drawings," states, in part, that the certificate holder shall prescribe activities affecting quality by documented instructions, procedures, or drawings and shall require that these instructions, procedures, and drawings be followed. The two findings discussed above represent a Violation of 10 CFR 71.111 and are cited in the Form 591S attached with these Inspector Notes.

CP-16-108 controls the process for documenting and resolving conditions adverse to quality through the GNF corrective action program (CAP). Condition Reports (CRs) are used to document such conditions. The CR process provides for the assignment of a priority classification to CRs (Priority A, B or C) with different levels of cause determination and corrective action response depending on the priority level assigned. The procedure provides for the identification and processing of potential Part 21 reportability issues through reference to WI-16-108-07, "Reporting of Defects and Noncompliances Under 10 CFR Part 21."

The team reviewed Part 71 related CRs and associated documents issued in the last two years. Most of the CRs were closed out and the team verified that corrective actions were appropriate for the apparent causes identified in the CRs. The team reviewed in depth two CRs for which Non-conformance Assessments (NCAs) had been performed. The team assessed that the NCAs were comprehensive and identified multiple corrective and preventive actions that were being tracked for completion through the CAP process. One of the CRs, involving concerns with design engineering controls, is discussed in further detail in Section 4.2 of this inspection report. The team also reviewed CRs that were issued in response to a Notice of Violation issued during the previous NRC Part 71 inspection conducted in 2006. The team assessed that the Part 71 related CR issues were addressed satisfactorily.

The team reviewed WI-16-108-07, "Reporting of Defects and Noncompliances Under 10 CFR Part 21," Revision 0.0, 10/21/13, that addresses Part 21 posting and reportability requirements. No concerns were identified.

The team concluded that overall, GNF was using the NCM and CR systems to properly document and address Part 71 quality issues. Resolution of issues was appropriate to the extent and nature of the nonconformance or condition adverse to quality.

4.1.3 Documentation Controls

The team noted that GNF is one of many nuclear business entities of General Electric (GE) that are interrelated. The inspection was performed during a transition phase for GE where it was in the process of developing common procedures for use by its separate nuclear business units. Previously, separate nuclear business units had their own procedures for performing their business functions. Due to this transition period, there were older procedures and newer recently developed common procedures (CPs) that the team reviewed while assessing the area of documentation controls. Through interviews with document control and design engineering personnel the team was able to determine which of the many active procedures were being used to perform the document control process at GNF.

The team reviewed sections of NEDO-11209-A revision 10, the GNF Quality Assurance Program Description (QAPD) for 10 CFR Part 71, the Business Process Description (BP), Supporting Document (SD), GNF/GE Common Procedures (CPs), and Work Instructions (WIs),

specifically related to document control. The team specifically reviewed the following documents/procedures associated with document control:

- NEDO-11209-A, "GE Hitachi Nuclear Energy Quality Assurance Program Description," Revision 10, 12/20/12
- BP-06-01, "IMS Document Management and Use," Revision 1.0, 3/6/13
- SD-06-100-05-G01, "Issuing Authorities Guide," Revision 0.0, 1/17/14
- CP-03-100-G400, "Design Release," Revision 0.1, 11/27/13
- CP-03-100-G600, "Design Documentation and Records," Revision 0.1, 12/3/13
- CP-06-100, "Procedure Control Process," Revision 9.1, 2/3/2014
- CP-06-202, "Procedural Distribution by Index," Revision 3, 1/3/14
- CP-06-500, "Procedure Use and Adherence," Revision 0.0, 10/15/12
- CP-17-101, "Product Quality Assurance Records," Revision 1.0, 12/2/13
- WI-06-100-05, "Issuing Authority Responsibilities", Revision 3.0, 7/2/2013
- Issuing Authority Training Power Point, 11/01/2013

The team determined that GE implements separate document control just for procedures. This separate document control has control over all the procedures related to GE's nuclear business units including GNF. This document control for procedures does not control any of the final engineering design documents developed in accordance with design procedures. While the procedure document control group controls new, and revisions to, engineering design procedures, it does not control engineering design products such as drawings, Safety Analysis Reports (SARs), calculations, project plans, and design basis among others. Document control of engineering documents is performed by the GE design engineering department.

The two document control departments employ electronic records systems, thereby eliminating the need for paper copies of documents if a computer screen is available. Hard copies are only required if steps in a procedure required sign-offs, such as a maintenance procedure.

Both the procedure and engineering product document controls are user controlled systems whereby the user of an electronic copy must verify the latest revision to that document from the electronic master list. Users of the electronic system do have the ability to print hardcopies of procedures and engineering documents. However, all printed copies have "Uncontrolled When Printed or Transmitted Electronically" on the bottom of each page. Therefore, it is extremely important for the user of a printed hardcopy to continuously check the electronic master document list for current revisions.

Both the procedure and engineering product document controls use a "no signature" system where no one physically signs a procedure or engineering product document. New procedures/ engineering products and revised procedures/engineering products are transferred beyond the initiator to additional reviewers and approvers and the initiator and all reviewers/approvers attach their signatures electronically to the document. As the documents are passed along electronically for review and approval, they are sent to the reviewing or approving individual's work station where access is password protected to prevent anyone gaining unauthorized access to the workstation. Every electronic procedure and engineering product has a second file associated with it which represents a "traveler." The second file traveler shows the flow of the document electronically through initiation, review, approval, and issuing by the proper authority with the date that each electronic signature was added.

The final issuing of procedures is by an issuing authority. All new and revised procedures go through the electronic initiation, review, and approval signature process and then are sent to the issuing authority. The issuing authority is one individual that controls the master procedure electronic data base. The issuing authority individual is one of only a few people that can make changes in the electronic procedure system.

The issuing authority individual goes through a verification checklist which includes review of the electronic traveler before adding the revised or new procedure to the electronic system and showing it current on the master electronic document list. There is an isolated remote computer backup system in place by the GE IT staff should the main master document electronic system go down or become damaged for any reason. The issuing authority notifies GE nuclear employees (including GNF employees) electronically of new and revised procedures. The team interviewed the issuing authority individual and his supervisor and was given a demonstration of the whole electronic work flow of new and revised procedures. The team determined that adequate procedure document control management exists at GNF as related to 10 CFR Part 71 activities.

For engineering documents, the final issuing authority is the initiator of the engineering product; such as drawings, calculations, specifications, design basis, project plans, etc. As was the case for procedures, the initiation, review, and approval of engineering documents is all electronic. The same computer controls are in place for engineering documents as for procedures. All signatures are electronic and a traveler file with the signature information is attached to each engineering document.

For engineering documents, the initiator of the document is the issuing authority. After final approval, the engineering document is sent back to the initiator to place the document in the controlled document data base and update the master document list and supersede/void any previous revisions. As was the case for procedures, GE/GNF employees have read only access to the engineering documents except for the initiator of a new engineering document or reviser of an existing engineering document. The team interviewed IT personnel that administer the engineering product document control system and, like the procedure document control system, there is a remote isolated computer backup system in place should the main engineering document electronic system go down or become damaged for any reason. The team determined that adequate document control and records management exist at GNF for 10 CFR Part 71 activities.

4.1.4 Audit Program

The team reviewed GNF's audit program to determine whether plans, procedures, and records were available. The team determined whether GNF scheduled and performed internal QA audits in accordance with approved procedures and checklists and whether qualified & independent personnel performed the audits.

The team reviewed procedures CP-18-100, "Quality Assurance Internal Audit Requirements," Revision 2.0, 8/7/13 and CP-18-03, "Lead Auditor Certification and Audit Team Training Requirements." Lead auditor qualifications for several lead auditors were verified against CP-18-03 and no concerns were identified. The team reviewed GNF annual internal audit schedules for the past several years and verified that Part 71 transportation activities were specifically identified for auditing every two years; this action addresses a finding from the

NRC's last Part 71 inspection in 2006. The team reviewed the audit plan and completed audit checklist for Audit Number NQA-2012-04; conducted to assess for Part 71 Subpart H compliance. The audit report was comprehensive and identified several issues that were entered into the corrective action program for appropriate resolution. Overall, no concerns were identified with GNF's internal audit program for 10 CFR Part 71 activities.

4.2 Design Control (Design Development and Modifications)

The team reviewed sections of NEDO-11209-A revision 10, the GNF Quality Assurance Program Description (QAPD) for 10 CFR Part 71, GNF/GE Procedural Responsibilities and Instruction (PRI), Common Procedures (CPs), and Work Instructions (WIs), specifically related to design development/control and modification activities. The team held discussions with GNF/GE engineering and licensing staff associated with design control. The team focused its review on GNF design activities related to the currently submitted Part 71 amendment (SAR revision 8) for packaging RAJ-II (currently at CoC 9309 revision 9).

The team reviewed the following documents/procedures associated with design control:

- NEDO-11209-A, "GE Hitachi Nuclear Energy Quality Assurance Program Description," Revision 10, 12/20/12
- PRI-03-18, "GNF-A Change Management Process (CMP)," Revision 11.0, 8/19/13
- CP-03-100, "Design Process," Revision 0.0, 11/25/13
- CP-03-100-G400, "Design Release," Revision 0.1, 11/27/13
- CP-03-100-G600, "Design Documentation and Records," Revision 0.1, 12/3/13
- CP-17-101, "Product Quality Assurance Records," Revision 1.0, 12/2/13
- WI-03-100-30, 'Verification by Design Review, Revision 0.0, 11/25/13

As stated under document controls, GNF is just one of many nuclear business units of GE which are interrelated. GNF itself does not have a design engineering department for its 10 CFR Part 71 packagings. GE does have an engineering department for its nuclear businesses at the GNF facility site, which provides design engineering support for GNF's NPC and RAJ-II package designs for which they hold NRC CoCs.

The team focused its review of GNF/GE design engineering to activities related to the currently submitted Part 71 amendment (SAR revision 8) for the RAJ-II packaging (CoC 9309 currently at revision 9).

During its review of recently written GNF Condition Reports (CRs) the team noted a CR was initiated that documented concerns with the recent SAR revision 8 submitted to the NRC for the RAJ-II amendment. The CR, number 7498, was written to address errors discovered in the SAR revision 8. As a result of CR 7498, GNF initiated a Continuous Improvement Nonconforming Assessment Report CR7498 CI 254 NCA, Revision 0 (an apparent cause analysis). The team noted that the NCA Report identified five apparent causes that contributed to the identified issues. The team had extensive discussions with GNF licensing, (GNF/GE) design engineering, and logistics staff about the reasons for CR 7498 being written and how the apparent causes described in the CR7498 CI 254 NCA Report are being addressed. The team determined that while corrective actions underway and those planned were appropriate, final assessment of their full implementation and effectiveness will necessitate an NRC follow-up

inspection in the area of design controls in approximately one year. The follow-up inspection will focus on the development of procedures by GNF that address: 1) package design change management, 2) package design change and associated licensing change overall project management, 3) license amendment process ownership, and 4) changing licensing documents for 10 CFR Part 71 shipping containers.

The team found the amendment to the RAJ-II packaging to be a relatively small project within the GNF/GE design engineering department with one engineering staff member acting in the complete role as the responsible/project engineer. The current project engineer had not been involved with the project from the inception, but had been involved with the SAR revision 8 submittal to the NRC.

As GNF had self-identified in CR 7498, there was no project plan or overall project reviews for the team to review for the amendment. Therefore, the team focused on the design control processes for revising licensing drawings, developing calculations, performing owner acceptance reviews, and performing design independent verifications.

As discussed in the document control section, GNF, as one of the business entities supported by the GE design engineering department; has all its design engineering documents processed electronically. Other than the licensing drawings for the RAJ-II amendment being revised, the only other engineering documents developed for the project or affected by the project were calculations and the SAR. The GNF/GE RAJ-II amendment project engineer stated that there were no new specifications associated with the amendment.

The calculations developed for the RAJ-II amendment were developed electronically, signed by the responsible engineer (initiator) electronically, independently verified and signed electronically by the reviewer, and then approved electronically. The independent verifier is able to make electronic comments on the calculation and send them back to the initiator for discussion or incorporation during the process. The initiator finally receives the approved calculation back electronically and places the calculation into the engineering document control system. An electronic traveler accompanies every calculation.

For the RAJ-II amendment, GNF had partnered with Westinghouse and Westinghouse had responsibility for revising some chapters of the SAR and developing supporting calculations. The GNF/GE RAJ-II project engineer stated that she had owner accepted the Westinghouse calculations and also independently verified the results prior to adding the Westinghouse calculations into the GNF/GE engineering document control system.

The team assessed that GNF, through the GE design engineering department, was effectively implementing its basic design control procedures. The team found that engineering documents were receiving the proper independent verification reviews and approvals. Overall, no new concerns were identified by the team in the design control area other than those that had already been identified by GNF on CR 7498 and in Non-conformance Assessment CR 7498 CI 254 NCA Report, revision 0.

4.3 Maintenance Controls

The team reviewed GNF's activities regarding refurbishment of the RAJ-II packaging. The team reviewed various GNF implementing procedures and applicable check sheets to verify

compliance with those documents. While no maintenance or refurbishment was occurring for the NPC packaging, the team did review completed records for previous NPC work and verified procedural compliance and acceptance. In addition to RAJ-II and NPC, the team reviewed GNF's maintenance requirements, inspection & maintenance procedures, and completed maintenance records for the UX30 packagings. No significant concerns were identified.

With regard to the NPC packaging, the team reviewed maintenance records to determine whether maintenance materials were procured from approved sources and that maintenance material was controlled. The team noted that GNF issued purchase order 437071368 for the procurement of safety related Band Clamp Assemblies from a supplier on the GNF Approved Supplier List (ASL). The supplier procured the band clamps as commercial grade material from a company specified on the GNF purchase order and then performed and documented a pressure test on each band clamp assembly to the purchase order specification. The supplier then provided the band clamps to GNF with a Certificate of Conformance stating that the band clamps were supplied in accordance with GNF purchase order requirements. The team determined during a review of the supplier's receipt paperwork that there was no evidence of the band clamps having undergone formal commercial grade dedication to reclassify them as safety related components through the suppliers commercial grade dedication procedures. Consistent with a GNF design study summary (DRF No. 0000-0068-4957), the band clamp assemblies underwent a GNF approved hydrostatic pressure test and were permanently marked to indicate successful passage of this test. GNF initiated Condition Report No. 9455 to address the suppliers' failure to formally dedicate the band clamp assemblies. While the failure to ensure the dedication process is a violation of 10 CFR 71.111, "Instructions, procedures, and drawings," the failure constitutes a violation of minor significance and is not subject to formal enforcement action in accordance with the NRC Enforcement Policy.

The Team reviewed a GNF safety related purchase order (no. 437061010) of a nylon-locking (nylock) nut used on the band clamp assembly to maintain tension in the band clamp. The team assessed appropriate implementation of GNF's commercial grade dedication procedures that included compliance to the nylock critical characteristics defined within DRF No. 0000-0068-4957. The team noted that the nylock nuts were independently tested and appropriately GNF inspected. No concerns were noted.

The team observed inbound UX-30 cylinder and UF₆ cylinder inspections. The team noted the inspections were comprehensive, that attributes were appropriately inspected, and that the results were adequately recorded on the applicable forms and data sheets as defined and required by procedure. The tools and equipment the team observed being used during these inspections were observed to be in good condition and calibrated when required. The team reviewed a sample of recently shipped GNF and customer owned packagings to ensure that acceptance and maintenance tests were performed satisfactory to the requirements of the UX-30's Safety Analysis Report Packaging (SAR) Section 8.0, "Acceptance Tests and Maintenance Program." In addition, the team interviewed shipping/receiving and quality assurance personnel, inspectors, and reviewed various work packages to ensure completion of cylinder and overpack annual and five (5) year maintenance requirements. Overall, the UX-30 overpacks and UF₆ cylinders are routinely and satisfactorily inspected and maintained prior to use.

The team witnessed GNF refurbish RAJ-II packagings and determined, through direct observation or review of the refurbish checklists and special routing forms; that the maintenance

requirements from the SAR and implementing procedures were being adequately captured and addressed during the refurbishment process. The team noted that refurbishing operations included weld examinations and visual inspections to insure no missing parts or components (nuts, bolts, gaskets, plugs, etc.) as well as no shipping damage. As part of the refurbishment, missing or damaged parts were replaced as necessary. Damaged packagings that required repair were segregated and stored in a designated location pending a quality assurance disposition to ship the damaged packagings for repairs to another Certificate of Compliance holder (Columbiana Hi-Tech) with an NRC approved QAP.

The team reviewed GNF's maintenance attributes, inspection and maintenance procedures, completed maintenance records, shipping records (bill of lading, declarations, manifest/container/marking/labeling inspection checklists, transaction reports (NRC Form 741) and final shipment releases), and personnel training and qualification records. The team reviewed the maintenance requirements in the SAR sections on operating procedures (Chapter 7) and maintenance (Chapter 8) for the RAJ-II and NPC packagings against the procedures used by GNF to implement those requirements. The team determined that the GNF procedures adequately implemented the operating and maintenance requirements in the respective SARs.