



SAFETY INSPECTION REPORT AND COMPLIANCE INSPECTION

1. CERTIFICATE/QUALITY ASSURANCE PROGRAM (QAP) HOLDER: Global Nuclear Fuel - Americas, LLC (GNF) 3901 Castle Hayne Road P.O. Box 780 Wilmington, NC 28402		2. NRC/REGIONAL OFFICE Headquarters U. S. Nuclear Regulatory Commission Mail Stop TWFN 4B-34 Washington, DC 20555-0001	
REPORT NUMBER(S) 71-0254/2015-201			
3. CERTIFICATE/QAP DOCKET NUMBER(S) QAP 71-0254, CoC's: 71-9294, 71-9309	4. INSPECTION LOCATION Wilmington, NC	5. DATE(S) OF INSPECTION February 5, 2015 at GNF 2/9 - 4/2/2015 at Headquarters	

CERTIFICATE/QUALITY ASSURANCE PROGRAM HOLDER:

The inspection was an examination of the activities conducted under your QAP as they relate to compliance with the Nuclear Regulatory Commission (NRC) rules and regulations and the conditions of your QAP Approval and/or Certificate(s) of Compliance. The inspection consisted of selective examinations of procedures and representative records, interviews with personnel, and observations by the inspector. The inspection findings are as follows:

- ☐ 1. Based on the inspection findings, no violations were identified.
- ☒ 2. Previous violation(s) closed.
- ☒ 3. The violation(s), specifically described to you by the inspector as non-cited violations, are not being cited because they were self-identified, non-repetitive, and corrective action was or is being taken, and the remaining criteria in the NRC Enforcement Policy, to exercise discretion, were satisfied.

1 Non-cited violation(s) was/were discussed involving the following requirement(s) and Corrective Actions(s):

10 CFR 71.105 paragraph (d), under "Quality assurance program," states, in part, that the licensee, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained.

Contrary to the requirements of 10 CFR 71.105 paragraph (d), during a follow-up inspection conducted February 5, 2015 at GNF, it was brought to the NRC's attention the following example where GNF did not provide for proper indoctrination and training of personnel performing activities affecting quality, as necessary

- ☐ 4. During this inspection, certain of your activities, as described below and/or attached, were in violation of NRC requirements and are being cited in accordance with NRC Enforcement Policy. This form is a NOTICE OF VIOLATION, which may be subject to posting in accordance with 10 CFR 19.11.
(Violations and Corrective Actions)

Statement of Corrective Actions

I hereby state that, within 30 days, the actions described by me to the Inspector will be taken to correct the violations identified. This statement of corrective actions is made in accordance with the requirements of 10 CFR 2.201 (corrective steps already taken, corrective steps which will be taken, date when full compliance will be achieved). I understand that no further written response to NRC will be required, unless specifically requested.

TITLE	PRINTED NAME	SIGNATURE	DATE
CERTIFICATE/QAP REPRESENTATIVE	Bryce MacDonald, Manager, Logistics		4/6/15
NRC INSPECTOR	Jon N. Woodfield		4/6/15
BRANCH CHIEF	Patricia Silva <i>David W. Petrak</i>		4/8/15

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2/9 - 4/2/2015 at Headquarters

(Continued)

to assure suitable proficiency was achieved and maintained.

During the initial NRC inspection conducted February 3-7, 2014, which necessitated this follow-up inspection, the inspection team was told that there were no GNF procedures that addressed: 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. However, during the follow-up February 5, 2015 inspection GNF stated that a procedure(s) did exist addressing these four activities, but the two GNF personnel performing quality activities for a Safety Analysis Report Packaging (SARP) revision 8 submitted to the NRC for a RAJ-II packaging amendment prior to the 2014 inspection had not been trained in it/them and the procedure(s) was/were not part of their training requirements. SARP revision 8 was withdrawn by GNF from the NRC after errors in the submittal were discovered by GNF. If the two GNF personnel had been trained in the existing procedure(s) for which they were unaware, the errors would have been prevented by following the procedure(s) guidance.

It should be noted that GNF has been going through a procedure rewrite/upgrade program for several years and a current procedure exists which replaced the procedure(s) that was/were available to the two GNF personnel prior to the 2014 NRC inspection. The current procedure WI-13-104-01, "Packaging Documentation Control," has also been revised several times since its creation.

This violation is being treated as a Non-cited Violation consistent with Section 2.3.2.a of the Enforcement Policy. This violation is in the licensee's corrective action program as Condition Report 13684.

Note: Since the follow-up inspection was only scheduled for one day on February 5, 2015 at GNF's facility, the inspection could not be completed in one day due to the need to review more documents to determine if a violation had occurred. The inspection and documentation review continued at the NRC headquarters office with the finding of inadequate indoctrination and training of personnel performing activities affecting quality receiving final disposition as a Non-cited violation under the Enforcement Policy. The inspection exit meeting with GNF was performed on April 2, 2015 by teleconference.

INSPECTOR NOTES COVER SHEET

Licensee/Certificate Holder (name and address)	Global Nuclear Fuel – Americas, LLC (GNF) 3901 Castle Hayne Road P.O. Box 780 Wilmington, NC 28402
Licensee/Certificate Holder contacts	Bryce MacDonald, Manager, Logistics 910-675-6537
Docket No.	071-0254
Inspection Report No.	71-0254/2015-201
Inspection Date(s)	February 5, 2015 at GNF, 2/9 – 4/2/2015 NRC Headquarters
Inspection Location(s)	Global Nuclear Fuel – Americas, LLC (GNF) Wilmington, North Carolina
Inspectors	Jon Woodfield, Team Leader, Safety Inspector
Summary of Findings and Actions	<p>This inspection was a focused follow-up inspection of issues from the previous February 3-7, 2014 GNF inspection. The inspection was to determine if GNF adequately addressed the two findings from the 2014 NRC inspection under their corrective action program. In addition, the inspection team was to verify that GNF had developed procedures 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; in accordance with GNF Continuous Improvement Non-conforming Assessment Report CR 7498 CI 254 NCA, Revision 0 (an apparent cause analysis).</p> <p>Overall, the team assessed that GNF was adequately implementing their QA program with regard to QA, Management Controls, and Design Controls in the focused inspection areas. GNF continues to effectively implement their NRC approved QA Program for activities subject to 10 CFR Part 71.</p> <p>A Non-cited Violation regarding the lack of indoctrination and training of personnel performing activities affecting quality was identified by the NRC and is described in these inspector notes and discussed in the attached Form 591S. GNF acknowledged the issue and captured it on a Condition Report.</p>
Lead Inspector Signature/Date	Jon N. Woodfield <i>Jon N. Woodfield 4/6/15</i>
Inspector Notes Approval Branch Chief Signature/Date	Patricia Silva <i>for David W. Petach 4/8/15</i>

Inspection History

Prior to the 2015 inspection, the most recent GNF inspection was in February 2014. That inspection involved a review of GNF's Quality Assurance Program (QAP) implementation at the Wilmington, North Carolina location. Inspection activities focused on management controls, design activities, and maintenance controls, and how these activities were being controlled under GNF's NRC-approved QAP. A follow-up review of GNF corrective actions from two Notice of Violations (NOV) 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 Packaging (SARP) Chapters 7 and 8 for the two packaging CoCs that GNF holds and uses for transportation of NRC licensed material from the Wilmington facility. The inspection resulted in one NOV with results documented using a Form 591S with Inspector Notes and can be accessed through ADAMS accession number ML14078A627.

GNF was also 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

The overall purpose of the 2015 inspection was to assess GNF's compliance with 10 CFR Parts 21 and 71, and to verify that the transportation packagings for which GNF is the holder of the CoC, can be verified to comply with Part 71 in design requirements. The focus of this follow-up inspection was to determine if GNF adequately addressed the two findings and resulting NOV from the 2014 NRC inspection under their corrective action program. In addition, the inspection team was to verify that GNF had developed procedures 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; in accordance with GNF Continuous Improvement Non-conforming Assessment Report CR 7498 CI 254 NCA, Revision 0 (an apparent cause analysis).

Primary Inspection Procedures/Guidance Documents

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 Components According to Importance to Safety"

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

INSPECTOR NOTES: APPLICABLE SECTIONS FROM IP 86001 WERE PERFORMED DURING THE FOCUSED FOLLOW-UP INSPECTION WITH RESULTS DOCUMENTED BELOW UNDER THE BASIC HEADINGS OUTLINED IN NUREG-6314

4.1 Management Controls

4.1.2 Nonconformance Controls and Corrective Action Controls

The team reviewed GNF Condition Report (CR) 9344 and Continuous Improvement Plan (CIP) 289 that were written to address the first finding/example from the February 2014 inspection which resulted in the NOV cited against GNF for not following prescribed instructions and procedures for quality affecting activities. The documents evaluated the reasons for the procedures not being followed and determined that the GNF Traceway system for tracking repairs was not able to control procedure step compliance when nuclear packaging was sent off site for repairs by outside shops utilizing the repair suppliers procedures and travelers. To correct the procedure non-compliance issue, procedures WI-15-100-02 and CP-15-104 were revised to make the design engineering repair approval step compliant with the actual step practice being followed. The team reviewed the changes made under WI-15-100-02, "GNF-A Nonconforming Material Control," revision 0.1 and CP-15-104, "Material Review Process," revision 0.2 to address the issue and found the changes adequate. It should be noted that the revisions of these procedures when reviewed by the team were at 0.2 and 0.3, respectively. The team also reviewed the Nonconformance Assessment Report Response to CR 9344 dated April 30, 2014, and found it thorough and adequate. Reinforcement training on compliance to the sequential steps in these procedures was also provided to GNF personnel.

GNF on its own also found inconsistencies with the requirements of procedure CP-15-104 Material Review Process Attachment E, the GNF Traceway material inspection report system disposition routing, and the GNF QA Program requirements. To address these issues, GNF initiated Condition Report 9430 on its own and the team reviewed the resolution and actions associated with its closure. Under this CR, additional changes were made to CP-15-104 at revision 0.2 to correct all the inconsistencies. The team reviewed the additional changes to CP-15-104 from CR 9430 and found them adequate.

The team reviewed GNF Condition Report 9352 and Continuous Improvement Plan 290 that were written to address the second finding/example from the February 2014 inspection which resulted in the NOV cited against GNF for not following prescribed instructions and procedures for quality affecting activities. The documents attributed the reason for the procedures not being followed to a delay in performing evaluations to determine if the five damaged NPC packagings could possibly be repaired. There was also a turnover of the container design engineer and the quality engineer which added time to the delay in completing the evaluation and performing the scrapping processing. The CR stated that since the identification of this issue, the five NPC packaging containers had been scrapped and properly tagged as scrap. The CR also evaluated that there was no risk of the five damaged NPC packagings being used in service since the GNF Traceway Inspection Report system locked out the five containers from being used. The inspection team walked down all five of the scrapped NPC packagings and found all to now be properly identified as scrapped and their identification numbers crossed out according to procedure. To evaluate the extent of condition for not properly identifying scrapped NPC packagings and other packagings, GNF created a list of all scrapped packagings from its master records. GNF then proceeded to physically locate the scrapped packages at its facility and verify the packagings were properly identified as scrapped in accordance with procedures. Only one additional packaging was found to be improperly identified as scrapped outside procedure

requirements. The team walked down this additional packaging and verified that it was now properly identified as scrapped in accordance with procedures. As part of its corrective actions, GNF revised procedure WI-15-100-02 under revision 0.2 to enhance the visibility of nuclear packaging scrapping requirements. In addition, GNF created form WI-15-100-02-F02, "Checklist For Scrap/Re-purpose Nuclear Shipping Container," to aid the person implementing the procedure in handling nonconforming nuclear containers in the event that they are scrapped and removed from service or scrapped and re-purposed. The team reviewed and verified the changes made to WI-15-100-02 and the existence of new form WI-15-100-02-F02 and found the enhancements acceptable.

Although not classified as findings in support of the NOV from the February 2014 GNF inspection, the team did make several observations which GNF put onto one blanket Condition Report. Condition Report 9346 was initiated to address: 1) the lack of specific direction from the statement "Initiate an electronic IR/NCR when required" on Attachment 3 of WI-15-1-02, 2) the lack of evidence that during the procurement of quality Category A NPC Band Clamps that the procurement was Safety Related (SR) or commercial grade dedication took place, 3) the inconsistencies between the NPC packaging operating procedure inspection requirements tables wording and with what is shown in the NPC SARP chapter 7, and 4) the release of RAJ-II SARP revision 8 drawings prior to receiving NRC approval. The team reviewed the resolution of issues 1, 3, and 4 in the CR and found them acceptable. However, issue 2 was significant enough that GNF generated CR 9455 once it was determined that the Category A NPC Band Clamps had not been procured SR and had not been commercial grade dedicated. Addressing the issue, CR 9455 stated that the lack of Band Clamp documented dedication under the supplier's program had no effect on quality because the critical characteristics had been verified as part of GNF's receipt inspection per Quality Control Inspection Instruction (QCII) 177D4970 Item 42. Also in the CR there is documentation of discussions and preventive actions undertaken between the supplier and GNF to prevent the reoccurrence of this issue. Finally in the CR, there is evidence that GNF's responsible design engineer, nuclear container quality engineer, and supplier quality engineer approved its band clamp supplier's new procurement documents which will now be used to procure band clamps from sub suppliers. The team reviewed the actions taken to close these two CRs and found them acceptable.

The team assessed that the actions taken in CRs 9344, 9352, and CIPs 289, 290 to address the findings/examples supporting the issuance of the February 2014 Inspection NOV and the actions taken in CRs 9430, 9346, and 9455 to address other inspection observations were appropriate and adequate for resolution and to prevent reoccurrence.

4.1.3 Documentation Controls

As noted from the February 2014 Inspection, GNF is one of many nuclear business entities of General Electric (GE) that are interrelated. The 2014 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.

GNF provided an update to the team on the progress that had been made in developing common procedures. At the time of the follow-up inspection, GNF stated that 99.2 percent of the procedures within the scope of the project had been simplified into common procedures. The team found the progress to be excellent and the transition period almost over. The inspection team in 2014 had found that the combination of new and existing old procedures still in force to be confusing and difficult for GNF employees to utilize the proper procedures to

perform their work. With the near completion of the common procedure project at GNF, there should be better procedure compliance through simplification going forward.

4.2 Design Controls

4.2.1 Design Development

During the February 2014 GNF inspection, the team had noted a CR was initiated that documented concerns with, at the time, the recently submitted to the NRC SARP revision 8 for a RAJ-II amendment. CR 7498 was written to address errors discovered in the SARP revision 8. As a result of CR 7498, GNF initiated a Continuous Improvement Non-conforming Assessment Report CR 7498 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. During the February 2014 inspection, 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 CR 7498 CI 254 NCA Report were to be addressed. In response to CR 7498 and the CR 7498 CI 254 NCA Report, GNF initiated corrective actions. The inspection team in 2014 determined that while the corrective actions underway and those planned were appropriate, final assessment of their full implementation and effectiveness would necessitate an NRC follow-up inspection in the area of design controls in approximately one year. Based on the actions identified in CR 7498, CIP 254 and the CR 7498 CI 254 NCA Report, this follow-up inspection was to focus on the development of procedures by GNF that addressed: 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.

However, during the follow-up inspection GNF stated that procedures had existed at the time of the RAJ-II SARP revision 8 errors which provided guidance on the four activities listed above.

However, the two GNF personnel performing quality activities for the SARP revision 8 submitted to the NRC for the RAJ-II packaging amendment prior to the 2014 inspection had not been trained in it/them and the procedure(s) was/were not part of their training requirements. SARP revision 8 was withdrawn from the NRC by GNF after errors in the submittal were discovered by GNF. If the two GNF personnel had been trained in the existing procedure(s) for which they were unaware, the errors would have been prevented by following the procedure(s) guidance.

The team identified the lack of training in and knowledge of these procedures as a finding.

10 CFR 71.105 "Quality assurance program," paragraph (d), states, in part, that the licensee, certificate holder, and applicant for a CoC shall provide for indoctrination and training of personnel performing activities affecting quality, as necessary to assure that suitable proficiency is achieved and maintained. The finding discussed above represents a non-compliance of 10 CFR 71.105 paragraph (d) and is a Non-cited Violation on the Form 591S to which these inspector notes are attached.

This non-compliance is being treated as a Non-cited Violation instead of a Severity Level IV Violation consistent with Section 2.3.2.a of the Enforcement Policy for the following reasons:

1. GNF has placed the violation in its corrective action program as Condition Report 13684.

2. GNF will restore compliance within a reasonable period of time by performing the corrective actions listed in Condition Report 13684 by approximately the end of March 2015.
3. The violation is not repetitive as a result of inadequate corrective action.
4. There is no indication or evidence that this violation was willful.

As discussed under document controls, GNF has a project in place for developing common procedures for use by its separate nuclear business units. This project has been ongoing for an extended period of time and is nearing completion. The procedure(s) that the two individuals were not trained in and resulted in the Non-cited Violation has/have since been rolled into another procedure under the common procedure project. The team therefore reviewed the following current procedures during the follow-up inspection:

- CP-03-100-G400, "Design Release," Revision 2.1, 11/10/2014
- CP-03-100, "Design Process," Revision 3.0, 10/15/2014
- CP-16-106, "Change Management Process," 5.0, 1/9/2015
- WI-13-104-01, "Packaging Documentation Control," 1.0, 2/2/2015

The team assessed that overall, GNF now has in place procedures 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. Other than the one finding, no additional concerns were identified during the follow-up inspection by the team in the design control area.

GNF cancelled the RAJ-II SARP revision 8 and the amendment from any further NRC review soon after the February 2014 inspection and before this inspection. While the follow-up inspection team verified that GNF now has procedures in place to address the four areas of concern, the team did not review any ongoing Part 71 packaging design activities for compliance to the current procedures. The follow-up inspection team therefore recommends that the next GNF full inspection be performed in three years instead of the standard five year cycle for Part 71 CoC holders.