

November 4, 2008

Lisa Price, CEO  
Global Nuclear Fuel  
3901 Castle Hayne Rd  
Wilmington, NC 28401

SUBJECT: NRC INSPECTION REPORT NO. (99901376/2008-201) AND NOTICE OF  
NONCONFORMANCE

Dear Ms. Price:

On September 8-12, 2008, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at Global Nuclear Fuel (GNF) facility in Wilmington, NC. The enclosed report presents the results of this inspection.

This was a limited scope inspection that focused on assessing your compliance with the provisions of Title 10, Part 21 of the *Code of Federal Regulations* (10 CFR Part 21), "Reporting of Defects and Noncompliance." This NRC inspection report does not constitute NRC endorsement of your overall quality assurance or Part 21 programs.

Based on the results of this inspection, the NRC inspectors found that the implementation of your Quality Assurance (QA) program failed to meet certain NRC requirements imposed on you by your customers. Specifically, the NRC inspectors determined that there were inadequacies in GNF's 10 CFR Part 21 procedure in that it had not been maintained up to date with the current regulations. The specific findings and references to the pertinent requirements are identified in the Notice of Nonconformance enclosed in this letter.

Please provide a written statement or explanation within 30 days from the date of this letter in accordance with the instructions specified in the enclosed Notice of Nonconformance. We will consider extending the response time if you show good cause for us to do so.

In accordance with 10 CFR 2.390 of the NRC's "Rules of Practice," a copy of this letter, its enclosures, and your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system (ADAMS), accessible at <http://www.nrc.gov/reading-rm/adams.html>. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the Public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material is withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of

information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21.

Sincerely,  
**/RA/**

John A. Nakoski, Chief  
Quality and Vendor Branch 2  
Division of Construction Inspection  
& Operational Programs  
Office of New Reactors

Docket No. 99901376

Enclosures:

1. Notice of Nonconformance
2. Inspection Report 99901376/2008-201 and Attachment

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Sincerely,  
/RA/

John A. Nakoski, Chief  
Quality and Vendor Branch 2  
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## NOTICE OF NONCONFORMANCE

Global Nuclear Fuel  
3901 Castle Hayne Rd.  
Wilmington, NC 28401

Docket Number 99901376  
Inspection Report No. 2008-201

Based on the results of an NRC inspection conducted at Global Nuclear Fuel (GNF), Wilmington, NC facility on September 8-12, 2008, the NRC staff has found that certain activities were not conducted in accordance with NRC requirements.

Criterion V, "Instructions, Procedures, and Drawings" of Appendix B to 10 CFR Part 50, states in part that "Activities affecting quality shall be prescribed by documented instructions, procedures, or drawings, of a type appropriate to the circumstances and shall be accomplished in accordance with these instructions, procedures, or drawings."

Contrary to this requirement, the NRC inspectors found that:

1. GNF Policy and Procedure (P&P) 70-42, "Reporting of Defects and Noncompliance Under 10 CFR Part 21," dated October 13, 2006 had not been maintained current with applicable NRC regulations in that it did not contain the current 10 CFR Part 21 definitions.
2. The NRC inspectors also identified that GNF P&P 70-42 did not contain all of the requirements for notification letter content that are identified in 10 CFR Part 21; the procedure did not contain the requirements to identify (1) the name of the individual responsible for the corrective actions and (2) the length of time taken to complete the action.

These issues have been identified as Nonconformance 99901376/2008-201-01.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001, with a copy to the Chief, Quality and Vendor Branch 1, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to a Notice of Nonconformance" and should include: (1) the reason for the noncompliance, or if contested, the basis for disputing the noncompliance; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid noncompliances; and (4) the date when your corrective action will be completed. Where good cause is shown, the NRC will consider extending the response time.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or the NRC Agencywide Documents Access and Management System (ADAMS), to the extent possible, it should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. ADAMS is accessible from the NRC Web site at <http://www.nrc.gov/reading-rm/adams.html>. If personal

Enclosure

privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request withholding of such material, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim of withholding (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Requirements for the Protection of Safeguards Information."

Dated at Rockville, Maryland, this 4th day of November 2008



## EXECUTIVE SUMMARY

Global Nuclear Fuel  
99901376

The purpose of this inspection was to verify that Global Nuclear Fuel (GNF) implemented an adequate 10 CFR Part 21 program that met U.S. Nuclear Regulatory Commission (NRC) regulatory requirements. The NRC inspectors reviewed portions of the Quality Assurance (QA) program and 10 CFR Part 21 controls that GNF had established and implemented to meet the regulations set forth in 10 CFR Part 21. The inspection was conducted at GNF's facility in Wilmington, North Carolina.

The NRC inspection basis was:

- 10 CFR Part 21, "Reporting of Defects and Noncompliance."

The NRC inspectors implemented Inspection Procedure (IP) 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance" during the conduct of this inspection.

There were no recent NRC inspections performed at GNF's facility in Wilmington, NC, prior to this inspection. The last NRC Vendor Inspection performed at the GNF facility occurred between August 14 and September 1, 1995 (Ref. NRC Inspection Report No. 99900003/95-01, issued March 5, 1996). After reviewing the 1995 inspection report in preparation for the 2008 inspection, it was determined that there were no items that were necessary for follow up from the previous inspection, given the significant amount of time between the two inspections. The results of the NRC's September 8-12, 2008, inspection are summarized below.

The NRC staff also observed the performance of a limited scope audit (LSA) of GNF to assess the Nuclear Procurement Issues Committee (NUPIC) quality assurance audit process used for suppliers of components to the nuclear industry. This LSA was based on last NUPIC audit findings performed on August 13-24, 2007. The NRC staff implemented Inspection Procedure (IP) 43005, "NRC Oversight of Third-Party Organizations Implementing Quality Assurance Requirements." The trip report of the NRC staff's observations, including a list of the persons contacted during the trip, is documented in a Trip Report dated November 4, 2008, (ADAMS Accession # **ML082960066**).

### 10 CFR Part 21 Program

The NRC inspectors identified one nonconformance for GNF's failure to maintain 10 CFR Part 21 implementing procedures consistent with (1) the requirements for notification letter content and (2) the current definitions of 10 CFR Part 21.

The NRC inspectors concluded, with the exception of the issues identified in NON 99901376/2008-201-01, identified above, that the GNF 10 CFR Part 21 program requirements were in accordance with the regulatory requirements of 10 CFR Part 21 and were being implemented effectively.

## REPORT DETAILS

### 1. 10 CFR Part 21 Program

#### a. Inspection Scope

The NRC inspectors reviewed the implementing policies and procedures that govern the Global Nuclear Fuel (GNF) 10 CFR Part 21 process to verify compliance with 10 CFR Part 21. These documents included:

- GNF Policy and Procedure (P&P) 70-42, "Reporting of Defects and Noncompliance Under 10 CFR Part 21," dated October 13, 2006
- GE Hitachi Nuclear Energy (GEH) P&P 20-20, "GE Hitachi Nuclear Energy – Global Nuclear Fuel Interface," dated August 21, 2008
- GE Wilmington Employee Relations Manual PP-6, "Bulletin Board Policy," dated January 22, 2007
- GE Corrective Action Request (CAR) 43516, dated August 29, 2007
- GE CAR 46362, dated September 9, 2008
- GNF Procedural Responsibilities and Instructions (PRI 3-02), "Safety-Related Classification," dated November 14, 2007
- GNF Common Procedure CP-16-01, "Corrective Action Process and Self-Assessments," Revision 3, dated March 14, 2008
- GNF PRI 15-06, "GNF-A Nonconforming Material Control," dated July 6, 2007
- GNF Procedural Responsibilities and Requirements (PRR) 15, "Nonconforming Materials, Parts, or Components," dated January 8, 2008
- GNF PRI 17-01, "Product Quality Records" dated December 17, 2007
- GNF PRR 17, "Quality Assurance Records" dated December 17, 2007.

The NRC inspectors reviewed GNF's log of Potential Safety Concerns (PSCs) and Potentially Reportable Conditions (PRCs) and reviewed a sample of PSCs and corrective action reports (CARs) generated by GNF in the past five years to ensure that GNF's processes were effective in identifying and evaluating conditions adverse to quality that may require entry into the 10 CFR Part 21 process. The NRC inspectors reviewed a sample of 10 CFR Part 21 evaluations (PRCs) performed by GNF to verify that GNF had adopted adequate measures to evaluate deviations and failures to comply that could result in a substantial safety hazard. The NRC inspectors also reviewed a sample of notifications sent to purchasers or affected licensees, and purchaser's records to ensure GNF's procedures maintain legible, retrievable, and safely stored records in accordance with 10 CFR Part 21 requirements.

The NRC inspectors sampled GNF's 10 CFR Part 21 program implementation activities related to 10 CFR Part 21 postings and procurement documents.

#### b. Observations and Findings

##### b.1 10 CFR Part 21 Policies and Procedures

GNF P&P 70-42 described the GNF process for identifying and evaluating potential defects and failures to comply associated with 10 CFR Part 21. In accordance with P&P 70-42,

nonconformances determined to have the potential to adversely affect a basic component's ability to perform its intended function are sent to the GE-Hitachi Safety Evaluation Program (SEP) Program Manager (PM), who in turn initiates a PSC. The SEP PM formats the issue into the PSC standard, and dispatches it to the appropriate reviewing entities. Each PSC is tracked by the SEP PM and must be assessed by the reviewing entity within 10 working days to determine if a deviation or failure to comply has occurred. If the assessment concludes that a deviation or failure to comply has occurred or if ten days passes without a conclusion being reached, the PSC is converted to a PRC. The initiation of a PRC represents the discovery phase of the 10 CFR Part 21 evaluation and starts the 60 day evaluation period. In accordance with GNF P&P 70-42, a PRC can be closed in three ways: (1) as not reportable, (2) with a transfer of information per 10 CFR Part 21.21(b), or (3) as a reportable condition per 10 CFR Part 21.21(d). If the determination is made that notification is required, an SEP Evaluation is initiated that will be sent to the NRC along with the Notification of Potential Defects and Failures to Comply.

The NRC inspectors verified that GNF P&P 70-42 contained the appropriate timeliness controls per 10 CFR Part 21, including (1) evaluating deviations and failures to comply within 60 days, (2) providing an interim report to the NRC if the evaluation cannot be completed within 60 days, (3) notifying the customer or affected licensees within 5 days of determining that GNF cannot perform the review, (4) informing the GNF responsible officer within 5 working days if notification of NRC is required, (5) notifying the NRC within 2 days if a defect or failure to comply exists, and (6) submitting a written report to the NRC within 30 days of initial notification that a defect or failure to comply exists.

The NRC inspectors found, however, that GNF P&P 70-42 had not been maintained current with applicable NRC regulations in that it did not contain the current 10 CFR Part 21 definitions. Additionally, GE issued CAR 43516 for inadequate procedural maintenance as a result of a past NUPIC finding that identified that PRI 3-02 included out-of-date 10 CFR Part 21 definitions. The CAR included corrective action to revise the procedure to read: "Refer to GNF P&P 70-42 for a full definition of "Basic Component," per 10 CFR Part 21. However, as stated above, the definitions in GNF P&P 70-42 were not correct. After the NRC inspectors identified this issue, GNF initiated CAR 46362 to resolve the inconsistency. The corrective actions for CAR 46362 included consolidating GNF P&P 70-42 into GEH P&P 70-42, subsequently retiring GNF P&P 70-42, and checking other "mirror" P&Ps for inconsistencies that should be eliminated. The failure of GNF to maintain its 10 CFR Part 21 implementing procedure consistent with the current regulations in effect has been identified as an example of Nonconformance 99901376/2008-201-01.

The NRC inspectors also identified that GNF P&P 70-42 did not contain all of the requirements for notification letter content identified in 10 CFR Part 21; the procedure does not contain the requirements to identify (1) the name of the individual responsible for the corrective actions and (2) the length of time taken to complete the action. The NRC inspectors found that, contrary to the procedural inadequacy, a sample of 10 CFR Part 21 notifications sent to the NRC did contain all required information. The GNF QA personnel acknowledged the oversight and indicated an intention to resolve the issue during the consolidation of GNF P&P 70-42 into GEH P&P 70-42. The failure of GNF to adopt adequate procedures to implement the requirements of 10 CFR Part 21 has been identified as an example of Nonconformance 99901376/2008-201-01.

GEH P&P 20-20 stated that GEH provides the review of fuel-related PRC evaluations for GNF and provides Safety Evaluation Program administration under GEH P&P 70-42, which provides 10 CFR Part 21 guidance similar to that contained in GNF P&P 70-42. GNF CP-16-01 described the implementation of GNF corrective action program requirements, including the responsibilities and procedural steps for the initiation, evaluation, and closure of CARs as well as the completion of periodic CAR critiques, CAR trending, and focused self-assessments. The procedure also provided a link to the 10 CFR Part 21 program. GNF PR&R 15 defined procedural requirements and responsibilities for the determination of reportable nonconformances and referenced P&P 70-42 for instructions to determine 10 CFR Part 21 compliance. GNF PRI 15-06 described the implementation of deliverables contained within PR&R 15 and also contained a statement requiring the review of nonconforming material for reportability per P&P 70-42. The NRC inspectors found that these procedures provided an adequate link to the GNF Part 21 program.

#### b.2 10 CFR Part 21 Implementation

The NRC inspectors determined that 10 CFR Part 21 notifications submitted to the NRC by GNF contained all the information required by 10 CFR Part 21.21(d)(4) and met the timeliness requirements for submittal.

The NRC inspectors verified that GNF performed triennial audits and annual evaluations of its safety-related suppliers, including suppliers of completed assemblies, Zirconium single piece water rod pretubes, channel fastener assemblies, and stainless steel welded tubes for safety-related applications. The NRC inspectors verified that the GNF audits provided objective evidence of the adequacy, effectiveness, and implementation of safety-related suppliers' QA programs to ensure compliance with the requirements of 10 CFR Part 21 and Appendix B to 10 CFR Part 50.

The NRC inspectors also verified that GNF identified the applicability of 10 CFR Part 21 when issuing safety-related procurement documents to its suppliers. The NRC inspectors found that all three of the safety-related purchase orders sampled from the seven issued by GNF in the past five years identified Part 21 applicability.

GE Procedure PP-6 identified the locations of bulletin boards throughout the GE Wilmington facility (17 in total) and stated that each of the locations should have a 10 CFR Part 21 posting. The NRC inspectors verified that a sample of these locations contained Part 21 postings.

The NRC inspectors verified that GNF retained evaluations and failures to comply for five years after the evaluation; any notifications sent to purchasers and affected licensees for five years; and records of purchasers of basic component for ten years after delivery of basic component or service associated with the basic component. The NRC inspectors found that all records were retained safely and properly stored.

#### c. Conclusions

The NRC inspectors concluded, with the exception of the issues identified in NON 99901376/2008-201-01, that the GNF 10 CFR Part 21 program requirements were consistent with the regulatory requirements of 10 CFR Part 21 and were being implemented effectively.

## ATTACHMENT

### 1. PERSONS CONTACTED

Jennifer O'Connor	GNF Manager of Quality Assurance Program
Kimberly Clark	GNF Quality Leader
Michael Short	Shop Manager
Dave Nasman	Welding Quality Engineer
Carolyn Odom	Fuel Channel Gauging Operator
Larry Ward	Level III NDT
Jerry Norris	Clip Welder
Joe Johnson	Level I NDT (Ultrasonic Tester)
DJ Whittman	QC Inspector
Daniel Lee	Supplier Quality Engineer
Andy Lingenfelter	Vice President, Fuel Engineering
Dale Porter	Safety Evaluation Program Manager
Chuck Pinckney	Quality Systems Coordinator

### 2. INSPECTION PROCEDURES USED

Inspection Procedure 36100, "Inspection of 10 CFR Part 21 and 50.55(e) Programs for Reporting Defects and Nonconformance."

Inspection Procedure 43002, "Routine Inspections of Nuclear Vendors."

### 3. LIST OF ITEMS OPENED, CLOSED, AND DISCUSSED

There were no previous NRC inspections performed at GNF's facility in Wilmington, North Carolina, prior to this inspection.

<u>Item Number</u>	<u>Status</u>	<u>Type</u>	<u>Description</u>
99901376/2008-201-01	Opened	Nonconformance	Criterion V