



HITACHI

GE Hitachi Nuclear Energy

Richard Wittmeier
Senior Vice President
Nuclear Quality

P.O. Box 780 M/C A-10
3901 Castle Hayne Road
Wilmington, NC 28402

T (910) 819-6240
Richard.Wittmeier@ge.com

April 23, 2009
MFN 09-242

U.S. NRC Regulatory Commission
Attn: Document Control Desk
Washington, DC 2005-0001

SUBJECT: Reply to Notices of Violation

REFERENCE: NUCLEAR REGULATORY COMMISSION INSPECTION REPORT
05200010/2008-201, NOTICE OF VIOLATION TO GENERAL
ELECTRIC-HITACHI NUCLEAR ENERGY

GE-Hitachi Nuclear Energy (GEH) has received the NRC's letter dated March 25, 2009, providing the results of inspection 05200010/2008-201. As required by 10 CFR 2.201, GEH is providing a written explanation that addresses the identified issues, including reason for the violation, corrective actions that have been taken, corrective steps that will be taken, and the date when full compliance will be achieved. This information is provided in the attachment, which addresses each of the NRC identified Notices of Violation.

GEH will request a meeting to discuss this response with appropriate NRC personnel.

GEH is committed to continuous improvement and has taken prompt, comprehensive corrective actions to address the Notices of Violation identified by the inspection team.

Sincerely,

Richard Wittmeier
Senior Vice President
Nuclear Quality

FE01
D068
NRD

April 23, 2009

Page 2

Attachments:

1. GEH Reply to NOV 052000010/2008-201-01
2. GEH Reply to NOV 052000010/2008-201-02
3. GEH Reply to NOV 052000010/2008-201-03
4. GEH Reply to NOV 052000010/2008-201-04
5. GEH Reply to NOV 052000010/2008-201-05
6. GEH Reply to NOV 052000010/2008-201-06

cc: Jerald Head
James Klapproth
Mark Harvey
Russ Bastyr
Harold Neems
John Nakoski (NRC)

Attachment 1
Reply to NRC Notice of Violation 05200010/2008-201-01
Docket Number 05200010

The Notice of Violation

The Notice of Violation provides the following description of the violation:

Section 21.21, "Notification of failure to comply or existence of a defect and its evaluation," of Part 21 of Title 10 of the Code of Federal Regulations, "Reporting of Defects and Noncompliance" (10 CFR Part 21), requires, in part, that each individual, corporation, partnership, dedicating entity, or other entity subject to 10 CFR Part 21 adopt procedures to evaluate deviations and failures to comply as soon as practicable in order to identify defects and failures to comply associated with substantial safety hazards.

Section 7.7.3 of GNF CP 23-01, "Engineering Computer Programs," Revision 1, dated February 14, 2006, states that GEH internal users of software are to document and report to GEH Computer Department any engineering computer program technical usage problems, including potential errors.

Section 7.6.2 of GNF CP 23-01, states that GEH Computer Department documents all problems in engineering computer program problem reports and transmits them to the design and development organization managers for evaluation.

Section 7.7.6 of GNF CP 23-01, states that during the evaluation process, the problem is to be evaluated for any potential reportable conditions in accordance with the requirements of GNF P&P 70-42, "Reporting of Defects and Non-Compliance under 10 CFR Part 21," dated September 25, 2008.

Contrary to the above, as of December 19, 2008, GEH failed to perform a Part 21 evaluation when another GEH organization indicated that a software problem had impacted their use of the code. Specifically, GEH Engineering Computer Program problem report 2007-20 reported usage problems with the application of the GEXL critical quality boiling length correlation built into the TRACG code and was not adequately forwarded to GEH Nuclear Quality Assurance for Part 21 processing. As a result, GEH failed to document the evaluation of Engineering Computer Program problem report 2007-20 for potential safety concerns, and subsequent Part 21 reporting.

GEH's Response to the Violation

The Notice of Violation concludes that GEH failed to document a Part 21 evaluation required by GNF CP 23-01. GEH is contesting this violation based on the following information provided. In summary, the change involved software supporting a fuel product still under development, no deviation existed, as defined in 10CFR21, related to existing in-service product, and neither a departure from the technical requirements of a purchase order nor a failure to comply existed because the change involved software supporting

product under development. Accordingly, GEH believes no Part 21 evaluation was required

I. Reason for the Violation

A. Background

GEH provides the following additional information in order to provide a better understanding of the issue and why GEH is contesting the Notice of Violation.

- GEXL correlations are produced for each new fuel product line, consistent with the requirements documented in GESTAR II. While the form of the correlation is standardized, the coefficients and application ranges are tailored for each version. GEXL versions are unique to each fuel design and its associated experimental database. As an outcome of the design review of the GEXL17 correlation for GNF2 fuel, specific restrictions on GEXL parameters were approved and documented.
- GEXL-01A is a software program that can execute the GEXL correlation as a stand-alone module. Other programs can be configured to link with this module. The PANACEA code links with this module.
- GNF issued problem report 2007-20 as part of the process to correct (perfective maintenance¹) the GEXL-01A computer program. The purpose of the correction was to adapt the coding to properly reflect the new requirements for GEXL17, which are unique for application to the GNF2 fuel product line.
- The GEXL-01A module is not used in TRACG, so the error report was not applicable to TRACG. Furthermore, TRACG was not affected by the correlation parameter restrictions necessary to accommodate GNF2. TRACG utilizes its own internal routines to execute GEXL, regardless of the particular fuel product line. For application to transient analyses, the TRACG routines have sufficient flexibility (e.g., through input) to accommodate GEXL17 for GNF2.
- Problem report 2007-20 generated an affirmative response, i.e., that there was a potential downstream impact associated with the change. This response was from the software team (specifically, from the manager responsible for the PANACEA code). The affirmative response acknowledged the link to GEXL-01A and served to trigger two additional problem reports (2007-22 for PANAC11A and 2007-23 for PANAC11P). These problem reports highlighted the GEXL-01A issue to the downstream users of PANAC11A and PANAC11P, respectively.
- The responses to problem reports 2007-22 and 2007-23 indicated that no users were affected by the change.
- Note that the GNF2 fuel design has not been proposed for the ESBWR.

¹ NQA-2a-1990 and NQA-1-1994 requirements for software include item 3.6, "Operations and Maintenance Phase." Activities for software in this phase include responding to new or revised requirements (perfective maintenance).

- Problem report 2007-20 was closed in June 2007. Problem reports 2007-22 and 2007-23 were also closed in June 2007. At this point, the measures necessary to correct, verify, and approve the software changes were complete. These dates were over a year ahead of GNF2 fuel deliveries to customers and the associated reload analyses. The first reload of GNF2 fuel went critical at the Fitzpatrick plant on October 8th, 2008.
- Analyses supporting GNF2 Lead Use Assemblies (LUAs) were performed on a conservative basis, which is the standard process used by Global Nuclear Fuels. The parameter restrictions developed for the GEXL17 correlation were not required to support LUAs.

Problem report 2007-20 and subsequent actions solely addressed a fuel product that was under development. These activities were not for the purpose of addressing a coding error applicable to fuel supplied to operating plants or GEH's design certification submittals. The description of the issue provided in the problem report stated that it was an enhancement.

B. Analysis

In general, the GEH process for treating changes in analytic software (i.e., "problem reporting") is consistent with the NRC guidance provided in Reference 1 for this NOV response. GEH shares information regarding computer code problems with the user community, which allows sufficient information to be obtained to assess the potential impact of any changes to the software. The problem reporting process is applied to all engineering computer program changes (for released programs), regardless of the significance of the change.

Problem reports 2007-20, 2007-22 and 2007-23 were generated as required by GEH internal procedures. The change associated with these reports implemented new software requirements for GEXL-01A and were not for the purpose of correcting an error with broad applicability. The reporting process worked appropriately, highlighting the changes to the organization and driving an evaluation to confirm that there were no unanticipated effects. No safety significance was ever expected, nor was a concern determined to exist as a result of this process.

As noted in the Notice of Violation, CP 23-01, step 7.7.6, provides that "during the evaluation process, the ECP problem will be evaluated for any potentially reportable conditions in accordance with the requirements of GNF P&P 70-42 or GEH P&P 70-42 and initiate action if appropriate." In evaluating the problem reports, the P&P 70-42 criteria for a potential safety concern or reportable condition were never met because the problem related to a fuel design that had not been delivered to a customer. Thus a written notification to the Safety Evaluation Program (SEP) manager was never required.

II. **Corrective Actions Taken**

No corrective actions have been taken with respect to this issue.

III. Planned Corrective Actions

No corrective actions are planned to address this issue.

IV. Date When Full Compliance Will Be Achieved

As noted above, GEH believes that there has been no violation.

Reference:

1. NRC Information Notice 96-29: "Requirements In 10 CFR Part 21 For Reporting And Evaluating Software Errors," May 20, 1996.

Attachment 2
Reply to NRC Notice of Violation 05200010/2008-201-02
Docket Number 05200010

The Notice of Violation

The Notice of Violation provides the following description of the violation:

Criteria III, "Design Control", of Appendix B to Part 50 of Title 10 of the Code of Federal Regulations (10 CFR Part 50), "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," states, in part, that design control measures shall provide for verifying and checking the adequacy of the design by the use of alternate or simplified calculational methods.

NEDO-11209-04A, "GE Nuclear Energy Quality Assurance Program Description," Revision 8, dated March 31, 1989, states that design verification is a process for an independent review of designs against design requirements to confirm that the designer's methods and conclusions are consistent with requirements, and that the resulting design is adequate for its specified purpose.

Global Nuclear Fuel (GNF) Common Procedure (CP) 03-09, "Independent Design Verification," Revision #1, dated January 4, 2006, provides instructions for independent verification of computer software programs designed, developed, and used by GEH. Appendix F of GNF CP 03-09 provides instructions for the use of non-Level 2 codes for alternative calculations and verifications of software code during the development of GEH software products to verify correctness of an original calculation and developer's assumptions.

Appendix F of GNF CP 03-09 allows for the use of several different versions of non-Level 2 computer codes, if appropriate justification is documented. Contrary to the above, as of December 19, 2008, GEH failed to document the justification or rationale for the use a particular version of a non-Level 2 codes during alternate calculations to verify original calculations and developer's assumptions.

Contrary to the above, as of December 19, 2008, GEH failed to document the justification or rationale for the use a particular version of a non-Level 2 code during alternate calculations to verify original calculations and developer's assumptions.

GEH's Response to the Violation

GEH is not contesting the violation and has taken steps to address the issues identified in the inspection report. However, GEH notes that GNF CP 03-09 did not explicitly require that justification be documented as indicated in the violation and that GEH's program met the requirements of 10 CFR 50 Appendix B prior to the change, as explained below.

I. Reason for the Violation

A. Background

The procedures for independent design verification (CP 03-09 or EOP 42-6.00) direct engineers performing verification activities to:

- Confirm that the assumptions, inputs, data, and methods are identified and are appropriate
- If a computer program, or other computation application (e.g., spreadsheet), that is not approved software (e.g., other than a Level-2 engineering computer program) was used as the method of doing the original calculation, an alternate method of calculation or analysis must be performed and verified
- Assure that the design adequately meets the intended requirements and/or application

These requirements summarize relevant design control measures that GEH/GNF has established to satisfy 10 CFR 50, Appendix B, Criterion III.

10 CFR 50, Appendix B, Criterion XVII, "Quality Records," requires that "Sufficient records shall be maintained to furnish evidence of activities affecting quality. The records shall include at least the following: Operating logs and the results of reviews, inspections, tests, audits, monitoring of work performance, and materials analyses." The GEH/GNF procedures for design records (CP 03-08 and EOP 42-10.00) require that analyses and calculations be documented in sufficient detail such that a technically qualified person can understand the analyses and calculations without recourse to the originator. GEH's documented engineering analyses meet this requirement.

The issue of code versions surfaced during the December 2008 inspection of GEH's TRACG-based calculations for the ESBWR Design Certification Document (DCD). However, the use of multiple versions of TRACG had been the subject of prior discussions with the NRC staff and subject to an audit [Ref.1 for this NOV]. The design intent, rationale, and basis for each code version were extensively reviewed with the staff in support of a technical audit of the ESBWR (Fall 2006). As reviewed during this audit, each code version was created and applied in order to meet specific design objectives, e.g., corrective or perfective maintenance to TRACG models necessary to support of DCD analyses. Furthermore, all of the changes to TRACG models have been properly captured in the software documentation required under GEH and GNF procedures.

B. Analysis

In order to meet the Appendix B design control requirements, when applied to design activities, non-Level-2 computer programs are purposefully applied by designers and examined by qualified engineers serving as independent verifiers. In these cases, additional verification requirements are applied, i.e., alternate calculations. The corresponding record of the analyses supports this review and verification.

The Appendix B requirement for design records states that (at least) "results of reviews" will be documented. GEH's verification records comply with this requirement and include evidence of the review, as well as the results. The GEH requirement for alternate calculations under Appendix F of CP 03-09 states, "where alternate calculations are performed to verify the correctness of the original calculation, a review shall also be performed to address the appropriateness of assumptions, design input data used, and the computer program or other calculation method used." The requirement is that the review will be performed, not that justification will be documented, which is the wording in the Violation. GEH's design record files contain evidence of the review as required. The scope of the review, design output, and approvals are recorded.

The documented discussions of rationale that the staff apparently expected were not explicitly required as part of the design quality records. While GEH has established design control measures as required under 10 CFR 50, Appendix B, Criterion III, GEH believes that documentation of the justification for the review is a valuable improvement to our program. Accordingly, GEH will incorporate the additional documentation requirement as an enhancement and has taken steps as described below.

II. Corrective Actions Taken

Subsequent to the 2006 technical audit discussed in the Background section above, code version information was also provided to the staff in a response to a Request for Additional Information (RAI) [Ref. 2 for this NOV]. Based on the December 2008 discussions with the NRC inspection team, as a corrective action, GEH updated the Reference 2 responses to include a specific discussion of the rationale associated with code versions [Ref. 3 for this NOV] and provided Reference 4.

GEH maintains Engineering Services Instructions (ESI) to provide detailed, prescriptive work instructions to engineering personnel. These instructions may include supplemental requirements and represent acceptable means to comply with GEH quality procedures. Based on discussions with the NRC inspection team, CAR 47253 was initiated to update ESI 30-01, "Alternate Calculations for Verification of Non-Level-2 Computer Code Calculations." The requirement for a documented discussion of the rationale regarding code versions was added to the ESI and the CAR was closed on March 23, 2009. The new requirement to provide a written discussion of the reasoning justifying the use of a non-Level-2 program is applied to all GEH and GNF analysis activities, not just those supporting the ESBWR.

III. Planned Corrective Actions

In Reference 5 for this NOV, GEH committed that safety analyses for the ESBWR DCD, Revision 6, and future revisions of LTRs NEDO-33337 "ESBWR Initial Core Transient and Accident Analyses" and NEDO-33338 "ESBWR Feedwater Temperature Operating Domain Transient and Accident Analyses" will be performed with the TRACG04P Level-2 Engineering Computer Program. As a result, non-Level-2 versions of TRACG will not be applied to future DCD analyses, alleviating further need for a discussion of rationale concerning code versions.

IV. Date When Full Compliance Will Be Achieved

The ESI 30-01 change is already in place addressing all future non-Level-2 Software usage. Additionally the commitment made in Reference 5 for this NOV will be achieved with the submittal of DCD Revision 6.

References:

1. Attachment, "AUDIT RESULTS SUMMARY REPORT - ESBWR DCD Chapters 6 and 21, TRACG for LOCA," electronic communication, Michelle Honcharik (NRC) to James F. Harrison, "TRACG SE References for Proprietary Review," March 4, 2009.
2. MFN 08-607, R.E. Kingston (GEH) to USNRC Document Control Desk, "Response to Portion of NRC Request for Additional Information Letter No.1 05 - Related to ESBWR Design Certification Application - RAI Number 21.6-92 Supplement 1," July 31, 2008.
3. MFN 08-607 Supplement 1, R.E. Kingston (GEH) to USNRC Document Control Desk, "Response to Portion of NRC Request for Additional Information Letter No.1 05 - Related to ESBWR Design Certification Application - RAI Number 21.6-92 Supplement 1," January 29, 2009.
4. MFN 09-182, R.E. Kingston (GEH) to USNRC Document Control Desk, "Response to Portion of NRC Request for Additional Information Letter No. 293 - Related to ESBWR Design Certification Application – RAI Number 21.6-92 Supplement 2," March 16, 2009.
5. MFN 09-14, R.E. Kingston (GEH) to USNRC Document Control Desk, "Submittal of Case Matrix to TRACG and Event Analyses Reflecting the dP Loss Coefficient Resolution," February 10, 2009.

Attachment 3
Reply to NRC Notice of Violation 05200010/2008-201-03
Docket Number 05200010

The Notice of Violation

The Notice of Violation provides the following description of the violation:

Criterion XVI, "Corrective Action", of Appendix B to 10 CFR Part 50 states, in part, that measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected.

NEDO-11209-04A states that conditions adverse to quality or nonconformance such as: failures, malfunctions, deficiencies, and deviations in material and equipment are promptly identified, documented, and corrected or otherwise handled in accordance with established procedures. In addition, NEDO-11209-04A states that corrective action follow-up and closeout procedures provide for assuring that corrective action commitments are implemented in a systematic and timely manner. Furthermore, NEDO-11209-04A states that corrective action documentation and request forms or formal letters are used to document the corrective-action-related requests, responses and follow-up.

GNF CP 23-01, "Engineering Computer Programs," Revision 1, dated February 14, 2006, requires that software problems be presented as notifications to potentially affected users. Section 7.7.5 of GNF CP 23-01 requires internal software users to respond to Engineering Computer Program (ECP) problem reports within 30 days of notification.

Contrary to the above, as of December 19, 2008, of the 54 internal user responses required for the four ECP problem reports evaluated (2008-44, 2008-14, 2008-09 and 2007-42), 23 responses were received after 30 days or were not received by the GEH Computer Department.

GEH's Response to the Violation

GEH is not contesting the violation and has taken steps to address the issues identified in the inspection report.

I. Reason for the Violation

A. Background

GEH and GNF have established a requirement that engineering teams applying Engineering Computer Programs (ECPs) to design analyses must respond to software error notifications within 30 days. This time period allows these teams to evaluate the problem reports and gather sufficient information to assess the safety significance of the

notification (e.g., determine if any analyses supporting plant safety evaluations or licensing submittals have been impacted).

B. Analysis

While measures have been established as required by Appendix B, they were not executed. Responsible managers and engineers failed to meet the requirement. The failure to comply with the 30-day requirement was not addressed through the corrective action program. Internal audits failed to identify the issue.

An investigation into the underlying causes for late responses revealed that the main issue was a lack of understanding that a response to the problem notifications were required, even if there was no application of a computer program in a particular area of responsibility.

II. **Corrective Actions Taken**

Based on the NRC inspection team's finding, CAR 47149 was initiated in December 2008 to address the issue of timeliness of responses. Key actions are summarized below:

- The reporting process was clarified and "no application" has been formally established as a required response (when applicable).
- All delinquent responses to outstanding error notifications for software problems were received (January 2009).

Additional corrective actions are relevant and have been implemented:

- CAR 47152 was initiated to enhance the ECP problem report format. As a result, a standard reminder was added to error notifications. The reminder states that responses acknowledge that 10 CFR part 21 reporting requirements have been considered, which emphasizes the (pre-existing) requirements under GEH's CP 23-01 and Policy & Procedure 70-42, "Reporting of Defects and Noncompliance Under 10 CFR Part 21."
- CAR 47962 was initiated to improve the problem reporting process. Specifically, the CAR drove an evaluation of process improvements aimed at ensuring sustained performance for timely responses. As a result, the problem report process was changed to implement the initiation of CARs for Type-A² ECP problem reports, which leverages GEH's and GNF's corrective action program and system for tracking commitments. Senior management is reviewing the status of the corrective action program on a monthly basis for effectiveness and timeliness. This corrective action also makes the ECP problem report process consistent with GEH's commitments in Reference 1, which describes changes relevant to its Part 21 reporting program.

² GEH and GNF classify software errors as types A and B, which are simply those that have an impact on calculated numerical results and those that do not.

Issues associated with deficiencies in internal audits are being addressed in connection with the Notices of Violation 05200010-2008-201-05 and 05200010-2008-201-06.

The actions to address timeliness of responses to error notifications are complete.

III. Planned Corrective Actions

GEH is performing a review (CAR48167) of its policies and procedures to confirm that any periodic or time-limited actions associated with regulatory requirements have been identified and are being met. Any nonconformances will be documented in a corrective action and appropriately addressed.

IV. Date When Full Compliance Will Be Achieved

Corrective actions for engineering software error reporting have been implemented. Full compliance has been achieved. Delinquent responses to problem reports have been obtained and the ECP problem reporting process has been modified to address deficiencies.

The additional, broader review of policies and procedures discussed under item III will be completed by August 31, 2009.

Reference:

1. MFN 09-236, Richard Wittmeier (GEH) to the US NRC Document Control Desk, "Reply to a Notice of Violation," April 9, 2009.

Attachment 4
Reply to NRC Notice of Violation 05200010/2008-201-04
Docket Number 05200010

The Notice of Violation

The Notice of Violation provides the following description of the violation:

Criterion XVI, "Corrective Action", of Appendix B to 10 CFR Part 50 states, in part, that measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected.

NEDO-11209-04A states that conditions adverse to quality or nonconformance such as: failures, malfunctions, deficiencies, and deviations in material and equipment are promptly identified, documented, and corrected or otherwise handled in accordance with established procedures. NEDO-11209-04A also stated that procedures provide for significant conditions adverse to quality to be identified, their causes to be determined, and for corrective action to be taken.

GNF CP 23-01 provides the instructions for the GEH software Corrective Action Program (CAP) for Level 2 software codes.

GNF CP 16-01, "Corrective Action Process and Self-Assessments," Revision 3, dated March 14, 2008, provides instructions for General Electric Nuclear Energy's Corrective Action Report process that is used in many departments throughout GEH. Appendix F of GNF CP 03-09 provides instructions for the use of non-Level 2 codes for alternative calculations and verifications of software code during the development of GEH software products to verify correctness of an original calculation and developer's assumptions.

Contrary to the above, as of December 19, 2008, GEH failed to have an adequate corrective action program for Level 1 software code errors. GEH was not able to provide the NRC Inspection Team documentation that showed where errors in Level 1 codes were processed through either the General Electric Nuclear Energy's Corrective Action Report process or the GEH software Corrective Action Program.

GEH's Response to the Violation

GEH is not contesting the violation and has taken steps to address the issues identified in the inspection report.

I. Reason for the Violation

A. Background

GEH analytic software is developed and maintained under CP 23-01 "Engineering Computer Programs." Software managed under this procedure carries a designation that reflects its "level" with respect to the software life cycle. Two important levels are:

- Level-1 – Approved for development. This designation complies with the NQA-1-1994 standard for software, which requires a review of the software design to ensure that requirements have been addressed. Level-1 computer programs are subjected to additional development activities and requirements (e.g., testing), which can lead to a Level-2 designation.
- Level-2 – Approved for operational use or "production." This designation complies with the NQA-1-1994 standard, which requires documented approval of the software for operational use. Level-2 programs are actively maintained, i.e., under configuration management and subject to error reporting.

As stated in CP 23-01, Level-1 and 4 (retired) ECPs are not authorized for design applications, which is consistent with the NQA standard. For this reason, the ECP error reporting process excludes Level-1 and 4 ECPs.

B. Analysis

The analysis performed to support corrective action for this issue determined that error reporting should not be necessary for Level-1 ECPs, since these programs are developmental (by definition) and should not be applied to design. However, the basic issue that the NRC staff cited was that non-Level-2 software had been applied to safety analyses and it was not clear that these computer programs were subject to error reporting. Following this line of questioning led to an examination of the applicable software requirements (i.e., NQA-1-1994) and the GEH / GNF procedures that allowed the use of non-Level-2 computer programs.

Various procedures govern the design process (e.g., GEH and GNF employ procedures to control activities such as design reviews, the generation of design records, etc.). The procedure governing independent verification defines acceptable means of verifying design analyses. The verification criteria for computer-based calculations only recognize approved (e.g., Level-2) or non-approved (e.g., non-Level-2) software. Under this procedure, Level-1 software is not granted any particular status or recognition and is subject to the same requirements as non-Level-2 software. Thus, for the purpose of design verification, the fact that a program may be Level-1 is incidental.

In all cases, verification of design calculations must confirm that the assumptions, inputs, data, and methods are identified and are appropriate. The verification requirements for non-Level-2 software also include alternate calculations. There are no additional requirements. These limited requirements imply a philosophy or approach that the use of non-Level-2 computer programs is treated as an instance or single event, equivalent to a hand calculation. There is no presumption of re-use or continued use for design purposes. As a consequence, requirements for maintenance activities, such as error reporting, have not been explicitly addressed.

It should be noted that business-wide programs, such as the Corrective Action Program (CAP) and company policies such as P&P 70-42 for defect reporting, apply to all GEH and GNF activities. These programs have broad scope and include design analyses. An error in an analysis due to a problem with non-Level-2 software would, at a minimum, be treated as a condition adverse to quality. A formal CAR would be required, which would include an evaluation of the effects and extents of the problem.

II. Corrective Actions Taken

Based on the NRC inspection team's finding, CAR 47150 was initiated in December 2008. The major points from the CAR analysis were:

- The GEH level designations in CP 23-01 governing engineering computer program development and maintenance were confirmed to be consistent with the NQA-1-1994 standard.
- A key procedure (Independent Design Verification Procedure) governing the design process contains links to CP 23-01. The verification procedure defines acceptable means of performing analyses in terms of the CP 23-01 definitions. This procedure contains the provisions for the use of non-Level-2 computer programs, which includes requirements for alternate calculations. These provisions have been determined to be deficient relative to the requirements in the NQA standard.

In order to comply with the NQA-1-1994 standard, computer programs are either developed under the standard, or the requirements of item 10.2, "Software Developed Not Using This Standard" should be applied. The requirements under item 10.2 go beyond testing and include maintenance activities (e.g., configuration management and error reporting). Non-Level-2 computer programs have not been developed using the NQA standard, so as a minimum, the requirements of section 10.2 must be applied to their operational use.

III. Planned Corrective Actions

As a result of the CAR 47150 analysis, CARs 47878 and 47880 were initiated to correct the GEH and GNF procedures governing verification. The corrective actions will implement the additional requirements of NQA-1-1994, item 10.2, into the GEH design process as discussed above. The NQA-based requirements for "Software Developed Not Using This Standard" will be implemented as a means to comply with CP 03-09, "Independent Design Verification." In other words, going forward, non-Level-2 software will be required to meet the new criteria in order to be accepted for application to design. This change will assure that GEH's application of software to produce or manipulate data that is used directly in the design, analysis, and operation of structures, systems, and components³ will comply with the requirements of NQA-1-1994.

³ This description of software and its application was taken from NQA-1-1994, Section 2.1, "Applicability."

April 23, 2009

Page 17

In the interim period, the requirement for verification of non-Level-2 software with alternate calculations, for each use or application, will continue to be applied.

In all cases, the application of Level-2 engineering computer programs (preferred) will continue to be acceptable.

IV. Date When Full Compliance Will Be Achieved

Full compliance will be achieved through the completion of CARs 47878 and 47880, which is scheduled for June 30, 2009

Attachment 5
Reply to NRC Notice of Violation 05200010/2008-201-05
Docket Number 05200010

The Notice of Violation

The Notice of Violation provides the following description of the Violation:

Criteria XVIII, "Audits", of Appendix B to 10 CFR Part 50 states, in part, that a comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program.

NEDO-11209-04A states that a comprehensive system of planned and documented audits is carried out to verify product quality and compliance with the QA Program. NEDO 11209- 04A further states that audits are conducted at scheduled intervals as documented in audit schedule planning.

NEDO-11209-04A also states GEH staff-level organizations are required to perform annual self-audits to determine the effectiveness of, and verify compliance with, assigned portions of the QA Program. Each organization prepares plans for the conduct of internal audits prior to February 1 of each year so that during the course of each year all aspects of the QA Program are included in at least one self-audit.

Section 2.3.3 of GNF Policy and Procedures (P&P) 70-14, "GNF Quality Assurance Audit Requirements," dated November 2, 2007, requires that an annual audit plan is prepared to ensure that a representative sample of GEH's quality system elements and all 18 criteria of 10 CFR 50, Appendix B, are audited. Section 2.11.6 of GNF P&P 70-14 also requires audit records are maintained for a minimum of three years or three years from the completion date of any corrective action.

Contrary to the above, as of December 19, 2008, GEH failed to have the GEH NQA audit plans for 2006 and 2007.

GEH's Response to the Violation

GEH is not contesting the violation and has taken steps to address the issue identified in the inspection report.

I. Reason for the Violation

A. Background

P&P 70-14, Nuclear Energy Quality Assurance Audit Requirements, revision dated August 12, 2008, section 4.3 directs scheduling of audits. Section 4.3.3 of P&P 70-14 specifically states, "The annual NQA audit plan of internal audits shall be developed by NQA to ensure that a representative sample of the elements of the GEH quality system, all applicable 18 criteria of 10CFR50, Appendix B, and all applicable elements of ISO-9001 are audited annually within GEH by NQA. The Manager of NQA shall prepare this plan by February 1 each year."

B. Analysis

A review of P&P 70-14, dated January 20, 2009, identified that Section 2.3.3 and Section 2.11.6 provide guidance for the retention of Audits and associated support documents specific to individual audits performed. No mention is made in the procedure specifying the requirement for the retention of the GEH Internal Nuclear Audit Planning & Schedule Document. The apparent cause for this violation was identified as inadequate procedural guidance.

II. Corrective Actions Taken

The January 20, 2009 revision to P&P 70-14 added appropriate steps to enhance and provide rigor in the creation of the GEH Internal Audit Planning & Schedule Document.

- The existence and retention of the 2008 and 2009 audit schedules was verified.

III. Planned Corrective Actions

P&P 70-14 will be revised to require retention of the GEH Internal Audit Planning & Schedule Document for a three-year period.

IV. Date When Full Compliance Will Be Achieved

Actions to achieve full compliance will be accomplished through a revision of GEH Procedure P&P 70-14, scheduled to be completed by May 29, 2009.

Attachment 6
Reply to NRC Notice of Violation 05200010/2008-201-06
Docket Number 05200010

The Notice of Violation

The Notice of Violation provides the following description of the Violation:

Criteria XVIII, "Audits", of Appendix B to 10 CFR Part 50 states, in part, that a comprehensive system of planned and periodic audits shall be carried out to verify compliance with all aspects of the quality assurance program and to determine the effectiveness of the program. The audits shall be performed in accordance with written procedures or checklists by appropriately trained personnel not having direct responsibility in the areas being audited. Audit results shall be documented and reviewed by management having responsibility in the area audited.

NEDO-11209-04A requires that QA audits be conducted using pre-established written procedures or checklists by appropriately trained personnel not having direct responsibilities in the area being audited. In addition, NEDO-11209-04A requires that audit results are documented by the auditors and transmitted for review by management having responsibility in the area audited.

Contrary to the above, as of December 19, 2008, GEH failed to include specific criteria in its checklists, and as such failed to adequately document the basis of the audit findings to support the audit conclusions. For example:

1. Engineering Computer Programs (ECPs) are audited as part of the annual Global Nuclear Fuels-America nuclear fuel design audit. This annual audit only includes a sample of the more than 100 ECPs being used by GEH for compliance with applicable policies and procedures. The checklists used for these audits only contain general information on software criteria. GEH has different requirements and governing policies for its different software types. GEH audit checklists do not specify the criteria against which the software are to be audited in order that the auditors can evaluate the compliance of the software program to GEH policies and procedures.
2. The GEH NQA audit of GNF-A (Audit Q0617, dated October 27, 2006) included an assessment of the Part 21 program and was found to be satisfactory. GEH's basis for this assessment cited P&P 70-42, "Reporting of Defects and Non-Compliance under 10 CFR Part 21, without documenting how this satisfied 10 CFR Part 21."

GEH's Response to the Violation

GEH is not contesting the violation and has taken steps to address the issues identified in the inspection report.

I. Reason for the Violation

The GEH Audit program was reviewed. Specifically an analysis of P&P 70-14, Nuclear Energy Quality Assurance Audit Requirements, revision dated August 12, 2008, was performed. P&P 70-14 failed to establish the methodology to specify the audit criteria specific to the type of software being audited.

NQA Audit Q0617 was reviewed and it was determined that question 1.B.3 of the audit assessed 10CFR Part 21. Review of the objective evidence for this question was found to be inadequate. The apparent cause of the inadequate objective evidence was determined to be.

- P&P 70-14 provided minimal guidance to assure consistent documentation of objective evidence in support of the audit conclusions.
- Management prior to the 2008 time period did not establish and maintain adequate implementation of P&P 70-14 relative to documentation of objective evidence.

II. Corrective Actions Taken

The following Actions were taken to address adequate documentation of objective evidence for GEH Audits.

P&P 70-14 was revised on January 20th to included expanded guidance on the requirements on the documentation of objective evidence in audit checklists during the audit performance.

Training was held for lead auditor and lead auditors currently being certified on the January 20, 2009 revision to P&P 70-14.

The training included:

- Presentation of P&P 70-14 requirements for the documentation of objective evidence
- Management expectation for the implementation of the requirements of P&P 70-14

III. Planned Corrective Actions

A revision will be made to P&P 70-14 to establish the methodology to specify the audit criteria specific to the type of software being audited.

April 23, 2009

Page 22

IV. Date When Full Compliance Will Be Achieved

Actions to achieve full compliance will be accomplished through a revision of GEH Procedure P&P 70-14, scheduled to be completed by May 29, 2009.