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Subject: Reply to Notice of Nonconformance NRC Inspection Report
05200010/2006-201, dated June 14, 2006.

On June 14, 2006, the NRC issued a Notice of Nonconformance (NON) to the General Electric Nuclear Energy (GENE) facility in Wilmington, North Carolina. The NON identified two Nonconformances, the bases for which are delineated in NRC Inspection Report No. 05200010/2006-201 (Reference 1).

This letter provides a response to the NRC Inspection Report. Attachment #1 addresses the Nonconformances identified in Enclosure 1 of the subject NRC Inspection Report and provides: 1) Restatement of the Nonconformance; 2) Reason for the Nonconformance; 3) Description of Actions that have been or will be taken to correct the identified findings; 4) Description of Actions that have been or will be taken to prevent recurrence; and 5) Date when full compliance will be achieved. Attachment #2 addresses the Unresolved Items identified in Enclosure 2 of the subject NRC Inspection Report.

GE will continue to work toward completion of the required actions and provide periodic updates upon request.

If you have any questions, please do not hesitate to contact me.

Sincerely,

David Hinds
FOR

David H. Hinds,
Manager, ESBWR

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References:

1. MFN 06-193, Letter from U.S. Nuclear Regulatory Commission to David H. Hinds, *NRC Inspection Report 05200010/2006-201 and Notice of Nonconformance*, June 14, 2006
2. MFN 06-031, Letter from U.S. Nuclear Regulatory Commission to David H. Hinds, *NRC Inspection Report 05200010/2005-201 and Notice of Nonconformance*, January 11, 2006

Attachments:

1. GE Response to INSPECTION REPORT 05200010/2006-201 – Nonconformance
2. GE Response to INSPECTION REPORT 05200010/2006-201 – Unresolved Items

cc: WD Beckner USNRC (w/o enclosures)
AE Cabbage USNRC (with enclosures)
LA Dudes USNRC (w/o enclosures)
RP McIntyre USNRC (with enclosures)
GB Stramback GE/San Jose (with enclosures)
eDRF 0000-0056-0217

Attachment #1

GE Response to INSPECTION REPORT 05200010/2006-201 - Nonconformance

Nonconformance 05200010/2006-201-01**1. Restatement of Nonconformance 2006-201-01**

Criterion XVI, "Corrective Action," of 10 CFR Part 50, Appendix B, 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. The identification of the significant condition adverse to quality, the cause of the condition, and the corrective action taken shall be documented and reported to appropriate levels of management.

GENE Policy and Procedure (P&P) 70-11, "Quality Policy and Quality System Requirements," dated January 4, 2005, Section 8.15, describes the general requirements for implementation of a corrective action process including: (1) identification of the potential deficiency; (2) determination of the cause; (3) documenting recommended actions to correct deficiency; (4) documenting recommended actions to preclude recurrence; (5) and ensuring proper levels of management are made aware of the deficiency to achieve resolution.

NEDO-11209-04A describes, in part, the general requirements for implementation of a corrective action program. Procedures and practices are established which provide assurance that conditions adverse to quality are promptly identified, documented, and corrected or otherwise handled in accordance with established procedures. Corrective action followup and closeout procedures provide for assuring that corrective action commitments are implemented in a systematic and timely manner.

EOP 75-3.00, Revision 10, "Self-Assessment, Corrective Action, and Audits," dated May 12, 2005, specifies the responsibilities for actions to promptly identify, record and correct conditions adverse to quality and to assure that these conditions do not affect the quality of a product or service.

Contrary to the above, GENE's corrective action process has not been effective at addressing and correcting the root causes of nonconformances. Additionally, GENE did not adequately implement the requirements to process and complete corrective actions in a timely manner in accordance with GENE QA program. This issue is identified as Nonconformance 05200010/2006-201-01.

2. Reason for Nonconformance 2006-201-01

Nonconformance 05200010/2006-201-01 notes two distinct issues: A) Generic issue relative to overall timeliness of the corrective action process, and B) Specific issue relative to closure of an External (External Audit or External Non-audit) CAR (CAR 40521) without concurrence of the customer, regulatory authority or other external organization.

CARs 40893 and 41212 were initiated to address issues A & B respectively.

Issue A

An apparent Root Cause evaluation was conducted through an investigation of ESBWR CAR performance based on Key Performance Indicators. At the time, ESBWR had a negative trend with respect to completing initial CAR responses within the 30-day requirement period and completing corrective and preventive actions on time. A meeting was held on May 3, 2006 to discuss ESBWR CAR behaviors and propose new actions to improve ESBWR CAR program effectiveness. It was determined that these defects were a symptom of a lack of adequate management and team attention to the Corrective Action program.

Issue B

Step 4.4.10 of EOP 75-3.00 instructs the acceptance of the CAR for closure in the CAR Tracking System (CTS). However, a note to step 4.4.10 states, "CAR closure of an External (External Audit or External Non-audit) CAR is contingent upon the concurrence of the customer, regulatory authority or other external organization." In this specific incident the person that accepted the CAR did not follow the procedural note as prescribed in EOP 75-3.00. Also, procedure EOP 75-3.00 step 4.4.9 states "Transmit the External CAR with all actions completed to the appropriate customer, regulatory authority or other external organization for concurrence (I)." The omission of this step by the initiator highlights the initiator's need for additional training for a further understanding of the procedural requirements contained in EOP 75-3.00. A review of CTS software that implements and documents the CAR process was performed. This review demonstrated that CTS software does not provide safeguards, which prompt the user to enter the external concurrence as required procedurally. This can contribute to the omission of the external concurrence. The feasibility of adding a prompt in the CTS software will be explored as a possible preventive action.

3. Corrective Actions that have or will be taken to correct the identified findings

Issue A

Corrective Action #1: Coordinate an investigation of ESBWR Team CAR behaviors concurrent with the investigations being led by Manager – Engineering Quality and Safety Evaluations for Engineering Team CAR issues. Determine proper corrective and preventive actions to supplement the actions completed under CAR 40521 (CAR now closed). Modify CAR (40893) to define and track the supplemental actions. Include an effectiveness review with this CAR 40893 to follow up on ESBWR team CAR performance/timeliness.

Action Completion: A meeting was held on May 3, 2006 to discuss ESBWR CAR behaviors and propose new actions to improve ESBWR CAR program effectiveness. As a result, CA #2 (CAR 40893) and PA #1 (CAR 40893) were added to supplement the previous actions under CAR 40521.

Completion Date: May 11, 2006

Corrective Action #2: Assign unassigned CARs to a single person identified as the Responsible Person. Establish the practice of assigning new CARs to a designated Responsible Person to provide a central coordination point.

Action Completion: Unassigned CARs assigned to designated Responsible Person and established the practice of assigning future unassigned CARs to a designated Responsible Person.

Completion Date: June 29, 2006

Issue B

Because concurrence for closure of CAR 40521 was later received from the NRC, this is a procedural violation and had no effect on the corrective and preventive actions taken and its acceptability. The NRC acceptance was received under NRC Inspection Report 05200010/206-201. Since this concurrence has been obtained, no corrective actions are required for CAR 41212.

4. Preventive Actions that have or will be taken to prevent recurrence**Issue A**

Preventive Action #1: The newly assigned Responsible Person for ESBWR CARs will participate in the periodic ESBWR management staff meeting, to ensure that the Corrective Action Program is receiving adequate attention from ESBWR Management. Provide CAR status reviews during these periodic meetings to maintain a high attention level.

Due Date: July 28, 2006 – Action initiated and participation in periodic staff meetings is ongoing.

Preventive Action #2: Establish the practice of notifying the appropriate Engineering Functional Manager of any open CAR responses approaching the 30-day completion date.

Action Completion: A weekly notice to the General Manager, Functional Managers/Process Owners and Responsible Persons identifying CAR responses that are due in the next two weeks has been implemented and is in the process of being added into ESI 20-5.00.

Completion Date: May 19, 2006 – Action initiated and notification is ongoing.

Preventive Action #3: Establish the practice of notifying the ESBWR Engineering Manager and appropriate Action Owners of any open ESBWR CAR actions that are overdue or approaching the due date.

Action Completion: A weekly notice to the ESBWR Manager, Functional Leads, Quality Engineers and CAR Action Owners identifying all CAR actions or responses that are due in the next two weeks has been implemented. Copies of notices are stored in eDRF Section 0000-0055-8634.

Completion Date: July 07, 2006 – Action initiated and notification is ongoing.

Issue B

Preventive Action #1: Review ESBWR completed CARs. Determine the population of External CARs that were closed without required external concurrence. Obtain external concurrences if it has not already been received. Determine the effects of closing the CAR without external concurrence.

Due Date: October 02, 2006

Preventive Action #2: Submit a CTS enhancement request to explore the possibilities of adding a prompt that will notify users of the need for customer, regulatory authority, or other external organization concurrence for CAR closure. The prompt also should contain a reminder that such concurrence is required to be documented.

Action Completion: Support Central Case #5116650 was initiated on 7/12/06, to "add a prompt for external CARs that will notify users of need for customer, regulatory authority, or other external organization concurrence for CAR closure. The prompt should also contain a reminder that such concurrence is required to be documented. Documentation can be done in the Initiator Closure Statement block. Additional blocks for customer statement are not needed. Advise if this enhancement is feasible." This enhancement will be tracked to closure in Support Central for CTS module.

Completion Date: July 12, 2006

Preventive Action #4: Train the individual that did not obtain external concurrence prior to performing the closure acceptance of CAR 40521 on the requirements of EOP 75-3.00 section 4.4.10, 4.4.11, and the associated note.

Action Completion: Training was provided for the individual that accepted the External CAR 40521 prior to receiving concurrence from the regulatory authority. This training was documented in the training database.

Completion Date: July 11, 2006

5. Date when full compliance will be achieved

Compliance with the programmatic requirements of the GE Corrective Action Program will be achieved with the initiation of weekly CAR status meetings the week of July 24, 2006 and the maintenance of weekly notifications as identified in PA's 1, 2 and 3.

Training of ESBWR personnel to the requirements of EOP 75-3.00 will be completed by October 2, 2006.

Nonconformance 05200010/2006-201-02

1. Restatement of Nonconformance 2006-201-02

Chapter 17, "Quality Assurance," of the ESBWR Design Control Document (DCD) describes the GENE QA program for the design and construction phase of the ESBWR program. Chapter 17 commits to meet the requirements of ANSI/ASME NQA-1-1983 and the NQA-1a-1983 addenda as endorsed by the NRC in Regulatory Guide 1.28, Revision 3 (August 1985). Chapter 17 also references GE NEDO-33181, Revision 1 and NEDO-11209-04A, Revision 8.

NEDO-33181, Revision 1, dated October 2005, provides the QA system and the program description which GENE will implement as supplier of ESBWR engineering services for contractual requirements for Phase 1 and Phase 2 of the DOE NP-2010 COL (US NRC construction and operating license) Demonstration Project. This encompasses all quality related activities performed by GE, as well as those performed by its subcontractors during execution of the program.

NEDO-11209-04A is the QA program description that applies to all GENE activities performed affecting the quality of items and services supplied to nuclear power plants and establishes GENE's compliance with the provisions of Appendix B to 10 CFR 50. NEDO-11209-04A was in place for implementation of all previous simplified boiling water reactor (SBWR) design and test activities.

GENE Policy and Procedure (P&P) 70-11, "Quality Policy and Quality System Requirements," dated January 4, 2005, defines the GENE quality policy, including the overall requirements for the Nuclear Energy business quality system. P&P 70-11, Section 8.2.1 states that Nuclear Quality Assurance (NQA) is responsible for developing, issuing, and maintaining P&P 70-11 and the QA Program description (NEDO-11209-04A). P&P 70-11, Section 8.4.2 requires that all safety-related products meet the applicable quality requirements of NEDO-11209 and the applicable licensing commitments.

Contrary to the above, during the review of Nonconformance 05200010/2005-201-02 and Unresolved Item (URI) 05200010/2005-201-01, the NRC inspectors identified that not all ESBWR project documents reference the appropriate ANSI/ASME NQA-1-1983 edition, as described and committed to in Chapter 17 of the ESBWR DCD. This issue has been identified as Nonconformance 05200010/2006-201-02.

2. Reason for Nonconformance 2006-201-02

CAR 40911 was initiated to address the identified Nonconformance pertaining to documentation and use of the proper year and addenda of ASME NQA-1.

The inconsistency of identifying, in various ESBWR related documents, the appropriate ASME NQA-1 year and addenda resulted from using documents prepared for previous BWR projects, e.g., the ESBWR composite specification and the GENE Quality Assurance Program Description, NEDO-11209, cited various editions of ASME NQA-1.

3. Corrective Actions that have or will be taken to correct the identified findings

- Corrective Action #1:** Establish the correct year and addenda of NQA-1 to reference in ESBWR project documents and the DCD.
- Action Completion:** After engineering review, it has been established that ESBWR project documents shall properly reference the requirements of ANSI/ASME NQA-1-1989 and Addenda 1a-1989, 1b-1991 and 1c-1992, which is consistent with the current requirements of regulation 10CFR50.55a.
- Completion Date:** June 06, 2006
- Corrective Action #2:** Revise the appropriate ESBWR documents to reflect the correct year and addenda of NQA-1. Initiate revisions to ESBWR Purchase Orders, if necessary.
- Action Completion:** Revisions to ESBWR Purchase Orders are not required because SQAR NEDC-33260 Rev. 0 already requires the correct revision of NQA-1-1989 Edition with 1a-1989, 1b-1991 and 1c-1992 Addenda. The current NIAC audit checklist Rev. 4, which is used for supplier audits, already addresses the requirements of NQA-1-1989 Edition with 1a-1989, 1b-1991 and 1c-1992 Addenda. The ESBWR QA Plan and DCD will be revised under CA #3 and CA #4 respectively.
- Completion Date:** June 29, 2006
- Corrective Action #3:** Revise and issue the ESBWR QA Plan to reference the correct NQA-1 requirements as decided in CA #1.
- Due Date:** July 21, 2006
- Corrective Action #4:** Revise and issue the ESBWR DCD to reference the correct NQA-1 requirements as decided in CA #1.
- Due Date:** February 28, 2007

4. Preventive Actions that have or will be taken to prevent recurrence

- Preventive Action #1:** Communicate to the appropriate ESBWR staff the correct year and addenda of NQA-1 to be used on the ESBWR project. Communicate to necessary ESBWR staff any revisions needed to ESBWR project documents as a result of CA #2.
- Action Completion:** GE QA has determined the appropriate QA Program specification requirements for each type of supplier to be: For the ASME Code Supplier and sub-tier suppliers each should have implemented a Quality Assurance Program in compliance with ANSI/ASME NQA-1-1989 Edition with 1a-1989, 1b-1991, and 1c-1992 Addenda, Quality Assurance Program Requirements for Nuclear Facilities, as modified and supplemented in NCA-4120 (b) and NCA-4134 [per ASME Section III, 2001 Edition, NCA-4000].

For metallic Material Organizations, the Quality System Programs should meet the requirements of NCA-3800.

For non-metallic material manufacturers and constituent suppliers, the Quality System Programs should meet the requirements of NCA-3900.

For suppliers of Safety-Related ASME components, which contain individual parts, which by code definition are specifically exempt from code requirements. Special attention is required for parts that perform a Safety-Related function, they must be provided as Safety-Related in accordance with a QA Program accepted by the Buyer.

This information was communicated to the ESBWR Engineering and Program Management leaders with instructions to forward the information to the DCD chapter leads within their areas of responsibility, requesting review and change to the DCD. They are requested to review POs and revise any POs specifying a QA program (if not performed under GE's QA Program) to be consistent with the SQAR and above specification. A copy of the correspondence email to the ESBWR Engineers and Program Management is filed under the CAR 40911 section of eDRF 0000-0039-8808.

Completion Date: June 30, 2006

5. Date when full compliance will be achieved

The next complete revision of the DCD will incorporate the correct NQA-1 revision as decided in CA #1 (CAR 40911). Expected completion date February 28, 2007.

Attachment #2**GE Response to INSPECTION REPORT 05200010/2006-201 – Unresolved Items****Unresolved Item 05200010/2005-201-01 (OPEN)****1. Restatement of Unresolved Item 2005-201-01**

During the previous inspection, the NRC inspectors identified that Chapter 17 of the ESBWR DCD did not include an Introduction Section that describes what the ESBWR QA program is based upon and how it will be implemented by GENE and its various domestic and international participants. The NRC inspectors also noted that they were unable to review or verify the activities associated with the transition from the SBWR to ESBWR design, particularly as it relates to the qualification test activities that were performed for the SBWR design in the mid- 1990s and are being used to support the ESBWR design certification application. GENE was requested to provide appropriate documentation in the DCD Chapter 17 Introduction Section describing the details of the QA program commitments and background information regarding the transition from the SBWR to ESBWR design.

2. Status of Actions for Unresolved Item 2005-201-01

CAR 40522 was initiated to address the identified Nonconformance.

GENE is currently working to complete corrective action #2 as described in CAR 40522, to revise and issue the ESBWR DCD to include an Introduction Section with background information regarding the transition from the SBWR to ESBWR design. Expected completion date is February 28, 2007.

Unresolved Item 05200010/2005-201-02 (OPEN)**1. Restatement of Unresolved Item 2005-201-02**

During the previous inspection, the NRC inspectors discussed the need to recapture the design and test control implementation inspection documentation issued by the NRC staff for the SBWR design certification qualification testing activities which are being used to support ESBWR design certification. This documentation includes all NRC Inspection Reports, GENE responses to inspection findings, and NRC replies to GENE responses. GENE was requested to recapture this SBWR inspection documentation for inclusion in the ESBWR Chapter 21 FSER for Quality Assurance Inspections related to Testing and Computer Code Evaluation.

2. Status of Actions for Unresolved Item 2005-201-02

CAR 40523 was initiated to address the identified Nonconformance.

GENE is currently working to complete corrective action #2 as described in CAR 40523, with an expected completion date of September 29, 2006. The first of the test program QA overview summaries has been drafted and internally reviewed. The remainder of the review summaries is scheduled for preparation, review and completion to support the above date. The related document library is complete and ready to support the overview summaries.