January 11, 2006

Mr. David H. Hinds, Manager, ESBWR
GE Nuclear Energy
PO Box 780, M/C L60
Wilmington, North Carolina 28402-0780

SUBJECT: NRC INSPECTION REPORT 05200010/2005-201 AND NOTICE OF NONCONFORMANCE

Dear Mr. Hinds:

On November 15-17, 2005, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the General Electric Nuclear Energy (GENE) facility in Wilmington, North Carolina. The purpose of the inspection was to determine if the implementation of selected portions of GENE's quality assurance program and quality activities performed to support design certification of the economic simplified boiling water reactor (ESBWR) were conducted under the appropriate provisions of NEDO-11209-04A, "GE Nuclear Energy Quality Assurance [QA] Program Description," Revision 8, dated March 31, 1989, the most recent revision that has been approved by the NRC. The enclosed report presents the details of that inspection.

During this inspection it was found that the implementation of your QA program failed to meet certain NRC requirements. GENE did not adequately implement the ESBWR design control process as required by the GENE QA program. GENE did not document the revised completion date for the ESBWR Design Control Document (DCD) verification when the schedule was not met and did not maintain and update the work plan/detailed schedule for the ESBWR program. Additionally, GENE did not perform the Corrective Action Request (CAR) acceptance reviews within the required 30 day period and did not document and complete the required corrective/preventive actions identification and the response/closure activities associated with several ESBWR CARs. The specific findings and reference to the pertinent requirements are identified in the enclosure of this letter.

Five nonconformances are cited in the enclosed Notice of Nonconformance (NON), and two unresolved items are described in detail in the enclosed report. You are requested to respond to the NON, and should follow the instructions specified in the enclosed NON when preparing your response. Furthermore, the ESBWR design certification is subject to resolution of the issues identified.

In accordance with Section 2.390, "Public Inspections, Exemptions, Requests for Withholding," of Part 2 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 2), "Rules of Practice for Domestic Licensing Proceedings and Issuance of Orders," a copy of this letter, its enclosures,

and your response will be made available electronically for public inspection in the NRC Public Document Room (PDR) or from the NRC's document system (ADAMS), accessible from the NRC Web site at http://www.nrc.gov/reading-rm/adams.html.

Sincerely,

/RA/

David B. Matthews, Director
Division of New Reactor Licensing
Office of Nuclear Reactor Regulation

Enclosures:
1. Notice of Nonconformance
2. Inspection Report 05200010/2005-201

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NOTICE OF NONCONFORMANCE

General Electric Nuclear Energy
Wilmington, North Carolina

Docket Number 05200010
Inspection Report Number 2005-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted November 15-17, 2005, of activities supporting General Electric Nuclear Energy's (GENE's) design certification for economic simplified boiling water reactor (ESBWR), it appears that certain activities were not conducted in accordance with NRC requirements.

1. Criterion III, "Design Control," of Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 50), Appendix B, states, in part, that design control measures shall provide for verifying or checking the adequacy of design, such as by the performance of design reviews, by the use of alternate or simplified calculational methods, or by the performance of a suitable testing program.

   GENE Policy and Procedure (P&P) 70-11, "Quality Policy and Quality System Requirements," dated January 4, 2005, Section 8.2.3, describes the general requirements for verification of product conformance with the quality system requirements. Specifically, Section 8.2.3 requires, in part, that product conformance be independently verified by a planned method prior to release of a product. If the required verification is not complete at the time of product release, Section 8.2.3 requires that the affected organizations be notified of the deferred verification schedule and any necessary hold requirements. Section 8.6 provides the overall requirement for technical requirements and design inputs. Section 8.6 requires, in part, that all technical requirements and design inputs be documented, verified, controlled, and verified for application.

   GENE NEDO-11209-04A, Revision 8, "Quality Assurance Program Description," dated March 31, 1989 (NEDO-11209-04A), states, in part, 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.

   GENE Engineering Operating Procedure (EOP) 42-6.10, Revision 6, "Deferred Design Verifications," dated May 21, 2004, defines the processes for deferring design verification and for clearing previous deferrals. Section 4.2 provides the requirements for modifying a deferred verification which includes preparing a letter that provides the modification information for a previous deferral.

   EOP 25-5.00, Revision 10, "Work Planning and Scheduling," dated June 11, 2003, requires that the work be scheduled. Section 4.2.2 requires the use of appropriate methods/tools to maintain and control the schedule and Section 4.2.3 requires, in part, that the work plan be updated as necessary to document customer or internally initiated changes.

EOP 42-6.00, Revision 15, "Independent Design Verification," dated August 23, 2004, provides the requirements for performing design verification. Section 4.1 provides the requirements for design verification including establishing verification methods and identifying responsible verifiers.

Contrary to the above, GENE did not implement the ESBWR design control process as required by the GENE QA program. This is evidenced by the following examples: (1) a letter was not prepared documenting the revised completion date of the ESBWR Design Control Document (DCD) verification when the schedule was not met; (2) the work plan/detailed schedule for the ESBWR project was not maintained or updated; and (3) design and verification documentation was not complete prior to ESBWR DCD design verification. This issue has been identified as Nonconformance 05200010/2005-201-01.

2. Criterion VII, "Control of Purchased Material, Equipment, and Services," of 10 CFR Part 50, Appendix B, states, in part, that measures shall be established to assure that purchased material, equipment, and services conform to the procurement documents. These measures shall include provisions, as appropriate, for source evaluation and selection, objective evidence of quality furnished by subcontractor, source inspection, and examination of products upon delivery.

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

   P&P 70-14, "Nuclear Energy Quality Assurance Requirements," dated January 20, 2005, documents the process required to identify, develop, and implement the Nuclear Energy (NE) QA audits for both internal and external audits. Section 4.1.4 describes that responsible NE components shall conduct QA audits of suppliers, service providers, joint venture/subsidiary companies, business partners, and others with whom they have a business quality/interface to ensure conformance to applicable NE quality system requirements passed on to these entities or otherwise required in these interfaces.

   NEDO-11209-04A states, in part, that GENE suppliers are subject to audit/evaluation by line-QA personnel for evaluation of the sufficiency of the supplier's QA program and for adequacy of implementation.

   EOP 45-1.00, "Procurement Initiation and Control," Revision 13, dated March 31, 2005, specifies the requirements for procurement of direct material, equipment, and services, including the application of technical, engineering, customer, and quality requirements on the purchase orders (POs) and requirements for establishing and maintaining the Approved Suppliers List (ASL).

   Contrary to the above, external supplier audits performed by the GENE Nuclear Quality Assurance (NQA) Quality System group for three suppliers of engineering services for ESBWR design activities (Black and Veatch Corporation; Empresarios Agrupados Internacional, S.A.; and Shimizu Corporation), did not identify and audit/document against the appropriate QA program requirements (American National Standards Institute/ American Society of Mechanical Engineers [ANSI/ASME] NQA-1-1983), consistent with the

Chapter 17 of the ESBWR DCD and the NEDO-11209-04A topical report. Additionally, GENE did not document the completion of either the Corrective/Preventive Actions identification or the Response/Closure portions of the GENE CARs for the findings identified during the Quality System audits at ESBWR team participants: Black and Veatch Corporation; Empresarios Agrupados Internacional, S.A.; and Shimizu Corporation. This issue has been identified as Nonconformance 05200010/2005-201-02.

3. Criterion II, "Quality Assurance Program," of 10 CFR Part 50, Appendix B, states, in part, that measures shall be established to provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained.

   P&P 70-30, "Personnel Proficiency in Quality-Related Activities," dated August 4, 2003, establishes the minimum requirements on personnel proficiency for employees who perform activities which affect the quality of products. The procedure requires both technical and procedural proficiency.

   NEDO-11209-04A states, in part, that training and experience qualifications are defined for each position in GENE. In addition, the QA program provides for indoctrination and training of personnel performing activities affecting quality in order to provide assurance that proficiency is achieved and maintained.

   EOP 75-5.00, Revision 13, "Quality and Technical Training," dated September 30, 2004, defines the quality and technical process to assure personnel proficiency in quality-related activities. The procedure requires that qualifications for technical positions be documented, and training assignments and completion records for personnel be recorded and maintained in a centralized training database.

   Contrary to the above, GENE has not been documenting and maintaining training records in a centralized training database as required by the GENE QA program. This issue is identified as Nonconformance 05200010/2005-201-03.

4. Criterion XVIII, "Audits," of 10 CFR Part 50, Appendix B, 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.

   P&P 70-11, Section 8.5.2, describes the use of an ongoing continuous improvement process to establish strategic directions. Section 8.19 further describes the system for planning and documenting audits. The procedure requires audits to be performed using pre-established procedures or checklists by appropriately trained and qualified personnel.

   P&P 70-14, Section 4.1.3, requires each business component to perform internal QA self-audits to ensure conformance and compliance with applicable quality system requirements.

   NEDO-11209-04A describes, in part, the general requirements for a comprehensive system of planned and documented audits to verify product quality and compliance with the QA program. In accordance with the description, GENE 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.

Contrary to the above, GENE did not perform internal self-audits of the ESBWR program as required by the GENE QA program. The 2005 schedule of internal audits did not reflect the ESBWR program, and discussions with the representatives from the General Electric (GE) Quality Systems and Services Group, who have corporate responsibility for internal self-assessments of various line organizations including the ESBWR program, indicated that none were planned or scheduled for the remainder of the year. This issue is identified as Nonconformance 05200010/2005-201-04.

5. 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.

   P&P 70-11, 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 the 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. The procedure describes in detail the process for generation of a CAR, including a discussion of determining appropriate priority levels for potential deficiencies. E0P 75-3.00, Appendix A, requires that CARs be reviewed and accepted for action within 30 days of initiation of the request.

   Contrary to the above, GENE did not complete the acceptance reviews associated with several ESBWR CARs within the 30-day period as required by the GENE QA program. Additionally GENE did not complete the implementation of corrective actions associated with a number of ESBWR-related CARs within the documented due dates or complete those corrective action after the assigned due dates. This issue is identified as Nonconformance 05200010/2005-201-05.

Please provide a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555, with a copy to the Chief, New Reactor Licensing Branch (NRBA), Division of New Reactor Licensing (DNRL), Office of Nuclear Reactor Regulation (NRR), within 30-days of the date of the letter transmitting this Notice of Nonconformance. This reply should be clearly marked as a "Reply to Notice of Nonconformance" and should include: 1) a description of steps that have been or will be taken to correct these items; 2) a description of steps that have been or will be taken to prevent recurrence; and 3) the dates your corrective actions and preventative measures were or will be completed.

Because your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document system Agency-wide 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 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.

Dated this 10th day of January 2006.

U.S. NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR REACTOR REGULATION

Report No:	05200010/2005-201
Organization:	General Electric Nuclear Energy 3901 Castle Hayne Rd Wilmington, NC 28401
Vendor Contact:	Mr. David H. Hinds ESBWR Engineering Manager (910) 675-6363
Nuclear Industry:	General Electric Nuclear Energy (GENE) is engaged in the supply of advanced and standardized boiling water reactor (BWR) designs to utilities. GENE also furnishes engineering services, nuclear replacement parts, and dedication services for commercial grade electrical and mechanical equipment.
Inspection Dates:	November 15 -17, 2005
Inspectors:	Richard P. McIntyre, Lead Inspector, EQVA/DE/NRR Kerri A. Kavanagh, EQVA/DE/NRR Greg S. Galletti, EQVB/DE/NRR Aida Rivera-Varona, EQVA/DE/NRR Larry Rossbach, NRBA, DNRL, NRR
Approved by:	Dale F. Thatcher, Chief Quality and Vendor Branch A Division of Engineering Office of Nuclear Reactor Regulation

Enclosure 2

1.0 INSPECTION SUMMARY

The purpose of this inspection at General Electric Nuclear Energy (GENE) in Wilmington, North Carolina, was to determine if the implementation of selected portions of GENE's quality assurance (QA) program and quality activities performed to support design certification of the economic simplified boiling water reactor (ESBWR) were conducted under the appropriate provisions of NEDO-11209-04A, "GE Nuclear Energy Quality Assurance Program Description," Revision 8, dated March 31, 1989, the most recent revision that was approved by the NRC. The inspection also assessed whether the pertinent provisions of NEDO-11209-04A and NEDG-33181, "NP-2010 COL Demonstration Project Quality Assurance Plan," Revision 1, dated October 2005, were implemented for ESBWR design activities conducted at GENE offices in San Jose, California, and Wilmington, North Carolina,.

The inspection was conducted at GENE's facility in Wilmington, North Carolina. The inspection bases were:

- Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 50, Appendix B), and

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

1.1 NONCONFORMANCES

- Nonconformance 05200010/2005-201-01 was identified and is discussed in Section 3.2 of this report.

- Nonconformance 05200010/2005-201-02 was identified and is discussed in Section 3.4 of this report.

- Nonconformance 05200010/2005-201-03 was identified and is discussed in Section 3.5 of this report.

- Nonconformance 05200010/2005-201-04 was identified and is discussed in Section 3.6 of this report.

- Nonconformance 05200010/2005-201-05 was identified and is discussed in Section 3.7 of this report.

1.2 UNRESOLVED ITEMS

- Unresolved Item 05200010/2005-201-01 was identified and is discussed in Section 3.1.b.1 of this report.

- Unresolved Item 05200010/2005-201-02 was identified and is discussed in Section 3.1.b.2 of this report.

2.0 STATUS OF PREVIOUS INSPECTION FINDINGS

There were no Nuclear Regulatiory Commission (NRC) inspections related to ESBWR performed at GENE Wilmington, North Carolina facility prior to this inspection.

3.0 INSPECTION FINDINGS AND OTHER COMMENTS

3.1 QUALITY ASSURANCE PROGRAM

a. Inspection Scope

The NRC inspectors reviewed the QA program commitments and the implementation process for ESBWR design certification activities. Specifically, the NRC inspectors reviewed the ESBWR Design Control Document (DCD), "GENE Policies and Procedures," and NEDO-11209-04A, Revision 8, dated March 31, 1989, which governs the implementation of quality activities performed for ESBWR design activities.

b. Observations and Findings

b.1 ESBWR Quality Assurance Program

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

NEDG-33181, Revision 1, 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 Department of Energy (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.

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 NQA is responsible for developing, issuing, and maintaining P&P 70-11 and the NEDO-11209-04A QA Program Description. P&P 70-11, Section 8.4.2 requires that all safety-related products meet the applicable quality requirements of NEDO-11209-04A and the applicable licensing commitments.

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 Part 50. NEDO-11209-04A was in place for implementation of all previous simplified boiling water reactor (SBWR) design and test activities.

During the review of Chapter 17 of the ESBWR DCD, the NRC inspectors noted that it does 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 noted that this information was included in the SBWR design certification submittal and was documented in SBWR Standard Safety Analysis Report (SSAR) 25A5113, Revision A. The NRC inspectors 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 is requested to provide appropriate documentation in a DCD Chapter 17 "Introduction" section describing the details of QA program and commitments, and background information regarding the transition from the SBWR to ESBWR design. This issue has been identified as Unresolved Item (URI) 05200010/2005-201-01.

b.2 SBWR Qualification Test Program Quality Assurance Inspections

As part of the SBWR design certification review, the NRC staff conducted in-depth inspections at the principal GENE SBWR test facilities to determine if these testing activities performed to support design certification of the SBWR were conducted under the appropriate provisions of the NEDO-11209-04A, Revision 8 and NEDG-31831, "SBWR Design and Certification Program Quality Assurance Plan," dated May 1990. SBWR design certification qualification testing activities were conducted by GENE at test facilities such as the PANDA test facility in Switzerland, the PANTHERS test facility in Italy, and the GIRAFFE test facility in Japan. The data from these qualification testing activities is being used to support ESBWR design certification.

The NRC inspectors discussed with GENE personnel how best to recapture the design and test control implementation inspection documentation issued by the NRC staff for the SBWR design certification qualification testing activities cited above. To adequately document this design and test control implementation inspection documentation in Chapter 21 of the ESBWR Final Safety Evaluation Report (FSER), the NRC staff will need to recapture all of the NRC inspection reports, GENE responses to inspection findings, and NRC replies to the GENE responses. During the inspection at Wilmington, the NRC was told that these inspection records are located in the GE salt mine storage archives. The NRC staff will need GENE to recapture this documentation for FSER Chapter 21 purposes. The effort to recapture the inspection documentation records is identified as URI 05200010/2005-201-02.

c. Conclusions

The NRC inspectors determined that the GE ESBWR QA program requirements were adequately described in Chapter 17 of the ESBWR DCD, NEDO-11209-04A, and the various implementation procedures and guidelines and were consistent with the requirements of 10 CFR Part 50, Appendix B. The NRC inspectors determined, however, that an introduction section is required in Chapter 17 of the ESBWR DCD to describe what the ESBWR QA program is based upon and how it is to be implemented by GENE and its various domestic and international ESBWR team participants. This issue was identified as URI 05200010/2005-201-01.

The staff also identified the need for a GENE effort to recapture the NRC inspection documentation records related to the GENE SBWR design certification testing programs that will be used to support design certification of the ESBWR. This issue was identified as URI 05200010/2005-201-012.

3.2 DESIGN PROCESS

a. Inspection Scope

The NRC inspectors reviewed the implementation of the GENE design process for the ESBWR program. Specifically, the NRC inspectors reviewed the policies and procedures governing the implementation of the GENE ESBWR design process, and reviewed design record files (DRFs) for selected ESBWR systems.

b. Observations and Findings

The NRC inspectors reviewed the GENE policies and procedures governing the design process to assure those guidelines provided adequate description of the process and implementation requirements consistent with the requirements of 10 CFR Part 50, Appendix B, Criterion III, "Design Control."

b.1 Design Verification Deferral

P&P 70-11, Section 8.2.3, describes the general requirements for verification of product conformance with the quality system requirements. Specifically, Section 8.2.3 requires that product conformance be independently verified by a planned method prior to release of a product. If the required verification is not complete at the time of product release, Section 8.2.3 requires that the affected organizations be notified of the deferred verification schedule and any necessary hold requirements.

NEDO-11209-04A states, in part, 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.

GENE Engineering Operating Procedure (EOP) 42-6.10, Revision 6, "Deferred Design Verifications," dated May 21, 2004, defines the processes for deferring design verification and for clearing previous deferrals. Specifically, Section 2.4 states that verification of an engineering controlled document can only be deferred using the Engineering Review Memorandum/Engineering Change Notice (ERM/ECN) process within the Product Data Management System (PDMS). Section 4.1 requires that for a deferred verification, the following information must be entered into PDMS: (1) the document to be deferred; (2) the affected project; (3) any limitations on the application of the data or product hold requirements resulting from the deferred verification; (4) the schedule date when design verification will be completed; and (5) the reason for the deferral. Section 4.2 provides the requirements for modifying a deferred verification which includes preparing a letter that provides the modification information for a previous deferral. This letter must include the DRF number associated with the ERM/ECN.

By letter dated August 24, 2005, GENE submitted the ESBWR DCD for NRC final design approval and design certification. The ESBWR DCD were labeled "Conditional Release - pending closure of design verifications" since GENE had not completed design verification for all of the DCDs at the time of submittal. The GENE cover letter also stated that the conditional release status will be identified on the documents until closure of the internal documentation which was scheduled for the end of October 2005.

The NRC inspectors reviewed the ERM/ECN associated with the deferral of the design verification of the ESBWR DCDs. The NRC inspectors verified that the ERM/ECN contained the required information for the deferred verification including the scheduled completion date of 60 days after submittal to the NRC. The NRC inspectors identified that the deferred verification was not complete at the time of the inspection. Additionally, GENE did not prepare a letter documenting the revised completion date of the DCD design verification as required by the GENE QA program. At the time of the inspection, GENE did not have a documented schedule for completion of the DCD design verification. In a letter to the NRC dated November 30, 2005, GENE stated that DCD Revision 1 will include the removal of "Conditional Release" status from all Tier 1 and Tier 2 documents by February 28, 2006.

b.2 Work Plan and Project Schedule

EOP 42-1.00, Revision 13, "Design Process," dated August 23, 2004, defines the process for performing, documenting, and certifying design activities. The procedure requires work planning and scheduling, work performance, issue/deliver output documentation, and work completion. Specifically, Section 4.1.1 requires that the work be planned and scheduled per EOP 25-5.00.

EOP 25-5.00, Revision 10, "Work Planning and Scheduling," dated June 11, 2003, requires that the work be scheduled. Specifically, Section 4.1.1 requires the development and documentation of the work plan for the overall job, including appropriate consideration of purchase order requirements, quality requirements, organizational interfaces, verifications, and job closures. Section 4.2.2 requires the use of appropriate methods/tools to maintain and control the schedule and Section 4.2.3 requires that the work plan be updated as necessary to document customer or internally initiated changes.

The NRC inspectors reviewed the "Work Plan/Quality Plan (ESBWR Design Certification)" dated January 11, 2005, which stated that a detailed project schedule is maintained as part of the ESBWR project. Representatives of ESBWR engineering provided the NRC inspectors a copy of the current detailed project schedule available in PDMS (also known as eMatrix) which was dated July 8, 2005. The July ESBWR project schedule did not have project completion dates beyond the end of August 2005. Discussions with the ESBWR engineering representatives revealed that the detailed project schedule is maintained by the GENE supplier, Black and Veatch, and that updates to the detailed project schedule are e-mailed to GE. Arevised detailed project schedule dated August 26, 2005, was provided by representatives of GE ESBWR engineering. This schedule was not available in eMatrix. According to the ESBWR engineering representative, the August schedule represented a transition to the next phase of the work plan which included completion of DCD verification and NRC request for additional information (RAI) responses. The NRC inspectors reviewed the August schedule and noted that completion dates for individual activities, such as the DCD verification, were not specified in the detailed project schedule. The NRC inspectors determined that GENE did not

maintain or update the work plan for the ESBWR project as required by the GENE QA program. The NRC inspectors determined that this contributed to GENE's inability to provide an accurate completion date of the DCD verification at the time of the inspection.

b.3 Design Process and Verification

P&P 70-11, Section 8.6, provides the requirements for technical requirements and design inputs. The procedure requires that all technical requirements and design inputs be documented, controlled, and verified. The procedure also requires that when technical requirements and design inputs are provided to suppliers, customers, etc., prior to completion of verification, that the technical requirements and design inputs be identified as unverified and be controlled.

EOP 42-6.00, Revision 15, "Independent Design Verification," dated August 23, 2004, provides the requirements for performing design verification. Section 2.7 permits design verification to be initiated prior to design completion and to be performed in stages during the design process. Specifically, Section 2.8 specifies that design verification includes verification of both elements of the design and the overall design. Overall design includes, but is not limited to, whether all relevant topics have been considered in the design, the overall design approach is adequate, all necessary inputs have been considered and the design satisfies the design requirements. Section 4.1 provides the requirements for design verification including establishing verification methods and identifying responsible verifiers.

GENE Design Requirement 26A6452, Revision 0, "ESBWR System Design Specification Standard," dated March 25, 2005, establishes the guidelines and procedures for the preparation of the system design specifications for the ESBWR Design Certification Program. Section 10.5 of Appendix A provides the content requirements of a system design specification. Section 10.5.2 describes the listing of the supporting and supplemental documents for the applicable system design specification. A supporting document is mandatory in order to complete the requirement of the document where it is called out. Examples of mandatory documents in a system design specification include the subject system's piping and instrumentation diagram (P&ID), process flow diagram (PFD), and logic diagram (LD), if applicable. Section 10.5.2 specifically states that only documents that will be issued as part of the ESBWR design certification effort should be listed in this section. Section 10.5.4 describes the detailed design requirements to be satisfied by the system and its components. Section 10.5.4 specifically states that the level of detail provided in this section only needs to be sufficient to support the ESBWR DCD for design certification.

The NRC inspectors reviewed the implementing procedures and policy guidelines governing the GENE design process applied to the ESBWR project. The NRC inspectors verified that the guidance was consistent with the requirements for design control described in 10 CFR Part 50, Appendix B, Criterion III.

The NRC inspectors reviewed the DRFs for the isolation condenser system (ICS) (DRF-0000-0044-6235) and the standby liquid control (SLC) system (DRF-0000-0041-4682) to verify that the verification completed for these systems at the time of the inspection was completed by individuals that were not the responsible engineer or their supervisor. The NRC inspectors noted that the verification of the DCD for the SLC system was complete prior to August 24, 2005, whereas the ICS design specification was not complete until August 31, 2005,

after the ESBWR DCD was submitted to the NRC. The NRC inspectors discussed the DCD design verification process with the responsible manager of these systems. The GENE representative confirmed that the preferred process was to complete and verify the system design specification and other system documentation, if available, in order to use these documents as the bases for the ESBWR DCD verification. However, in some cases it was not possible to complete the verification of the system design specification, and as such, an alternate method, i.e., design notes, was implemented. The GENE representative stated that the design notes were provided as a bases of the verification and typically used other sources such as the Advanced Boiling Water Reactor (ABWR) SSAR as a starting point. The NRC inspectors reviewed the verification design notes for ICS and SLC systems and noted that both sets of notes were based on the SBWR and not the ABWR.

The NRC inspectors reviewed the system design specifications for the ICS and SLC systems and noted differences in the supporting documents required in the two system design specifications. Specifically, the ICS design specification only listed the ICS P&ID, whereas the SLC system design specification listed the SLC system P&ID and PFD as supporting documents. The NRC inspectors discussed these observations with the responsible manager of these systems who confirmed that supporting documents were included in Section 2.1.1 of a system design specification only if they were complete at the time of the system design specification development. Furthermore, the ICS verification design notes state the following:

> The ICS P&ID is the only supporting document to be prepared for the ESBWR Certification. This section is similar to Section 2.1.1 of SBWR design specification 25A5013 rev 1 (reference 1). Due to time constraints, the decision was made to not develop the Process Diagram (MPL B32-1020), Logic Diagrams (MPL B32-1030), or Piping Cycles (MPL B32-3000) for the DCD phase of this project. These could be developed during detailed engineering phase of the ESBWR.

The NRC inspectors determined that EOP 42-6.00 does not explicitly define the design verification process for the DCD which resulted in multiple processes being utilized. As such, GENE did not have complete design and verification documentation prior to DCD design verification as required by the GENE quality assurance program.

c. Conclusions

The NRC inspectors determined that the GENE design process requirements were described in the GENE policy and procedures, and were consistent with the requirements of 10 CFR Part 50, Appendix B, Criterion III. However, the NRC inspectors identified multiple examples where the design process was not implemented in accordance with the GENE procedures. These examples include: (1) uncontrolled deferred verification of the ESBWR DCDs; (2) ESBWR work plan/detailed schedule not current; and (3) incomplete design and verification documentation prior to the DCD design verification. This issue has been identified as Nonconformance 05200010/2005-201-01.

3.3 DOCUMENT CONTROL

a. Inspection Scope

The NRC inspectors reviewed the implementation of the GENE document control process for the ESBWR program. Specifically, the NRC inspectors reviewed the policies and procedures governing the implementation of the GENE ESBWR document control process.

b. Observations and Findings

The NRC inspectors reviewed the GENE policies and procedures governing the document control process to assure those guidelines provided adequate description of the process and implementation requirements consistent with the requirements of 10 CFR Part 50, Appendix B, Criterion VI, "Document Control."

P&P 70-11 requires that all documents generated during the implementation of the quality policy shall be retained as quality records.

EOP 75-6.00, Revision 7, "Quality Assurance Records," dated September 29, 2005, defines quality records as documents containing technical information supporting design processes. The EOP states that each document must be controlled by, but not limited to, a unique identification, revision number, granted approvals, verification status for design inputs, distribution control, and retention/retrieval.

EOP 42-8.00, Revision 10, "Document Initiation or Change by ERM/ECN," dated August 23, 2004, provides the requirements for the initiation or change of engineering controlled documents by use of the ERM/ECN. The ERM/ECN process is to control changes associated with design certification documents. EOP 42-8.00 states that all functions governed by the EOP are accomplished using the PDMS, including assigning of roles, capture of information in electronic forms and databases, electronic approvals, and electronic release of completed documents.

The NRC inspectors reviewed different EOPs in order to understand the procedure for document control and approval, including document change control. The NRC inspectors were able to access the PDMS including different DRFs for different ESBWR systems. The NRC inspectors verified that documents are appropriately identified and revisions to those documents are controlled by use of the ERM/ECN process.

c. Conclusions

The NRC inspectors concluded that the document control requirements have been appropriately implemented as required by GENE procedures to support the ESBWR program.

3.4 CONTROL OF PURCHASED MATERIAL, EQUIPMENT, AND SERVICES

a. Inspection Scope

The NRC inspectors reviewed the implementation of the GENE process of controlling purchased material, equipment, and services for the ESBWR program. Specifically, the NRC inspectors reviewed the policies and procedures governing the process to verify the quality of suppliers providing engineering services for the ESBWR design activities. The NRC inspectors also verified that the guidelines provided an adequate description of the process and implemented requirements consistent with the requirements of 10 CFR Part 50, Appendix B, Criterion VII, "Control of Purchased Material, Equipment, and Services."

b. Observations and Findings

b.1 Control of Purchased Material, Equipment, and Services

P&P 70-11, Section 8.19, requires that a comprehensive system of planned and documented audits be carried out to verify product quality and compliance with the QA program. It further states that QA audit requirements are provided in P&P 70-14.

P&P 70-14, "Nuclear Energy Quality Assurance Audit Requirements," dated January 20, 2005, documents the process required to identify, develop, and implement the Nuclear Energy (NE) QA audits for both internal and external audits. Section 4.1.4 describes that responsible NE components shall conduct QA audits of suppliers, service providers, joint venture/subsidiary companies, business partners, and others with whom they have a business quality/interface to ensure conformance to applicable NE quality system requirements passed on to these entities or otherwise required in these interfaces. These entities are referred to as "suppliers" and audits are called "supplier audits." Included in P&P 70-14 is a detailed description of the audit objectives, scheduling, planning, preparation, identification of audit personnel and qualification of those personnel, performance of activities associated with the audits, audit report requirements, and responses to audit results and audit records.

NEDO-11209-04A states, in part, that GENE suppliers are subject to audit/evaluation by QA personnel for evaluation of the sufficiency of the supplier's QA program and for adequacy of implementation. Each supplier of safety-related equipment or services is audited initially to determine acceptability of their QA program. It further states that QA representatives responsible for supplier audit and surveillance are typically assigned responsibilities such as participation in pre-production reviews with supplier personnel to assure mutual understanding of quality requirements.

EOP 45-1.00, Revision 13, "Procurement Initiation and Control," dated March 31, 2005, specifies the requirements for procurement of direct material, equipment, and services, including the application of technical, engineering, customer, and quality requirements on the purchase orders (POs) and requirements for establishing and maintaining the Approved Suppliers List (ASL).

The NRC inspectors reviewed the above program, implementing procedures, and policy guidelines governing the GENE control of purchased engineering services for the ESBWR program. The NRC inspectors verified that the guidance was consistent with the requirements

for control of purchased material, equipment, and services as described in 10 CFR Part 50, Appendix B, Criterion VII. The NRC inspectors verified that the GENE process adequately specified the requirements for procurement of material, equipment, and services, including the appropriate application of technical, engineering, and quality requirements on the POs, and for supplier audits for ASL status.

GENE has approximately 12 suppliers for design engineering services/activities for the ESBWR program. The NRC inspectors chose a sample of five of these suppliers for review: Black and Veatch Corporation; Empresarios Agrupados Internacional, S.A.; Shimizu Corporation; Toshiba Corporation; and Hitachi Ltd. Currently, GENE has a Memorandum of Understanding (MOU) in place with each supplier which identifies contractual type arrangements, but also includes a paragraph identifying quality requirements for work performed. GENE stated that they are in the process of finalizing an ESBWR Masters Service Agreement for the above mentioned team participants. This agreement includes compliance with 10 CFR Part 21 and also a QA section that will require the team participants to maintain a documented quality assurance program compliant with an ESBWR Quality Assurance Requirements (EQAR-1) document. The EQAR-1 document was still being developed at the time of the inspection.

As part of the review for these five suppliers the NRC inspectors reviewed quality records such as the ASL, NQA audit plans, NQA audit reports and audit checklists, Corrective Action Request (CAR) forms, and supplier responses to audit findings. When reviewing the documents the NRC inspectors identified that the GENE NQA was inconsistently identifying the QA program requirements that were applicable and required to be reviewed in the Audit Information/Scope/ POs/Procurement Specifications and the Audit Criteria Sections of the Audit Reports. It was not clear from the audit reports as to what version of the ANSI/ASME NQA-1 standard was applicable for each supplier, and in the case of Empresarios Agrupados Internacional, ASME-NQA-1-2000 was listed as quality program requirements. This identification is not consistent with the NEDO-11209-04A QA program description. Additionally, the NRC staff has previously stated in SECY-03-0117, "Approaches for Adopting More Widely Accepted International Quality Standards" that NQA-1-2000 is not in full compliance with 10 CFR Part 50, Appendix B, requirements.

During the review of the supplier audit reports, the accompanying audit findings and the CAR forms generated for Black and Veatch Corporation; Empresarios Agrupados Internacional, S.A.; and Shimizu Corporation ESBWR suppliers; GENE could not provide the NRC inspectors documentation for GENE closure of the CARs issued for the audit findings. GENE had not documented the completion of the corrective/preventive actions identification and the response/closure portions of the GENE CARs for the supplier audit findings. Late in the inspection, GENE did provide evidence that Shimizu had responded back to the GENE audit findings, however, the CARS for identified findings were still incomplete.

c. Conclusions

Based on the areas reviewed, the NRC inspectors concluded that GENE oversight of suppliers for the ESBWR program generally met the requirements of NEDO-11209-04A and were consistent with 10 CFR Part 50, Appendix B, Criterion VII. However, the NRC inspectors identified several examples where the process of controlling purchased material, equipment, and services for the ESBWR program were not implemented in accordance with GENE procedures. These examples include: (1) GENE failure to identify the QA program

requirements that conformed to GE ESBWR DCD Chapter 17 and NEDO-11209-04A; and (2) GENE had not documented the completion of either the corrective/preventive actions identification and the response/closure portions of the GENE CARs for supplier audit findings at Black and Veatch Corporation; Empresarios Agrupados Internacional, S.A.; and Shimizu Corporation. This issue has been identified as Nonconformance 05200010/2005-201-02.

3.5 TRAINING AND QUALIFICATION OF PERSONNEL

a. Inspection Scope

The NRC inspectors reviewed the implementation of the GENE personnel training and qualification process for the ESBWR program. Specifically, the NRC inspectors verified that the GENE personnel training and qualification process was consistent with the requirements of 10 CFR Part 50, Appendix B, Criterion II, "Quality Assurance Program."

b. Observations and Findings

P&P 70-30, "Personnel Proficiency in Quality-Related Activities," dated August 4, 2003, establishes the minimum requirements on personnel proficiency for employees who perform activities which affect the quality of products. The procedure requires both technical and procedural proficiency. The procedure stated the following for each of the disciplines:

- Technical Discipline

Qualification for technical positions shall be documented in position guides, or equivalent POs for subcontracted employees, and shall include minimum education, experience, and/or technical training requirements.

- Procedural System

Each employee, prior to assignment of work activities affecting the quality of products, shall be indoctrinated in the applicable quality system procedure.

NEDO-11209-04A states, in part, that training and experience qualifications are defined for each position in GENE. In addition, the QA program provides for indoctrination and training of personnel performing activities affecting quality in order to provide assurance that proficiency is achieved and maintained.

EOP 75-5.00, Revision 13, "Quality and Technical Training," dated September 30, 2004, defines the quality and technical process established by GENE to assure personnel proficiency in quality-related activities as required by GENE P&P 70-30. This procedure states:

> Qualifications for technical positions, including minimum education, experience, and/or special training requirements, shall be documented.
>
> Training assignments and completion records for GENE personnel shall be recorded and maintained in a centralized training database controlled as a Quality Information System.

GENE Engineering Service Instruction (ESI) 10-2.00, Revision 1, "Technical Proficiency," dated April 13, 2005, defines requirements for personnel performing activities affecting quality to assure that suitable proficiency is achieved and maintained. This instruction states:

> Documentation of the responsible engineer's proficiency development will include a record of the quality documents requirements, quality and technical documents reviewed and a record of training courses attended. In addition, proficiency status will be documented for each analysis area (i.e., qualified to perform, verify, mentor or process lead). This documentation may reside in the individuals training record or be kept in a central controlled database.

b.1 Procedural Training

The NRC inspectors reviewed the required procedural training and qualification requirements of personnel and suppliers working on the ESBWR program. Representatives of ESBWR Engineering provided the NRC inspectors a copy of a spreadsheet that documented all procedural training taken by each ESBWR employee. The NRC inspectors noted that the spreadsheet did not identify which training was required for each employee. As such, the NRC inspectors were not able to verify that the training completed by each employee was all the required training for that employee. The NRC inspectors were informed by ESBWR Engineering representatives that GENE uses a database to track procedural training requirements which is an acceptable method to comply with GENE's procedures. However, GENE representatives also stated that the ESBWR Engineering organization has been using the spreadsheet as their tracking method which is not consistent with GENE procedures.

This deficiency was previously identified by GENE in CAR 20380 dated August 10, 2005, with a proposed resolution of making the training database current and consistent with the spreadsheet. The NRC inspectors reviewed the training database record of two ESBWR employees. For one of the employees, the training database implied that the employee had not completed any of the required training. However, the spreadsheet used to track training for the same employee implied that all the training was completed. The GENE representatives also confirmed that the training database had not been updated as specified in the CAR.

b.2 Technical Training

The NRC inspectors reviewed the required technical training and qualification requirements of personnel and suppliers working on the ESBWR program. GENE develops an annual Qualification and Proficiencies Report for each organization to record the latest proficiencies of the ESBWR employees based on their education, experience, and technical training. GENE representatives stated that the Qualification and Proficiencies Report was an acceptable method to comply with GENE procedures. However, the NRC inspectors noted that the Qualification and Proficiencies Reports did not contain records for the criteria or requirements for employees to become proficient in each field as required by procedures.

The NRC inspectors reviewed a Qualification and Proficiencies Report generated for the Systems Engineering organization. The NRC inspectors noted that a Qualification and Proficiencies Report was not available for ESBWR Engineering. As such the NRC inspectors

were unable to verify any qualifications or technical training for ESBWR Engineering personnel as required by GENE procedures.

b.3 Supplier Training

The NRC inspectors reviewed CAR 19858, dated February 18, 2005, which identified a failure to meet the commitment to train suppliers working on the ESBWR program outside GENE facilities/site (i.e., Panlyon and Theofaneous) to the applicable GENE requirements/procedures. GENE representatives provided the inspector records that confirmed that the required procedural training was provided to these suppliers. However, this action had not been documented in the CAR.

c. Conclusions

The NRC inspectors determined that the GENE personnel training and qualification process requirements were described in the GENE policy and procedures, and were consistent with requirements of 10 CFR Part 50, Appendix B, Criterion II. However, the NRC inspectors identified several examples where the personnel training and qualification process was not implemented in accordance with GENE procedures. The NRC inspectors concluded that training had not been adequately identified, documented, and maintained as required by GENE procedures to support the ESBWR program. This issue has been identified as Nonconformance 05200010/2005-201-03.

3.6 AUDITS

a. Inspection Scope

The NRC inspectors reviewed implementation of the GENE audit process for the ESBWR program. Specifically, the NRC inspectors reviewed the policies and procedures governing the implementation of the GENE ESBWR audit program, and reviewed the GE Nuclear Quality Assurance (NQA) audit of the GENE ESBWR program performed in January 2005.

b. Observations and Findings

b.1 Policies and Procedures Governing Audits

The NRC inspectors reviewed GENE policies and procedures governing the audit process to assure those guidelines provided an adequate description of the process and implementation requirements consistent with the requirements of 10 CFR Part 50, Appendix B, Criterion XVIII, “Audits.”

NEDO-11209-04A describes, in part, the general requirements for a comprehensive system of planned and documented audits to verify product quality and compliance with the QA program. In accordance with the description, GENE 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.

P&P 70-14 requires all audits to be retained for a period of 3 years or until all corrective actions have been completed (if that exceeds 3 years).

P&P 70-11, Section 8.5.2, describes the use of an ongoing continuous improvement process to establish strategic directions. The procedure requires audits to be performed using pre-established procedures or checklists by appropriately trained and qualified personnel.

EOP 75-2.00, Revision 13, "Qualification and Certification of Personnel," dated January 14, 2005, further describes the qualification process for lead auditors defines criteria for the qualification, training requirements, skill maintenance, and record of qualification.

The NRC inspectors reviewed the NQA audit performed January 2005 by GENE. The NRC inspectors verified that the audit was performed in accordance with requirements specified in the implementing procedures and policy guidelines. The NRC inspectors verified that the auditors used a detailed audit checklist describing each major audit activity and that the checklists were completed and written evaluations were documented. The NRC inspectors verified that lead auditors and auditors were current in qualification to perform activities. Qualification training records and qualification status information was provided in the audit packages as required by procedures. The NRC inspectors also verified that additional technical experts on the audit were adequately qualified to perform the activities assigned to them during the audit. The NRC inspectors also verified that all issues identified by the audit team were adequately identified within the CAR system for evaluation, and determination of corrective and preventive actions.

b.2 External Audits

NEDO-11209-04A, Revision 8, Section 18, describes both internal audits and audits performed by General Electric (GE) of GENE suppliers. The NEDO provides a high-level discussion of the purpose of the audits, applicability to GE organizations, schedule and planning including documentation to support the audits, and actions taken to correct any noncompliance identified as a result of the audit. The NEDO also describes the criteria for determining the frequency of supplier audits. As a minimum, supplier audits are performed every 3 years or more frequently based on (1) importance, complexity, and quality requirements of the item, (2) results of previous audits, (3) history of performance of product or purchased service, and (4) effectiveness of implementation of suppliers QA program.

The NRC inspectors verified that the current audit schedule of ESBWR suppliers and other GENE suppliers were performed within the required triennial period in accordance with procedural requirements for such evaluations.

b.3 Internal Self-Assessments/Audits

P&P 70-14, Section 4.1.3, requires each business component to perform internal QA self-audits to ensure conformance and compliance with applicable quality system requirements. Also in accordance with Section 4.1.3, audit of a business component performed by NQA does not relieve that business component from performing internal self audits.

EOP 75-3.00, Section 4.9, requires the performance of annual self-assessments of assigned CARs or other process product issues to identify opportunities for significant process

improvements. Requirements to document results of self-assessments are further described in EOP 75-6.00, Revision 7.

As part of the review of audit activities, the NRC inspectors attempted to review any internal self-assessments conducted by the ESBWR organization. During discussions with GENE, the NRC inspectors identified that no internal ESBWR self-assessments had been performed. The 2005 schedule of internal audits did not include the ESBWR program, and discussions with the representatives from the GENE Quality Systems and Services Group, who have corporate responsibility for internal self-assessments of various line organizations including ESBWR, indicated that none were scheduled for the remainder of the year.

The NRC inspectors noted that this deficiency was apparently previously identified by a GENE customer and as a result, corrective actions were initially taken by GENE to develop a self-assessment procedure. The effort was halted to address the current self-assessment guidance already embodied within the EOPs and P&Ps and to better determine what changes to that guidance are necessary to ensure adequate implementation of a QA program for all GENE divisions.

c. Conclusions

The NRC inspectors determined that the GENE audit program requirements were adequately described in GENE policy and implementation guidelines, and were consistent with the requirements for conducting audits described in 10 CFR Part 50, Appendix B, Criterion XVIII. The NRC inspectors determined, however, that requirements to perform internal self-assessments were not adequately implemented in accordance with those administrative requirements. This issue has been identified as Nonconformance 05200010/2005-201-04.

3.7 CORRECTIVE ACTIONS

a. Inspection Scope

The NRC inspectors reviewed the implementation of the GENE corrective action process associated with the ESBWR program. Specifically, the NRC inspectors reviewed the policies and procedures governing the implementation of the GENE ESBWR corrective action program, and reviewed the current status of corrective actions associated with the GENE ESBWR program. These corrective actions are primarily the result of: (1) the GE NQA audit of the GENE ESBWR program performed in January 2005; (2) the Duke NuStart Audit dated September 12, 2005, (NuStart Audit No. GE05-01) of the ESBWR program; and (3) GENE ESBWR self-identified issues.

b. Observations and Findings

b.1 Policies and Procedures Governing Corrective Actions

The NRC inspectors reviewed GENE policies and procedures governing the corrective action process to assure that those guidelines provided adequate description of the process and implementation requirements consistent with the requirements of 10 CFR Part 50, Appendix B, Criterion XVI, “Corrective Actions.”

NEDO-11209-04A describes, in part, the general requirements for the 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.

P&P 70-11, 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) documented recommended actions to correct deficiency; (4) documented recommended actions to preclude recurrence; and (5) ensuring proper levels of management are made aware of the deficiency to achieve resolution.

EOP 75-3.00 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. The procedure describes in detail the process for generation of a CAR, including a discussion of determining appropriate priority levels for potential deficiencies. Examples of situations which would require the generation of a CAR are also provided for reference. The procedure further details step by step procedures for CAR initiation, CAR response, corrective and preventive action completion, CAR closure, and CAR effectiveness review. CARs are tracked in the electronic commitment tracking system (CTS) and contains the official quality records assigned for each CAR. CTS is the means of advising top management, including the quality council, on the status and adequacy of a system as a result of the analysis and audit of the CARs. The procedure states that CARs shall be maintained for a period of 3 years after a CAR is closed. EOP 75-3.00, Appendix A, provides detailed instructions for initiating a CAR and requires that corrective action requests be reviewed and accepted for action within 30 days of initiation of the request.

In addition to these general guidelines, the GE Engineering Service Group, has a set of ESIs which further describe the corrective action process and implementation requirements. ESI 20.500, "Corrective Action Program Management," specifies the requirements for Engineering and Technology implementation of the EOP 75-3.00. It provides a general description for the initiation of CARs, generation of responses and the requirements for individual review and acceptance of CAR results. ESI 20-05.10, "Engineering and Technology Quality Council," describes the formation and assigned duties for supporting the CAR. The council is required to meet on a regular basis to review CARs to ensure proper assignment, problem description, assign priority, and trend codes. ESI 20-5.20, "CAR Critique Process," defines the process for evaluating the adequacy of responses to significant CARs (i.e., Priority A1 internal or A1/A2 external). Issues such as adequacy of root cause evaluation, appropriate and completeness of causal factors determination, accuracy of effects and extent of condition, thoroughness of corrective and preventive actions are described.

The NRC inspectors reviewed the implementing procedures and policy guidelines governing the GENE corrective action program applied to the ESBWR program. The NRC inspectors verified that the guidance was consistent with the requirements for corrective actions described in 10 CFR Part 50, Appendix B, Criterion XVI and contained the necessary elements to ensure conditions adverse to quality were identified, prioritized, evaluated, and corrected in a timely manner.

The NRC inspectors also reviewed selected CARs generated as a result of activities associated with the ESBWR project. Specifically, the NRC inspectors reviewed the CARs generated as a result of the GENE NQA internal audit of the ESBWR program documented on February 18, 2005, the Duke NuStart Audit documented in an audit report dated September 12, 2005, and several internal self-identified deficiencies. The NRC inspectors confirmed that issues identified in the CARs were consistent with the results of the audits and internal findings. However, the NRC inspectors identified several deficiencies in implementing the CAR process including: (1) many instances where the specified corrective actions and additional required activities associated with these CARs were not performed within the required due dates; (2) several instances where acceptance of the proposed corrective actions by the initiator, process owner, or responsible manager had not been completed in the required 30-day time frame; and (3) many instances where corrective actions were completed after the assigned due dates.

The NRC inspectors noted that these deficiencies were previously identified by GENE in CAR 19883 regarding CAR timeliness dated February 24, 2005. The CAR clearly states that there are no expectations for timeliness contained within the procedures for implementation of the corrective action program. However, the NRC inspectors noted that none of the corrective actions associated with the CAR proposed such procedural modifications, and based on the NRC inspector's review of current CARs associated with the ESBWR program, the issue of timeliness of corrective actions continues to be a pervasive problem.

b.2 Management Review of Corrective Actions

P&P 70-11, Section 8.18, requires periodic review of the quality management system to ensure suitability, adequacy, and effectiveness. Item g. of this section identifies that recommendations for improvement be identified. Section 8.18.2, requires a review of the output of the management review including identification of actions necessary to improve the effectiveness of the quality management system, and assignment of responsibility for completing required actions.

EOP 75-3.00 further 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.

The NRC inspectors reviewed the GE Nuclear Quality System Status and Adequacy Review, dated May 31, 2005, to gain additional understanding of how GE Nuclear Management periodic reviews of the QA program were implemented. The GE Nuclear Quality System Status and Adequacy Review is conducted annually as a means of identifying areas for continued improvement and assessing the current adequacy of the corrective action program. The report is developed by a group of GENE QA and engineering managers. Sources of information used in the report include, but are not limited to, analysis reports of CAR data, NRC inspections, NQA audits, industry audits, and individual observations.

The NRC inspectors observed that the report contained a detailed evaluation of the corrective action program, and in many instances descriptions of future activities or enhancements to line organization quality system programs. However, the NRC inspectors noted that there is currently no system in place to track the assignment of responsibility for completing required actions, and no formal method for evaluating the progress with implementing such required actions (i.e., these actions are not necessarily captured as CARs or other formal records and

therefore are not tracked in any formal manner). The NRC inspectors noted that in some instances proposed enhancement actions were identified as being implemented or initiated by calendar quarter while other line organizations identified such actions and have initiated CARs to formally track those specific actions. Discussions with GENE QA personnel indicate that there is no current programmatic requirement to enter such proposed activities into CTS or maintain a system to track the actions or progress associated with completing these actions. Hence there is no formal mechanism to ensure complete and timely resolution of actions identified within the report.

c. Conclusions

The NRC inspectors determined that GENE corrective action program requirements were adequately described in GENE policy and implementation guidelines, and were consistent with the requirements for conducting audits described in 10 CFR Part 50, Appendix B, Criterion XVIII. The NRC inspectors determined, however, that requirements to process and complete corrective actions were not adequately implemented in accordance with those administrative requirements. This issue has been identified as Nonconformance 05200010/2005-201-05.

3.8 QUALITY ASSURANCE RECORDS

a. Inspection Scope

The NRC inspectors reviewed the implementation of the GENE QA records process for the ESBWR program. Specifically, the NRC inspectors reviewed the policies and procedures governing the implementation of the GENE ESBWR records program, and reviewed various QA records including design record files and associated technical information related to the GENE ESBWR program.

b. Observations and Findings

b.1 Policies and Procedures Governing Quality Assurance Records

The NRC inspectors reviewed GENE policies and procedures governing the QA records process to assure those guidelines provided an adequate description of the process and implementation requirements consistent with the requirements of 10 CFR Part 50, Appendix B, Criterion XVII, "Quality Assurance Records."

P&P 70-11, Section 8.10, and P&P 70-50, "GE-NE Handling and Storage of Quality Assurance Records," dated September 11, 2000, provides the requirements for the preparation, retention, storage, authentication, retrievability, and readability of quality records. The procedures provide additional requirements for the retention of lifetime (e.g., permanent) and non-lifetime (e.g., non-permanent) electronic records.

NEDO-11209-04A states, in part, that QA records shall comply with the provisions of Regulatory Guide 1.88, Rev. 2, 1976 (RG-1.88) including the regulatory position relative to N45.2-9-1974 (N45.2). QA records are classified as lifetime or non-lifetime in accordance with the definitions in ANSI N45.2. Records classified as lifetime shall be provided to the owner or stored and maintained in accordance with N45.2. For non-lifetime records, storage will be

provided in metal file cabinets as permitted in National Fire Protection Association (NFPA)-1975 for class 3 records. Both lifetime and non-lifetime records shall be listed in an index or system of indexes which shall include the length of time for record retention and the location of each for retrieval. The indexes provide a table of record types, storage maintenance responsibilities and retention classification (i.e., lifetime or non-lifetime), and retention durations for each category of record.

EOP 75-6.00 describes the system for creation, identification, control, transmittal, retrieval, and retention of records. Appendix A of EOP 75-6.00 provides a detailed matrix of document types, examples of each, minimum retention periods, standard retention methods, and disposition after archiving or expiration of retention requirements. To supplement the document control description in EOP 75-6.00, GENE has developed an additional series of EOPs to further define the records process requirements. EOP 60-3.10, Revision 9, "Design Document Distribution," dated September 29, 2005, prescribes the requirements, procedures, and responsibilities for the distribution of design documents. Design documents are archived as QA records in accordance with EOP 76-6.00. EOP 42-10.00, Revision 14, "Design Record File," dated May 21, 2004, defines the procedure for the generation of the individual DRF associated with a design project. The procedure includes line organization responsibilities, processes for the creation and release of DRFs as quality records in accordance with record requirements, and provides a very detailed checklist of DRF content requirements with cross references to the EOPs that govern the individual content field requirements. The procedure also describes the requirements for formatting of quality records in electronic media format. EOP 60-3.00, "Document Requirement," dated September 29, 2005, which provides general guidance for the preparation of EOPs including the responsibilities and requisite information necessary for inclusion in the EOPs.

The NRC inspectors reviewed implementing procedures and policy guidelines governing the GENE QA records program applied to the ESBWR project. The NRC inspectors verified that the guidance was consistent with requirements for QA records described in 10 CFR Part 50, Appendix B, Criterion XVII, RG-1.88, and ANSI N45.2. The NRC inspectors also verified that the GENE records process contained the necessary elements to ensure that QA records were adequately identified, controlled, and retained in accordance with those requirements.

The NRC inspectors did, however, identify a discrepancy in the records retention requirements associated with the CARs. Specifically, the NRC inspectors noted that both GENE P&P 70-14, Section 4.11.6, and GENE EOP 75-6.00, Table 1, states that records for individual audits including CARs associated with those audits shall be maintained for a period of three years or until the corrective actions are completed. Contrary to this, GENE EOP 75-3.00, states that CARs shall be maintained for a period of three years after the CAR is closed. Discussions with the GENE staff during the inspection verified that GENE EOP 75-3.00 contained the correct record retention requirement, and the other two procedures contained erroneous information.

During the inspection, the NRC inspectors discussed the QA record program with GENE staff and used the GENE eMatrix information system which is part of the GENE QA record management system. GENE employs a combination of QA records in hard copy which are maintained within the QA record center and QA records in electronic form within the eMatrix application. The records include, but are not limited to all DRFs, licensing correspondence, safety analyses, calculations, codes and standards, drawings, and other relevant information associated with GENE. The eMatrix application is a commercial software data management

system that is customized for GENE use. It is maintained as a quality information system in accordance with EOP 40-2.00, Revision 2, "Quality Information Systems," dated June 26, 1996, which provides the specifications for the control of software products defined as quality information systems.

The NRC inspectors reviewed various QA records related to the ESBWR program, including CARs, DRFs, design specifications, inspection reports, audit reports, and personnel training and qualification records. In most cases, the NRC inspectors found the records to be adequately maintained, controlled, and retrievable. However, during the inspection the team observed several instances where design information was not readily retrievable within the eMatrix system, or required a significant amount of lead time to locate and retrieve from the records center. While eMatrix is the system dedicated to maintaining quality records for permanent status, the team was unable to retrieve technical information from within the eMatrix system associated with the ESBWR design. Specific examples include: (1) the PANDA test program information file listed within the eMatrix file index, but the actual records were identified as being on various microfiche files within the records center. Retrieval of those records could be performed, but would have taken several days to process; (2) the SLC system design specification could not be retrieved from within the eMatrix system, and (3) the moisture separator reheater system showed the framework of the various documents included within the eDRF, but the NRC inspectors were unable to access those documents directly from within the system. In some cases, the records appeared to be recognized in the eMatrix, but when the NRC inspectors attempted to retrieve those documents, they were unable to do so.

c. Conclusions

The NRC inspectors determined that the GENE QA records program requirements were described in GENE policy and implementation guidelines, and were consistent with the requirements for conducting audits described in 10 CFR Part 50, Appendix B, Criterion XVII. The NRC inspectors determined, however, that requirements for the retention of CAR records were inconsistently described in the GENE EOPs governing such records. Additionally, the NRC inspectors identified that certain records associated with the ESBWR design were not readily retrievable from within the eMatrix document system. While this issue did not significantly impede the inspection activities, it is identified as a weakness in the GENE QA program.

4.0 ENTRANCE AND EXIT MEETINGS

In the entrance meeting on November 15, 2005, the NRC inspectors discussed the scope of the inspection, outlined the areas to be inspected, and established interfaces with GE staff and management. In the exit meeting on November 17, 2005, the NRC Inspectors discussed their concerns and findings with GE management and staff.

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