November 12, 2009

Russell Bastyr Quality Assurance Manager GE Hitachi Nuclear Energy 3901 Castle Hayne Road Wilmington, NC 28401

#### SUBJECT: NRC INSPECTION REPORT 05200010/2009-201 AND NOTICE OF VIOLATION

Dear Mr. Bastyr:

On September 14 -18, 2009, the U.S. Nuclear Regulatory Commission (NRC) conducted an inspection at the General Electric-Hitachi (GEH) Nuclear Energy facility in Wilmington, North Carolina. The enclosed report presents the results of that inspection.

This was a limited scope inspection that focused on assessing GEH's compliance with selected portions of Appendix B to Part 50 of Title 10 of the *Code of Federal Regulations* (10 CFR Part 50), "Quality Assurance Program Criteria for Nuclear Power Plants and Fuel Reprocessing Plants." The inspection focused on the radiation shielding calculations and associated codes used in the development of the ESBWR design certification. This NRC inspection report does not constitute NRC endorsement of GEH's overall quality assurance (QA) program.

Based on the results of this inspection, the NRC has determined that three Severity Level IV violations of NRC requirements occurred. These violations were evaluated in accordance with the NRC Enforcement Policy. The current Enforcement Policy is included on the NRC's Web site at (<u>http://www.nrc.gov/about-nrc/regulatory/enforcement/enforc-pol.pdf</u>).

The violations are cited in the enclosed Notice of Violation (NOV), and the circumstances surrounding them are described in detail in the subject inspection report. The violations are being cited in this NOV because a review of GEH's QA program documentation and implementation identified that (1) GEH failed to provide procedural guidance for managing the different computer databases currently used to control the training records of GEH personnel, (2) GEH failed to (a) provide adequate guidance for the conduct of receipt inspections of design and engineering work from its suppliers, and (b) perform an adequate annual evaluation of Empresarios Agrupados Internacional, S.A. (EA) in 2008; and (3) GEH failed to adequately classify a corrective action as a Significant Condition Adverse to Quality and consequently failed to perform a root cause evaluation and extent of condition.

You are required to respond to this letter and should follow the instructions specified in the enclosed NOV when preparing your response. The NRC will use your response, in part, to determine whether further enforcement action is necessary to ensure compliance with regulatory requirements.

In accordance with 10 CFR 2.390, "Public Exemptions, Requests for Withholding," the agency will make a copy of this letter, its enclosures, and your response available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material be withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Requirements for the Protection of Safeguards Information."

Sincerely,

/**RA**/

Richard Rasmussen, Chief Quality and Vendor Branch 2 Division of Construction Inspection & Operational Programs Office of New Reactors

Docket No. 05200010

Enclosures: Notice of Violation Inspection Report No. 05200010/2009-201 In accordance with 10 CFR 2.390, "Public Exemptions, Requests for Withholding," the agency will make a copy of this letter, its enclosures, and your response available electronically for public inspection in the NRC Public Document Room or from the NRC's Agencywide Documents Access and Management System (ADAMS), accessible at http://www.nrc.gov/reading-rm/adams.html. To the extent possible, your response should not include any personal privacy, proprietary, or safeguards information so that it can be made available to the public without redaction. If personal privacy or proprietary information is necessary to provide an acceptable response, then please provide a bracketed copy of your response that identifies the information that should be protected and a redacted copy of your response that deletes such information. If you request that such material be withheld from public disclosure, you must specifically identify the portions of your response that you seek to have withheld and provide in detail the bases for your claim (e.g., explain why the disclosure of information will create an unwarranted invasion of personal privacy or provide the information required by 10 CFR 2.390(b) to support a request for withholding confidential commercial or financial information). If safeguards information is necessary to provide an acceptable response, please provide the level of protection described in 10 CFR 73.21, "Requirements for the Protection of Safeguards Information."

Sincerely,

/RA/

Richard Rasmussen, Chief Quality and Vendor Branch 2 Division of Construction Inspection & Operational Programs Office of New Reactors

Docket No. 05200010

Enclosures: Notice of Violation Inspection Report No. 05200010/2009-201

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#### OFFICIAL RECORD COPY

# NOTICE OF VIOLATION

GE Hitachi Nuclear Energy 3901 Castle Hayne Road Wilmington, NC 28401 Docket Number 05200010 Inspection Report Number 2009-201

Based on the results of a Nuclear Regulatory Commission (NRC) inspection conducted on September 14 - 18, 2009, at the General Electric – Hitachi (GEH) Nuclear Energy facility in Wilmington, North Carolina, the following violations of NRC requirements were identified:

A. Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50 states, in part, that "the applicant shall establish at the earliest practicable time, consistent with the schedule for accomplishing the activities, a quality assurance (QA) program which complies with the requirements of this appendix. This program shall be documented by written policies, procedures, or instructions and shall be carried out throughout plant life in accordance with those policies, procedures, or instructions. The program shall provide for indoctrination and training of personnel performing activities affecting quality as necessary to assure that suitable proficiency is achieved and maintained."

Section 2.3.1 of GEH's Policy and Procedure 70-30, "Personnel Proficiency in Quality Related Activities," dated August 4, 2003, stated that records may be retained in an employee's file, as separate file or as a centralized computer database.

Section 2.5 of GEH's Engineering Operating Procedure 75-5.00, "Quality and Technical Training," Revision 15, dated May 11, 2009, stated that training assignment and completion records for GEH personnel shall be recorded and maintained in a centralized database and controlled as a Quality Information System.

Contrary to the above, as of September 18, 2009, the GEH QA program did not provide procedural guidance for managing the centralized computer database. Furthermore, as of September 18, 2009, there were 12 databases used to control training records, six of which had been migrated to a new centralized database in accordance with the requirements of procedures 70-30 and 75-5.00. Although a procedure is currently in development for the new centralized database, GEH is currently using multiple databases for which no procedure exists on how to manage these databases.

This issue has been identified as Violation 05200010/2009-201-01.

This is a Severity level IV violation (Supplement VII).

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

assessed by the applicant or designee at intervals consistent with the importance, complexity, and quantity of the product or services."

Engineering Operating Procedure (EOP) 30-5.00, "Supplier Design Services Document Review," Revision 10, dated March 20, 2009, required GEH engineers and/or managers performing receipt inspections to verify that "all necessary inputs were correctly identified and applied" in design packages received from suppliers and to document this review by checking a box on form NEO-866, "Review/Acceptance of Purchased Design Service Documents," dated March 2007.

Section VII, "Control of Purchased Material, Equipment, and Services," of the GE Nuclear Energy Quality Assurance Program Description," Revision 8, dated March 31,1989 required, as a minimum, a triennial audit and annual evaluations of safetyrelated suppliers and stated that "When an evaluation is performed, the results are documented and approved by responsible QA personnel. This evaluation considers pertinent factors, such as: the results of previous audits; history of performance of product and/or purchased service; effectiveness of implementation of the supplier's QA Program; and the importance, complexity, and quality requirements of the item or service concerned."

Contrary to the above:

- 1. EOP 30-5.00 failed to provide adequate guidance for personnel verify that "all necessary inputs were correctly identified and applied" in design packages received from suppliers (i.e., which inputs are necessary, how to verify that they were correctly identified and applied, etc.). The NRC inspectors found that the GEH engineers who performed receipt inspections of calculations had varying interpretations of the intent of this statement, and as such, were implementing the requirement inconsistently.
- 2. GEH did not perform an adequate review of the work performed by Empresarios Agrupados Internacional, S.A. (EA) between October 2007 and October 2008 to justify EA's continued status as an approved supplier. The latest supplier QA Program Evaluation conducted by GEH of EA, dated October 9, 2008, was inadequate in that the following sections of the evaluation were marked "N/A," even though there were 5 CARs issued as a result of the 2007 EA audit, one CAR for errors in calculations, and 7 receipt inspections that should have been evaluated and documented on the annual evaluation:
  - Results of previous source verifications, audits, and receiving inspections.
  - Nature and severity of corrective action requests (CARs) including evaluation of supplier's responsiveness to and effectiveness of corrective action programs.
  - Review and evaluate the supplier's furnished documents and records such as Certificates of Conformance, nonconformance notices, and corrective actions.

These issues have been identified as examples of Violation 05200010/2009-201-02.

This is a Severity level IV violation (Supplement VII).

C. Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50 states, in part, that "Measures shall be established to assure that conditions adverse to quality, such as failures, malfunctions, deficiencies, deviations, defective material and equipment, and nonconformances are promptly identified and corrected. In the case of significant conditions adverse to quality, the measures shall assure that the cause of the condition is determined and corrective action taken to preclude repetition. 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."

Appendix A, "Priority Level of CARs," of Corrective Action procedure CP-16-01, "Corrective Action Process," Revision 5, dated May 1, 2009, stated the definition of a Priority Level A, a Significant Condition Adverse to Quality (SCAQ), as "a condition adverse to quality, which, if uncorrected, could have a serious effect on safety or operability." Appendix A of CP-16-01 also required that for a SCAQ, an identification of causal factors, an independent root cause investigation, and an extent of condition evaluation be performed. Appendix A also required that preventive actions be taken in order to prevent recurrence.

Contrary to the above, CAR 48406, opened in response to the radiation shielding error associated with the MCNP energy spectrum, was not appropriately classified as a Priority Level A, a SCAQ, and did not include an identification of causal factors, an independent root cause investigation, and an extent of condition. CAR 48406 should have been classified as a Priority Level A instead of a Priority Level C because:

- 1. The error could have had a serious effect on worker safety given the potential for a personnel overexposure in the event of a fuel drop accident, and
- 2. The significant increase in the radiation zoning designation for the upper drywell had a significant negative effect on operations by no longer permitting continuous operations in the upper drywell during refueling operations and restricting access to this area.

This issue has been identified as Violation 05200010/2008-201-03.

This is a Severity level IV violation (Supplement VII).

Pursuant to the provisions of 10 CFR 2.201, GEH is hereby required to submit a written statement or explanation to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, DC 20555-0001 with a copy to Richard Rasmussen, Chief, Quality and Vendor Branch 2, Division of Construction Inspection and Operational Programs, Office of New Reactors, within 30 days of the date of the letter transmitting this Notice of Violation (Notice). This reply should be clearly marked as a "Reply to a Notice of Violations" and should include: (1) the reason for the violation or, if contested, the basis for disputing the violation; (2) the corrective steps that have been taken and the results achieved; (3) the corrective steps that will be taken to avoid violations; and (4) the date when full compliance will be achieved. Your response may reference or include previous docketed correspondence, if the correspondence adequately addresses the required response. Where good cause is shown, consideration will be given to extending the response time.

Since your response will be made available electronically for public inspection in the NRC Public Document Room or from the NRC's document 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. 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 12<sup>th</sup> day of November 2009.

#### U.S. NUCLEAR REGULATORY COMMISSION OFFICE OF NEW REACTORS DIVISION OF CONSTRUCTION INSPECTION & OPERATIONAL PROGRAMS VENDOR INSPECTION REPORT

Docket No.:	05200010		
Report No.:	05200010/2009-201		
Vendor:	General Electric–Hita 3901 Castle Hayne R Wilmington, NC 2840	Road	nergy
Vendor Contact:	Russell Bastyr Quality Assurance Ma 910-819-5960	anager	
Background:	The U.S. Nuclear Regulatory Commission (NRC) under Title 10, Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants," of the <i>Code of Federal Regulations</i> (10 CFR Part 52) is conducting a design certification review of GEH's ESBWR. The NRC Inspection Team focused its inspection on the radiation shielding calculations and associated codes that GEH used in the development of the ESBWR design.		
Inspection Dates:	September 14 - 18, 2	2009	
Inspectors:	Yamir Diaz-Castillo Sabrina Cleavenger Charles Hinson Ilka T. Berrios Bryan Broadhead	NRO/DCIP/CQVB NRO/DCIP/CQVB NRO/DCIP/CHPB NRO/DNRL/NGE1 ORNL	Team Leader Assistant Team Leader
Approved by:	Richard Rasmussen, Quality & Vendor Bra Division of Constructi & Operational Prog Office of New Reacto	inch 2 ion Inspection rams	

### EXECUTIVE SUMMARY

#### General Electric-Hitachi Nuclear Energy 05200010/2009-201

The purpose of this inspection was to review GEH's quality assurance (QA) program and its implementation as it relates to radiation shielding calculations and associated codes implemented in support of the ESBWR Design. The inspection was conducted at GEH's facility in Wilmington, North Carolina.

The NRC inspection basis was 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*.

The NRC inspectors implemented Inspection Procedure (IP) 35017, "Quality Assurance Implementation Inspection" in combination with IP 43003, "Routine Vendors Inspections," during the conduct of this inspection.

Prior to this inspection, four previous NRC inspections were performed, one in December 2008 (0520010/2008-201); one in December 2006 (0520010/2006-202); one in April 2006 (0520010/2006-201); and one in November 2005 (0520010/2005/201). A previous NRC audit was also performed in December 2006, as part of an ESBWR design certification review. All five inspections and the audit were performed at GEH's facility in Wilmington, North Carolina.

This inspection was performed based on requests from Office of New Reactors (NRO), Division of Construction, Inspection, and Operational Programs (DCIP), Health Physics Branch (CHPB), to review GEH's radiation shielding calculations and associated codes for the ESBWR.

With the exception of the areas described below, the NRC inspectors concluded that GEH's QA policies and procedures were in compliance with the applicable requirements of Appendix B to 10 CFR Part 50 and that GEH personnel were implementing these policies and procedures effectively.

#### Quality Assurance Program - Training and Qualification

The NRC inspectors issued Violation 05200010/2009-201-01 for GEH's failure to provide procedural guidance for managing the different computer databases currently used to control the training records of GEH personnel.

#### Control of Purchased Material, Equipment and Services

The NRC inspectors issued Violation 05200010/2009-201-02 for GEH's failure to (1) provide adequate guidance for the conduct of receipt inspections of design and engineering work from its suppliers and (2) perform an adequate annual evaluation of EA in 2008.

#### Corrective Action

The NRC inspectors issued Violation 05200010-2009-202-03 for GEH's failure to adequately classify a corrective action as a Significant Condition Adverse to Quality and for consequently failing to perform a root cause evaluation and extent of condition.

# **REPORT DETAILS**

### 1. <u>Quality Assurance Program - Training and Qualification</u>

### a. Inspection Scope

The NRC inspectors reviewed GEH's QA policies and implementing procedures that govern the control of training and qualification of personnel performing activities affecting quality to verify compliance with the requirements of Criterion II, "Quality Assurance Program," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed the following policies and procedures established by GEH:

- NEDO-11209-04A, General Electric Nuclear Energy Quality Assurance Program Description (QAPD), Section 2, "Quality Assurance Program," Revision 8, dated March 31, 1989.
- NEDO-33260, Quality Assurance Requirements for Suppliers of Equipment and Services to the GEH ESBWR Project, Section 2, "Quality Assurance Program," Revision 5, dated April, 2008.
- Policies and Procedures (P&Ps) 70-30, "Personnel Proficiency in Quality Related Activities," dated August 4, 2003.
- Engineering Operating Procedure (EOP) 30-5.00, "Supplier Design Services Document Review," Revision 10, dated March 20, 2009.
- EOP 75-5.00, "Quality and Technical Training," Revision 15, dated May 11, 2009.

## b. Observations and Findings

Section 2.1 of GEH's QAPD provided a general description of GEH's requirements for the indoctrination, training and qualification of personnel performing activities affecting quality in order to provide assurance that appropriate proficiency was achieved and maintained.

Section 2.3 of NEDO-33260 provided additional training and qualification requirements imposed by GEH on its suppliers in addition to the training and qualification requirements already established in the supplier's QA program.

P&P 70-30 established the minimum personnel proficiency requirements to be implemented within GEH. Specifically, the procedure stated that there are two areas in which employees who perform activities affecting the quality of products must be proficient: technical discipline and procedural system. Section 2.3.1 of P&P 70-30 stated that "documentary evidence assuring that procedural system indoctrination and training requirements have been assessed shall be maintained by the employee's manager responsible for personnel administration for a minimum of three years or the duration of assignment. Records may be retained in an employee's file, as a separate file or as a centralized computer database."

EOP 75-5.00 defined the quality and technical training processes established by GEH to assure personnel proficiency in quality related activities per P&P 70-30. The technical training process was divided into various stages: (1) Determine Requirements; (2) Assess Needs; (3) Develop

Training Course; (4) Assign Training; (5) Complete Training; and (6) Maintain Records. Section 2.5 of EOP 75-5.00 stated that "training assignment and completion records for GEH personnel shall be recorded and maintained in a centralized training database controlled as a Quality Information System."

During the review of the training records in response to corrective action request (CAR) No. 49259, which required that ESBWR managers and leaders be trained in the development of new working instructions for specific implementation of EOP 30-5.00, the NRC inspectors asked GEH staff for information on the centralized database that was required to be maintained by P&P 70-30 and EOP 75-3.00. GEH's QA staff stated that they were in the process of integrating all training records into one centralized training database. Upon further discussions, GEH staff clarified that, at the time of the inspection, each department controlled its own training records using a different computer database, of which there were 12 in total. The NRC inspectors inquired about the procedure used for managing each of the databases and whether the use of the database was captured in any procedure, as required by Criterion II of Appendix B to 10 CFR Part 50. GEH's QA staff stated that no procedure existed for the maintenance of the different databases. This issue has been identified as Violation 05200010-2009-201-01.

### c. <u>Conclusions</u>

Except for the issue identified in Violation 05200010/2009-201-01, the NRC inspectors concluded that GEH's program requirements for training and qualification of personnel performing activities affecting quality were consistent with the regulatory requirements of Criterion II of Appendix B. Based on the limited sample of training and qualification records reviewed, the NRC inspectors also determined that GEH's QAPD and associated training and qualification procedures were being effectively implemented.

## 2. Control of Purchased Material, Equipment and Services

#### a. Inspection Scope

The NRC inspectors reviewed GEH's QA policies and implementing procedures that govern the control of purchased material, equipment, and services to verify compliance with the requirements of Criterion VII, "Control of Purchased Material, Equipment, and Services," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed the following policies and procedures established by GEH:

- NEDO-11209-04A, General Electric Nuclear Energy Quality Assurance Program Description (QAPD), Section 2, "Quality Assurance Program," Revision 8, dated March 31, 1989.
- EOP 30-5.00, "Supplier Design Services Document Review," Revision 10, dated March 20, 2009.
- Common Procedure (CP)-04-107, "Order Placement," Revision 2, dated July 16, 2009.
- CP-04-204, "Attachment T Preparation Instruction," Revision, 1, dated May 8, 2009.
- CP-07-02, "Supplier Approval," Revision 8, dated July 17, 2009.

- CP-18-02, "Supplier Audits and Surveys," Revision 3, dated July 10, 2009.
- P&P 70-14, "Nuclear Energy Quality Assurance Audit Requirements," dated June 26, 2009.
- New Units Process Instruction (NUPI)-30-20, "Suppliers Engineering Work Receiving and Inspection," Revision 0, dated September 19, 2009.
- NUPI-30-21, "Engineering Peer Review," Revision 0, dated September 10, 2009.
- Form CP-18-02-03, "Audit/Survey Evaluation Checklist/Third Party Assessment," dated July 17, 2009.
- Form NEO-866, "Review/Acceptance of Purchased Design Service Documents," dated March 2007.
- Form NEO-873, "Attachment T: Technical, Quality and Administrative Requirements," Revision 4, dated April 30, 2009.
- EOP 42-5.00, "Material Requests," Revision 13, dated February 21, 2006 (superseded by initial issue of CP-04-107 on April 30, 2009).
- EOP 45-1.00, "Procurement Initiation and Control," Revision 14, dated January 31, 2006 (superseded by initial issue of CP-04-107 on April 30, 2009).
- Form RC-0876A, "Supplier QA Program Evaluation," dated August 13, 2007 (superseded by CP-07-02-02 on October 3, 2008).
- Administrative Guide (AG) 002, "Evaluation and Approval of Suppliers," Revision 12, dated August 13, 2007 (superseded by CP-07-02 on October 3, 2008).
- AG-003, "Supplier Audits and Surveys," Revision 14, dated November 13, 2006 (superseded by CP 18-02 on July 10, 2009).

In addition, the NRC inspectors also reviewed the following purchase orders (POs) and internal audits:

- PO 431005866, dated March 13, 2006, issued to EA for Design Control Document (DCD) support, including dose assessment and radiation shielding criteria.
- PO 437019146, dated September 25, 2008, issued to EA for ESBWR DCD Chapter 12 Request for Additional Information (RAI) response work.
- PO 437007195, dated December 12, 2007, issued to EA for non-safety related contract labor in support of ESBWR licensing activities.
- GEH NPP Quality Audit Report (NPP-2009-02), dated March 13, 2009; Audit Plan, dated February 6, 2009; and Checklist, dated February 23-27, 2009.

- NQA Internal Audit Report (NQA 2009-03), dated July 4, 2009; and Checklist, dated May 29 June 4, 2009.
- GEH NPP Audit Report of Corrective Action Program (NPP-2008-03), dated January 9, 2009.
- GEH Surveillance Report of ESBWR Procurement Process (NPP-2008-06), dated June 16, 2008.

Furthermore, the NRC inspectors also reviewed the following radiation shielding calculational packages:

- 092-134-R-Z-07502, "Radiation Shielding Criteria," Revision 2, dated October 9, 2006.
- 092-134-F-Z-07516, "ESBWR Handling Accident Dose Rate in the Upper Drywell," Revision 1, dated December 16, 2008.
- 092-134-F-Z-07519, "Dose Rates Around the Inclined Fuel Transfer Tube," Revision 3, dated March 13, 2008.
- GE-NE-0000-0084-1469, "Dose Rate Calculations Using a GE14E Fuel Assembly During Fuel Handling Operations," Revision 1, dated June 2, 2009.
- GE-NE-0000-0084-1469, "Dose Rate Calculations Using a GE14E Fuel Assembly During Fuel Handling Operations," Revision 0, dated April 26, 2008.
- b. Observations and Findings

#### Technical Analysis of Radiation Shielding Calculations

In the course of the review and evaluation of Chapter 12, "Radiation Protection," of GEH's DCD, there were two instances in which requests for additional information (RAIs) resulted in the identification of errors associated with the implementation of radiation shielding codes used by GEH in calculating dose rates in various areas of the ESBWR design. The two RAIs associated with the identification of these errors were 12.2-19 (Monte Carlo N-Particle energy spectrum) and 12.4-19 (radius vs. diameter). In each of these instances, EA had used incorrect input data to run shielding codes to obtain estimated dose rates from plant components.

The radius vs. diameter error associated with RAI 12.4-19 was related to the incorrect use of input data in modeling the dose rates in the various rooms and areas adjacent to the inclined fuel transfer system tube (IFTT) during transfer of a spent fuel assembly through the IFTT. Specifically, EA had incorrectly input the diameter of the fuel transfer tube instead of inputting the radius of the fuel transfer tube into the shielding model, resulting in a lower calculated dose rate value (by a factor of ten) from the IFTT. This error was not considered to be significant because corrected dose rates in the various uncontrolled rooms and areas adjacent to the IFTT were relatively low (between 6  $\mu$ Sv/h (0.6 mrem/h) and 250  $\mu$ Sv/h (25 mrem/h)) during normal operation.

The Monte Carlo N-Particle (MCNP) energy spectrum error associated with RAI 12.2-19 was related to the incorrect use of the input files for the MCNP computer code. Specifically, EA had mistakenly used the average photon energies to represent the boundaries for each energy group instead of the maximum photon energy for each energy group when converting source strength outputs from the ORIGEN computer code to be compatible with MCNP input requirements. This change (i.e., use of the correct input files for the MCNP code) resulted in 50% increase in calculated dose rates in the upper drywell from a fuel drop accident. This error was considered significant because (1) the error could have had a serious effect on worker safety given the potential for a personnel overexposure in the event of a fuel drop accident and, (2) the significant increase in the radiation zoning designation for the upper drywell had a significant negative effect on operations by no longer permitting continuous operations in the upper drywell during refueling operations and restricting access to this area.

EA gave a presentation that provided a detailed description of the error associated with RAI 12.2-19. EA stated that, when converting source strength outputs from the ORIGEN computer code to be compatible with the MCNP code input requirements, EA had used the average photon energies to represent the boundaries for each energy group input instead of the maximum photon energy for each energy group input. This input error had the effect of lowering the resulting calculated MCNP output dose rate values. As a result, the dose rate values from the dropped fuel assembly calculated by EA in response to the initial RAI 12.2-19 were lower than they should have been. EA did not become aware of this input error until they received Supplement 2 to RAI 12.2-19. In Supplement 2 to RAI 12.2-19, the NRC staff had requested that GEH calculate the expected dose rates to a worker in the upper drywell from a dropped fuel assembly which had an extended burn-up of 58 GWD/MTU (the dose rate from an extended burn-up fuel assembly would be expected to be higher than that from a fuel assembly with a normal burn-up of 35 GWD/MTU). When EA was preparing their response to Supplement 2, EA realized that it had made an error in determining the input parameters for use in the MCNP shielding code. EA corrected the error by using the appropriate energy group inputs in preparing the response to Supplement 2, and the resulting calculated dose rates in the upper drywell from a dropped fuel assembly (with normal burn-up) increased by a factor of 50% from the calculated dose rate initially provided in EA's/GEH's response to the initial RAI 12.2-19.

The correction of the energy group inputs to the MCNP shielding code also resulted in significant increases in the calculated dose rates for other plant areas. In order to evaluate the accuracy of GEH's shielding calculations in determining the revised dose rates in these areas, the NRC inspectors performed the following confirmatory shielding calculations:

- 1. Calculation of the dose rates in the upper drywell from a fuel bundle dropped on the reactor vessel flange shield/seal ring.
- 2. Calculation of the dose rates to accessible areas surrounding the IFTT.
- 3. Calculation of the dose rates to a person above the spent fuel pool from a raised spent fuel assembly.

The NRC inspectors performed the above confirmatory calculations in order to evaluate the acceptability of EA's revised calculated dose rates in the upper drywell from a dropped fuel assembly and how the changed source term affected the dose rates in the accessible areas surrounding the IFTT and the dose rates to a person working above the spent fuel pool assembly. The results from the confirmatory calculations were acceptable because they

demonstrated that the revised dose rates calculated by EA were conservative and within the same order of magnitude as the inspector's calculations.

#### Procurement Documents

EOP 42-5.00 defined the responsibilities and procedural requirements for the release of technical, engineering, customer, and quality requirements for procurement. EOP 42-5.00 required that Form NEO-873 be filled out for purchase requests in which design basis, engineering, and quality requirements were not fully specified in the body of the PO. EOP 42-5.00 was superseded by CP-04-107 in April 2009.

CP-04-107 specified the requirements for controlled procurement of material, services, and labor, including the application of technical, engineering, customer, and quality requirements to POs. CP-04-107 required that specific information (project application, customer technical and quality requirements, design requirements, material/service classification, applicable Code requirements, etc.) be identified on the Item Master File (IMF) and/or in an Attachment T (Form NEO-873) to the PO.

CP-04-204 provided instructions for the preparation and completion of Form NEO-873, "Attachment T: Technical, Quality, and Administrative Requirements." When completed, Form NEO-873 documented specified technical and quality requirements applicable to the scope of work specified in the associated PO, including a brief description of the work scope by task, a listing of the required input of documents needed to perform the task, and a listing of deliverables required by the task.

The NRC inspectors examined a sample of procurement documents issued to Empresarios Agrupados Internacional, S.A. (EA) to ensure that all of the applicable technical and quality requirements relevant to the scope of work were translated into POs. For the POs sampled, the NRC inspectors verified that GEH had appropriately identified the safety classification of the services and, for safety-related work, had invoked the requirements of Appendix B to 10 CFR Part 50 and 10 CFR Part 21 in addition to requiring that the work be performed under EA's Appendix B QA program, which had been approved by GEH. The POs also required EA to furnish QA records and Product Quality Certificates to GEH to support the DCD sections, RAI responses, and calculations provided under the POs. The NRC inspectors verified that these records had been furnished by EA and retained as quality records by GEH.

#### Acceptance and Oversight of Contracted Work

EOP 30-5.00 defined the responsibilities and procedural requirements for the review, approval, and control of documentation from suppliers for design services. The procedure also required that applicable supplier submitted documents be entered into the Product Data Management System (PDMS) as elements of the design basis or into the Design Record File (DRF) as engineering controlled documents. EOP 30-5.00 required that the responsible engineer and/or responsible manager perform a final review of supplier received design documents to confirm that all documents had been received, the delivered documents met the PO requirements, all necessary inputs were correctly identified and applied, and all comments and technical issues were resolved.

EOP 30-5.00 required that Form NEO-866 be completed and filed in the DRF to provide objective documented evidence of GEH's review of documents received from suppliers. Form NEO-866 documented the review and acceptance of purchased design service documents and

included checkboxes to verify that all the requirements of EOP 30-5.00 had been met (i.e., all documents had been received, necessary inputs were correctly identified and applied, etc.) Work Instruction NUPI-030-20 defined the process for the receipt and inspection of engineering documents, design, and analyses received from suppliers and provided criteria for the use of NEO-866 and the implementation of EOP 30.500.

EOP 30-5.00 and Form NEO-866 both required GEH engineers and/or managers performing receipt inspections to verify that "all necessary inputs were correctly identified and applied" in design packages received from suppliers, however, these documents failed to provide adequate guidance for personnel to implement the requirement (i.e., which inputs are necessary, how to verify that they were correctly identified and applied, etc.). The NRC inspectors found that the GEH engineers who performed receipt inspections of calculations had varying interpretations of the intent of this statement, and as such, were implementing the requirement inconsistently. As such, the NRC inspectors found that there was inconsistency in actions taken by GEH employees to satisfy this requirement, ranging from (1) performing a simple verification that the appropriate number of RAI responses that were requested from EA were received (ensuring that the end deliverable was received) to (2) reading tables of input data submitted by EA as part of design calculations to make sure they seemed reasonable. Through interviews with GEH engineers, the NRC inspectors found that, generally, GEH engineers did not perform a comparison of the design inputs transmitted to EA versus those used in calculations to verify that the design inputs submitted were those applied. GEH's failure to provide adequate guidance for the conduct of receipt inspections of design and engineering work from its suppliers has been identified as an example of Violation 05200010-2009-201-02. Furthermore, GEH's failure to adequately apply the requirements of EOP-30-5.00 and NEO-866 contributed to GEH not identifying the errors associated with the implementation of radiation shielding codes used by GEH in calculating dose rates in various areas of the ESBWR design.

As a result of errors in calculations performed by EA and supplied to GEH for the ESBWR DC, GEH initiated a mandatory peer review of work products received from EA in early September, 2009. On September 10, 2009, GEH issued Revision 0 of work instruction NUPI-030-21 to provide working level instructions for the performance of peer reviews of engineering documents. NUPI-030-21 provided acceptance criteria for the review of design/analysis inputs, assumptions, work methods, results, and supplier documentation. Although these reviews were required to be documented, none had been completed as of the dates of this inspection and hence none were available for NRC review.

#### Qualification and Evaluation of Suppliers

EOP 45-1.00 set forth the requirement that safety-related suppliers must be audited by GEH on a triennial basis and be evaluated on an annual basis consistent with their scope of supply. EOP 45-1.00 was superseded by CP-04-107 in April 2009.

AG-003 provided instructions to implement the requirements of EOP 45-1.00 for the performance of supplier audits. The procedure set forth requirements for the selection of audit team members, audit planning and conduct, and the use of standardized checklists for audits (audit teams were required to use the standard NIAC checklist, but could make modifications as needed to support the scope of the audit). AG-003 was superseded by CP 18-02 in July 2009.

AG-002 provided the implementing guidance for the conduct of annual supplier evaluations as well as maintenance of the Approved Supplier List (ASL). AG-002 stated that annual evaluations should be conducted of audited suppliers during non-audit years and documented

on Form RC-0876A. However, the procedure did not provide any specific instructions for the performance of the annual evaluation, such as how to complete the Form RC-0876A (what level of detail should be described in the evaluation, what documents should be reviewed, etc.). AG-002 was superseded by CP-07-02 in October 2008. The NRC inspectors noted that, unlike AG-002, CP-07-02 provided thorough instructions for completion of supplier QA evaluation form, as described in Appendix F of the procedure.

P&P 70-14 defined the overarching requirements for QA audits performed by GEH. These audits included internal QA program audits GEH conducted of its own program in addition to audits and surveillances GEH conducted of its suppliers.

CP-18-02 defined the responsibilities, requirements, and processes for the performance of supplier audits and included guidance for lead auditors and quality engineers to review past performance of suppliers in preparation for audits, surveys, and evaluations. The procedure also directed quality engineering personnel to complete a Form CP-18-02-03 when subcontracting audit/survey services or receiving an audit report from a third party for use in supplier evaluation. The completion of Form CP-18-02 ensured the quality and completeness of audit reports received by GEH from third parties by providing for verification of the content of the audit package and assessment of the audit results, including follow up actions performed by the vendor.

CP-07-02 defined the requirements for the implementation of GEH P&P 70-14 and CP-18-02 and provided instructions for the approval of suppliers and maintenance of the ASL. CP-07-02 delineated the personnel responsible for scheduling and performing supplier audits and evaluations and set forth requirements for supplier qualification and maintenance of qualification, such as an initial qualification audit, approval of the supplier's QAPD, and triennial audit and annual evaluations. CP-07-02 also identified the requirement for quality engineers to complete a Supplier Approval Status (SAS) Input Form and submit it to the ASL Administrator in order to add a supplier to the ASL or update its status.

The NRC inspectors verified that EA had been qualified via an audit in October 2007, as documented in Audit Report Number Q0710; dated October 17, 2007 (audit was performed under AG-003). During that audit, GEH identified five audit findings, one audit concern, and one audit recommendation. The audit was performed with a comprehensive audit checklist and an audit plan. Supplier corrective action requests (CARs) were opened for all findings identified in the audit, including the audit concern and the audit recommendation, resulting in a total of seven supplier CARs. The NRC inspectors identified that although, in general, a sufficient level of supporting documentation was recorded in the audit checklist to furnish evidence of quality on behalf of the supplier, there were instances of poor attention to detail and completeness in the report. These examples included missing citations for reference documents, incomplete checklist boxes, and a lack of supporting evidence for an issue identified as an audit concern. Although these examples were indicative of an inattention to detail, they were not significant enough to bring into question the validity of the audit results or the quality of the audit performed.

The NRC inspectors verified that GEH had performed an annual assessment of EA in October 2008 to support EA's continued status as an approved supplier on the GEH ASL. This assessment, dated October 9, 2008, was documented on a Form RC-0876A, "Supplier QA Program Evaluation." The NRC inspectors found that GEH did not perform a thorough review of EA's work between October 2007, and October 2008. Specifically, the following sections of the evaluation were marked "N/A:"

- Results of previous source verifications, audits, and receiving inspections.
- Nature and severity of CARs including evaluation of supplier's responsiveness to and effectiveness of corrective action programs.
- Review and evaluate the supplier's furnished documents and records such as Certificates of Conformance, nonconformance notices, and corrective actions.

Even though these sections were marked as not applicable, there were seven receipt inspections that should have been evaluated and documented on the annual evaluation, seven CARs issued as a result of the 2007 EA audit, and one CAR issued for errors in calculations performed by EA in support of RAI 12.4-19 (EA inadvertently used the fuel transfer tube diameter value instead of the radius value for dose calculations). These items represented 15 missed opportunities to evaluate EA's performance and identify any adverse trends. These issues have been identified as examples of Violation 05200010-2009-201-02.

#### c. <u>Conclusions</u>

Except for the issues identified in Violation 05200010/2009-201-02, the NRC inspectors concluded that GEH's program requirements for the control of purchased material, equipment, and services were consistent with the regulatory requirements of Criterion VII of Appendix B to 10 CFR Part 50. Based on the limited sample of documents reviewed, the NRC inspectors also determined that GEH's QAPD and associated procedures for the control of purchased material, equipment, and services were being effectively implemented.

3. <u>Corrective Actions</u>

#### a. Inspection Scope

The NRC inspectors reviewed GEH's QA policies and implementing procedures that govern the corrective action process to verify compliance with the requirements of Criterion XVI, "Corrective Action," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed the following policies and procedures established by GEH:

- NEDO-11209-04A, GE Nuclear Energy QAPD, Section 16, "Corrective Action," Revision 8, dated March 31, 1989.
- NEDO-33260, Quality Assurance Requirements for Suppliers of Equipment and Services to the GEH ESBWR Project, Section 16, "Corrective Action," Revision 5, dated April, 2008.
- EOP 75-3.00, "Self-Assessment, Corrective Action and Audits," Revision 11, dated May 12, 2006.
- EOP 75-3.00, "Self-Assessment, Corrective Action and Audits," Revision 12, dated November 5, 2007.
- CP-16-01, "Corrective Action Process," Revision 5, dated May 1, 2009.

• CP-16-02, "Suppliers Corrective Action Request" Revision 2, dated May 12, 2009.

In addition, the NRC inspectors also reviewed corrective action requests (CARs) that were initiated in 2007 and 2009 in response to the issues identified with the radiation shielding calculations.

#### b. Observations and Findings

Section 16 of GEH's QAPD provided a general description of GEH corrective action program. This section stated that procedures and practices are established and documented to provide assurance that conditions adverse to quality or nonconformances such as: failures, malfunctions, deficiencies, and deviations in material and equipment are promptly identified, documented, and corrected or otherwise handled in accordance with established procedures.

Section 16 of NEDO-33260 indicated that GEH suppliers and sub-suppliers must have and implement a QA program conforming to the basic requirements of Section 16 of the American Society of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)-1-1994.

CP-16-01 established the process for identifying, recording and correcting conditions adverse to quality, and defined the requirements and responsibilities for assessing enhancements and recommendations. This procedure detailed the process for (1) identifying and documenting apparent conditions adverse to quality under the scope of GEH's quality program, (2) investigating and correcting those adverse conditions, and (3) closing CARs upon completion of corrective action.

The NRC inspectors noted that CP-16-01 was a revision of EOP 75-3.00. The NRC inspectors further examined previous revisions of EOP 75-3.00 and CP-16-01, since those revisions were in use between 2007 and 2009 when the NRC and GEH staff started discussing possible discrepancies in the radiation shielding calculations.

CP-16-02 described the steps for obtaining and documenting corrective and/or preventive actions from GEH suppliers in response to quality issues related to services, equipment or materials received.

The NRC inspectors examined four CARs (43918, 48406, 48563, and 49208) generated by GEH in response to problems identified with the radiation shielding calculations. The NRC inspectors noted that two CARs were supplier CARs issued to EA and the other two were GEH internal CARs. The NRC inspectors confirmed that all of the CARs were adequately closed by reviewing the objective evidence contained in the CAR packages, including corrective actions and the acceptance of actions taken to address and close the CARs.

During the review of CAR 48406, which was opened in response to the radiation shielding error associated with the MCNP energy spectrum, the NRC inspectors noted it had been classified as Priority C, Broke/Fix. GEH defines a Priority C, Broke/Fix classification as "an adverse condition that has or would have minimal effect on the safe or reliable operation of the plant or no customer impact. Corrective actions taken are typically adequate to resolve the condition for this classification." The NRC inspectors noted that Appendix A to CP-16-01, "Priority Level of CARs," defined a Priority Level A, a Significant Condition Adverse to Quality (SCAQ), as "a condition adverse to quality, which, if uncorrected, could have a serious effect on safety or operability." Appendix A of CP-16-01 also required that for a SCAQ, an identification of causal factors, an independent root cause investigation, and an extent of condition evaluation be

performed. Appendix A also required that preventive actions be taken in order to prevent recurrence. However, none of the requirements associated with classifying a CAR as a SCAQ were performed for CAR 48406, which should have been classified as Priority Level A instead of Priority Level C because:

- 1. The error could have had a serious effect on worker safety given the potential for a personnel overexposure in the event of a fuel drop accident and,
- 2. The significant increase in the radiation zoning designation for the upper drywell had a significant negative effect on operations by no longer permitting continuous operations in the upper drywell during refueling operations and restricting access to this area.

This issue has been identified as Violation 05200010-2009-201-03.

In response to the two CARs (43918, opened November 1, 2007; and 48563, opened June 3, 2009) that were written related to the radiological engineering work performed by EA, GEH initiated a CAR (49028) to determine if a trend adverse to quality existed and if so, to identify the cause and establish a corrective action plan to prevent reoccurrence. As part of this trending CAR, GEH performed a review of a sample of radiological (8) and structural (3) engineering calculations prepared by EA. The sample size was based on the total numbers of calculations provided by EA that were referenced in the DCD. Although no findings of significance were identified that would indicate a trend adverse to quality, GEH identified areas for improvement that focused on the communication between GEH and EA and the oversight of EA by GEH. GEH initiated an internal CAR (49398) to address the findings of the trending CAR.

As part of this trending CAR, the following actions were performed:

1. GEH performed a review of a sample of the radiological engineering calculations and structural engineering calculations prepared by EA to determine if a trend adverse to quality existed. No trends of safety significance that would represent a condition adverse to quality were identified.

Although a trend adverse to quality wasn't identified, GEH identified some areas for improvement for which GEH took the following preventative actions:

- 1. CAR 49398, dated September 15, 2009 was opened to address communication problems between GEH and EA.
- 2. GEH also issued a new work instruction, "Engineering Peer Review," dated September 10, 2009, to provide instructions to the staff on how to perform and document technical reviews of all supplier work and applied it to work performed by EA.
- c. <u>Conclusions</u>

The NRC inspectors concluded that GEH's program requirements for corrective actions are consistent with the regulatory requirements of Criterion XVI of Appendix B to 10 CFR Part 50. Based on the limited sample of CARs reviewed, the NRC inspectors determined that GEH's QAPD and associated corrective action procedures were being effectively implemented with the exception of the issue identified in Violation 05200010-2009-201-03.

# 4. <u>Audits</u>

### a. Inspection Scope

The NRC inspectors reviewed GEH's QA policies and implementing procedures that govern the process for internal audits to verify compliance with the requirements of Criterion XVIII, "Audits," of Appendix B to 10 CFR Part 50. Specifically, the NRC inspectors reviewed the following policies and procedures established by GEH:

- NEDO-11209-04A, General Electric Nuclear Energy QAPD, Section 18, "Audits," Revision 8, dated March 31, 1989.
- P&P 70-14, "Nuclear Energy Quality Assurance Audit Requirements," dated June 26, 2009.

In addition, the NRC inspectors also reviewed a sample of internal audits performed by GEH of its QA program.

#### b. Observations and Findings

Section 18 of GEH's QAPD identified the general requirements for establishing a regular schedule of internal audits of QA program activities. The QAPD also set forth high level guidance for planning and conducting internal audits as well as managing audit findings.

P&P 70-14 described the requirements for internal audits performed within the GEH organization and required that an internal audit schedule be established such that the applicable elements of the GEH QA Program were audited at least annually.

The NRC inspectors verified, for a sample of internal audits conducted in 2008 and 2009, that internal audits of QA Program activities for the ESBWR Project, Nuclear Plant Projects (NPP) Procurement, and for the Corrective Action Program had been scheduled at least annually and had been conducted using a checklist to ensure that all applicable regulatory and quality requirements and criteria were evaluated. The checklists contained an adequate level of objective evidence to support the classification of checklist criteria as satisfactory or unsatisfactory, and CARs were opened for all findings and recommendations identified in audit reports. The NRC inspectors also verified that audit plans identifying the audit scope, focus, and applicable checklist criteria had been prepared and approved prior to the initiation of the audit activity.

#### c. <u>Conclusions</u>

The NRC inspectors concluded that GEH audit program requirements for the ESBWR design certification project were consistent with the regulatory requirements of Criterion XVIII of Appendix B to 10 CFR Part 50. Based on the limited sample of audits reviewed, the NRC inspectors determined that the GEH's QAPD and associated audit procedures were being effectively implemented. The NRC inspectors did not identify any issues in this area.

### 5. Entrance and Exit Meetings

On September 14, 2009, the NRC inspectors presented the scope of the inspection during an entrance meeting with Rich Wittmeier, Quality Leader Executive, and other GEH personnel. On September 18, 2009, the NRC inspectors presented the results of the inspection during an exit meeting with James F. Klapproth, Senior Vice President of Engineering, and other GEH personnel. On October 20, 2009, during a phone call with GEH staff, the NRC inspectors discussed an additional finding not previously identified. A list of entrance/exit meeting attendees is included as an attachment to this report.

# ATTACHMENT

# 1. PERSONS CONTACTED

NAME	COMPANY	TITLE	ENTRANCE	EXIT	INTERVIEWED
J. Klapporth	GEH	Engineering Senior Vice President		$\checkmark$	
R. Wittmeier	GEH	Quality Leader Executive	$\checkmark$	$\checkmark$	
R. Bastyr	GEH	Nuclear Quality Assurance Leader	$\checkmark$	$\checkmark$	
L. Tucker	GEH	ESBWR Engineering Manager		$\checkmark$	
R. Kingston	GEH	ESBWR Licensing Manager		$\checkmark$	
D. Hinds	GEH	New Units Engineering Manager	$\checkmark$	$\checkmark$	
I. Nir	GEH	New Units Engineering Manager		$\checkmark$	
B. Gage	GEH	Sourcing Manager	$\checkmark$		
C. Alonso	GEH	Sourcing Quality Leader	$\checkmark$		
P. Ragan	GEH	Sourcing Quality			
Y. C. Lee	GEH	Quality Program Manager			
S. Coleman	GEH	Quality Program Manager		$\checkmark$	
J. Atento	GEH	Quality Program Manager		$\checkmark$	
W. Marquino	GEH	Engineering Manager			
M. Colby	GEH	Engineering Manager	$\checkmark$	$\checkmark$	
B. Johnson	GEH	Senior Project Manager	$\checkmark$		
E. Kirstein	GEH	Engineering Technical Leader	$\checkmark$	$\checkmark$	
L. Auman	GEH	Engineering Technical Leader			
D. Taylor	GEH	Senior Licensing Manager	$\checkmark$	$\checkmark$	
T. Enfinger	GEH	Senior Licensing Engineer	$\checkmark$	$\checkmark$	
D. Piepmeyer	GEH	Senior Project Manager	$\checkmark$	$\checkmark$	
J. McLamb	GEH	Senior Project Engineer	$\checkmark$		
J. Elmerick	GEH	Senior Engineer	$\checkmark$	$\checkmark$	
J. Cascone	GEH	Senior Engineer	$\checkmark$	$\checkmark$	
M. Gerdes	GEH	Support Services Quality Leader		$\checkmark$	
T. Check	GEH	Supply Chain Leader		$\checkmark$	
M. Acaro	GEH	Principal Engineer			$\checkmark$

NAME	COMPANY	TITLE	ENTRANCE	EXIT	INTERVIEWED
Y. Diaz-Castillo	NRC	Inspection Team Leader	$\checkmark$	$\checkmark$	
S. Cleavenger	NRC	Inspection Assistant Team Leader	$\checkmark$	$\checkmark$	
C. Hinson	NRC	NRC Technical Specialist	$\checkmark$	$\checkmark$	
I. Berrios	NRC	NRC Licensing Project Manager	$\checkmark$	$\checkmark$	
B. Broadhead	ORNL	Technical Specialist	$\checkmark$		

# 2. INSPECTION PROCEDURES USED

Inspection Procedure 35017, "Quality Assurance Implementation Inspection."

Inspection Procedure 43003, "Reactive Inspections of Nuclear Vendors."

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

Item Number	<u>Status</u>	<u>Type</u>	<b>Description</b>
05200010/2009-201-01	Open	NOV	Criterion II
05200010/2009-201-02	Open	NOV	Criterion VII
05200010/2009-201-03	Open	NOV	Criterion XVI

### 4. LIST OF ACRONYMS USED

CPCDCDDDRFDEAEEOPEGEHGIFTTIrMCNPMNQANPDMSPP&PPRAIFQAGQAPDG	Code of Federal Regulation Common Procedure Design Control Document Design Record File Empresarios Agrupados Engineering Operating Procedure General Electric-Hitachi Inclined Fuel Transfer System Tube Monte Carlo N-Particle Juclear Quality Assurance Product Management Data System Policy and Procedure Request for Additional Information Quality Assurance Duality Assurance Program Description
	Quality Assurance Program Description