17. QUALITY ASSURANCE

17.0 Introduction

The GE-Hitachi Nuclear Energy Americas LLC (GEH) quality assurance program (QAP) used for the Economic Simplified Boiling-Water Reactor (ESBWR) is based on the standard GEH QAP documented in topical report (TR) NEDO-11209-04A, Revision 8, "GE Nuclear Energy Quality Assurance Program Description," which was approved by the U.S. Nuclear Regulatory Commission (NRC) by letter dated March 31, 1989. The ESBWR Design Control Document (DCD), Tier 2, Revision 7, Section 17.0, provides an overview of the implementation of the GEH QAP and states that the GEH QAP complies with Title 10 of the *Code of Federal Regulations* (10 CFR) Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants"; the implementing American National Standards Institute/American Society of Mechanical Engineers (ASME) N45.2 series daughter standards, ASME NQA-1-1983 and NQA-1a-1983; and the regulatory guides cited in NEDO-11209-04A. DCD Tier 2, Revision 7, Section 17.0, states that the GEH ESBWR work is controlled through NEDO-33181, Revision 2, "NP-2010 COL Demonstration Project Quality Assurance Plan," issued July 2006. NEDO-33181 describes the quality assurance (QA) plan scope, which GEH, as supplier for ESBWR engineering services, is implementing.

The staff inspected the implementation of the GEH QAP for the ESBWR activities as part of its review of DCD Tier 2, Revision 7, Section 17.0. The staff performed these inspections in November 2005, April 2006, and December 2006. As part of the November 2005 inspection, the staff identified unresolved item (URI) 05200010-2005-201-01, which requested a description in DCD Tier 2, Revision 7, Section 17.0, of the basis of the ESBWR QAP and how GEH and its various domestic and international ESBWR team participants will implement the program. In addition, in URI 05200010-2005-201-02, the staff requested information about the activities associated with the transition from the simplified boiling-water reactor (SBWR) to the ESBWR design, particularly as it relates to the qualification test program activities performed for the SBWR design certification (DC), which are now being used to support the ESBWR DC application.

During the December 2006 inspection, the staff reviewed Section 17.0 of Chapter 17 of the ESBWR DCD Tier 2, Revision 2, and verified that Section 17.0 adequately addresses the transition from the SBWR to ESBWR design and the basis of the GEH QAP. Section 17.0 describes the evolution of the ESBWR design as it relates to the SBWR test programs conducted at international supplier test facilities such as GIRAFFE, PANTHERS, and PANDA. Additionally, Section 17.0 states that NEDC-33260, Revision 1, "NP-2010 COL Demonstration Project, SQAR—ESBWR QA Requirements for Procurement of Engineering Services and Equipment," issued July 2006, describes the relationship, responsibilities, and requirements for the quality programs of suppliers and subtier suppliers. The staff verified that NEDC-33260 includes the appropriate NQA-1-1983 references and closed URI 05200010-2005-201-01. Section 21.7 of this report discusses the resolution of URI 05200010-2005-201-02.

17.1 Quality Assurance During Design

17.1.1 Regulatory Criteria

The ESBWR DCD Tier 2, Revision 7, Section 17.1, provided a description of the GEH QAP, as documented in NEDO-11209-04A, as required by the following regulations:

- 10 CFR Part 50, Appendix B, establishes the QA requirements for the design, construction, and operation of structures, systems, and components (SSCs) that prevent or mitigate the consequences of postulated accidents that could cause undue risk to the health and safety of the public. The pertinent requirements of 10 CFR Part 50, Appendix B, apply to all activities affecting the safety-related functions of those SSCs.

- 10 CFR 52.47(a)(19) requires "a description of the quality assurance program applied to the design of the structures, systems, and components of the facility. 10 CFR Part 50, Appendix B, 'Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants,' sets forth the requirements for quality assurance programs for nuclear power plants. The description of the quality assurance program for a nuclear power plant shall include a discussion of how the applicable requirements of 10 CFR Part 50, Appendix B were satisfied."

- 10 CFR 50.34(a)(7) requires that the safety analysis report (SAR) include a description of the QAP to be applied to the design, fabrication, construction, and testing of SSCs of a facility. The description of the QAP for a nuclear power plant shall include a discussion of how the program will satisfy the applicable requirements of 10 CFR Part 50, Appendix B.

The NRC used 10 CFR Part 50, Appendix B, the implementing ANSI/ASME N45.2 series daughter standards and the applicable Regulatory Guides to evaluate DCD Tier 2, Revision 7, Section 17.1, "Quality Assurance During Design".

17.1.2 Summary of Technical Information

The ESBWR DCD Tier 2, Revision 7, Section 17.1, describes the QAP used by GEH for the ESBWR. It is based on the standard GEH QAP, documented in TR NEDO-11209-04A, Revision 8, which the NRC approved by letter dated March 31, 1989.

17.1.3 Staff Evaluation

The staff reviewed the QAP information provided in DCD Section 17.1. Based on its review, the staff identified an area where it required further clarification to complete the review.

RAI 17.1-1 In DCD Tier 2, Revision 1, Section 17.1 is titled "Quality Assurance During Design and Construction," and Section 17.2 is titled "Quality Assurance During the Operations Phase." Based on the staff's review, Section 17.1 applies only to GEH QA during the design phase and not to construction. This is supported by the statement in Section 17.2 that "QA responsibilities during the plant

construction and operations phases are combined license (COL) holder scope." Provide an introductory paragraph in DCD Tier 2, Section 17.1, which specifically states section applicability, and consider revising the title of DCD Tier 2, Section 17.1, to be more representative of the section.

By letter dated October 6, 2006, GEH responded to the staff's request for additional information (RAI). GEH revised the title of Section 17.1 to "Quality Assurance During Design" and provided an introductory paragraph stating that Section 17.1 is applicable to the ESBWR design activities supporting the standard DC. These clarifications resolved RAI 17.1-1.

The staff performed several inspections to verify implementation by GEH of the QAP for the ESBWR DC. The staff conducted inspections in November 2005, April 2006, and December 2006, at GEH facilities in Wilmington, NC. The following reports document the results of these inspections.

NRC Inspection Report (IR) 05200010/2005-201, dated January 11, 2006, documents the November 2005 inspection. During this inspection, the staff found that the implementation of the GEH QAP failed to meet certain NRC requirements and cited five nonconformances and two URIs. Specifically, the staff found that GEH had not adequately implemented the ESBWR design control process as required by the GEH QAP. GEH did not document the revised completion date for the ESBWR DCD verification when the schedule was not met and did not maintain and update the work plan and detailed schedule for the ESBWR program. GEH 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 and preventive actions identification and the response and closure activities associated with several ESBWR CARs. GEH responded to IR 05200010/2005-201 by letter dated February 9, 2006, and provided corrective and preventive actions for the cited nonconformances. Sections 17.0 and 21.7 of this report discuss the resolution of the URIs.

NRC IR 05200010/2006-201, dated June 14, 2006, documents the April 2006 inspection. During this inspection, the staff reviewed the corrective and preventive actions documented in the GEH letter dated February 9, 2006, and closed the five previously identified nonconformances. The staff also discovered two additional nonconformances with NRC requirements. Specifically, the staff found that the GEH corrective action processes had not been effective in addressing and correcting the root causes of nonconformances. GEH did not adequately implement the requirements to process and complete corrective actions in a timely manner in accordance with its QAP. In addition, the staff found that several ESBWR project documents, including certain DCD sections, referenced editions of the ASME NQA-1 standard that are not consistent with DCD Chapter 17 QAP commitments. By letter dated July 21, 2006, GEH responded to IR 05200010/2006-201 and provided corrective and preventive actions for the cited nonconformances.

NRC IR 05200010/2006-202, dated January 19, 2007, documents the December 2006 inspection. During this followup inspection, the staff reviewed the corrective and preventive actions documented in the GEH letter dated July 21, 2006, and closed the two previously identified nonconformances. In addition, GEH provided supplemental information regarding the two URIs identified in the November 2005 inspection. The staff reviewed the supplemental documentation, as discussed in Sections 17.0 and 21.7 of this report, and closed these URIs.

17.1.4 Conclusions

On the basis of its review of the applicable information in DCD Tier 2, Revision 7, Section 17.1, and the QA implementation inspections performed at GEH facilities in Wilmington, NC, the staff determined that GEH has implemented the ESBWR QAP, consistent with the requirements of GEH TR NEDO-11209-04A, Revision 8. Therefore, the staff concludes that DCD Tier 2, Revision 7, Section 17.1, meets the requirements of 10 CFR 50.34(a)(7) and 10 CFR Part 50, Appendix B.

17.2 Quality Assurance During Construction and Operations

The staff reviewed the QAP information provided in DCD Tier 2, Revision 1, Section 17.2. Based on its review, the staff identified an area where it needed further clarification to complete its review.

RAI 17.2-1 DCD Tier 2, Revision 1, Section 17.2, briefly states that the COL applicant is responsible for the QA activities during construction and operating phases. The COL applicant could be responsible for the design phase, along with procurement, fabrication, installation, construction, and testing of SSCs. Provide an introductory paragraph in Section 17.2 that accounts for the COL applicant's QA responsibilities in all phases (design, construction, and operation) and consider a more representative section title.

By letter dated October 6, 2006, GEH responded to the staff's RAI. GEH revised the title of Section 17.2 to "Quality Assurance During Construction and Operations" and provided an introductory paragraph stating that the COL applicant is responsible for QA during construction and operations and for design activities necessary to adapt the certified standard plant design to the specific plant implementation. These clarifications resolved RAI 17.2-1. The staff agrees that the QA activities associated with construction and operations, including site-specific design activities, are the COL applicant's responsibility. These are addressed in DCD, Tier 2, Revision 7 COL Information Items 17.2-1-A QA Program for the Construction and Operations Phases and 17.2-2-A QA Program for Design Activities. COL Information Items identify the COL applicant activities that must be performed during the COL application phase.

17.3 Quality Assurance Program Document

DCD Tier 2, Revision 7, Section 17.3, states that the QA program document for the overall project is the COL applicant's responsibility. The staff agrees with this statement. This is COL Information Item 17.3-1-A Quality Assurance Program Document. COL Information Items identify the COL applicant activities that must be performed during the COL application phase.

17.4 Reliability Assurance Program During Design Phase

The ESBWR DCD Tier 2, Revision 7, Section 17.4, "Reliability Assurance Program During Design Phase," addresses the Commission's direction for the reliability assurance program (RAP) provided in the staff requirements memorandum (SRM) dated June 28, 1995. The guidance for RAP is presented in Item E, "Reliability Assurance Program," of SECY-95-132,

"Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs," dated May 22, 1995, and in NUREG-0800, "Standard Review Plan (SRP) for the Review of Safety Analysis Reports for Nuclear Power Plants", issued March 2007, Section 17.4, "Reliability Assurance Program." The purpose of the RAP is to provide reasonable assurance of the following:

- A reactor is designed, constructed, and operated consistent with the assumptions and risk insights for the SSCs in the scope of the RAP.
- These SSCs do not degrade to an unacceptable level of reliability, availability, or condition during plant operations.
- The frequency of transients that challenge these SSCs is minimized.
- These SSCs function reliably when challenged.

The purpose of the RAP can be achieved by implementing the program in two stages. The first stage applies to reliability assurance activities that occur before the initial fuel load and is referred to as the design reliability assurance program (DRAP). The NRC staff verifies the DRAP during the DC phase through the agency's safety evaluation (SE) review process. The NRC verifies implementation of the DRAP by the COL licensee through the inspections, tests, analyses, and acceptance criteria (ITAAC) process, as well as inspections and audits during detailed design and construction before initial fuel load.

The second stage applies to reliability assurance activities conducted during the operations phase of the plant's life cycle. These activities are implemented under operational programs as specified in Section 13.4, "Operational Program Implementation," of ESBWR DCD Tier 2, Revision 7. At issuance of a COL by the NRC, operational programs may become license conditions that are implemented by the licensee throughout the life of the plant. The NRC verifies implementation of these operational programs using inspections and audits for the duration of the license.

17.4.1 Regulatory Basis

ESBWR DCD Tier 2, Revision 7, Section 17.4, describes the RAP for the design phase, as prescribed by the Commission policy and regulatory provisions below:

- Commission policy contained in the SRM on SECY-95-132, Item E, requires a RAP codified by incorporation within the design-specific rulemaking for a DC applicant. Meeting this requirement provides evidence that (1) the reactor will be designed, constructed, and operated in a manner that is consistent with the assumptions and risk insights for these risk-significant SSCs, (2) the risk-significant SSCs will not degrade to an unacceptable level of performance or condition during plant operations, (3) the frequency of transients that challenge SSCs will be minimized, and (4) these SSCs will function reliably when challenged. The RAP becomes part of a COL application that references a certified design. In accordance with Commission policy documented in the SRM for SECY-95-132, the ITAAC process will verify the RAP for the design stage.

- In part, 10 CFR 52.47(b)(1) states that a DC application must contain proposed ITAAC that are necessary and sufficient to provide reasonable assurance that, if the inspections, tests, and analyses are performed and the acceptance criteria are met, a facility that incorporates the DC has been constructed and will be operated in conformity with the DC, the provisions of the Atomic Energy Act, and the NRC's regulations.

- SRP Section 17.4 provides review guidance for the RAP. The NRC staff bases its evaluation of the ESBWR RAP on SECY-95-132 and the guidance contained in SRP Section 17.4. The staff used the 1996 version of SRP Section 17.4 to perform its review. In comparing the 1996 version of SRP Section 17.4 with the 2007 version, the staff found that the 2007 version contains the following additional requirements or clarifications of existing requirements beyond those identified in the 1996 version:

  – clarification of the acceptance criteria for essential elements of the DRAP
  – clarification of the acceptance criteria for expert panel qualifications
  – identification of acceptance criteria for ITAAC for DRAP

  Though these items were not included in the 1996 SRP version used by the staff, the staff did address these items. Section 17.4.3 of this SER describes their disposition. Therefore, the staff concludes that the version of the SRP used, in combination with the additional review performed by the staff, is adequate for this review.

17.4.2 Summary of Application

ESBWR DCD Tier 2, Revision 7, Section 17.4, describes the following: the scope, purpose, and objectives of the DRAP; the organizations of GEH that are responsible for the DRAP (i.e., the essential elements of the DRAP); SSC identification and prioritization; design considerations; the process of defining failure modes; operational reliability assurance activities; the owner/operator's RAP; a sample case for DRAP implementation; and COL information items needed to implement the RAP. GEH also provided the following documents that, together with Section 17.4 of the ESBWR DCD, form the basis of the ESBWR DRAP and the DRAP ITAAC:

- Licensing Topical Report (LTR) NEDO-33289, Revision 2, "ESBWR Reliability Assurance Program," issued September 2008. LTR NEDO-33289 presents the plans for, and the constituents of, the generic RAP required by the SRP as part of the ESBWR DC.

- ESBWR DCD Tier 1, Revision 7, Section 3.6, "Design Reliability Assurance Program." This section of the DCD provides the DRAP ITAAC.

- LTR NEDO-33411, Revision 2, "Risk Significance of Structures, Systems and Components for the Design Phase of the ESBWR," issued February 2010. LTR NEDO-33411 describes the methodology for evaluating, identifying, and prioritizing SSCs according to their degree of risk significance, using a combination of probabilistic, deterministic, or other methods of analysis. This report also provides a list of risk-significant SSCs.

Section 17.4.13, "COL Information," and the associated Section 17.4.1, "Introduction," of DCD Tier 2, Revision 7, provide COL Information Items 17.4-1-A Identifying Site-Specific SSCs within the Scope of the RAP and 17.4-2-A Operation Reliability Assurance Activities. COL Information Item 17.4-1-A identifies the COL applicant activities that must be performed during the COL application phase in support of DRAP. COL Information Item 17.4-2-A identifies the COL applicant activities that must be performed during the COL application phase in support of the RAP during the operations phase.

17.4.3 Technical Evaluation

ESBWR DCD Tier 2, Revision 7, Section 17.4, together with LTRs NEDO-33289, Revision 2, and NEDO-33411, Revision 2, form the basis of the RAP for the ESBWR. Elements of the RAP for the ESBWR include the following:

- scope, purpose, and objectives of the RAP during the design phase
- essential elements of the RAP during the design phase
- SSC identification and prioritization
- dominant failure mode determination
- RAP implementation during the design phase
- RAP implementation during the operations phase
- COL information items

The NRC staff reviewed the documents that form the basis of the ESBWR RAP to ensure that the RAP meets the guidance in Item E of SECY-95-132 and SRP Section 17.4. As discussed in Section 17.4.1 of this SER, the staff used the 1996 version of SRP Section 17.4 to perform its review. The staff compared the 1996 version of SRP Section 17.4 with the 2007 version of SRP Section 17.4 and found that the 2007 version contains additional requirements or clarifications of existing requirements beyond those identified in the 1996 version. Though these items were not included in the SRP version used, the staff did address these items. The remainder of this section describes their disposition. Therefore, the staff concludes that the version of the SRP used, in combination with the additional review performed by the staff, is adequate for this review.

As with the certification of previous advanced reactor designs (e.g., the AP1000 and advanced boiling-water reactor (ABWR) designs), the staff's review of the ESBWR RAP included the issuance of RAIs to the applicant, followed by the evaluation of the applicant's responses to the RAIs. The staff issued 55 RAIs to the applicant during its review of the ESBWR RAP. These RAIs covered all aspects of the RAP. The following describes the staff's technical evaluation of the information contained in Section 17.4 of the DCD and LTRs NEDO-33289 and NEDO-33411.

17.4.3.1 Scope, Purpose, and Objectives of the DRAP

The NRC staff reviewed GEH's description of the RAP, provided in DCD Tier 2, Sections 17.4.1 ("Introduction"), 17.4.2 ("Scope"), 17.4.3 ("Purpose"), and 17.4.4 ("Objective"). The staff followed Item E of SECY-95-132 and the 1996 version of SRP Section 17.4 to ensure that this subject review area meets the guidance contained in these documents. The staff compared the SRP version used during the review with the 2007 version of SRP Section 17.4. For this subject review area, the 2007 version did not include any requirements, generic issues, bulletins, generic letters, or technically significant acceptance criteria beyond those identified in the version used by the staff. Therefore, the staff concludes that the 1996 version of SRP Section 17.4 is adequate for this review.

The SSCs in the scope of the ESBWR DRAP include (1) all RTNSS SSCs identified under ESBWR DCD Tier 2, Revision 7, Section 19A (Regulatory Treatment of Non-Safety Systems), and (2) all risk-significant SSCs identified under NEDO-33411. These SSCs provide defense in depth or result in significant improvements in the probabilistic risk assessment (PRA) evaluations. The purpose of the ESBWR DRAP is to ensure that plant safety, as estimated from the PRA, is maintained during the detailed design and construction phases. The objective of the ESBWR DRAP is to ensure that the reactor is designed and constructed consistent with the key assumptions and risk insights for the SSCs within the scope of the DRAP. The PRA and other sources identify the within-scope SSCs. The DRAP also identifies key assumptions related to operation, maintenance, and monitoring activities that the owner/operator should consider in implementing operational reliability assurance activities, to ensure that, when challenged, such SSCs function reliably throughout the plant's life with the reliability assumed in the PRA. Within-scope SSCs are subject to the QA activities established under the provisions of SRP Section 17.5, "Quality Assurance Program Description—Design Certification, Early Site Permit and New License Applicants."

Based on the discussion in this section, the staff concludes that GEH has adequately described the scope, purpose, and objectives of the DRAP and meets the guidance in Item E of SECY-95-132 and SRP Section 17.4. Therefore, this subject review area is acceptable.

17.4.3.2 GEH Organizations Responsible for the DRAP

The NRC staff reviewed the description of the GEH organizations that are responsible for developing, coordinating, and implementing the DRAP; DCD Section 17.4.5, "GEH Organization for DRAP," provides this description. The staff performed this review in accordance with Item E of SECY-95-132 and the 1996 version of SRP Section 17.4 to ensure that this subject review area meets the guidance contained in these documents. For this subject review area, the staff compared the SRP version used during the review with the 2007 version of SRP Section 17.4. The 2007 version clarified the acceptance criteria for the essential elements of DRAP (i.e., organization, design control, procedures and instructions, corrective action, records, and audits). The version used by the staff did not include these clarified acceptance criteria; however, the staff did address this item as described in the following discussion. Therefore, the staff concludes that the version of the SRP used, in combination with the additional review performed by the staff, is adequate for this review.

Based on its review, the staff prepared the following RAIs for areas where it needed additional information to complete its review:

RAI 17.4-4 In Revision 0 of DCD Section 17.4.5, GEH did not describe the essential elements for the DRAP in DCD Section 17.4. The staff has interpreted the essential elements, as described in SECY-95-132, Item E, to mean the application of the following essential elements to the DRAP:

- organization
- design control
- procedures and instructions
- corrective action
- records
- audits

GEH should ensure that the DRAP provides an overview of the process for implementing these essential elements.

RAI 17.4-5 In Revision 0 of DCD Section 17.4.5, GEH did not provide details of its DRAP organizational structure. This should include a discussion of the interface controls among the PRA, the DRAP, and design organizations. GEH should also consider developing an expert panel within the GEH organization with a charter that includes determining the list of SSCs in the scope of the DRAP. The members of the expert panel should be subject matter experts with experience in systems, operations, and maintenance. GEH should discuss the PRA organization within the design organization. GEH should also develop an internal procedure describing how the organization will implement the DRAP.

RAI 17.4-6 In Revision 0 of DCD Section 17.4.5, GEH did not discuss the measures that will be established to identify and control the design interfaces and to coordinate the participating design organizations. Since the ESBWR full-scope PRA is not complete and is subject to change, GEH should describe the process used to control changes in the PRA that could affect the list of SSCs in the scope of the DRAP. In addition, GEH should describe how the design control process provides a feedback mechanism for notifying the PRA organization of changes in the design of within-scope SSCs that could affect the PRA. GEH should also describe its configuration control process for maintaining the list of SSCs within the scope of the DRAP, similar to the control of a quality list.

In response to RAIs 17.4-4, 17.4-5, and 17.4-6. GEH revised DCD Section 17.4.5 to state that the ESBWR engineering organization is responsible for the design analysis and PRA engineering necessary to support the development of the DRAP. The ESBWR PRA personnel participate in the design change control process, which includes providing inputs related to the DRAP to the design process. GEH applies ESBWR engineering design procedural controls to the DRAP. Specific procedures provide guidance on the design process, control of design changes, and storage and retrieval controls. In addition, the procedure for design change control defines the process for evaluating design changes in engineering controlled documents to ensure that the total effect is considered before a change is approved and that the affected documents are identified and changed accordingly. The list of SSCs within the scope of the DRAP is maintained in accordance with NEDO-33289, Revision 2, "ESBWR Reliability Assurance Program Plan," issued September 2008. The staff finds that the changes made to DCD Tier 2, Revision 7, Section 17.4.5, adequately describe the interfaces between the various GEH organizations responsible for the DRAP. The staff concludes that DCD Tier 2, Revision 7, Section 17.4.5, meets the requirements in Item E of SECY-95-132 and SRP Section 17.4.

Therefore, the concerns associated with RAIs 17.4-4, 17.4-5, and 17.4-6 are resolved.

The NRC submitted the following additional RAIs to GEH:

RAI 17.4-7 GEH should develop an internal procedure for implementing the DRAP. The procedure should also describe interface controls among all of the organizations involved in the DRAP. The procedure should describe the process for identifying and prioritizing the list of SSCs in the scope of the DRAP.

RAI 17.4-8 GEH should describe, in detail, the corrective action process applied to within-scope SSCs.

RAI 17.4-9 GEH should describe, in detail, the controls for records of activities involving within-scope SSCs.

RAI 17.4-10 GEH should describe, in detail, the audit plans for conducting QA audits of DRAP activities.

To address staff concerns, GEH submitted NEDO-33289 and added it to DCD Section 17.4.14, "References." The staff finds that NEDO-33289 and DCD Tier 2, Revision 7, Sections 17.4.5 and 17.4.7, contain sufficient details about the interfaces among the GEH ESBWR engineering organization, the PRA organization, and the design change control process. GEH also sufficiently addressed the essential elements of the DRAP (i.e., organization, design control, procedures and instructions, corrective action, records, and audit plans) in NEDO-33289 and DCD Tier 2, Revision 7, Section 17.4. Therefore, RAIs 17.4-7 through 17.4-10 are resolved.

RAI 17.4-51 In RG 1.206, "Combined License Applications for Nuclear Power Plants," issued April 2007, Section C.III.1, Chapter 17, Subsection C.I.17.4.4 (page C.III.1-180), states that the COL applicant should describe, in the final safety analysis report, the essential elements (organization, design control, procedures and instructions, records, corrective action, and audit plans) for developing and implementing the DRAP in accordance with the provisions in SRP Section 17.4. While the essential elements for developing and implementing the DRAP that are applied by a COL applicant referencing the ESBWR DCD may be similar to those described in Section 17.4.5 of the ESBWR DCD, the COL applicant should impose its own essential elements for developing and implementing the DRAP. The staff requested that GEH add a COL information item to include the description of the essential elements for developing and implementing the DRAP that the COL applicant will apply before the initial fuel load.

In response to RAI 17.4-51, GEH stated that COL Information Item 17.4-1-A of the DCD will also require the COL applicant to provide a description of the essential elements for developing and implementing the DRAP (i.e., organization, design control, procedures and instructions, records, corrective action, and audit plans) that the applicant will apply before the initial fuel load.

The staff finds that the GEH response to RAI 17.4-51 sufficiently addresses the concerns associated with this RAI. The staff confirmed that COL Information Item 17.4-1-A of DCD Tier 2, Revision 7, was revised accordingly. Based on the above discussion, RAI 17.4-51 is resolved. The NRC verifies implementation of the essential elements of DRAP by the COL licensee through inspections and audits during detailed design and construction before initial fuel load.

Based on the preceding, the staff concludes that the information regarding the essential elements of the DRAP described in LTR NEDO-33289 and DCD Tier 2, Revision 7, Sections 17.4.5 and 17.4.7, meets the guidance in Item E of SECY-95-132 and SRP Section 17.4. Therefore, this subject review area is acceptable.

17.4.3.3 SSC Identification and Prioritization

The NRC staff reviewed the identification and prioritization of SSCs in the scope of the DRAP, which are described in DCD Section 17.4.6, "SSC Identification/Prioritization." As discussed in Item E of SECY-95-132 and SRP Section 17.4, the DC applicant should identify the SSCs in the scope of the DRAP. The staff performed this review in accordance with Item E of SECY-95-132 and the 1996 version of SRP Section 17.4 to ensure that this subject review area meets the guidance contained in these documents. The staff compared the SRP version used during its review with the 2007 version of SRP Section 17.4. For this subject review area, the 2007 version did not include any requirements, generic issues, bulletins, generic letters, or technically significant acceptance criteria beyond those identified in the version used by the staff. Therefore, the staff concludes that the 1996 version of SRP Section 17.4 is adequate for this review.

The following presents the staff's findings from the review of this subject area. In Revision 0 through Revision 4 of DCD Section 17.4.6, GEH did not provide any information concerning the list of SSCs in the scope of the DRAP. Therefore, the NRC staff issued the following RAI:

RAI 17.4-1 The staff requested that GEH provide the list of SSCs in the scope of the DRAP, including its evaluation methodology.

By letter dated October 6, 2006, GEH submitted its response to RAI 17.4-1. GEH stated that the process of developing and maintaining the list of risk-significant SSCs is described in NEDO-33289 and in a design specification report. GEH also stated that it will identify a comprehensive list of risk-significant SSCs at a later phase of DRAP development. In RAI 17.4-1, Supplement 1, the staff requested that GEH submit this design specification report and reference this document in DCD Section 17.4, so that the NRC staff can complete its review of the ESBWR DRAP. The NRC staff tracked RAI 17.4-1 as an open item in the SER with open items.

In response to RAI 17.4-1, Supplement 1, GEH stated that the list of risk-significant SSCs for the ESBWR DC application will be maintained in NEDO-33411, "Risk Significance of Structures, Systems and Components for the Design Phase of the ESBWR." GEH has submitted NEDO-33411 to the NRC.

The staff verified that Section 17.4 of DCD Tier 2, Revision 7, references NEDO-33411 and that

NEDO-33411 provides a list of risk-significant SSCs, including the methodology used to identify them. The SSCs in the scope of the DRAP include (1) all RTNSS SSCs identified in ESBWR DCD Tier 2, Revision 7, Section 19A, and (2) all risk-significant SSCs identified in NEDO-33411. Section 17.4.3.9 of this SER contains the staff's SE of NEDO-33411. Based on the above discussion, RAI 17.4-1 and the associated open item are resolved.

RAI 17.4-12 The staff determined that GEH should add the following COL information item to DCD Section 17.4.13:

> The COL applicant or holder will establish PRA importance measures, the expert panel process, and other deterministic methods to determine the site-specific list of SSCs under the scope of the DRAP.

In response to RAI 17.4-12, GEH stated that it would add a COL information item to the next revision of DCD Tier 2, Section 17.4. The staff confirmed that GEH added, in COL Information Item 17.4-2-A of DCD Tier 2, Revision 7, the following COL requirement: "Establish PRA importance measures, the expert panel process, and deterministic methods to determine the site-specific list of SSCs under the scope of the DRAP." Therefore, RAI 17.4-12 is resolved. The NRC verifies the identification of these SSCs by the COL licensee through the ITAAC process, as well as inspections and audits during detailed design and construction before initial fuel load.

RAI 17.4-50 Section 17.4.1 of the DCD, Revision 5, stated that the COL holder will establish PRA importance measures, the expert panel process, and deterministic methods to determine the site-specific list of SSCs in the scope of the DRAP. Per SECY-95-132, Item E, a COL applicant referencing the ESBWR design will need to address this same COL information item. The staff requested that GEH add a COL applicant information item to identify the site-specific SSCs in the scope of the DRAP.

In response to RAI 17.4-50, GEH stated that it would add this COL information item to the next revision of DCD Tier 2, Section 17.4. The staff confirmed that GEH added COL Information Item 17.4-1-A to DCD Tier 2, Revision 7, to identify site-specific SSCs in the scope of the DRAP. Therefore, RAI 17.4-50 is resolved. The NRC verifies the identification of these SSCs by the COL applicant through the agency's SE review process.

RAI 17.4-3 The NRC staff requested additional information in DCD Section 17.4 concerning the use of PRA importance measures (i.e., Fussell-Vesely (FV) importance greater than 1 percent and risk achievement worth (RAW) greater than 5). GEH should add PRA importance measure threshold values to DCD Section 17.4.6.

In response to RAI 17.4-3, GEH stated that Level I basic events representing component failures are identified as risk-significant if their importance values for RAW are greater than or equal to 5.0 or, for FV, greater than or equal to 0.01.

The NRC staff finds that this change to DCD Tier 2, Revision 7, Section 17.4.6, resolves the concern in RAI 17.4-3. Section 17.4.3.9 of this SER contains the staff's SE of NEDO-33411,

which provides the detailed methodology used to evaluate, identify, and prioritize the list of risk-significant SSCs.

Based on the discussion in this section, the staff concludes that DCD Tier 2, Revision 7, Section 17.4.6, adequately describes the identification and prioritization of risk-significant SSCs in the scope of the DRAP and references NEDO-33411, which provides the list of risk-significant SSCs and describes the methodology for evaluating and identifying them. Therefore, DCD Section 17.4.6 is acceptable. Section 17.4.3.9 of this SER contains the staff's SE of NEDO-33411.

17.4.3.4 Design Considerations

The NRC staff reviewed DCD Section 17.4.7, "Design Considerations," which describes the evaluation of the reliability of within-scope SSCs that will be performed at the detailed design stage by appropriate design reviews and reliability analyses. The staff performed this review in accordance with Item E of SECY-95-132 to ensure that this subject review area meets that guidance. Based on its review, the staff identified the following area where it needed additional information to complete its review:

RAI 17.4-55 All within-scope SSCs should be subject to the QA controls that are described in the QAP description submitted by the applicants for a DC or COL, in accordance with the provisions in the 2007 version of SRP Section 17.5. For example, the non-safety-related within-scope SSCs should be subject to QA controls, in accordance with the provisions of Section V, "Non-Safety-Related SSC Quality Controls," in SRP Section 17.5. However, it was not clear from DCD Section 17.4, that the within-scope SSCs are subject to these QA controls. The staff requested that GEH clarify, in DCD Section 17.4, that all within-scope SSCs are subject to these QA controls.

In response to RAI 17.4-55, GEH referred to DCD Section 17.1.22, "Non-Safety-Related SSC Quality Controls," which states that non-safety-related SSCs that perform safety-significant functions have QA requirements commensurate with the importance of the item's function and that Table 3.2-1 of the ESBWR DCD identifies these SSCs. Notes 5(h) and 5(i) in Table 3.2-1 explain the basis for items designated as Quality Class S for non-safety-related RTNSS functions. However, Table 3.2-1 does not consider non-safety-related SSCs that are risk-significant but not designated as RTNSS. Therefore, to address the staff's request, GEH will revise ESBWR DCD Table 3.2-1 to clarify that the non-safety-related SSCs that are risk-significant but not designated as RTNSS are assigned Quality Class S.

The staff finds that the GEH response to RAI 17.4-55 sufficiently addresses the concerns associated with this RAI. All within-scope SSCs are subject to the appropriate QA activities, in accordance with the provisions in Section 17.5 of the SRP. The staff confirmed that Table 3.2-1 of DCD Tier 2, Revision 7, was revised accordingly (also refer to the Section 3.2, "Classification of Structures, Systems, and Components," of this SER). Based on the above discussion, RAI 17.4-55 is resolved.

The staff finds that GEH adequately discussed design considerations in DCD Tier 2, Revision 7, Section 17.4.7. The staff finds that the design considerations included in DCD Tier 2,

Revision 7, Section 17.4.7, meet the guidance in Item E of SECY-95-132 and, therefore, are acceptable.

17.4.3.5 Determining Dominant Failure Modes

The NRC staff reviewed the process for determining the dominant failure modes of within-scope SSCs, which is described in DCD Section 17.4.8, "Defining Failure Modes," in accordance with Item E of SECY-95-132 and the 1996 version of SRP Section 17.4, to ensure that this subject review area meets the guidance contained in these documents. The staff compared the SRP version used during its review with the 2007 version of SRP Section 17.4. For this subject review area, the 2007 version did not include any requirements, generic issues, bulletins, generic letters, or technically significant acceptance criteria beyond those identified in the version used by the staff. Therefore, the staff concludes that the 1996 version of SRP Section 17.4 is adequate for this review.

As discussed in Item E of SECY-95-132 and SRP Section 17.4, the application should describe an acceptable process to determine dominant failure modes that considers industry experience, analytical models, and applicable requirements.

The following provides the staff's findings from the review of this subject area. The determination of dominant failure modes of within-scope SSCs includes the evaluation of historical information, analytical models, and existing requirements. A significant historical record exists for many boiling-water reactor (BWR) systems and components, and that record can be evaluated. An analytical approach is necessary for those SSCs that do not have an adequate historical basis to identify critical failure modes. Inputs may include a PRA importance analysis, a root-cause analysis, an analysis of failure modes and effects, and a review of operating experience. In addition, equipment performance information, including vendor manuals, American Society of Mechanical Engineers Section XI technical specifications (TSs), RTNSS, and other regulatory requirements are reviewed to identify important safety functions. Based on its review, the staff identified the following areas where it needed additional information to complete its review of the process for determining dominant failure modes:

RAI 17.4-11 In Revision 0 to DCD Section 17.4.8, GEH stated, "Many boiling-water reactor (BWR) systems and components have compiled a significant historical record, so an evaluation of that record is performed." The staff found that GEH had not used an evaluation of the historical records for BWR systems and components to develop the DRAP. GEH should clarify the source of information used to define dominant failure modes, as described in DCD Section 17.4.8.

RAI 17.4-48 Revision 5 to DCD Section 17.4.8 described a process for defining dominant failure modes of within-scope SSCs. However, it was not clear whether the COL applicant or the COL holder was responsible for determining the dominant failure modes of these SSCs. The staff requested that GEH clarify, in DCD Section 17.4, whether the COL applicant or the COL holder is responsible for determining the dominant failure modes of these SSCs and include this as a COL information item in DCD Section 17.4.13.

In response to RAI 17.4-11, GEH stated that it had not evaluated the historical records for BWR

systems and components but these records would be evaluated in the COL application phase of the DRAP, in accordance with NEDO-33289. The staff confirmed that GEH added the following requirement as COL Information Item 17.4-2-A to DCD Tier 2, Revision 7, Section 17.4.1:

> Establish a reliability database using historical data on equipment performance as available. The compilation and reduction of this data provides the plant with a source of component reliability information. Data used in PRA fault-tree analyses may also be a viable initial source.

In response to RAI 17.4-48, GEH stated, in DCD Section 17.4.1, that the dominant failure modes of within-scope SSCs are addressed by the COL licensee. The staff confirmed that GEH added COL Information Item 17.4-2-A to DCD Tier 2, Revision 7, to state the COL requirement for determining the dominant failure modes of within-scope SSCs.

The staff finds that the GEH response to RAIs 17.4-11 and 17.4-48 sufficiently addresses the concerns associated with these RAIs. Based on the above discussion, RAIs 17.4-11 and 17.4-48 are resolved.

Based on the discussion in this section, the staff concludes that the process for determining dominant failure modes of within-scope SSCs is adequate and meets the guidance in Item E of SECY-95-132 and SRP Section 17.4. Therefore, this subject review area is acceptable.

17.4.3.6 DRAP Implementation

The NRC staff reviewed DCD Section 17.4.11, "DRAP Implementation - Example Case." In this section, GEH provided an example of the implementation of the DRAP using the isolation condenser system (ICS) in Section 17.3.11 of the SBWR SAR. GEH used this example to guide early design work in the ESBWR. The staff performed its review in accordance with Item E of SECY-95-132 and the 1996 version of SRP Section 17.4 to ensure that this subject review area meets the guidance contained in these documents. The staff compared the SRP version used during its review with the 2007 version of SRP Section 17.4. For this subject review area, the 2007 version did not include any requirements, generic issues, bulletins, generic letters, or technically significant acceptance criteria beyond those identified in the version used by the staff. Therefore, the staff concludes that the 1996 version of SRP Section 17.4 is adequate for this review.

The following presents the staff's findings from the review of this subject area. The staff requested the following additional information to complete its review:

RAI 17.4-2 In Revision 0 to DCD Section 17.4.1, GEH stated, in part, that "included in this explanation of the DRAP is a descriptive example of how the DRAP applies to one potentially important system, the Isolation Condenser System (ICS). The ICS example shows how the principles of DRAP will be applied to the other systems identified by the PRA as being significant with respect to risk."

The staff notes that GEH had incorporated references to design reliability improvements to the ICS in the SBWR SAR, Section 17.3.11. However, GEH withdrew the SBWR application in 1995 and did not include this information from

the SBWR application in the ESBWR DC application. If GEH used the DRAP to improve the reliability of an ESBWR system, then GEH should provide an example in DCD Section 17.4.11.

In response to RAI 17.4-2, GEH described the ICS and the major differences between the ESBWR ICS and the conventional BWR ICS and supplied information about design reliability improvements to the ICS in DCD Section 17.4.11. GEH also included risk information and identified failure modes and maintenance requirements for the ICS. The staff reviewed the revised information in DCD Tier 2, Revision 7, Section 17.4.11, and concluded that this information resolved the concern in RAI 17.4-2.

The staff concludes that the case example provided for DRAP implementation in DCD Tier 2, Revision 7, Section 17.4.11, is sufficient to meet the guidance in SECY-95-132 and SRP Section 17.4 and, therefore, is acceptable.

17.4.3.7 Implementation of the Reliability Assurance Process during the Operations Phase

The NRC staff reviewed the GEH proposed implementation of the reliability assurance process during the operations phase, which is described in DCD Section 17.4.9, "Operational Reliability Assurance Activities," and Section 17.4.10, "Owner/Operator's Reliability Assurance Program," in accordance with Item E of SECY-95-132 and the 1996 version of SRP Section 17.4, to ensure that this subject review area meets the guidance contained in these documents. The staff compared the SRP version used during its review with the 2007 version of SRP Section 17.4. For this subject review area, the 2007 version did not include any requirements, generic issues, bulletins, generic letters, or technically significant acceptance criteria beyond those identified in the version used by the staff. Therefore, the staff concludes that the 1996 version of SRP Section 17.4 is adequate for this review.

As discussed in Item E of SECY-95-132 and SRP Section 17.4, the NRC expects licensees to implement the RAP during the operations phase by integrating into operational programs the reliability assurance activities for within-scope SSCs. With the exception of reliability assurance related to the design and operation of non-safety-related within-scope SSCs, the objective of the RAP during the operations phase can be accomplished within (1) the QAP that meets the requirements of 10 CFR Part 50, "Domestic Licensing of Production and Utilization Facilities," Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," (2) the maintenance rule program that meets the requirements of 10 CFR 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," and (3) the underlying maintenance and surveillance programs. Implementation of the maintenance rule following the guidance contained in RG 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," Revision 2, issued March 1997, is one acceptable method for crediting the maintenance rule program in the implementation of the RAP during the operations phase, provided that these SSCs are categorized as having high safety significance (HSS).

The following presents the staff's findings from the review of this subject area. The staff identified the following areas where it needed additional information to complete its review of this subject:

RAI 17.4-13 Per the discussion of RAP during the operations phase in SECY-95-132 and SRP Section 17.4, GEH should state in DCD Section 17.4.9 whether, and if so, how, the RAP process will be implemented through existing operational programs, including the maintenance and surveillance program(s), the QAP, and the maintenance rule program.

In response to RAI 17.4-13, GEH stated that it would revise DCD Tier 2, Section 17.4.9, to state that the operational reliability assurance activities are the responsibility of the COL licensee and will be implemented through the COL licensee's maintenance and surveillance programs, the QAP, and the maintenance rule program. In accordance with COL Information Item 17.4-2-A, the COL licensee will implement these operational reliability assurance activities that meet the objectives of the RAP during the operations phase. The GEH response to RAI 17.4-13 is sufficient to meet the guidance in SECY-95-132 and SRP Section 17.4 and, therefore, is acceptable. The staff confirmed that DCD Tier 2, Revision 7, Section 17.4.9, was revised accordingly. Therefore, RAI 17.4-13 is resolved.

RAI 17.4-14 GEH should include reliability data from test results collected from TS surveillance tests and other relevant testing and from industry operating experience for both safety-related and RTNSS SSCs, as available. This information can also be obtained from reliability estimates in the ESBWR PRA. GEH should add a reference to these sources for reliability estimates and monitoring information to DCD Section 17.4.9.

In response to RAI 17.4-14, GEH stated that it would revise DCD Tier 2, Section 17.4-9, to identify the use of TS surveillance test data and industry operating data for safety-related equipment, when available, as sources for reliability estimates and monitoring information. The GEH response to RAI 17.4-14 was incomplete, however, in that it did not address RTNSS SSCs and the ESBWR PRA as a source of reliability information, as stated in RAI 17.4-14. Upon reviewing DCD Tier 2, Revision 7, Section 17.4.9, the staff confirmed that GEH added RTNSS SSCs and the reference to ESBWR PRA information and that Section 17.4.9 is otherwise satisfactory. These clarifications resolved RAI 17.4-14.

RAI 17.4-16: The staff determined that the following COL information items related to operational reliability assurance activities should be added to DCD Section 17.4.13 to meet the guidance in SECY-95-132 and SRP Section 17.4:

- The COL applicant is responsible for integrating the objectives of operational reliability assurance activities into the QAP developed to implement 10 CFR Part 50, Appendix B. This program should also address failures of non-safety-related within-scope SSCs that result from design and operational errors, in accordance with SECY-95-132, Item E.

- The COL applicant is responsible for performing the tasks necessary to maintain the reliability of within-scope SSCs. The applicant may cite, for example, cost-effective maintenance enhancements, such as condition monitoring and using condition-directed maintenance, as well as time-directed or planned periodic maintenance.

- The COL applicant's maintenance rule (10 CFR 50.65) program is required to monitor the effectiveness of the COL applicant's maintenance activities needed for operational reliability assurance. As such, it is an important element of the RAP during the operations phase. If the COL applicant proposes to use its maintenance rule program to implement the RAP during the operations phase, the SSCs in the scope of the maintenance rule program that are classified as HSS should encompass all within-scope SSCs.

- In addition to the specific tasks necessary to maintain SSC reliability, the operational reliability assurance activities should include the following:

  – A reliability database contains historical data on equipment performance, as available. The compilation and reduction of these data provide the plant with a source of component reliability information. Data used in PRA fault-tree analyses may also be a viable initial source.

  – Surveillance and testing establish the level of performance or condition being maintained for within-scope SSCs and identify, to the extent possible, declining trends between surveillances, before performance or conditions degrade to unacceptable levels without being detected (or before they fail).

  – The maintenance plan describes the nature and frequency of maintenance activities to be performed on plant equipment. The plan includes the selected SSCs identified in the DRAP.

Based on its response to RAI 17.4-16 and the associated supplemental RAIs, GEH added the following COL requirements to COL Information Item 17.4-2-A in DCD Tier 2, Revision 7, Section 17.4.13:

- Integrate the objectives of operational reliability assurance activities into the QAP, including addressing failures of non-safety-related risk-significant SSCs in the scope of the DRAP that result from design and operational errors, in accordance with SECY-95-132, Item E.

- Evaluate and maintain the reliability of SSCs as identified in the DRAP. This includes determining the dominant failure modes of SSCs. The program may cite, for example, reliability analysis, cost-effective maintenance enhancements, such as condition monitoring and using condition-directed maintenance, as well as time-directed or planned periodic maintenance.

- Use the maintenance rule (10 CFR 50.65) program to monitor the effectiveness of maintenance activities needed for operational reliability assurance.

- Consider all SSCs that are in the scope of the DRAP as HSS within the scope of the maintenance rule program or provide an expert panel justification for any exceptions.

  Note: The expert panel, in accordance with common industry practice and guidance in NUMARC 93-01, develops the final list of risk-significant SSCs from various inputs, including the PRA risk importance calculations and industry operating experience. It is necessary for the expert panel to include all SSCs that are in the scope of the DRAP in the HSS category of SSCs within the scope of the maintenance rule. However, risk-importance calculations, plant specifics, and other factors may change the risk significance of certain SSCs in the operational RAP that were previously determined to be risk-significant within the bounds of the DRAP. Therefore, differences may exist between the DRAP and operational RAP risk significance that the expert panel should evaluate and justify.

- Establish a reliability database using historical data on equipment performance, as available. The compilation and reduction of these data provide the plant with a source of component reliability information. Data used in PRA fault-tree analyses may also be a viable initial source.

- Use surveillance and testing to establish the level of performance or condition being maintained for SSCs in the scope of the RAP and identify, to the extent possible, declining trends between surveillances before performance or conditions degrade to unacceptable levels without being detected (or before they fail).

- Develop a maintenance plan to describe the nature and frequency of maintenance activities to be performed on plant equipment. The plan includes the selected SSCs identified in the DRAP.

Based on discussions during the ESBWR Design-Centered Working Group meeting held on April 1, 2009, the COL requirements described above should be COL applicant information items; the COL applicant will provide a description of these operational reliability assurance activities. These activities are implemented under operational programs that have their own milestones, specified in Section 13.4, “Operational Program Implementation,” of ESBWR DCD Tier 2, Revision 7, and some are implemented after fuel load (e.g., inservice testing). Therefore, the staff agrees that COL Information Item 17.4-2-A should be a COL applicant information item in which the COL applicant will describe the operational reliability assurance activities that are consistent with the above requirements. The staff confirmed that GEH had revised Section 17.4.13 and the associated Section 17.4.1 of DCD Tier 2, Revision 7, to incorporate these COL information items. Therefore, RAI 17.4-16 is resolved.

Based on the discussion in this section, the staff concludes that the proposed implementation of the reliability assurance process during the operations phase, which is described in Sections 17.4.9 and 17.4.10 of DCD Tier 2, Revision 7, is adequate and meets the guidance in Item E of SECY-95-132 and SRP Section 17.4. Therefore, this subject review area is acceptable.

17.4.3.8 COL Information Items

The NRC staff reviewed the COL information items, which appear in DCD Section 17.4.13 and the associated Section 17.4.1, in accordance with Item E of SECY-95-132 and the 1996 version of SRP Section 17.4, to ensure that this subject review area meets the guidance contained in these documents. The staff compared the SRP version used during its review with the 2007 version of SRP Section 17.4. For this subject review area, the 2007 version did not include any requirements, generic issues, bulletins, generic letters, or technically significant acceptance criteria beyond those identified in the version used by the staff. Therefore, the staff concludes that the 1996 version of SRP Section 17.4 is adequate for this review.

In Revision 2 of DCD Section 17.4.13, GEH listed only one COL information item related to the RAP during the operations phase. As discussed in the previous sections of this SER, the NRC staff found that the following additional COL information items are needed to meet the guidance in Item E of SECY-95-132 and SRP Section 17.4. The COL information items for DCD Tier 2, Revision 7, Section 17.4.13, and the associated Section 17.4.1 are as follows:

- **COL Information Item 17.4-1-A**

  The COL applicant will identify the site-specific SSCs within the scope of the RAP and describe the quality elements for developing and implementing the DRAP (that is, organization, design control, procedures and instructions, records, corrective action, and audit plans) that will be applied before the initial fuel load.

- **COL Information Item 17.4-2-A**

  The COL applicant will provide a description of operational reliability assurance activities. These activities are consistent with the following requirements:

  – Integrate the objectives of operational reliability assurance activities into the QA program, including addressing failures of non-safety-related, risk-significant SSCs that result from design and operational errors in accordance with SECY-95-132, Item E.

  – Establish PRA importance measures, the expert panel process, and deterministic methods to determine the site-specific list of SSCs within the scope of the DRAP.

  – Evaluate and maintain the reliability of SSCs as identified in the DRAP. This includes determining the dominant failure modes of SSCs. The program may cite, for example, reliability analysis, cost-effective maintenance enhancements, such as condition monitoring and using condition-directed maintenance, as well as time-directed or planned periodic maintenance.

  – Use the maintenance rule (10 CFR 50.65) program to monitor the effectiveness of maintenance activities needed for operational reliability assurance.

  – Consider all SSCs that are in the scope of the DRAP as HSS within the scope of

the maintenance rule program, or provide expert panel justification for any exceptions.

Note: The expert panel, in accordance with common industry practice and guidance in NUMARC 93-01, develops the final list of risk-significant SSCs from various inputs, including the PRA risk importance calculations and industry operating experience. The expert panel must include all SSCs that are in the scope of the RAP in the HSS category of SSCs within the scope of the maintenance rule. However, risk importance calculations, plant specifics, and other factors may change the risk significance of certain SSCs in the operational RAP that were previously determined to be risk-significant within the bounds of the DRAP. Therefore, differences may exist between the DRAP and operational RAP risk significance that the expert panel should evaluate and justify.

– Establish a reliability database using historical data on equipment performance as available. The compilation and reduction of these data provide the plant with a source of component reliability information. Data used in PRA fault-tree analyses may also be a viable initial source.

– Use surveillance and testing to establish the level of performance or condition being maintained for SSCs in the scope of the RAP and identify, to the extent possible, declining trends between surveillances before performance or conditions degrade to unacceptable levels without being detected (or before they fail).

– Develop a maintenance plan to describe the nature and frequency of maintenance activities to be performed on plant equipment. The plan includes the selected SSCs identified in the DRAP.

As discussed in the previous sections of this SER, the staff's review of Section 17.4.13 and the associated Section 17.4.1 of DCD Tier 2, Revision 7, confirmed that these sections include all necessary COL information items and meet the guidance in Item E of SECY-95-132 and SRP Section 17.4. Therefore, this subject review area is acceptable.

17.4.3.9 Risk Significance of SSCs for the Design Phase of the ESBWR, NEDO-33411

The NRC staff reviewed NEDO-33411, in accordance with Item E of SECY-95-132 and SRP Section 17.4, to ensure that the identification and prioritization of risk-significant SSCs meet the guidance contained in these documents. The objective of NEDO-33411 is to identify the SSCs that are considered risk-significant in the design phase of the ESBWR. NEDO-33411 contains the scope of the assessment, the risk-significance methodology, the expert panel review, and the list of risk-significant SSCs.

17.4.3.9.1 Scope

The NRC staff reviewed, in accordance with Item E of SECY-95-132 and SRP Section 17.4, the scope of the assessment provided in NEDO-33411, which is described in Section 1.0, "Introduction," of NEDO-33411. As discussed in Item E of SECY-95-132 and the 2007 version

of SRP Section 17.4, the scope of the assessment should use a combination of probabilistic, deterministic, or other methods of analysis for evaluating, identifying, and prioritizing SSCs according to their degree of risk significance.

The following provides the staff's findings from the review of this subject area. The scope of the assessment described in NEDO-33411 includes the use of probabilistic and deterministic analyses to identify the risk-significant SSCs. These analyses include the use of at-power and shutdown PRAs for internal and external events resulting in core damage and large radiological releases, seismic risk based on the seismic margins analysis (SMA), RTNSS Criteria C and D, risk insights and assumptions, operating experience from currently operating reactors, and expert panels.

Based on the discussion in this section, the staff concludes that the scope of the assessment described in Section 1.0 of NEDO-33411 is adequate and meets the guidance in Item E of SECY-95-132 and SRP Section 17.4. Therefore, this subject review area is acceptable.

17.4.3.9.2 Risk-Significance Methodology

The NRC staff reviewed, in accordance with Item E of SECY-95-132 and SRP Section 17.4, the detailed methodology used to evaluate, identify, and prioritize the list of risk-significant SSCs, which is given in Section 2.0, "Risk Significance Methodology," of NEDO-33411. As discussed in Item E of SECY-95-132 and the 2007 version of SRP Section 17.4, the application should describe an acceptable methodology for evaluating, identifying, and prioritizing SSCs according to their degree of risk significance, using a combination of probabilistic, deterministic, or other methods of analysis. The staff expects the methodology to include the use of information obtained from the following sources:

- risk evaluations that cover the full spectrum of potential events and the range of plant operating modes considered in ESBWR DCD Tier 2, Chapter 19.0, "Probabilistic Risk Assessment and Severe Accidents," which includes the use of non-PRA evaluations (e.g., SMA) when PRAs have not been performed

- industry operating experience and relevant component failure databases

- expert panels

The roles and responsibilities of expert panels should be described, since they play an important part in reviewing the information associated with risk-significance determinations and could compensate for the limitations of the PRA.

The staff's findings from the review of this subject area are described below. Based on its review, the staff identified the following areas where it needed additional information to complete its review:

RAI 17.4-19 Section 2.1, "Risk Significant Thresholds," of NEDO-33411, Revision 0, provided the common-cause failure (CCF) threshold criteria (i.e., common-cause basic events having an RAW greater than or equal to 50 are considered potentially

risk-significant). The RAW for a common-cause event generally reflects the relative increase in core damage frequency (CDF) or large release frequency (LRF) that would exist if a set of components or an entire system were made unavailable. The staff requested that GEH provide the basis for the common-cause threshold criteria.

In response to RAI 17.4-19, GEH provided the basis for the risk-significance threshold criteria of CCFs. The basis includes the following:

- The guidance presented in the 2005 report NEI 00-04, Revision 0, "10 CFR 50.69 SSC Categorization Guideline," uses a RAW significance threshold for CCF events (i.e., RAW greater than or equal to 20) that is a factor of 10 greater than the threshold for single-failure events (i.e., RAW greater than or equal to 2). For consistency, the CCF threshold for the ESBWR (i.e., RAW greater than or equal to 50) is also a factor of 10 greater than the ESBWR single-failure threshold (i.e., RAW greater than or equal to 5). RG 1.201, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance," Revision 1, issued May 2006, endorses NEI 00-04, with appropriate clarifications and exceptions.

- The current guidance in NEI 00-04 suggests that risk-significant CCF events have a RAW value of greater than or equal to 20. This value is used for current operating plants, which have CDF values of approximately $1x10^{-6}$/year (yr) and higher. For a CDF of $1x10^{-5}$/yr, a RAW of 20 corresponds to a CDF of $2x10^{-4}$/yr, if the CCF event is true. This corresponds to a CDF increase of $1.9x10^{-4}$/yr. A risk-significant increase in CDF is typically accepted as $1.0x10^{-6}$/yr for operating plants. A RAW value of 50 for the ESBWR correlates to a CDF increase of approximately $6x10^{-7}$/yr, much less than the increase for an operating plant with a RAW value of 20.

The staff finds that the GEH response to RAI 17.4-19 is adequate. In determining the risk significance of SSCs, the common industry practice for operating reactors is to apply recommended thresholds (i.e., FV greater than or equal to 0.005 at the component level and RAW greater than or equal to 2.0) for plants with CDF values in the range of $1x10^{-4}$/yr to $1x10^{-6}$/yr. However, this practice may not necessarily apply to new reactors that have significantly lower CDF and LRF values (e.g., $1x10^{-8}$/yr for the ESBWR). Also, as stated in Appendix A to RG 1.174, "An Approach for Using Probabilistic Risk Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," Revision 1, issued November 2002, the thresholds for defining risk significance should be a function of the baseline CDF and LRF, rather than being fixed for all plants. The following risk-significance thresholds, described in Section 17.1.2 of NEDO-33201, "ESBWR Certification Probabilistic Risk Assessment," Revision 5, issued February 2010, are applied for the ESBWR and were reviewed by the staff under Chapter 19 of the ESBWR DCD:

- FV greater than or equal to 0.01
- RAW greater than or equal to 5.0 for individual events
- RAW greater than or equal to 50 for CCFs

In addition, FV values for basic events representing the various failure modes of the same

component are summed and then compared to the threshold. Basic events that do not meet the threshold values are considered potentially not risk-significant (NRS), and the expert panel reviews the results to complete the risk-significance determination. The threshold values used for individual events (i.e., FV greater than or equal to 0.01 and RAW greater than or equal to 5.0) are consistent with those values used in the certified "ABWR Standard Safety Analysis Report," Chapter 19, Appendix 19K, issued August 1996. The use of a threshold criterion for CCF events is an appropriate strategy in prioritizing SSCs according to risk significance, based on NEI 00-04, which provides guidelines for categorizing SSCs according to their risk significance for current operating plants in support of 10 CFR 50.69, "Risk-Informed Categorization and Treatment of Structures, Systems and Components for Nuclear Power Reactors," and which RG 1.201 endorses, with appropriate clarifications and exceptions. Based on the preceding discussion, the staff finds that the GEH use of risk-significance threshold criteria is adequate. Therefore, RAI 17.4-19 is resolved.

RAI 17.4-25 Section 2.1.2 of NEDO-33411, Revision 0, stated the following:

> For example, a system that has an undeveloped basic event above the risk thresholds is evaluated in a sensitivity study by quantifying the effect of deleting that system entirely. If the revised CDF is less than 1.0×10^{-6}/yr and if the revised results do not introduce any new systems above the risk thresholds, then the system is considered NRS. Undeveloped events representing functions that are safety-related or RTNSS are retained and evaluated with respect to other basic events representing those functions.

An undeveloped event represents a higher level event that is not broken down into lower basic events, because further resolution of that event is not necessary for proper evaluation, or the information necessary for developing this event is not currently available. For example, an undeveloped event may represent multiple failure modes of a single component, a single train of components, multiple components in parallel, and so on. The staff's understanding of the criterion described in GEH's statement quoted above is that undeveloped events not representing functions that are safety-related or RTNSS are subject to the 1.0×10^{-6}/yr criteria, and undeveloped events representing functions that are safety-related or RTNSS are evaluated with respect to other basic events representing those functions. Though the 1.0×10^{-6}/yr criteria may be appropriate for some undeveloped events (e.g., an undeveloped event representing failure of several systems), it is not appropriate in the general sense. The staff requested that GEH justify or revise the 1.0×10^{-6}/yr criterion used for evaluating risk significance of undeveloped events to a more appropriate criterion.

In response to RAI 17.4-25, GEH stated that it would update the methodology in Section 2.1.2 to specify that undeveloped events are evaluated on a case-by-case basis. Initially, the undeveloped events will be treated as single component failures and will be subject to the most limiting FV and RAW significance thresholds described in Section 2.1 of NEDO-33411; this process ensures that all potentially risk-significant undeveloped events are identified. Once identified, the undeveloped events can be either included as risk-significant or dismissed as

NRS, with appropriate justification. For example, one reason for dismissing an undeveloped event could be a RAW less than 50 for a system that requires multiple component failures to fail its function.

The staff finds that the GEH response to RAI 17.4-25 sufficiently addresses the concerns associated with this RAI. The process for evaluating undeveloped events for risk significance is appropriate and would capture all potentially risk-significant undeveloped events. The staff confirmed that NEDO-33411 was revised accordingly. Based on the above discussion, RAI 17.4-25 is resolved.

RAIs 17.4-20, 30, and 31 — These RAIs addressed the GEH use of SMA to identify risk-significant SSCs. From NEDO-33411, Revision 0, it was not clear whether the scope of the DRAP included SSCs that were determined to be NRS based on PRA results, but risk-significant based on SMA results. The staff requested that GEH clarify this issue.

In response to RAIs 17.4-20, 17.4-30, and 17.4-31, GEH stated that SSCs that are identified as NRS based on PRA results, but are risk-significant based on SMA, are not in the scope of the DRAP because their assumed PRA reliabilities are not what causes them to be risk-significant.

The staff found that the GEH response to RAIs 17.4-20, 17.4-30, and 17.4-31 did not address the concerns associated with these RAIs. The risk-significant SSCs identified by SMA are credited as part of the safe-shutdown paths evaluated under SMA. In addition to being capable of withstanding seismic events, these SSCs need to have high reliability and availability to perform their safe-shutdown functions. Therefore, these SSCs should be in the scope of the DRAP. The SMA is another tool used to identify risk-significant SSCs for the DRAP, in accordance with SECY-95-132. In Supplement 1 to RAIs 17.4-20, 17.4-30, and 17.4-31, the staff requested that GEH include in the DRAP the SSCs identified as risk-significant under SMA or provide a more appropriate basis for not including these SSCs.

In response to Supplement 1 to the RAIs 17.4-20, 17.4-30, and 17.4-31, GEH stated that SSCs identified as risk-significant under SMA will be included in the scope of the DRAP.

The staff finds that the GEH response to Supplement 1 to RAIs 17.4-20, 17.4-30, and 17.4-31 sufficiently addresses the concerns associated with these RAIs. The staff confirmed that GEH clarified NEDO-33411 to state that the scope of the DRAP includes the risk-significant SSCs identified by SMA. Based on the above discussion, RAIs 17.4-20, 17.4-30, and 17.4-31 are resolved.

The detailed methodology that GEH used to evaluate, identify, and prioritize the list of risk-significant SSCs includes the use of the following:

- quantitative results from the PRA models described in Chapter 19 of DCD Tier 2
- focused PRA analyses to identify RTNSS SSCs (i.e., RTNSS Criteria C and D)

- insights from the SMA
- risk insights and assumptions from the PRA and severe accident evaluations
- industry operating experience to identify SSCs not modeled explicitly in the PRA that could contribute significantly to either initiating a core damage event or causing an adverse operator interaction at an ESBWR
- expert panel to review the information associated with risk-significance determinations

Based on the discussion in this section, the staff concludes that the detailed methodology that GEH used to evaluate, identify, and prioritize the list of risk-significant SSCs described in Section 2.0 of NEDO-33411 is adequate and meets the guidance in Item E of SECY-95-132 and SRP Section 17.4. Therefore, this subject review area is acceptable.

17.4.3.9.3 Risk-Significant SSCs in the Scope of the DRAP

The NRC staff reviewed, in accordance with Item E of SECY-95-132 and the 2007 version of SRP Section 17.4, the list of risk-significant SSCs, which GEH developed under NEDO-33411, Sections 2.0 and 3.0, "Expert Panel Review." As discussed in Item E of SECY-95-132 and SRP Section 17.4, the application should contain a complete list of risk-significant SSCs based on an acceptable methodology that uses a combination of probabilistic, deterministic, or other methods of analysis.

The following provides the staff's findings from the review of this subject area. The SSCs in the scope of the ESBWR DRAP include: (1) all RTNSS SSCs identified under ESBWR DCD Tier 2, Revision 7, Section 19A, and (2) all risk-significant SSCs identified under NEDO-33411. The staff confirmed that GEH identified the risk-significant SSCs in accordance with the risk-significance methodology presented in Section 2.0 of NEDO-33411. Based on its review, the staff identified areas where it needed additional information to complete its review of the list of risk-significant SSCs.

In the following RAIs, the staff identified additional SSCs that are considered potentially risk-significant, based on specific PRA results and risk insights, and should be evaluated for inclusion in Table 6 of NEDO-33411. The following RAIs identify these additional SSCs:

- 17.4-30 and Supplement 1 (SSCs associated with the standby liquid control system)
- 17.4-31 and Supplement 1 (SSCs associated with the ICS)
- 17.4-32, 33, 34 (SSCs associated with the uninterruptible alternating current (ac) power supply system)
- 17.4-38, 39 (SSCs associated with the gravity-driven cooling system)
- 17.4-44 and Supplement 1 (main control room and remote shutdown panel)

- 17.4-45 (SSCs associated with the ICS)

- 17.4-52 (SSCs associated with low-voltage distribution and uninterruptible ac power supply)

In response to these RAIs, GEH reevaluated the risk significance of these additional SSCs, considering the requantified PRA results associated with Revision 5 of NEDO-33201. The staff confirmed these evaluations and verified the risk significance of the additional SSCs identified in the RAIs listed above. The staff confirmed that GEH had included the additional SSCs determined to be risk-significant in Table 6 of NEDO-33411, Revision 2. Based on the above discussion, the RAIs listed above are resolved.

The staff requested that GEH provide the bases for considering some SSCs as NRS. The following RAIs identify these SSCs:

- 17.4-26 (SSCs associated with the balance of plant chilled water system)

- 17.4-26 (SSCs associated with the condensate and feedwater system)

- 17.4-29 (SSCs associated with the instrument air system)

- 17.4-46 and Supplement 1 (SSCs associated with the standby liquid control system electrical heaters)

- 17.4-54 (SSCs associated with the control rod drive system and condensate and feedwater system)

In response to these RAIs, GEH provided the bases for considering these SSCs as NRS. The staff finds that the GEH response sufficiently addressed the concerns associated with these RAIs. Also, the staff confirmed that these SSCs are NRS under the requantified PRA results associated with Revision 5 of NEDO-33201. Based on the above discussion, the RAIs listed above are resolved.

The staff requested in RAI 17.4-36, and in Supplement 1 of this RAI, that GEH more clearly identify the risk-significant SSCs in Table 6 of NEDO-33411 through the use of text descriptions and specific SSC identification numbers, when applicable. Clearly identifying the risk-significant SSCs is important to ensure that the list of risk-significant SSCs is effectively communicated to the organizations that implement the DRAP (e.g., the COL applicants, design engineers, QA staff) in accordance with the essential elements (i.e., organization, design control, procedures and instructions, records, corrective action, and audit plans) discussed in Section 17.4.5 of the DCD. In response to RAI 17.4-36, Supplement 1, GEH more clearly described the risk-significant SSCs using text descriptions, which the staff determined to be acceptable (note, the risk-significant SSCs are not identified through specific component identification numbers because component identification numbers have not been assigned to these SSCs within the DCD). The staff confirmed that the clarified text descriptions were incorporated into Revision 2 of NEDO-33411; therefore, RAI 17.4-36 is resolved

Based on the discussion in this section, the staff confirmed that GEH identified the risk-significant SSCs in accordance with the risk-significance methodology presented in Section 2.0 of NEDO-33411. The staff concludes that the evaluation and identification of risk-significant SSCs described in Sections 2.0 and 3.0 of NEDO-33411 are adequate and meet the guidance in Item E of SECY-95-132 and SRP Section 17.4. Therefore, this subject review area is acceptable.

In conclusion, based on the discussion in this section, the staff finds that LTR NEDO-33411 adequately identifies the risk-significant SSCs in the scope of the DRAP and describes the evaluation methodology used to determine these risk-significant SSCs. LTR NEDO-33411 meets the guidance in Item E of SECY-95-132 and SRP Section 17.4. Therefore, LTR NEDO-33411 is acceptable.

17.4.4 Conclusions

The NRC staff reviewed Section 17.4 of ESBWR DCD Tier 2, Revision 7, including the referenced LTR NEDO-33289 and LTR NEDO-33411, Revision 2. The review confirmed that GEH has addressed the required information relating to the RAP. In addition, the staff concludes that the ESBWR RAP is acceptable and meets the guidance in Item E of SECY-95-132 and SRP Section 17.4.

References

American National Standards Institute (AISC)

— — — — —, ANSI N45.2, "Quality Assurance Program Requirements for Nuclear Facilities," 1977.

American Society of Mechanical Engineers (ASME)

— — — — —, ASME "Rules for Inservice Inspection of Nuclear Power Plant Components," ASME Boiler and Pressure Vessel Code, Section XI, New York, NY.

— — — — —, ASME Code Case NQA-1-1983 Edition and NQA-1a-1983 Addenda, "Quality Assurance Requirements for Nuclear Facility Applications," 1983.

GE-Hitachi Nuclear Energy Americas LLC (GEH)

— — — — —, GE, NEDC-33260, "NP-2010 COL Demonstration Project, SQAR—ESBWR QA Requirements for Procurement of Engineering Services and Equipment," Revision 1, July 2006.

— — — — —, GE, NEDO-33181, "NP-2010 COL Demonstration Project Quality Assurance Plan," Revision 2, July 2006 (ADAMS Accession No. ML063450235).

— — — — —, GE, "Revision 1 to DCD Tier 2—ESBWR PRA and Severe Accidents—Chapter 19 (26A6642BY, Revision 1)," September 30, 2006 (ADAMS Accession No. ML062760180).

— — — — —, GE, "ABWR Standard Safety Analysis Report," Chapter 19, Appendix 19K, "PRA-Based Reliability and Maintenance (26A6100, Revision 9)," August 1996.

— — — — —, GE, NEDO-11209-04A, "GE Nuclear Energy Quality Assurance Program Description," Revision 8, March 1989.

— — — — —, GEH, "ESBWR Design Control Document Tier 2," Revision 6, August 2009.

— — — — —, GEH, NEDO-33201, "ESBWR Certification Probabilistic Risk Assessment," Revision 5, February 2010.

— — — — —, GEH, Licensing Topical Report NEDO-33411, "Risk Significance of Structures, Systems and Components for the Design Phase of the ESBWR," Revision 2, February 2010.

— — — — —, GEH, Licensing Topical Report NEDO-33411, "Risk Significance of Structures, Systems and Components for the Design Phase of the ESBWR," Revision 1, July 2009.

— — — — —, GEH, Licensing Topical Report NEDO-33289, “ESBWR Reliability Assurance Program,” Revision 2, September 2008 (ADAMS Accession No. ML100110150).

— — — — —, GEH, Licensing Topical Report NEDO-33411, “Risk Significance of Structures, Systems, and Components for the Design Phase of the ESBWR,” Revision 0, March 2008.

— — — — —, GEH, Licensing Topical Report NEDO-33289, “ESBWR Reliability Assurance Program Plan,” Revision 2, September 2008

— — — — —, GE Nuclear Energy, “Application for Design Certification of the Simplified Boiling Water Reactor (SBWR),” MFN No. 161-92, Project No. 681, SLK-9289, August 27, 1992.

— — — — —, Hinds, David H. GE, to Document Control Desk, NRC, Subject: “Reply to Notice of Nonconformance NRC Inspection Report 05200010/2005-201, dated January 11, 2006,” February 9, 2006 (ADAMS Accession No. ML060440566).

— — — — —, Hinds, David H. GE, to Document Control Desk, NRC, Subject: “Reply to Notice of Nonconformance NRC Inspection Report 05200010/2006-201, dated June 14, 2006—Revision 1,” July 21, 2006 (ADAMS Accession No. ML062070133).

— — — — —, Hinds, David H., GE, to Document Control Desk, NRC, Subject: “Response to NRC Request for Additional Information Letter No. 56—DCD Chapter 17—RAI Numbers 17.1-1, 17.2-1, and 17.4-1 through 17.4-12,” October 6, 2006 (ADAMS Accession No. ML062890336).

— — — — —, Hinds, David H., GE, to Document Control Desk, NRC, Subject: “Additional Information Related to Response to NRC Request for Additional Information Letter No. 56—DCD Chapter 17—RAI Numbers 17.1-1, 17.2-1, and 17.4-1 through 17.4-12—NEDO-33289, ‘NP-2010 COL Demonstration Project Reliability Assurance Program Plan,’ October 2006,” November 7, 2006 (ADAMS Accession No. ML063210320).

— — — — —, Hinds, David H., GE, to Document Control Desk, NRC, Subject: “Response to Portion of NRC Request for Additional Information Letter No. 79 Related to ESBWR Design Certification Application—Reliability Assurance Program—RAI Numbers 17.4-13 through 17.4-16,” November 22, 2006 (ADAMS Accession No. ML063410276).

— — — — —, Kingston, Richard E., GEH, to Document Control Desk, NRC, Subject: “Response to Portion of NRC Request for Additional Information Letter No. 342 Related to ESBWR Design Certification Application ESBWR RAI Numbers 17.4-51 and 19.1-144 S04,” June 8, 2009 (ADAMS Accession No. ML091590725).

— — — — —, Kingston, Richard E., GEH, to Document Control Desk, NRC, Subject: “Response to Portion of NRC Request for Additional Information Letter No. 362 Related to ESBWR Design Certification Application—RAIs 17.4-36 S01, 17.4-52, 17.4-53 and 17.4-54,” August 18, 2009 (ADAMS Accession No. ML092310076).

— — — — —, Kingston, Richard E., GEH, to Document Control Desk, NRC, Subject: “Partial Response to NRC Request for Additional Information Letter No. 362 Related to ESBWR Design Certification Application—Quality Assurance—RAI Numbers 17.4-23 S02 and 17.4-55,”

August 23, 2009 (ADAMS Accession No. ML092360292).

— — — — —, Kingston, Richard E., GEH, to Document Control Desk, NRC, Subject: "Response to NRC Request for Additional Information Letter No. 206 Related to NEDO-33411, 'Risk Significance of Structures, Systems, and Components for the Design Phase of the ESBWR,' Revision 0—RAI Numbers 17.4-18 through 17.4-47," August 22, 2008 (ADAMS Accession No. ML082400086).

— — — — —, Kingston, Richard E., GEH, to Document Control Desk, NRC, Subject: "Response to NRC Request for Additional Information Letter No. 235 Related to ESBWR Design Certification Application—RAI Numbers 17.4-48, 17.4-49, and 17.4-50," November 4, 2008 (ADAMS Accession No. ML083120154).

— — — — —, Kingston, Richard E., GEH, to Document Control Desk, NRC, Subject: "Response to NRC Request for Additional Information Letter No. 258 Related to ESBWR Design Certification Application RAI Numbers 17.4-20 S01, 17.4-23 S01, 17.4-30 S01, 17.4-31 S01, 17.4-40 S01, 17.4-44 S01 and 17.4-46 S01," December 18, 2008 (ADAMS Accession No. ML083570393).

— — — — —, Kinsey, James C., GEH, to Document Control Desk, NRC, Subject: "Response to Portion of NRC Request for Additional Information Letter No. 56 Related to ESBWR Design Certification Application—DCD Chapter 17—RAI Number 17.4-1 S01," April 1, 2008 (ADAMS Accession No. ML080940085).

— — — — —, Kinsey, James C., GE, to Document Control Desk, NRC, Subject: "Response to Portion of NRC Request for Additional Information Letter No. 79 Related to ESBWR Design Certification Application—Reliability Assurance Program—RAI Numbers 17.4-15 S01 and 17.4-16 S01," May 11, 2007 (ADAMS Accession No. ML071450066).

— — — — —, Kinsey, James C., GEH, to Document Control Desk, NRC, Subject: "Response to Portion of NRC Request for Additional Information Letter No. 97 Related to ESBWR Design Certification Application—Quality Assurance—RAI Number 17.4-17," June 11, 2007 (ADAMS Accession No. ML071770558).

— — — — —, Kinsey, James C., GEH, to Document Control Desk, NRC, Subject: "Response to Portion of NRC Request for Additional Information Letter No. 79 Related to ESBWR Design Certification Application—Reliability Assurance Program—RAI Number 17.4-15 S02," June 11, 2007 (ADAMS Accession No. ML071720335).

— — — — —, Letter from David H. Hinds, GE, to Document Control Desk, NRC, Subject: "Additional Information Related to Response to NRC Request for Additional Information Letter No. 56—DCD Chapter 17—RAI Numbers 17.1-1, 17.2-1, and 17.4-1 through 17.4-12—NEDO-33289, 'NP-2010 COL Demonstration Project Reliability Assurance Program Plan,' October 2006," November 7, 2006 (ADAMS Accession No. ML063210320).

— — — — —, Letter from David H. Hinds, GE, to Document Control Desk, NRC, Subject: "General Electric Company—ESBWR Standard Plant Design—Revision 2 to Design Control Document Tier 1 and Tier 2, Chapter 1 (Introduction and General Description of Plant),"

November 30, 2006 (ADAMS Accession No. ML070160067).

— — — — —, Letter from David H. Hinds, GE, to Document Control Desk, NRC, Subject: "General Electric Company—ESBWR Standard Plant Design—Revision 2 to Design Control Document Tier 2, Chapters 2 through 5, 7 through 15, 17, and 18," October 31, 2006 (ADAMS Accession No. ML063100233).

U.S. Nuclear Energy Institute

— — — — —, Nuclear Energy Institute, "10 CFR 50.69 SSC Categorization Guideline," NEI 00-04, Revision 0, July 2005.

— — — — —, Nuclear Energy Institute, "Industry Guideline for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," NUMARC 93-01, Revision 2, April 1996.

U.S. Code of Federal Regulations

— — — — —, Title 10 of the *Code of Federal Regulations*, Part 50, "Domestic Licensing of Production and Utilization Facilities."

— — — — —, Title 10 of the *Code of Federal Regulations*, Part 52, "Licenses, Certifications, and Approvals for Nuclear Power Plants."

U.S. Nuclear Regulatory Commission (NRC)

Commission Papers

— — — — —, SECY-95-132, "Policy and Technical Issues Associated with the Regulatory Treatment of Non-Safety Systems (RTNSS) in Passive Plant Designs (SECY-94-084)," May 22, 1995 (ADAMS Accession No. ML003708005).

NUREG-Series Report

— — — — —, NURGEG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)," June 1996.

— — — — —, NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants (LWR Edition)," March 2007.

Regulatory Guides

— — — — —, Regulatory Guide 1.160, Revision 2, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," March 1997.

— — — — —, Regulatory Guide 1.174, Revision 1, "An Approach for Using Probabilistic Risk

Assessment in Risk-Informed Decisions on Plant-Specific Changes to the Licensing Basis," November 2002.

— — — — —, Regulatory Guide 1.182, "Assessing and Managing Risk Before Maintenance Activities at Nuclear Power Plants," May 2000.

— — — — —, Regulatory Guide 1.201, "Guidelines for Categorizing Structures, Systems, and Components in Nuclear Power Plants According to Their Safety Significance," Revision 1, May 2006.

— — — — —, Regulatory Guide 1.206, "Combined License Applications for Nuclear Power Plants," June 2007.

Other NRC Documents

— — — — —, Letter from David B. Matthews, NRC, to David H. Hinds, GE, Subject: "NRC Inspection Report for General Electric Nuclear Energy (GENE) General Economic and Simplified Boiling Water Reactor (ESBWR) Quality Assurance Implementation Follow-up Inspection," January 19, 2007 (ADAMS Accession No. ML070100142).

— — — — —, Letter from David B. Matthews, NRC, to David H. Hinds, GE, Subject: "NRC Inspection Report 05200010/2005-201 and Notice of Nonconformance," January 11, 2006 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML053560155).

— — — — —, Letter from David B. Matthews, NRC, to David H. Hinds, GE, Subject: "NRC Inspection Report 05200010/2006-201 and Notice of Nonconformance," June 14, 2006 (ADAMS Accession No. ML061590328).

ACRONYMS

ABWR	advanced boiling-water reactor
ac	alternating current
ADAMS	Agencywide Documents Access and Management System
ASME	American Society of Mechanical Engineers
BWR	boiling water reactor
CAR	corrective action request
CCF	common-cause failure
CDF	core damage frequency
CFR	Code of Federal Regulations
COL	combined license
DC	design certification
DCD	design control document
DRAP	design reliability assurance program
ESBWR	Economic Simplified Boiling Water Reactor
FV	Fussell-Vesely
GEH	GE Hitachi Nuclear Energy
HSS	high safety significance
ICS	isolation condenser system
IR	inspection report
LRF	large release frequency
LTR	Licensing Topical Report
NEI	Nuclear Energy Institute
NRC	U.S. Nuclear Regulatory Commission
NRS	not risk-significant
PRA	probabilistic risk assessment
QA	quality assurance
QAP	quality assurance program
RAI	request for additional information
RAP	reliability assurance program
RAW	risk achievement worth
RTNSS	regulatory treatment of non-safety systems
SAR	safety analysis report
SBWR	simplified boiling-water reactor
SMA	seismic margins analysis
SRM	staff requirements memorandum
SRP	standard review plan
SSC	structures, systems and components
TR	topical report
TS	technical specifications
URI	identified unresolved item