

17. QUALITY ASSURANCE

17.0 Introduction

The GE-Hitachi Nuclear America, LLC's (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, Section 17.0, provides an overview of implementation of the GEH QAP and states that the GEH QAP complies with Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing Plants," to Part 50, "Domestic Licensing of Production and Utilization Facilities," of Title 10 of the *Code of Federal Regulations* (10 CFR Part 50); 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 regulatory guides (RGs) shown in NEDO-11209-04A. DCD Section 17.0 states that the GEH ESBWR work is controlled through the "NP2010 COL Demonstration Project Quality Assurance Plan," NEDO-33181, Revision 2, 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 this DCD chapter. 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 Section 17.0 of what the ESBWR QAP is based upon 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, 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 suppliers' and subtier suppliers' quality programs. The staff verified that NEDC-33260 included 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, 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.
- Subpart B, “Standard Design Certifications,” to 10 CFR Part 52, “Early Site Permits; Standard Design Certifications; and Combined Licenses for Nuclear Power Plants,” requires in Section 52.47(a)(1)(i) that an application for a DC must contain “the technical information which is required of applicants for construction permits and operating licenses by 10 CFR Parts 20 and 50 its appendices, and Parts 73 and 100, and which is technically relevant to the design and not site-specific.”
- 10 CFR Part 52, Appendix O, “Standardization of Design: Staff Review of Standard Designs,” states that “the information submitted pursuant to Section 50.34(a)(7) of this chapter, shall be limited to the QAP to be applied to the design, procurement and fabrication of the structures, systems, and components for which design review has been requested....”
- 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.

17.1.2 Summary of Technical Information

The ESBWR DCD, Tier 2, 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 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 only applies to GEH QA during the design phase and not to construction. This is supported by the statement in Section 17.2 which states “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, North Carolina. 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/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/preventive actions identification and the response/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, documented 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 Section 17.1 and the QA implementation inspections performed at GEH facilities in Wilmington, North Carolina, the staff has 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 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 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 which 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 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. **This is COL Action Item 17.2-1.**

17.3 Quality Assurance Program Document

DCD Section 17.3 states that the overall project quality assurance program document (QAPD) is the COL applicant's responsibility. The staff agrees with this statement. **This is COL Action Item 17.3-1.**

17.4 Reliability Assurance Program During the Design Phase

The reliability assurance program (RAP) is implemented using the guidance contained 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 June 28, 1995, and draft Standard Review Plan (SRP) (NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear Power Plants") Section 17.4, "Reliability Assurance Program." The objectives of the design reliability assurance program (D-RAP) are to maintain the reliability of risk -significant SSCs consistent with the probabilistic risk assessment (PRA) assumptions. The D-RAP is implemented through D-RAP inspections, tests, analyses, and acceptance criteria (ITAAC) before fuel load.

17.4.1 Regulatory Criteria

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

- (1) Item E of SECY-95-132 outlines the requirements for the RAP. The RAP will be codified by incorporation within the design-specific rulemaking for an applicant for DC. The RAP provides reasonable assurance that (1) an advanced reactor is designed, constructed, and operated in a manner that is consistent with the assumptions and risk insights for risk-significant SSCs, (2) risk-significant SSCs do not degrade to an unacceptable level during plant operations, (3) the frequency of transients that challenge advanced reactor SSCs are minimized, and (4) risk-significant SSCs function reliably when challenged. The RAP also provides (1) a mechanism for establishing baseline reliability values for risk-significant SSCs identified by the risk determination methods used to implement the Maintenance Rule (10 CFR 50.65, "Requirements for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants") that is consistent with PRA reliability and availability assumptions, (2) a mechanism for establishing baseline reliability values for SSCs consistent with the defense-in-depth functions to minimize challenges to the safety-related systems, and (3) design and operational information to be used by a COL applicant/holder for ongoing plant reliability assurance activities. Once the site-specific D-RAP has been established and the risk-significant SSCs identified and prioritized, the procurement, fabrication, construction, and pre-operational testing would be implemented in accordance with the COL holder's D-RAP and would be verified using the ITAAC process.
- (2) In part, 10 CFR 52.47(a)(vi) states that an application for a DC must contain proposed tests, inspections, analyses, and acceptance criteria which are necessary and sufficient to provide reasonable assurance that, if the tests, inspections, and analyses are performed and the acceptance criteria are met, a plant that references the design is built and will operate in accordance with the DC.
- (3) Draft SRP Section 17.4, issued April 1996, provides review guidance for the RAP. The NRC staff's evaluation of the GEH ESBWR RAP is based on the staff positions discussed in SECY-95-132 and the guidance contained in draft SRP Section 17.4. As stated in draft SRP Section 17.4, an application for advanced reactor DC or COL should contain the following:
 - the description of the RAP used during the design that includes scope, purpose, objectives and essential elements of the D-RAP
 - the process used to evaluate and prioritize the SSCs in the design based on their degree of risk significance;
 - a list of the SSCs designated as risk significant
 - for those SSCs designated as risk significant, (1) a process to determine dominant failure modes that considers industry experience, analytical models, and applicable

requirements; and (2) key assumptions and risk insights from probabilistic, deterministic, or other methods that considered operations, maintenance, and monitoring activities.

17.4.2 Summary of Technical Information

The ESBWR DCD, Tier 2, Section 17.4, "Reliability Assurance Program During Design Phase," contains the scope, purpose, objectives, essential elements, organizations implementing the D-RAP, SSC identification and prioritization, design considerations, definition of failure modes, reliability assurance process in the operations phase (O-RAP), the owner/operator RAP, D-RAP implementation, and COL information needed to implement the D-RAP and O-RAP. GEH also provided the following documents which are the basis of the ESBWR D-RAP and the D-RAP ITAAC:

- NEDO-33289, "NP-2010 COL Demonstration Project Reliability Assurance Program Plan," issued October 2006. NEDO-33289 describes the GEH ESBWR RAP.
- DCD Appendix 1D, "Regulatory Treatment of Non-Safety Systems (RTNSS)," Revision 2, describes RTNSS for the ESBWR design.
- DCD, Tier 1, Section 3.6, Design RAP, Revision 3.
- DCD Chapter 19, "PRA-Based Reliability, Availability and Maintainability Analysis and Maintenance," Revision 1.

17.4.3 Staff Evaluation

17.4.3.1 Scope, Purpose, and Objectives of the D-RAP

The staff reviewed the RAP for ESBWR in accordance with Item E of SECY-95-132 and draft SRP Section 17.4 to ensure that the proposed RAP meets the guidance in these documents. The scope of the ESBWR D-RAP includes risk-significant SSCs, both safety-related and non-safety-related, that provide defense in depth or result in significant improvements in the PRA evaluations. The purpose of the ESBWR D-RAP is to ensure that plant safety, as estimated from the PRA, is maintained as the detailed design evolves through the implementation and procurement phases. The objectives of the ESBWR D-RAP are to identify key assumptions regarding any operation, maintenance, and monitoring activities that the owner/operator should consider in developing its RAP to assure that such SSCs can be expected to operate throughout plant life with the reliability assumed in the PRA.

The staff concludes that GEH adequately described the scope, purpose, and objectives of the D-RAP which meet the guidance in Item E of SECY-95-132 and draft SRP Section 17.4. Based on the above, the staff finds that the scope, purpose, and objectives of the ESBWR D-RAP are acceptable.

17.4.3.2 Essential Elements of D-RAP/GEH Organization That Implement D-RAP

The staff reviewed the GEH organization for D-RAP provided in Subsection 17.4.5 of the DCD. Based on its review, the staff identified the following areas where it needed additional information to complete its review:

RAI 17.4-4 In Revision 0 to DCD Subsection 17.4.5, GEH Organization for D-RAP, the DC applicant did not describe the essential elements for the D-RAP in DCD, Section 17.4. The essential elements, as described in SECY-95-132, Item E, have been interpreted by the NRC staff to mean the application of the following quality elements to the D-RAP:

- Organization
- Design Control
- Procedures and Instructions
- Corrective Action
- Records
- Audits

The applicant should provide an overview of the process for implementing these essential elements into the D-RAP.

RAI 17.4-5 The applicant should provide details on its D-RAP organizational structure. This should include a discussion of the interface controls between the PRA, D-RAP and design organizations. The applicant should also consider developing an expert panel within the GEH organization whose charter would include determining the list of risk significant SSCs within the scope of D-RAP. The expert panel should be composed of subject matter experts with experience in systems, operations, and maintenance. In DCD Subsection 17.4.5, "GE Organization for D-RAP," the applicant should discuss the PRA organization within the design organization. The applicant should also develop an internal procedure on how the organization will implement the D-RAP.

RAI 17.4-6 The applicant should discuss the measures that will be established for the identification and control of design interfaces and for coordination among participating design organizations. Since the ESBWR full scope PRA is not complete and subject to change, the applicant should describe the process used to control changes in the PRA which could affect the list of risk significant SSCs within the scope of D-RAP. In addition, the applicant should describe how the design control process provides a feedback mechanism for notifying the PRA organization of changes in the design of risk significant SSCs within the scope of D-RAP that could affect the PRA. The applicant should also describe its configuration control process for maintaining the list of risk significant SSCs within the scope of D-RAP similar to the control of a quality list (Q-list).

In response to RAIs 17.4-4, 17.4-5, and 17.4-6, GEH provided Revision 2 to DCD Subsection 17.4.5. That subsection states that the ESBWR engineering organization is responsible for the design analysis and PRA engineering necessary to support the development of the D-RAP. The ESBWR PRA personnel participate in the design change control process,

which includes providing inputs related to D-RAP in the design process. The GEH ESBWR engineering design procedural controls are applied to the D-RAP. 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 the affected documents are identified and changed accordingly. The list of risk-significant SSCs within the scope of the D-RAP is maintained in accordance with the ESBWR reliability assurance plan, NEDO-33289.

The staff found that the changes made to DCD Subsection 17.4.5 adequately overview the interfaces between the various GEH organizations responsible for the D-RAP. The staff concludes that DCD Subsection 17.4.5 meets the requirements in Item E of SECY-95-132 and draft SRP Section 17.4, and therefore, the concerns associated with RAIs 17.4-4, 17.4-5, and 17.4-6 are resolved.

RAI 17.4-7 The applicant should develop an internal procedure for implementing the D-RAP. The procedure should also describe interface controls between all of the organizations involved in the D-RAP. The procedure should describe the process for identifying and prioritizing the list of risk significant SSCs within the scope of D-RAP.

RAI 17.4-8 The applicant should describe, in detail, the corrective action process applied to risk significant SSCs within the scope of D-RAP.

RAI 17.4-9 The applicant should describe, in detail, the controls for records of activities involving risk significant SSCs within the scope of D-RAP.

RAI 17.4-10 The applicant should describe, in detail, the audit plans for conducting QA audits of D-RAP activities.

By letter dated November 7, 2006, GEH provided the staff with NEDO-33289 and added it to the list of references in DCD Subsection 17.4.14. The staff finds that NEDO-33289 and DCD, Tier 2, Revision 2, Subsections 17.4.5 and 17.4.7, contain details about the GEH ESBWR engineering organizational interface with the PRA organization and the design change control process. The applicant also addresses the quality elements (i.e., design controls, procedures, corrective action, control of records and audit plans) of the D-RAP in NEDO-33289 and DCD Section 17.4. Therefore, the concerns associated with RAIs 17.4-7 through 17.4-10 are resolved.

The NRC staff finds that the information regarding the GEH engineering and PRA organization responsible for the D-RAP and the essential quality elements of the D-RAP described in DCD Subsections 17.4.5 and 17.4.7 meets the guidance in Item E of SECY-95-132 and draft SRP Section 17.4 and, therefore, is acceptable.

17.4.3.3 SSC Identification and Prioritization

As discussed in Item E of SECY-95-132 and draft SRP Section 17.4, the DC applicant must identify and prioritize the list of risk-significant SSCs within the scope of D-RAP. In Revision 0 and Revision 2 to DCD Subsection 17.4.6, "SSC Identification and Prioritization," GEH did not

provide any information concerning the list of risk-significant SSCs within the scope of D-RAP or the PRA importance measures used to identify and prioritize risk-significant SSCs. Therefore, the staff requested the following information from the DC applicant:

RAI 17.4-1 In the Advanced Boiling Water Reactor (ABWR) Standard SAR, Chapter 19, Appendix 19K, PRA-Based Reliability and Maintenance, Table 19K-1, “ABWR SSCs of Greatest Importance for CDF—Level 1 Analysis,” the applicant provided a table that listed the risk significant SSCs along with PRA importance measure thresholds including risk rankings values for risk significant SSCs within the scope of RAP. This information is not in DCD Section 17.4 for the ESBWR design. Some of this information is also in NEDC-33201P, Chapter 19, Table 19-1, “ESBWR SSCs of Greatest Importance for CDF and Level I Analysis,” and Table 19-2, “ESBWR Initiating Event Contribution to CDF, Level 1 Analysis.”

In DCD Section 17.4, “Reliability Assurance Program During Design Phase,” the applicant should add a reference to the list of risk significant SSCs identified in the ESBWR NEDC-33201P, Chapter 19, Table 19-1, “ESBWR SSCs of Greatest Importance for Core Damage Frequency (CDF) and Level 1 Analysis,” and Table 19-2, “ESBWR Initiating Event Contribution to CDF, Level 1 Analysis.” The applicant should also add references to identify risk significant SSCs within the scope of D-RAP identified from PRA Level-I analysis for external events, PRA Level-II analysis, engineering judgment and operating experience supporting risk insights, and the expert panel process. The applicant should ensure that the list is all-inclusive of SSCs that have been identified to be within the scope of D-RAP.

In response to RAI 17.4-1, GEH stated that it will identify a comprehensive list of risk-significant SSCs within the scope of D-RAP at a later phase of development of the D-RAP. NEDO-33289 and design Specification 26A7107, “ESBWR Risk Significant SSCs,” describe the process of developing and maintaining the list of risk-significant SSCs.

GEH plans to complete the list of risk-significant SSCs for the ESBWR DC application in the near future. As described above, it will maintain the list of risk-significant SSCs in design Specification 26A7107. The DC applicant must provide design Specification 26A7107 to the NRC staff and reference this document in DCD Section 17.4 so that the NRC staff can complete its review of the ESBWR D-RAP. The staff identified this as **Open item 17.4-1**.

RAI 17.4-12 The staff determined that the following COL action item should be added to DCD Subsection 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 risk significant SSCs under the scope of D-RAP. The reliability of risk significant SSC, which are identified by the PRA and other sources, will be evaluated at the COL applicant or holder detailed design phase by appropriate design reviews and reliability analysis.

In response to RAI 17.4-12, GEH stated that it will add a COL action item to the next revision of DCD, Tier 2, Section 17.4. In Revision 3 to DCD Subsection 17.4.13, "COL Information," GEH added the requirement for the COL holder to "establish PRA important measures, the expert panel process, and deterministic methods to determine the site-specific list of risk-significant SSCs under the scope of the D-RAP." This resolved the concern in RAI 17.4-12.

RAI 17.4-3 The NRC staff requests additional information in DCD Section 17.4 concerning use of PRA importance measures (i.e., Fussell-Vesely Importance (FVI) greater than 1 percent and Risk Achievement Worth (RAW) greater than 5). The applicant should add PRA importance measure threshold values to DCD Subsection 17.4.6, "SSC Identification/Prioritization."

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 their FVI is greater than or equal to 0.01.

The NRC staff finds that this change to DCD Subsection 17.4.6 resolves the concern in RAI 17.4-3. The staff also finds that, with the exception of RAI 17.4-1, noted above, DCD Subsection 17.4.6 adequately describes the identification and prioritization of risk-significant SSCs within the scope of D-RAP and meets the guidance in Item E of SECY-95-132 and draft SRP Section 17.4.

17.4.3.4 Design Considerations

In Revision 2 of DCD Subsection 17.4.7, GEH stated that it will evaluate the reliability of risk-significant SSCs, which are identified by the PRA and other sources, at the detailed design stage by appropriate design reviews and reliability analyses.

The staff finds that the DC applicant adequately discussed design considerations in DCD Subsection 17.4.7. The staff finds that the design considerations included in DCD Subsection 17.4.7 meet the guidance in Item E of SECY-95-132 and draft SRP Section 17.4 and, therefore, are acceptable.

17.4.3.5 Defining Failure Modes and Operating Experience

The NRC staff reviewed DCD Subsection 17.4.8, "Defining Failure Modes," and requested the following information to complete its review:

RAI 17.4-11 In Revision 0 to DCD Subsection 17.4.8, "Defining Failure Modes," 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 had detailed discussions with the applicant concerning an evaluation of the historical records for boiling water reactor (BWR) systems and components. The staff found that the applicant had not used this information to develop D-RAP. The applicant should clarify the source of information used to define dominant failure modes as described in DCD Subsection 17.4.8.

In response to RAI 17.4-11, GEH stated that historical records for BWR systems and components had not been evaluated but would be evaluated in the COL application phase of D-RAP in accordance with NEDO-33289. The staff confirmed that GEH added COL action item concerning “use of industry wide operating experience” to NEDO-33289, Subsection 6, “Description of Expert Panel.” Subsection 6 states that the expert panel will make integrated decisions concerning historical records for risk-significant SSCs within the scope of D-RAP. This partially resolved the concern in RAI 17.4-11. However, GEH did not add this COL action item to DCD Subsections 17.4.8 or 17.4.13. The NRC staff determined that GEH needed to add this COL action item to DCD Subsections 17.4.8 or 17.4.13 to evaluate historical records for BWR systems and components related to risk-significant SSCs within the scope of D-RAP. In Revision 3 to DCD Subsection 17.4.13, GEH added the following requirement for the COL holder:

- Reliability Database—Historical data on equipment performance as available. The compilation and reduction of this data provided the plant with source of component reliability information. Data used in PRA fault-tree analyses may also be a viable initial source.

This resolves the concern in RAI 17.4-11. The staff finds that the applicant included historical information, analytical models and existing requirements to determine dominant failure modes in DCD Subsection 17.4.8. This meets the guidance in Item E of SECY-95-132 and draft SRP Section 17.4 and, therefore, is acceptable.

17.4.3.6 D-RAP Implementation

The staff reviewed Revision 0 to DCD Subsection 17.4.11 in which GEH stated that a prototypical example of implementation of the D-RAP is given for the isolation condenser system (ICS) in SBWR SAR Subsection 17.3.11. GEH is using this example to guide early design work in the ESBWR. Based on the above, the staff requested the following additional information to complete its review:

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

The staff notes that references to design reliability improvements of the ICS were incorporated into the GEH SBWR DCD Section 17.4. However, GEH later withdrew the SBWR application in 1995. This information from the SBWR application was not included in the ESBWR DC application. If GEH used the D-RAP to improve the reliability of an ESBWR system, then the applicant should provide an example in DCD Subsection 17.4.11, “D-RAP Implementation.”

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 Revision 2 of DCD Subsection 17.4.11.

GEH also included ICS risk information, ICS failure mode identification, and identification of ICS maintenance requirements. The staff reviewed the revised information in DCD Subsection 17.4.11 and concluded that the information resolved the concern in RAI 17.4-2. The staff concluded that the example of design reliability improvements provided in DCD Subsection 17.4.11 was sufficient to meet the guidance in SECY-95-132 and draft SRP Section 17.4 and, therefore, is acceptable.

17.4.3.7 Implementation of the Reliability Assurance Process During the Operations Phase

The NRC expects licensees to implement a reliability assurance process during the operations phase (O-RAP) in accordance with SECY-95-132, SECY-05-197, and NUREG-0800 (the SRP). The staff has determined that O-RAP may be implemented through (1) a QAP that meets the requirements of 10 CFR Part 50, Appendix B, (2) a program to monitor the effectiveness of maintenance in accordance with 10 CFR 50.65 (the Maintenance Rule), and (3) the underlying maintenance and surveillance programs themselves. If the COL holder's Maintenance Rule program is to be credited in the implementation of the RAP in the operations phase, along with the QAP and the underlying maintenance and surveillance programs, then the SSCs in the scope of the RAP, as modified for the operations phase, must be included in the HSS category within the Maintenance Rule program scope.

The staff reviewed GEH's proposed implementation of the reliability assurance process during the operations phase. Based on its review, the staff identified the following areas where it needed additional information to complete its review:

RAI 17.4-13 Per the O-RAP discussion in SECY-95-132 and draft SRP, Revision 0, Section 17.4, the applicant should state in DCD Subsection 17.4.9, "Operational Reliability Assurance Activities," whether, and if so, how, O-RAP process will be implemented through existing operational programs, including the maintenance and surveillance program(s), the QAP, and the Maintenance Rule program. The applicant should also add a reference to SECY-95-132 in DCD Subsection 17.4.14, "References."

The GEH response to RAI 17.4-13 stated:

Design Control Document Tier 2, Subsection 17.4.9 will be revised to state that the O-RAP will be implemented through the COL holder's maintenance and surveillance programs, QAP, and Maintenance Rule program. Also, a reference to SECY-95-132 will be added to Subsection 17.4.14, "References." DCD Impact DCD, Tier 2, Section 17.4, will be revised in Revision 3 as noted in the response to RAI 17.4-13."

GEH response to RAI 17.4-13 was acceptable. The staff review of Revision 3 of Subsection 17.4.9 of the GEH ESBWR DCD, Tier 2, confirmed that Subsection 17.4.9 stated that O-RAP will be implemented through the QA, Maintenance Rule, and maintenance and surveillance programs and that SECY-95-132 was added as a reference in Subsection 17.4.14. Therefore, RAI 17.4-13 is resolved.

RAI 17.4-14 The applicant should include reliability data from test results collected from Technical Specification (TS) surveillance tests and other relevant testing and from industry operating experience (IOE) for both safety-related and RTNSS SSCs as available. This information can also be obtained from reliability estimates in the ESBWR PRA. A reference to these sources for reliability estimates and monitoring information should be added to DCD Section 17.4.9, "Operational Reliability Assurance Activities." The GEH response to RAI 17.4-14 stated:

A statement regarding 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 will be added to DCD, Tier 2, Subsection 17.4.9, "Operational Reliability Assurance Activities." DCD Impact DCD, Tier 2, Section 17.4, will be revised in Revision 3 as noted in the response to RAI 17.4-14.

The GEH response to RAI 17.4-14 was incomplete in that it did not address the ESBWR PRA as a source of reliability information as stated in RAI 17.4-14.

The staff review of Revision 3 of Subsection 17.4.9 of the GEH ESBWR DCD, Tier 2, confirmed that GEH added the reference to ESBWR PRA information in Revision 3 and that Subsection 17.4.9 is otherwise satisfactory in Revision 3. These clarifications resolved RAI 17.4-14.

RAI 17.4-15: A COL applicant referencing the GEH ESBWR DCD should reference the guidance documents used to implement its O-RAP in DCD Subsection 17.4.9, "Operational Reliability Assurance Activities." For the Maintenance Rule element of the O-RAP, these documents include RG 1.160 and NUMARC 93-01 (and also RG 1.182 and the 2000 revision to Section 11 of NUMARC 93-01 if still effective). This information should also be added to DCD Subsection 17.4.14, "References." The GEH response to RAI 17.4-15 stated:

RG 1.160, "Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," NUMARC 93-01, "Industry Guidance for Monitoring the Effectiveness of Maintenance at Nuclear Power Plants," RG 1.182, "Assessing and Managing the Risk Before Maintenance Activities at Nuclear Power Plants," the revised NUMARC 93-01, Section 11, "Assessment of Risk Resulting from the Performance of Maintenance Activities," will be referenced in DCD, Tier 2, Subsection 17.4.9. DCD Impact DCD, Tier 2, Section 17.4 will be revised in Revision 3 as noted in the response to RAI 17.4-15.

The GEH response to RAI 17.4-15 was incomplete in that it failed to address the information to be added to DCD Subsection 17.4.14, as stated in RAI 17.4-15.

The staff review of Revision 3 of Subsection 17.4.9 of the DCD, Tier 2, confirmed that RG 1.160, NUMARC 93-01, and RG 1.182 were referenced therein as guidance documents for the Maintenance Rule program in implementing the O-RAP as specified in RAI 17.4-15. The staff review confirmed that these documents were also listed as references in Subsection 17.4.14 of Revision 3.

However, GEH did not reference the February 22, 2000, revision to Section 11 of NUMARC 93-01 (for implementation of paragraph (a)(4) of 10 CFR 50.65), which was endorsed by RG 1.182, in Subsection 17.4.9, nor did GEH list it as a reference in Subsection 17.4.14, as specified in RAI 17.4-15 and as committed to in the GEH response to RAI 17.4-15.

The staff identified this discrepancy to GEH in RAI 17.4-15, Supplements 01 and 02. Subsequently, in its letters MFN 06-486, Supplements 01 and 02, GEH indicated that it would include the references in Subsections 17.4-9 and 17.4-14 in Revision 4 to the ESBWR DCD, Tier 2. This RAI may be closed upon confirmation that in Revision 4 to the ESBWR DCD, Tier 2, the list of reference documents pertaining to the Maintenance Rule in Subsection 17.4.9 includes the February 22, 2000, revision to Section 11 of NUMARC 93-01 as a separate document and also that the revised Section 11 is listed as a separate document in Subsection 17.4.14, "References," as described in GEH's response and as shown in the draft Revision 4, Subsections 17.4.9 and 17.4.14, attached to the response. This is **Confirmatory Item 17.4-15**.

RAI 17.4-16: The staff determined that the following COL applicant/holder action items related to O-RAP should be added to DCD Subsection 17.4.13:

- The COL applicant is responsible for integrating the objectives of O-RAP into the QAP developed to implement 10 CFR Part 50, Appendix B. This program should also address failures of non-safety-related, risk-significant 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 risk-significant SSCs as identified in the D-RAP. 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 for monitoring the effectiveness of the COL applicant's maintenance activities needed for operational reliability assurance. As such it is an important element of O-RAP. If the COL applicant proposes to use its Maintenance Rule program in O-RAP implementation, the SSCs in the scope of the Maintenance Rule program that are classified as HSS should encompass all SSCs in the scope of the D-RAP.
- In addition to the specific tasks necessary to maintain SSC reliability at its required level cited above, the O-RAP activities should include:
 - Reliability data base—Historical data on equipment performance as available. The compilation and reduction of this data provides the plant with source of component reliability information. Data used in PRA fault-tree analyses may also be a viable initial source.
 - Surveillance and testing—establishes the level of performance or condition being maintained for SSCs within the scope of the RAP and

identifies declining trends in between surveillances prior to performance or condition degrading to unacceptable levels undetected (or failure) to the extent possible.

- Maintenance Plan—This plan describes the nature and frequency of maintenance activities to be performed on plant equipment. The plan includes the selected SSCs identified in the D-RAP.

The GEH response to RAI 17.4-16 stated the following:

COL Information Item 17.4-2: The COL holder is responsible for integrating the objectives of O-RAP into the QAP developed to implement 10 CFR Part 50, Appendix B. This program will also address failures of non-safety-related, risk-significant SSCs that result from design and operational errors in accordance with SECY-95-132, Item E.

COL Information Item 17.4-3: The COL holder is responsible for performing the tasks necessary to maintain the reliability of risk-significant SSCs as identified in the D-RAP. 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.

COL Information Item 17.4-4: The COL holder's Maintenance Rule (10 CFR 50.65) program is required for monitoring the effectiveness of the COL applicant's maintenance activities needed for operational reliability assurance.

COL Information Item 17.4-5: The COL holder shall consider all SSCs that are in the scope of the D-RAP 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 IOE.

It is prudent for the Expert Panel to include all SSCs that are in the scope of the D-RAP to be within the scope of the Maintenance Rule. However, risk importance calculations and other factors may change the risk significance of certain SSCs that were previously determined to be risk-significant within the bounds of the D-RAP. Therefore, exceptions between the D-RAP and O-RAP risk significance may exist, and should be evaluated and justified by the Expert Panel.

COL Information Item 17.4-6: The COL holder O-RAP activities should include:

- Reliability Database—Historical data on equipment performance as available.

The compilation and reduction of this data provides the plant with source of component reliability information. Data used in PRA fault-tree analyses may also be a viable initial source.

- Surveillance and Testing—Establishes the level of performance or condition being maintained for SSCs within the scope of the RAP and identifies declining trends in between surveillances prior to performance or condition degrading to unacceptable levels undetected (or failure) to the extent possible.
- Maintenance Plan—This plan describes the nature and frequency of maintenance activities to be performed on plant equipment. The plan includes the selected SSCs identified in the D-RAP.

COL Information Items 17.4-1 through 17.4-6 shall be available prior to fuel load for NRC inspection to confirm that they meet NRC regulations and guidance.

DCD Impact:

DCD, Tier 2, Section 17.4, will be revised in Revision 3 as noted in the response to RAI 17.4-16.

The GEH response to RAI 17.4-16 was incomplete in that it referred to a “COL Information Item 17.4-1,” stating that “COL Information Items 17.4-1 through 17.4-6 shall be available prior to fuel load...” but it did not provide COL Information Item 17.4-1. GEH provided only COL Information Items 17.4-2 through 17.4-6 to address the COL action items specified in RAI 17.4-16. The response was also incomplete in that it was not clear that COL Information Items 17.4-1 through 17.4-6 would be included in DCD Subsection 17.4.13 as prescribed in RAI 17.4-16.

The staff review of Subsection 17.4.13 of the DCD, Tier 2, Revision 3, confirmed that Subsection 17.4.13 included all COL action items even though they were not identified by number as described in the GEH response to RAI 17.4-16. In addition, review of Subsection 17.4.13 clarified that the GEH response to RAI 17.4-16 did not address COL Information Item 17.4-1 because it was an existing provision in the DCD that was not among the issues raised in the RAIs. The reviewer did note, however, in the second bullet under Subsection 17.4.13 of Revision 3 of the DCD, the use of the phrase “PRA important measures,” whereas it appeared from the context (i.e., D-RAP scope considerations and/or Maintenance Rule HSS category considerations) that “PRA importance measures” (e.g., risk achievement worth, risk reduction worth, cutsets, Fussell-Vesely, Birnbaum, etc.) may have been intended.

In its response to RAI 17.4-16, GEH committed to include a note, as quoted above, regarding expert panel considerations under COL Information Item 17.4-5. COL Information Item 17.4-5 became the fifth bullet under Subsection 17.4.13 in Revision 3 of the DCD, but the note was omitted. These discrepancies were identified to GEH in RAI 16.4-16, S01.

In its letter MFN 06-486, Supplement 1, GEH committed to make the correction and to include the omitted note. This RAI may be closed upon confirmation that Subsection 17.4.13 in Revision 4 of the ESBWR DCD, Tier 2, is corrected and contains the note as described in the GEH letter and in the draft Revision 4 Subsection 17.4.13 attached to the letter. This is **Confirmatory Item 17.4-16**.

RAI 17.4-17 The second sentence of the third paragraph of Subsection 17.4.2 of the ESBWR DCD Tier 2, should be revised to read: "This information forms part of the basis for the HSS category, as described in NUMARC 93-01, and as endorsed by RG 1.160, of the SSCs within the scope of the Maintenance Rule program, as prescribed by 10 CFR 50.65(b)." A new third sentence that incorporates the remainder of the existing second sentence should be added thus: "The Maintenance Rule Program ensures... [remainder of the existing second sentence]." A new fourth sentence should be added: "The HSS category within the Maintenance Rule Program scope must encompass the SSCs in the RAP scope as modified for the operations phase if the Maintenance Rule Program is to be used along with the QA and maintenance and surveillance programs in implementation of the RAP in the operations phase."

In its letter MFN 07-328, GEH responded to RAI 17.4-17 and agreed to modify the DCD as requested. The staff found the response to be satisfactory. RAI 17.4-17 may be closed upon confirmation that Subsection 17.4.2 of Revision 4 of the ESBWR DCD, Tier 2, is worded as described in GEH's response to RAI 17.4-17 and as shown in the draft Subsection 17.4.2 of Revision 4 of the DCD, Tier 2, attached to that response.

17.4.3.8 COL Information

"In Revision 2 of DCD Subsection 17.4.13, GEH listed only one COL action item related to O-RAP. The staff found that additional COL action items were needed to meet the guidance in Item E of SECY-95-132 and SRP Section 17.4. Discrepancies in the COL action/information items in DCD Subsection 17.4.13 were identified in RAI 17.4-16 and its Supplement 01. Subsection 17.4.13 in Revision 3 of the DCD included all the requested COL action/ information items and in its response to RAI 17.4-16, S01, GEH committed to correct the remaining discrepancies in Revision 4 (as shown in the draft Revision 4). Therefore, upon confirmation that Revision 4 is corrected satisfactorily, Subsection 17.4.13 will meet the guidance in Item E of SECY-95-132 and Section 17.4 of the SRP and will be acceptable."

17.4.4 Overall Conclusions

The NRC staff concludes that, with the exception of Open Item 17.4-1 (page 17-9 of this SER) and **Confirmatory Items 17.4-15** and **17.4-16**, the RAP meets the guidance in Item E of SECY-95-132 and draft SRP Section 17.4. The DC applicant must address the open item and confirmatory items noted above before the NRC staff can conclude that the ESBWR RAP is acceptable.

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References

American Society of Mechanical Engineers (ASME) Standard NQA-1-1983 Edition and NQA-1a-1983 Addenda, "Quality Assurance Requirements for Nuclear Facility Applications," 1983.

American National Standards Institute (ANSI) Standard N45.2, "Quality Assurance Program Requirements for Nuclear Facilities," 1977.

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

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

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