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Docket No. 52-010

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U.S. Nuclear Regulatory Commission
Document Control Desk
Washington, D.C. 20555-0001

Subject: **Transmital of NEDO-33181 Revision 6, NEDO-33260 Revision 5, and NEDO-33289 Revision 2, Related to ESBWR Design Certification Application – Chapter 17**

The purpose of this letter is to formally submit the following documents referenced by ESBWR DCD Revision 6, Chapter 17, Quality Assurance (Ref. 1).

Enclosure 1 contains GE Hitachi Nuclear Energy, "NP-2010 COL Demonstration Project Quality Assurance Plan," NEDO-33181, Revision 6, August 2009.

Enclosure 2 contains GE Hitachi Nuclear Energy, "Quality Assurance Requirements for Suppliers of Equipment and Services to the GEH ESBWR Project," NEDO-33260, Revision 5, April 2008.

Enclosure 3 contains GE Energy Nuclear, "ESBWR Reliability Assurance Program," NEDO-33289, Revision 2, September 2008.

If you have any questions about the information provided, please contact me.

Sincerely,

Richard E. Kingston

Richard E. Kingston
Vice President, ESBWR Licensing

Reference:

1. MFN 09-572, ESBWR Standard Plant Design Certification Application Design Control Document, Revision 6, Tier 1 and Tier 2, dated August 31, 2009

Enclosures:

1. GE Hitachi Nuclear Energy, “NP-2010 COL Demonstration Project Quality Assurance Plan,” NEDO-33181, Revision 6, August 2009.
2. GE Hitachi Nuclear Energy, “Quality Assurance Requirements for Suppliers of Equipment and Services to the GEH ESBWR Project,” NEDO-33260, Revision 5, April 2008.
3. GE Energy Nuclear, “ESBWR Reliability Assurance Program,” NEDO-33289, Revision 2, September 2008.

cc: AE Cubbage USNRC (with enclosures)
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LF Dougherty GEH/Wilmington (with enclosures)

Enclosure 1

MFN 10-007

GE Hitachi Nuclear Energy, "NP-2010 COL Demonstration Project Quality Assurance Plan," NEDO-33181, Revision 6, August 2009.

GE Hitachi Nuclear Energy

3901 Castle Hayne Rd
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NEDO-33181
Revision 6
Class I
DRF 0000-0037-8794

August 2009

NP-2010 COL DEMONSTRATION PROJECT QUALITY ASSURANCE PROGRAM

Prepared for:

U.S. Department of Energy
Cooperative Agreement: DE-FC07-07ID14778

Dominion Nuclear North Anna, LLC
Cooperative Agreement: DE-FC07-05ID14635

Approved by:

M. Harvey
Manager, Nuclear Plant Projects Quality

IMPORTANT NOTICE REGARDING CONTENTS OF THIS REPORT
Please Read Carefully

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Acknowledgement

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Statement of Policy and Authority

It is the policy of the GE Hitachi Nuclear Energy (GEH) / ESBWR Project to achieve and maintain high quality in products and services through timely and effective compliance with all quality requirements.

All managers within GEH and the ESBWR Project with quality related responsibilities have full authority to implement this QA Program within their respective areas of responsibility. Consistent with the contractual work scopes, which impose QA requirements, it is mandatory that all personnel comply with the policies, instructions, and procedures referenced in this document.

The implementation of this Quality Assurance Program has the unqualified endorsement and support of GEH management.

Introduction

This document describes the NP-2010 COL Demonstration Project Quality Assurance Program, which GE Hitachi Nuclear Energy (GEH), as supplier for ESBWR engineering services, will implement in fulfilling the contractual requirements within the scope of Cooperative Agreements:

DE-FC07-07ID14778	U.S. Department of Energy
DE-FC07-05ID14635	Dominion Nuclear North Anna, LLC

The NP-2010 COL Demonstration Project Quality Assurance Program is based on NEDO-11209-04A, GE Nuclear Energy Quality Assurance Program Description (Reference 1) and NEDO-32280, the GE Nuclear Energy ISO-9001 Quality System Description (Reference 2). It will be implemented through GEH procedures.

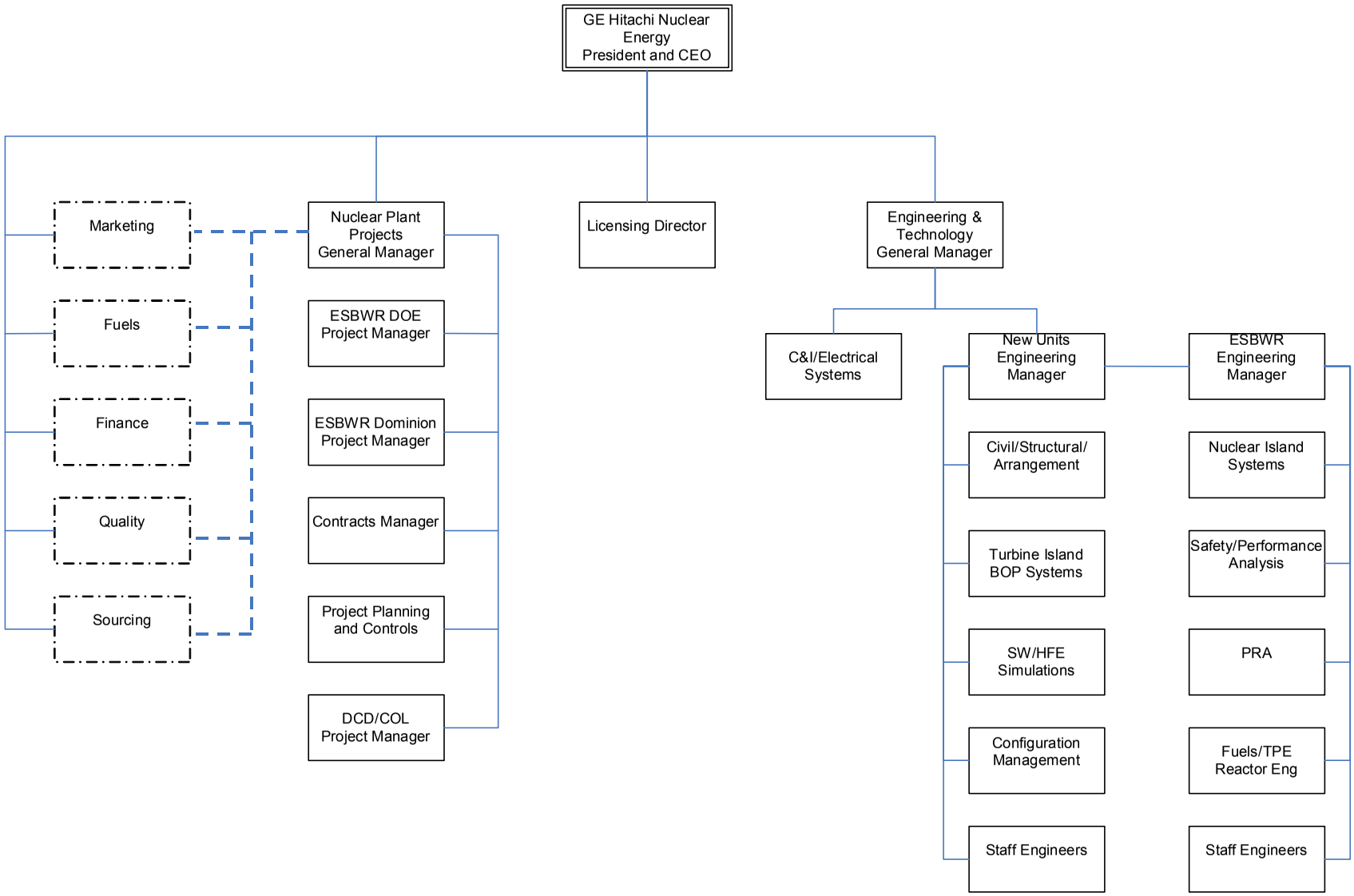
Program effectiveness will be evaluated by an annual performance based audit and supplemental Quality Assurance assessments, at the discretion of the NP-2010 COL Demonstration Project QA Manager.

1 Organization

Section 1 of Reference 1 and implementing procedures complies with Criterion I of 10 CFR 50, Appendix B, Section 4.1 of ISO 9001:2000 (applicable to Safety-Related Classification N only, see definitions of Safety-Related Classification in Section 2 of this document) and Quality Assurance requirements of the ESBWR Contract.

The GEH COL Demonstration Project Organization is shown in Figure 1.1.

Figure 1.1 – GEH COL Demonstration Project Organization



2 Quality Assurance Program

Section 2 of Reference 1 and implementing procedures complies with Criterion II of 10 CFR 50, Appendix B, Section 4.2 of ISO 9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

The GEH QA Program applies to Safety-Related (Class Q), Nonsafety-Related (Class N), and Special (Class S) items, as defined below. The standard GEH QA Program (Reference 1) is accepted by the NRC and is used on all GEH BWR nuclear power plant work. It is in full compliance with 10 CFR 50, Appendix B, ANSI/ASME N45.2, ANSI/ASME N45.2 series standards and applicable NRC Regulatory Guides.

ASME has accepted the implementation of GEH's QA program as meeting ASME quality requirements when it awarded GEH N-Certificate N-1888 in San Jose, NPT Certificate N-1151 in Wilmington and NA Certificate N-2510 in Wilmington.

Lloyd's Register Quality Assurance has accepted Reference 1 and the GEH Quality Management System Description, NEDO-32280 (Reference 2) as meeting the quality requirements of ISO 9001:2000 (Certificate No. 100503).

The standard GEH QA programs and their implementing procedures will continue to be revised as necessary to meet NRC, ASME and ISO requirements. The project requirements in the Quality Assurance Program are under configuration revision control.

The ESBWR Project uses the Safety-Related Classifications Q, N and S as defined below. This is a classification system used to identify structures, systems, components, parts and technical services. The definitions are as follows:

Safety-Related Classification Q (Safety-Related) – Safety-Related structures, systems, components, parts and technical services that provide safety-related functions necessary to assure:

a. The integrity of the reactor coolant pressure boundary; or

b. The capability to shut down the reactor and maintain it in a safe shutdown condition; or

c. The capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to 10CFR Part 50.34(a)(1) or 10CFR Part 100.11 guideline exposures, as applicable.

Safety-Related Classification N (Nonsafety-Related) – The classification of structures, systems, components, parts and technical services, which do not meet the definition of Safety-Related.

Safety-Related Classification S (Special) – The classification of structures, systems, components, parts, and technical services which do not meet the definition of Safety-Related, but are subject to special regulatory requirements (e.g., Seismic Category I equipment or a level of regulatory

imposed Quality Assurance) or Nonsafety-Related structures, systems, components, parts, and technical services, for which 10 CFR 50, Appendix B is not applicable, but are significant contributors to plant safety. Specific program controls applied to Safety-Related Classification S items are described in Section 24.

3 Design Control

Section 3 of Reference 1 and implementing procedures complies with Criterion III of 10 CFR 50, Appendix B, Section 7.3 of ISO 9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

Computer software used to produce or manipulate data, which is used in ESBWR design and analysis, meets the Quality Assurance requirements of Subpart 2.7 of ASME NQA-1-1994.

The GEH ESBWR - Software Quality Assurance Program Manual,NEDE-33245P (Reference 3) describes the Software Quality Assurance activities to be performed during the software life cycle phases of the ESBWR Safety-Related Classification Q and Safety-Related Classification N digital computer-based I&C system.

4 Procurement and Installation Document Control

Section 4 of Reference 1 and implementing procedures complies with Criterion IV of 10 CFR 50, Appendix B, Section 7.4 of ISO 9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

5 Instructions, Procedures and Drawings

Section 5 of Reference 1 and implementing procedures complies with Criterion V of 10 CFR 50, Appendix B, Section 4.2 of ISO 9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

6 Document Control

Section 6 of Reference 1 and implementing procedures complies with Criterion VI of 10 CFR 50, Appendix B, Section 4.2 of ISO-9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

7 Control of Purchased Items and Services

Section 7 of Reference 1 and implementing procedures complies with Criterion VII of 10 CFR 50, Appendix B, Section 7.4 of ISO 9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

8 Identification and Control of Items

Section 8 of Reference 1 and implementing procedures complies with Criterion VIII of 10 CFR 50, Appendix B, Section 7.5 of ISO 9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

9 Control of Special Processes

Section 9 of Reference 1 and implementing procedures complies with Criterion IX of 10 CFR 50, Appendix B, Section 7.5 of ISO 9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

10 Inspection

Section 10 of Reference 1 and implementing procedures complies with Criterion X of 10 CFR 50, Appendix B, Section 7.4 and 8.2 of ISO 9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

11 Test Control

Section 11 of Reference 1 and implementing procedures complies with Criterion XI of 10 CFR 50, Appendix B, Section 7.4 and 8.2 of ISO 9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

12 Control of Measuring and Test Equipment

Section 12 of Reference 1 and implementing procedures complies with Criterion XII of 10 CFR 50, Appendix B, Section 7.5 of ISO 9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

13 Handling, Storage, and Shipping

Section 13 of Reference 1 and implementing procedures complies with Criterion XIII of 10 CFR 50, Appendix B, Section 7.5 of ISO 9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

14 Inspection, Test, and Operating Status

Section 14 of Reference 1 and implementing procedures complies with Criterion XIV of 10 CFR 50, Appendix B, Section 7.5.3 of ISO 9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

15 Control of Nonconforming Items

Section 15 of Reference 1 and implementing procedures complies with Criterion XV of 10 CFR 50, Appendix B, Section 8.3 of ISO 9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

16 Corrective Action

Section 16 of Reference 1 and implementing procedures complies with Criterion XVI of 10 CFR 50, Appendix B, Section 8.5.2 and 8.5.3 of ISO 9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

17 Quality Assurance Records

Section 17 of Reference 1 and implementing procedures complies with Criterion XVII of 10 CFR 50, Appendix B, Section 4.2.4 of ISO 9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

18 Audits

Section 18 of Reference 1 and implementing procedures complies with Criterion XVIII of 10 CFR 50, Appendix B, Section 8.2.2 and 8.2.3 of ISO 9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

19 Contract Review

Section 4.3 of Reference 2 and implementing procedures complies with Section 5.2 and 7.2.2 of ISO 9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

Procedures for contract and contract amendment review, and coordination of these activities are established and maintained as part of the GEH Quality Assurance Program. Each proposal, contract or order is reviewed to ensure that:

a. The requirements are adequately defined and documented;

b. Any requirements differing from the proposal, contract or order are resolved; and

c. GEH has the capability to meet contractual or order requirements.

20 Control of Customer Supplied Product

Section 4.7 of Reference 2 and implementing procedures complies with Section 7.5.4 of ISO 9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

Customer supplied product shall be properly identified, maintained and stored through the use of established procedures, maintained as part of the GEH Quality Assurance Program.

21 Training

Section 4.18 of Reference 2 and implementing procedures complies with Section 6.2.2 of ISO 9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

Procedures for identifying the training needs are established and maintained as part of the GEH Quality Assurance Program. Training for personnel performing activities affecting quality is provided and appropriate records are kept in accordance with GEH procedures.

All GEH personnel on the ESBWR Team shall be indoctrinated and trained in the requirements of this Quality Assurance Program and implementing procedures. Records of this indoctrination and training shall be maintained in accordance with the applicable GEH procedures.

22 Servicing

Section 4.19 of Reference 2 and implementing procedures complies with Section 7.5.1 of ISO 9001:2000 (applicable to Safety-Related Classification N only). There is no requirement for servicing of the new plant design for the ESBWR Contract.

23 Statistical Techniques

Section 4.20 of Reference 2 and implementing procedures complies with Section 8.2 and 8.4 of ISO 9001:2000 (applicable to Safety-Related Classification N only) and the Quality Assurance requirements of the ESBWR Contract.

Where appropriate, the need for applying statistical techniques required for establishing, controlling and verifying process capability and product characteristics, shall be identified. Documented GEH procedures are established and maintained to implement and control the application of those statistical techniques required for problem solving, root cause determination and continuous improvement / process controls.

24 Safety-Related Classification S Controls

24.1 Nonsafety-Related SSC Quality Controls

Specific program controls are applied to Nonsafety-Related SSCs, for which 10 CFR 50, Appendix B is not applicable, that are significant contributors to plant safety. The following clarify the applicability of the QA Program to the nonsafety-related SSCs and related activities.

24.1.1 Organization

The verification activities described in this part may be performed by the GEH line organization.

24.1.2 QA Program

GEH QA requirements of Nonsafety-Related SSCs are contained in this document and appropriate procedures. Suppliers of these SSCs or related services describe the quality controls applied in appropriate procedures; a new or separate QA program is not required.

24.1.3 Design Control

GEH shall establish design control measures to ensure that the contractually established design requirements are included in the design. These measures ensure that applicable design inputs are included or correctly translated into the design documents, and deviations form those requirements are controlled. Design verification shall be performed in accordance with GEH internal QA program requirements.

24.1.4 Procurement Document Control

Procurement documents for items and services obtained by or for GEH shall include or reference documents describing applicable design bases, design requirements, and other requirements necessary to ensure component performance. The procurement documents are controlled to address deviations form the specified requirements.

24.1.5 Instructions, Procedures, and Drawings

GEH shall provide documents such as, but not limited to, written instructions, plant procedures, drawings, vendor technical manuals, and special instructions in work orders, to direct the performance of activities affecting quality. The method of instruction employed shall provide an appropriate degree of guidance to the personnel performing the activity to achieve acceptable functional performance of the SSC.

24.1.6 Document Control

GEH shall establish controls for the issuance and change of documents that specify quality requirements or prescribe activities affecting quality to ensure that correct documents are used. These controls include a review and approval of documents, identification of the appropriate revision for use, and measures to preclude the use of superseded or obsolete documents.

24.1.7 Control of Purchased Items and Services

GEH shall establish measures, such as inspection of items or documents upon receipt or acceptance testing, to ensure that all purchased items and services conform to appropriate procurement documents. Suppliers of these SSCs or

related services shall be qualified in accordance with GEH internal QA program requirements.

24.1.8 Identification and Control of Purchased Items

GEH shall establish measures where necessary, to identify purchased items and preserve their functional performance capability. Storage controls take into account appropriate environmental, maintenance, or shelf life restrictions for the items.

24.1.9 Control of Special Processes

GEH shall establish process and procedure controls for special processes, including welding, heat treating, and nondestructive testing. These controls are based on applicable codes, standards, specifications, criteria, or other special requirements for the special process.

24.1.10 Inspection

GEH shall establish documented instructions to ensure necessary inspections are performed to verify conformance of an item or activity to specified requirements or to verify that activities are satisfactorily accomplished. These inspections may be performed by personnel in the line organization through the GEH independent verification (IV) / simultaneous verification (SV) process that utilizes knowledgeable personnel to perform the verification function.

24.1.11 Test Control

GEH shall establish measures to identify required testing that demonstrates that equipment conforms to design requirements. These tests are performed in accordance with test instructions or procedures. The test results are recorded, and authorized individuals evaluate the results to ensure that test requirements are met.

24.1.12 Control of Measuring and Test Equipment (M&TE)

GEH shall establish measures to control M&TE use, and calibration and adjustment at specific intervals or prior to use.

24.1.13 Handling, Storage, and Shipping

GEH shall establish measures to control the handling, storage, cleaning, packaging, shipping, and preservation of items to prevent damage or loss and to minimize deterioration. These measures include appropriate marking or labels, and identification of any special storage or handling requirements.

24.1.14 Inspection, Test, and Operating Status

GEH shall establish measures to identify items that have satisfactorily passed required tests and inspections and to indicate the status of inspections, test, and operability as appropriate.

24.1.15 Control of Nonconforming Items

GEH shall establish measures to identify and control items that do not conform to specified requirements to prevent their inadvertent installation or use.

24.1.16 Corrective Action

GEH shall establish measures to ensure that failures, malfunctions, deficiencies, deviations, defective components, and nonconformances are properly identified, reported, and corrected.

24.1.17 Records

GEH shall establish measures to ensure records are prepared and maintained to furnish evidence that the above requirements for design, procurement, document control, inspection, and test activities have been met.

24.1.18 Audits

GEH shall establish measures for line management to periodically review and document the adequacy of the process and take any necessary corrective action. Audits independent of line management are not required. Line management is responsible for determining whether reviews conducted by line management or audits conducted by any organization independent of line management are appropriate. If performed, audits are conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings, and inspection and test activities.

24.2 Nonsafety-Related SSCs Credited for Regulated Events

The following criteria apply to fire protection (10 CFR 50.48), anticipated transients without scram (ATWS) (10 CFR 50.62), and the station blackout (SBO) (10 CFR 50.63) SSCs that are not safety-related.

GEH shall implement quality requirements to the fire protection system in accordance with Regulatory Position 1.7, “Quality Assurance,” in Regulatory Guide 1.189, “Fire Protection for Operating Nuclear Power Plants.”

GEH shall implement quality requirements to ATWS equipment in accordance with Generic Letter 85-06, “Quality Assurance Guidance for ATWS Equipment That Is Not Safety Related.”

GEH shall implement quality requirements to SBO equipment in accordance with Regulatory Position 3.5, “Quality Assurance and Specific Guidance for SBO Equipment That Is Not Safety Related,” and Appendix A, “Quality Assurance Guidance for Non-Safety Systems and Equipment,” in Regulatory Guide 1.155, “Station Blackout.”

24.3 Other Quality Controls

Compliance to other Regulatory Guides and Standards and their respective revisions, including exceptions, alternatives and clarifications are addressed in the appropriate Design Control Document (DCD) sections and in DCD Table 17.0-1 (Reference 4).

25 References

1. NEDO-11209-04A, GE Nuclear Energy Quality Assurance Program Description.
2. NEDO-32280, GE Nuclear Energy ISO-9001 Quality System Description.
3. NEDE-33245P, ESBWR - Software Quality Assurance Program Manual.
4. 26A6642BW, ESBWR Design Control Document, Chapter 17 Quality Assurance.

Enclosure 2

MFN 10-007

GE Hitachi Nuclear Energy, "Quality Assurance Requirements for Suppliers of Equipment and Services to the GEH ESBWR Project," NEDO-33260, Revision 5, April 2008.

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GE Hitachi Nuclear Energy

3901 Castle Hayne Rd
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NEDO-33260
Revision 5
Class I
DRF 0000-0049-6867

APRIL 2008

QUALITY ASSURANCE REQUIREMENTS FOR SUPPLIERS OF EQUIPMENT AND SERVICES TO THE GEH ESBWR PROJECT

Approved by:

M. Harvey
Manager, Nuclear Plant Projects Quality

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Appendix

Foreword

Suppliers of equipment and services to the GEH ESBWR Project shall meet the requirements of this document. This document does not supersede any requirements of the Contract/Purchase Order. If the Supplier believes that an inconsistency exists between this document and the specification(s) and referenced codes and standards in the Contract/Purchase Order, the Supplier shall immediately notify the Buyer for resolution.

1 Organization

The Supplier and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services, as defined in Section 2.1, shall each have and implement a Quality Assurance Program conforming to Basic Requirement 1 and Supplement 1S-1 of ASME NQA-1-1994.

2 Quality Assurance Program

The Supplier and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services, as defined in Section 2.1, shall each have and implement a Quality Assurance Program conforming to Basic Requirement 2 and Supplements 2S-1, 2S-2, 2S-3, and 2S-4 of ASME NQA-1-1994.

Applicable requirements of the Buyer's Contract/Purchase Order, the list of technical, quality and administrative requirements provided with the Contract/Purchase Order as Attachment T, and the requirements of this document (including changes/supplements of the Contract/Purchase Order) shall be passed on to all participating organizations within the Supplier and sub-tier suppliers. The Supplier shall assure that sub-tier suppliers comply with the Buyer's Contract/Purchase Order requirements.

Supplier shall establish, maintain and implement a documented Quality Assurance Program consistent with the quality classification of the assigned work scope, as defined below.

Supplier shall grant to Buyer, Buyer's Customer, and/or appropriate Regulatory Body representatives access to facilities for the purposes of reviewing status and completion progress of the Contract/Purchase Order work scope, manufacturing records (including Supplier's un-priced Contract/Purchase Orders), procedures, and quality records applicable to the work defined in the Contract/Purchase Order. This shall include the option to witness, check or audit all phases of Supplier's operation (including tests and inspections) as it pertains to the work on order. Manufacturing process procedures and travelers, inspection and test procedures, and other documents that control activities important to the acceptability of the work on an order shall be made available to the Buyer during surveillances and audits. A revision-controlled, English translation copy of these documents shall be made available to the Buyer during surveillances and audits. Supplier shall assure the same access to sub-tier supplier's facilities and operations.

2.1 Safety-Related Classification System

The ESBWR Project uses the Safety-Related classifications Q, S, and N as defined below. This is a classification system used for structures, systems, components, parts, and technical services. This document shall be applied to all classifications

including both the ASME Code and non-ASME Code items. Unless otherwise specified, the requirements specified in this document apply to all classifications.

2.1.1 Class Q (Safety-Related)

Safety-Related structures, systems, components, parts, and technical services are those that provide safety-related functions necessary to assure:

a. The integrity of the reactor coolant pressure boundary; or

b. The capability to shut down the reactor and maintain it in a safe shutdown condition; or

c. The capability to prevent or mitigate the consequences of accidents that could result in potential offsite exposures comparable to 10CFR50.34(a)(1) or 10CFR100.11 guideline exposures, as applicable.

Class Q structures, systems, components, parts, and technical services are items that are required to be designed and manufactured under a Quality Assurance Program complying with 10 CFR 50, Appendix B, or commercial grade items which have successfully completed the dedication process.

In all cases, Class Q includes Safety-Related design, analysis, inspection, testing, fabrication, replacement of parts, or consulting services that are associated with the Class Q structures, systems, components, parts, and technical services, whether these services are performed by the Supplier or others.

The Supplier and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services shall each have and implement a Quality Assurance Program conforming to applicable sections and elements of ASME NQA-1-1994 Edition, Parts I and II.

2.1.2 Class S (Special)

Structures, systems, components, parts, and technical services that do not meet the definition of Safety-Related, but are subject to special regulatory requirements (e.g., Seismic Category I equipment or equipment with regulatory imposed Quality Assurance requirements), or Nonsafety-Related structures, systems, components, parts, and technical services, for which 10 CFR 50, Appendix B is not applicable, but are significant contributors to plant safety, are classified as Class S.

The Supplier and sub-tier suppliers of Class S structures, systems, components, parts, and technical services shall each have and implement a Quality Assurance Program conforming to applicable sections and elements, as described below.

For ASME Code Section III equipment that is classified as Class S, the Supplier must meet the requirements of Section 2.1.4.

2.1.2.1 Organization

The normal line organization shall verify compliance with the following criteria. A separate or dedicated QA organization is not required.

2.1.2.2 QA Program

The Supplier's procedures shall describe the quality controls applied to the subject equipment. A new or separate QA program is not required.

2.1.2.3 Design Control

Supplier shall establish design control measures to ensure that the contractually established design requirements are included in the design. These measures shall ensure that applicable design inputs are included or correctly translated into the design documents, and deviations from those requirements are controlled.

2.1.2.4 Procurement Document Control

Procurement documents for items and services obtained by or for the Supplier shall include or reference documents describing applicable design bases, design requirements, and other requirements necessary to ensure item/service performance. The procurement documents shall be controlled to address deviations from the specified requirements.

2.1.2.5 Instructions, Procedures, and Drawings

Supplier shall provide documents such as, but not limited to, written instructions, plant procedures, drawings, vendor technical manuals, and special instructions in work orders, to direct the performance of activities affecting quality. The method of instruction employed shall provide an appropriate degree of guidance to the personnel performing the activity to achieve acceptable functional performance of the structures, systems, components, parts, and technical services.

2.1.2.6 Document Control

Supplier shall establish controls for the issuance and change of documents that specify quality requirements or prescribe activities affecting quality to ensure that correct documents are used. These controls shall include a review and approval of documents, identification of the appropriate revision for use, and measures to preclude the use of superseded or obsolete documents.

2.1.2.7 Control of Purchased Items and Services

Supplier shall establish measures, such as inspection of items or documents upon receipt or acceptance testing, to ensure that all purchased items and services conform to appropriate procurement documents.

2.1.2.8 Identification and Control of Purchased Items

Supplier shall establish measures where necessary, to uniquely identify purchased items and preserve their functional performance capability. Storage controls shall take into account appropriate environmental, maintenance, and shelf life restrictions for the items.

2.1.2.9 Control of Special Processes

Supplier shall establish process and procedure controls for special processes such as welding, heat treating and nondestructive testing. These controls shall be based on applicable codes, standards, specifications, criteria, and other special requirements for the special process.

2.1.2.10 Inspection

Supplier shall establish documented instructions to ensure necessary inspections are performed to verify conformance of an item or activity to specified requirements or to verify that activities are satisfactorily accomplished. Inspections need not be performed by personnel who are independent of the line organization. However, inspections shall be performed by knowledgeable personnel and shall not be performed by the individual that accomplished the activity.

2.1.2.11 Test Control

Supplier shall establish measures to identify required testing that demonstrates that equipment conforms to design requirements. These tests shall be performed in accordance with test instructions or procedures. The test results shall be recorded, and authorized individuals shall evaluate the results to ensure that test requirements are met.

2.1.2.12 Control of Measuring and Test Equipment (M&TE)

Supplier shall establish measures to control M&TE use, and calibration and adjustment at specific intervals or prior to use.

2.1.2.13 Handling, Storage, and Shipping

Supplier shall establish measures to control the handling, storage, cleaning, packaging, shipping, and preservation of items to prevent damage or loss and to minimize deterioration. These measures include appropriate marking or labels, and identification of any special storage or handling requirements.

2.1.2.14 Inspection, Test, and Operating Status

Supplier shall establish measures to identify items that have satisfactorily passed required tests and inspections and to indicate the status of inspections, test, and operability as appropriate.

2.1.2.15 Control of Nonconforming Items

Supplier shall establish measures to identify and control items that do not conform to specified requirements to prevent their inadvertent installation or use.

2.1.2.16 Corrective Action

Supplier shall establish measures to ensure that failures, malfunctions, deficiencies, deviations, defective components, and nonconformances are properly identified, reported, and corrected.

2.1.2.17 Records

Supplier shall establish measures to ensure records are prepared and maintained to furnish evidence that the above requirements for design, procurement, document control, inspection, and test activities have been met.

2.1.2.18 Audits

Supplier shall establish measures for line management to periodically review and document the adequacy of the Supplier's processes and quality controls applied to items and services, and take any necessary corrective action. Audits independent of line management are not required. Line management is responsible for determining whether reviews conducted by line management or audits conducted by any organization independent of line management are appropriate. If performed, audits shall be conducted and documented to verify compliance with design and procurement documents, instructions, procedures, drawings, and inspection and test activities.

2.1.3 Class N (Nonsafety-Related)

Classification of structures, systems, components, parts, and technical services, which do not meet the definition of either Class Q or Class S categories.

The Supplier and sub-tier suppliers of Class N structures, systems, components, parts, and technical services shall each have and implement:

a. An ISO-9001/2000 Quality Management System with current certification, or

b. A Quality Assurance Program conforming to applicable sections and elements of ISO-9001/2000, or

c. A system of controlled and documented processes and quality requirements appropriate for the scope of work and reasonably assuring an acceptable level of quality in the delivered product or service.

For ASME Code Section III equipment that is classified as Class N, the Supplier must meet the requirements of Section 2.1.4.

2.1.4 ASME Code Section III

For items and materials manufactured to Section III of the ASME B&PV Code, 2001 Edition, 2003 Addenda, the ASME Code Supplier and sub-tier suppliers shall each have and implement a Quality Assurance Program in compliance with the Basic Requirements and Supplements of ASME NQA-1-1994 Edition, Quality Assurance Program Requirements for Nuclear Facilities, as modified and supplemented in NCA-4110 (b) and NCA 4134.

For metallic material manufacturers and material Suppliers, the Quality System Programs shall meet the requirements of NCA-3800. For non-metallic material manufacturers and material Suppliers, the Quality System Programs shall meet the requirements of NCA-3900.

For items that are Class Q and ASME Code, the requirements of Paragraph 2.1.1 apply. Special attention is required on Safety-Related ASME components, which contain individual parts, which by code definition are specifically exempt from code requirements. If these parts perform a Safety-Related function, they must be provided as Class Q in accordance with a QA Program accepted by the Buyer.

2.2 Quality Assurance Plans

Supplier shall prepare one or more Quality Assurance Plans for any equipment that is in the Supplier's scope. These Quality Assurance Plans shall be submitted and approved by the Buyer prior to start of fabrication activities and shall be revised, if necessary, to reflect Buyer's comments. Each Quality Assurance Plan shall describe how the Supplier's Quality Assurance Program will be applied to the ESBWR Project for each applicable quality classification and shall address all requirements defined by the Contract/Purchase Order.

Quality Plans shall also contain the following as a minimum:

a. Scope of work;

b. List of Procedures for special processes;

c. Schedules of key activities;

d. Inspection and Test Plans including witness and hold points specified by the Buyer in the Notification List provided with the Buyer's Contract/Purchase Order, as well as Supplier established witness and hold points;

e. Procedure for scheduling and notification of witness and hold points;

f. List of Inspection and test procedures; and

g. Specification(s) and/or drawing(s) for structures, systems, and identifying Quality Plan boundaries.

2.3 Personnel Training and Qualifications

In addition to the training and qualification requirements of personnel as established in the Supplier's QA Program, the following shall also be accomplished:

a. Suppliers shall assure that personnel of the Supplier and sub-tier suppliers performing work for this project are indoctrinated in the appropriate requirements of this document and other documents specified in the Buyer's Contract/Purchase Order. Records of indoctrination shall be maintained in accordance with the Supplier's QA Program.

b. For Suppliers of Class Q and ASME Code Section III items, the Supplier shall establish measures to verify that qualification and certification of Supplier and sub-tier supplier nondestructive examination personnel satisfy the requirements of the American Society for Nondestructive Testing Recommended Practice SNT-TC-1A 1992 [per ASME Section III, 2001 Edition, NX-5500]. For Class N and S items, a Buyer approved equivalent standard for qualification of nondestructive examination personnel may be used.

c. Personnel training and qualification certifications shall be subject to review, surveillance, inspection, and audit by Buyer and Buyer's Customer.

d. Lead Auditors shall be certified per ASME/NQA-1-1994, Supplement 2S-3 and Appendix 2A-3.

e. Inspection and Test personnel shall be certified per ASME/NQA-1-1994, Supplement 2S-1 and Appendix 2A-1.

3 Design Control

The Supplier and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services shall each have and implement a Quality Assurance Program conforming to Basic Requirement 3, Supplement 3S-1, and Subparts 2.7 and 2.20 of ASME NQA-1-1994.

3.1 Buyer Supplied Software

Suppliers using Buyer supplied software shall immediately document and report to the Responsible Engineer identified on the Contract/Purchase Order, any problems, errors or discrepancies found in the software.

4 Procurement Document Control

The Supplier and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services shall each have and implement a Quality Assurance Program conforming to Basic Requirement 4 and Supplement 4S-1 of ASME NQA-1-1994.

4.1 Control of Information Between GEH and Suppliers

The Contract/Purchase Order is the only applicable document to control the design bases and other requirements necessary to assure adequate quality, and shall be included or referenced in documents for procurement of items or services.

Task input and output documents are identified in the Contract/Purchase Order by document identity, revision and status.

Documents may be transported as hard copy or electronic files, as directed by the Contract/Purchase Order. Electronic transmittal may be in the form of CDRom/DVDRom or as a file transferred by network connection through services such as ProjectNet or other collaboration or document management tools. File identification by document identity, revision and status shall be maintained during transport.

4.2 Supplier Change Requests (SCR)

The Supplier shall not deviate from the technical and quality requirements without Buyer's approval. Technical and quality requirements are defined as follows:

a. The list of technical, quality and administrative requirements are shown as an Attachment T or included in the Buyer's Contract/Purchase Order.

b. Applicable codes and standards invoked by the documents specified in Attachment T or the Buyer's Contract/Purchase Order.

c. Supplier generated documents, which have been approved without comments by the Buyer.

Any exception, deviation or change to the Buyer's technical and quality assurance requirements, codes and standards specified in the Contract/Purchase Order proposed by the Supplier shall be documented on the Buyer's Supplier Change Request form (SCR) and submitted to the Buyer for review and approval prior to implementation of the change requested.

The Supplier shall use the form and instructions included in Appendix B of this document for preparing the SCR.

The Supplier shall not proceed with actions proposed in the SCR until approved by the Buyer. In the event the Supplier proceeds without Buyer's approval, all costs incurred are to the Supplier's account.

If the Buyer approves the SCR, a copy of the approved SCR will be returned to the Supplier. If the change affects Buyer's documents, the documents will be revised and incorporated by revision to the Contract/Purchase Order.

If the Change affects Supplier's documents, the Supplier upon receipt of the approved SCR shall revise such documents and submit them for Buyer's approval.

5 Instructions, Procedures, and Drawings

The Supplier and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services shall each have and implement a Quality Assurance Program conforming to Basic Requirement 5 of ASME NQA-1-1994.

6 Document Control

The Supplier and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services shall each have and implement a Quality Assurance Program conforming to Basic Requirement 6 and Supplement 6S-1 of ASME NQA-1-1994.

7 Control of Purchased Items and Services

The Supplier and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services shall each have and implement a Quality Assurance Program conforming to Basic Requirement 7 and Supplement 7S-1 of ASME NQA-1-1994.

The Supplier shall audit sub-tier suppliers of Class Q items at least once every three years or at least once within the life of the activity.

The Supplier shall audit sub-tier suppliers of ASME Code items prior to accepting materials. ASME Code suppliers shall not be accepted based solely on their holding a Quality Systems Certificate. Periodic re-audit of ASME Code suppliers shall be performed.

7.1 Required Document Submittals

Document submittals, when required for approval and/or information by the Buyer, will be identified on the Contract/Purchase Order, or as a document submittal list provided with the Contract/Purchase Order as Attachment A or Table 2. Buyer and Supplier may change this list of document submittals during the

term of the Contract/Purchase Order as agreed to with such change incorporated as a revision to the Contract/Purchase Order.

Procedures and other documents specified in the list of document submittals, which will be used by the Supplier or sub-tier suppliers to accomplish the work on an order, shall be submitted to the Buyer for review and approval prior to use. Supplier shall indicate acceptance of sub-tier supplier documents prior to submittal to the Buyer for review. Sufficient time shall be allowed for the Buyer to review documents and submit comments for incorporation without impacting the Supplier's schedule. Procedure shall represent actual practice and shall be in sufficient detail to define the critical parameters for the process involved.

The Supplier shall provide the Buyer with a list of document submittals being provided to the Supplier by sub-tier suppliers that relate to Supplier's work defined on the Contract/Purchase Order. As Buyer and Supplier agree, specific documents for the Supplier's sub-tier supplier shall be included on the list of document submittals to Buyer. In the case when the fabricator is a direct subsidiary of the Supplier, then the fabricator's documents shall be submitted to satisfy the submittal requirements. In addition to the submittals required by the list of document submittals, the Supplier shall provide, to the extent possible, copies to the Buyer of such additional submittals from sub-tier suppliers as Buyer may request. These additional sub-tier supplier documents may be submitted to the Buyer in the language as received by the Supplier.

Consistent with the list of document submittals, additional detailed information such as schedule, number of copies, document numbers, and revision level shall be developed and submitted to the Buyer for information or approval. The contents of this submittal may be changed without revising the Contract/Purchase Order as long as the list of documents remains consistent with the list of document submittals.

A reusable document is a supplier document, which has been approved by the Buyer for one purchase package and, by mutual agreement, may be used to fulfill without change, a document required on another purchase package. Such reusable documents shall be identified on the list of document submittals.

Approval by the Buyer of Supplier's or sub-tier supplier's document does not relieve the Supplier of his responsibility to provide design, material, and equipment, which will fulfill the requirements of the Contract/Purchase Order.

Unless authorized by the Buyer and/or specifically controlled by Supplier's QA Program, fabrication and/or work affected by a document subject to Buyer's approval shall not be started until the applicable procedures, drawings or design data have been approved or approved with comment by Buyer. If the Supplier proceeds with work affected by a document subject to Buyer's approval prior to obtaining Buyer's approval, this work shall be at the Supplier's risk. Concurrence by Supplier with Buyer's comments is required if Supplier proceeds with the work

involving documents approved with comment. In this event, Supplier must promptly submit revised documents incorporating all comments, and the work and resulting records must reflect compliance with the comments. Revised areas should be clearly identified by a revision symbol at the change location or noted on a tabulation sheet attached to the document. In no event shall the Buyer's comments change the Contract/Purchase Order requirements, including scheduled delivery dates.

7.2 Commercial Grade Dedication

Dedicated commercial grade materials/parts for use as components in Class Q systems are not allowed unless the Supplier can provide sufficient evidence that the item(s) is not available from sources qualified to produce nuclear Safety-Related materials/parts, and can demonstrate the grade (i.e. quality and performance) of the item(s) to be used is equal to or higher than those produced by a qualified Safety-Related supplier. The Supplier shall also meet the following requirements:

a. The Buyer shall be notified and approval is required before the use of the component(s), which contain dedicated commercial grade materials/parts.

b. The dedication program, evaluation, and dedication plan for the item(s) shall be subject to Buyer review and concurrence prior to performing the dedication process.

c. The dedication program shall meet the requirements set forth in the United States Nuclear Regulatory Commission Generic Letters 89-02 and 91-05, and the related EPRI Report NP-5652. The process should also take into account the requirements defined in 10CFR21.

7.3 Certification and Release for Shipment

Prior to release for shipment, the Supplier shall perform a final inspection of the product to verify compliance with Contract/Purchase Order requirements, and also verify the adequacy of the documented evidence of this inspection.

Conditional release Purchase Orders shall not be released for shipment until Buyer clears all conditionalities.

A Product Quality Certificate (PQC) is required for Quality Class Q and S items. The Supplier shall complete and process the PQC form provided in the Contract/Purchase Order.

For source inspected items, the Buyer's PQC form (or a Buyer approved equivalent) requires the Supplier's and Buyer's Quality Representative's signatures of acceptance on the form. If the Buyer's Customer representative is present for final

release he/she will sign the PQC in the appropriate block. If the representative is not present for the final release, N/A should be included in the signature block.

For items not requiring source inspection by Buyer's Quality Representative, Supplier shall use the Buyer's PQC (or a Buyer approved equivalent), which will require the Supplier's QC signature.

If items required for Contract/Purchase Order are not included in a shipment, the Supplier shall identify on the PQC only those items included in the shipment and indicate on the PQC "Partial Shipment." On the final PQC, state: "This completes the Contract/Purchase Order."

Supplier shall review the Product Quality Certificate for accuracy of content and freedom from errors.

It is IMPORTANT that a copy of the approved PQC accompany the product to its destination. One (1) copy of each approved Deviation Disposition Request (including attachments) listed on the Product Quality Certification shall be attached to the Product Quality Certificate and accompany the product to its destination.

8 Identification and Control of Items

The Supplier and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services shall each have and implement a Quality Assurance Program conforming to Basic Requirement 8 and Supplement 8S-1 of ASME NQA-1-1994.

9 Control of Processes

The Supplier and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services shall each have and implement a Quality Assurance Program conforming to Basic Requirement 9 and Supplement 9S-1 of ASME NQA-1-1994.

10 Inspection

The Supplier and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services shall each have and implement a Quality Assurance Program conforming to Basic Requirement 10, Supplement 10S-1, and Subparts 2.4, 2.5, and 2.8 of ASME NQA-1-1994.

10.1 Inspection and Test Plans

The Supplier shall submit to the Buyer for approval, Inspection and Test Plans for the components and/or systems in their work scope. The Inspection and Test Plans shall identify frequency of each inspection/test, sequences of

inspection/tests, quality characteristics to be inspected/tested/examined, procedures to be used for each inspection test or special process, methods of inspection/test/examination, and accept/reject criteria. The Supplier shall also include on the Inspection and Test Plans the Buyer requested and Supplier established witness and hold points for the Buyer. Each Witness/Hold point should have a unique identification number assigned to it.

The Buyer and Buyer's Customer will review the inspection and test plans and may designate additional witness and/or hold points on the plan. Prior to submittal of inspection and test plans for Buyer approval, the Buyer's responsible engineer and/or quality representative may participate in planning with the Supplier to establish the witness and/or hold point notifications. Witness and/or hold point notifications as agreed to by the Buyer and Supplier will be indicated on the inspection and test plans. Should any quality problems develop during fabrication, the witness and/or hold points may be revised as required to assure Supplier compliance to contractual technical and quality assurance requirements.

10.1.1 Hold, Witness and Surveillance Points

A hold point is a designated stopping place during or following a specific activity at which the Buyer's inspection or witness is required before further work can be performed. The Supplier shall not proceed with processing past this point without Buyer's written approval unless prior written authorization is obtained from Buyer, or it is 48 hours after the scheduled time and date of a properly scheduled and notified Hold Point and the Buyer representative is not in attendance. The Buyer may ask for a delay and reschedule with at least 24 hours notice in advance of the scheduled time and date.

A witness point is an important step in manufacturing where the Supplier is obligated to notify the Buyer in advance of the operation performed, so that it may be witnessed. If the Buyer is not present at the time and date specified by the Supplier, the Supplier may proceed. The Buyer may verbally waive the witness point.

A surveillance point is a step in manufacturing where the Buyer may monitor or observe an activity to verify whether it confirms to specified requirements.

The Buyer may waive the witness of events. Waivers for Hold Points will be in writing. Waivers in no way absolve or relieve Supplier of complying with contractual requirements. Except for final release, the Supplier is not required to delay Hold Point events should the Buyer's Quality personnel not appear within 48 hours after the notified time, unless the Buyer specifically requests a delay and reschedule at least 24 hours in advance of the scheduled event.

Should the Supplier or Supplier's sub-tier supplier fail to provide proper and timely notification, the Buyer may require the Supplier or the sub-tier supplier to redo/re-perform the event scheduled for witnessing or inspection.

10.1.2 Notification Requirements

Unless contractually advised otherwise, the Supplier shall meet the following notification requirements.

Hold Points – Supplier shall provide 45 days advanced planning notice, 14 days preliminary notification, and 7 days final notification confirmation of the scheduled event (excluding Saturday, Sunday and Holidays).

Witness Points – Supplier shall provide 21 days advanced planning notice, 14 days preliminary notification, and 7 days final notification confirmation of the scheduled event (excluding Saturday, Sunday and Holidays).

Surveillance Points – Supplier shall provide 21 days advanced planning notice (excluding Saturday, Sunday and Holidays).

11 Test Control

The Supplier and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services shall each have and implement a Quality Assurance Program conforming to Basic Requirement 11 and Supplements 11S-1 and 11S-2 of ASME NQA-1-1994.

12 Control of Measuring and Test Equipment

The Supplier and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services shall each have and implement a Quality Assurance Program conforming to Basic Requirement 12 and Supplement 12S-1 of ASME NQA-1-1994.

13 Handling, Storage, and Shipping

The Supplier and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services shall each have and implement a Quality Assurance Program conforming to Basic Requirement 13, Supplement 13S-1, and Subparts 2.1, 2.2, and 2.15 of ASME NQA-1-1994.

13.1 Packaging, Identification and Marking

Prior to release for delivery to Buyer or Buyer's Customer, each piece part, component, or assembly shall be marked by stenciling, stamping, or marking by any suitable means not deleterious to the product. Marking or tagging of individual packages of like items at each packaging level is required. Hardware and/or software must be compatible and traceable to supporting documentation. (Certified material test reports, processing records, etc.)

Marking shall include, as a minimum, the following:

a. GEH purchase order number and revision number,

b. Purchase order item number,

c. Item nomenclature,

d. Item drawing number, part number (including revision level), and/or catalog number,

e. Material traceability data (ingot/heat number, heat treat lot number, heat code, serial number, etc.), and

f. Any other information as required by the Buyer's purchase order.

14 Inspection, Test, and Operating Status

The Supplier and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services shall each have and implement a Quality Assurance Program conforming to Basic Requirement 14 of ASME NQA-1-1994.

15 Control of Nonconforming Items

The Supplier and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services shall each have and implement a Quality Assurance Program conforming to Basic Requirement 15 and Supplement 15S-1 of ASME NQA-1-1994.

15.1 Nonconformance and Disposition of Supplier Deviations

Non-conformances to the Buyer's technical requirements with the disposition of "Repair" or "Use As Is" shall be submitted to the Buyer for review and approval. The Supplier shall be responsible for resolution of the Buyer's comments, if any, prior to implementation. The Buyer's technical requirements are those specified in the Contract/Purchase Order (including Codes and Standards) and the Supplier specifications, drawings, and documents that require Buyer's approval.

A deviation is defined as any nonconformance to Buyer's technical requirements, which will not or cannot be corrected to fully comply with specified requirements. Deviations shall be documented on the Buyer's Deviation Disposition Request (DDR) form for review and disposition.

DDRs are used to disposition a non-conformance on a one-time basis. The Supplier, using the form and following the instructions included in Appendix A of this document, shall prepare the DDR.

Buyer shall approve or disapprove Supplier's proposed disposition, or provide an alternate disposition, stating any necessary action to bring the part to an acceptable condition.

Where the DDR disposition is "disapproved," the hardware shall not be used unless it is returned to a compliant condition or to an alternate acceptable condition as defined by the disposition statement(s).

Where the DDR disposition is "other," action taken to meet an acceptable condition shall be as specified in the disposition statement(s).

Normally, the Buyer will return a copy of the DDR disposition to the Supplier. However, if verification of work on the product, caused by the disposition of the DDR is required, the original of the DDR will be returned to the Supplier for verification signatures. The verified original DDR shall be returned to the Buyer. A copy of the completed DDR will be returned to Supplier.

Buyer's response to a deviation request shall be only as authorized by the signature of the Buyer's procurement, technical and/or quality representative. Such authorization shall be to accept deviation(s) with provisions as submitted; to accept deviations subject to Buyer's authorized conditions; or to disapprove the deviation request.

Further fabrication operations, after the detection of the deviation and prior to Buyer's decision on the DDR, shall be at Supplier's risk.

Application of ASME Code Cases or Interpretations not listed in Buyer's technical specifications requires Buyer's approval by use of the DDR or Contract/Purchase Order change.

15.2 Reporting of Significant Defects and Failures to Comply

Suppliers and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services shall be responsible for the reporting of defects and failures to comply as defined in the United States Code of Federal Regulations Title 10 part 21, latest edition.

For items procured by the Buyer, the Supplier shall provide notification to the Buyer of any defect or failure to comply that is reported to the NRC. If the defect or failure to comply is discovered by the Supplier and the Supplier determines that it does not have the capability to perform the evaluation to determine if a defect exists, then the Supplier shall inform the Buyer within five (5) working days of this determination so that the Buyer may evaluate the defect or failure to comply.

The Supplier shall ensure that each procurement document issued by him or her, specifies, when applicable, that the provisions of this section apply.

Written communications and reports concerning this requirement must be addressed to the Buyer as defined in the Contract/Purchase Order. The written report required by this section shall include, but need not be limited to, the following information, to the extent known:

a. Name and address of the individual or individuals informing the Buyer.

b. Identification of the activity of the basic component supplied, which fails to comply or contains a defect.

c. Identification of the firm supplying the basic component, which fails to comply or contains a defect.

d. Nature of the defect or failure to comply and the safety hazard, which is created or could be created by such defect or failure to comply.

e. The date on which the information of such defect or failure to comply was obtained.

f. The corrective action, which has been, is being, or will be taken; the name of the individual or organization responsible for the action; and the length of time that has been or will be taken to complete the action.

g. Any advice related to the defect or failure to comply about the activity or basic component that has been, is being, or will be given to purchasers or licensees.

16 Corrective Action

The Supplier and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services shall each have and implement a Quality Assurance Program conforming to Basic Requirement 16 of ASME NQA-1-1994.

17 Quality Assurance Records

The Supplier and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services shall each have and implement a Quality Assurance Program conforming to Basic Requirement 17 and Supplement 17S-1 of ASME NQA-1-1994.

17.1 Document and Record Quality Requirements

The submittal of QA records shall be of a quality suitable for reproduction and should be submitted electronically in Adobe Acrobat .PDF format or TIFF format when possible.

When non-electronic documents are permitted by the Buyer, the following are the minimum quality requirements for the Supplier's and sub-tier supplier's non-electronic documents to be submitted to the Buyer in the form of a reproducible, such as drawings, diagrams, parts lists, bill of materials, procedures, specifications, calculations, instruction manuals, performance curves, test reports etc. for Buyer's information and approval as defined in the Contract/Purchase Order or attachments thereto.

a. Documents submitted to the Buyer shall be in Standard English.

b. Documents prepared for the Buyer shall be free from defects (ink marks, copy marks, misalignment, etc.).

c. Submitted drawings or data of non-electronic type must be of sufficiently high quality as to permit scanning into ASCII files and/or microfilming and adequate reproduction of said microfilm by the Buyer. It is preferable that originals be submitted when possible. If reproductions of originals are submitted, they must be full size, black line direct-reading prints. A reproduction must be of original quality having sharp, black, clean well-defined lines with a line density equal to or better than the original. The lettering must be large and of an open style permitting reductions up to 30X and blowback at 14.5X and remain open with no plugging or loss of legibility. The reproduction must maintain an evenly high contrast between image and background over the surface of the document. Reproductions with low contrast or heavy background density with thin, weak lines and lettering are not acceptable and will be returned to the Supplier for upgrading and redrafting at the Supplier's expense.

d. 8.5"X11" documents shall be shipped flat (unfolded) with ship-board (or equivalent) protectors on top and bottom of the package as necessary.

Supplier's documents received at any time that do not meet the above quality requirements will be returned to the Supplier for correction and re-submittal to the Buyer. Documents so returned to the Buyer shall contain the appropriate approved technical content. Buyer shall not be responsible for any delays in equipment or document schedules because of the return of documents for quality corrections. The Supplier shall not be relieved of his document submittal requirements until all such requirements therein, including quality, have been satisfied.

17.2 Required Quality Records

Deliverable quality records, required by Buyer, are specified either in the Contract/Purchase Order, or in the Quality Records List (QRL) identified in the Contract/Purchase Order, and transmitted to Supplier as part of the Contract/Purchase Order. Quality Records shall be legible, identifiable, and readable both in printed and electronic format.

For Class Q items, the QA records, which furnish documentary evidence of the quality of items and activities, shall include at least all the applicable generic record types identified in Table 1 of the NRC Regulatory Guide 1.28, Revision 3. The QA records specified in the regulatory guide are not intended to be all inclusive, and therefore the Supplier is responsible to assure that sufficient QA records are maintained to furnish evidence of quality of items and activities within his scope of work.

The Supplier shall develop and submit a detailed list of QA records, by component/equipment bases, which correspond to the adopted regulatory guide for his scope of work to the Buyer for review and concurrence. This list shall include a retention period, as recommended in Table 1 of NRC Regulatory Guide 1.28, Revision 3. For those QA records not submitted to the Buyer, i.e. considered by the Supplier as proprietary, the Supplier shall mark as such on the list and be responsible for preservation. No such records shall be destroyed or otherwise disposed of without the Buyer's concurrence or sending a copy of such records to the Buyer. When requested by the Buyer, the Supplier shall allow access to the Supplier's proprietary QA records or send a copy of such records to the Buyer.

Quality Records shall contain, as applicable, the following types of information:

a. Buyer's Contract/Purchase Order number, item number and revision utilized.

b. Product identification (name, Buyer's drawing number, equipment package number, or catalog number).

c. Part serial number, heat number, date codes.

d. The Supplier's number of the procedure (including revision level or date of issue), which was approved for use by the Buyer.

e. Test/inspection/examination type and date of performance.

f. Inspection/test/examination results (as required in the Contract/Purchase Order).

g. Identity and certification of inspector/tester/examiner that performed the operation.

Nondestructive examination reports shall indicate the qualification level of the examiner and/or the evaluator.

Heat treatment records shall include, as a minimum, temperatures, holding times, and cooling media and other information as specified.

As records are completed during the course of work, or when required records are generated by the Supplier's sub-tier supplier, the Supplier shall review them for conformance to requirements and note approval on the face of the records prior to submitting them to the Buyer for review and acceptance.

17.2.1 Radiographs

Radiographs, if required, are a quality record and are subject to review by Buyer's quality representative for identification, radiographic quality, quality of the item and for actions taken as a result of radiographic interpretations. Radiographic

Reader Sheets and the Radiographic Shooting Sketch are to be included in both the Radiographs Package and the Quality Records Package.

Supplier shall interpret radiographs prior to presentation to Buyer's quality representative for evaluation. This includes radiographs made by Supplier and sub-tier suppliers.

The final set of radiographs shall be processed with archival quality, i.e. the potential for preserving the radiographic image for forty (40) years.

17.2.2 Material Certifications

Supplier shall obtain and keep on file certificates of chemical analysis and mechanical properties, including results of all other tests required by the applicable ASME, ASTM or Buyer specification for all materials. Each item on the certification is to be marked for identification as to component, part, and project for which the material will be used.

ASME Code welding materials shall be tested and certified in accordance with NX-2400 of ASME Code Section III. Other welding materials shall be tested and certified in accordance with AWS A5.01. Supplier shall obtain certificates of weld metal analysis for each heat of covered electrodes and bare wire.

When required, material certification shall identify the material standard(s) /specification(s) used, and identify the grade, class, heat number and heat-treat condition as applicable. For Code materials, the Certified Material Test Report (CMTR) shall be prepared in accordance with NX-2130 of ASME Code Section III. The material manufacturer or material supplier's Quality System Certificate number and expiration date shall be identified on the CMTR or Certificate of Compliance.

For Class Q items, one copy of all material certifications, including welding materials, shall be submitted to the Buyer for review as soon as Supplier accepts material, but prior to release for fabrication. Material certifications and tests, which have been reviewed and are acceptable shall be stamped or signed by Buyer's quality representative. Copies of the Buyer's accepted certifications are to be submitted as QA Records.

17.2.3 Binders or Packages of Deliverable Quality Records

If the Product Quality Certificate (PQC - see 7.3) is the only deliverable quality record required by the Contract/Purchase Order it need not be bound in a binder.

Quality records for a single component/part, where only a few records are required, need not be transmitted in a binder. Such records shall be compiled into a records package with an index listing all records. Each page shall be numbered sequentially.

When quality records are required for delivery for more than one component/part or for an assembly of parts, the documents shall be bound in a standard stiff pressboard binder, sized for 8-1/2" x 11" paper. Binders shall contain a table of contents listing for each component/part. A divider sheet, tabbed to identify the component/part, may separate documents for each component/part. All PQCs may be grouped under one tab. Each page shall be numbered sequentially.

17.2.4 Presentation and Release of Quality Records

For items source inspected, the quality records specified in the Contract/Purchase Order shall be presented to the Buyer's quality representative for review and acceptance prior to release of product for shipment. Each document and table of contents shall bear evidence of Buyer's quality representative's acceptance. If the records do not comply with contractual requirements, the product shall not be released until satisfactory records are presented.

For each shipment released to the Buyer's facilities, the Supplier shall forward one set of the quality records package(s) with the hardware, unless otherwise specified in the Contract/Purchase Order.

For each shipment, the Supplier shall forward within two weeks:

a. Two sets of Quality Records, one that includes Radiographs if applicable, to the Buyer as specified in the Contract/Purchase Order.

b. The Buyer will then, after review and acceptance, forward one copy of the records to Buyer's Customer.

18 Audits

The Supplier and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services shall each have and implement a Quality Assurance Program conforming to Basic Requirement 18 and Supplement 18S-1 of ASME NQA-1-1994.

Supplier and sub-tier suppliers of Class Q structures, systems, components, parts, and technical services shall assure that their Buyer approved Quality Assurance Program is audited annually to determine the continued acceptability of the Supplier's QA Program.

Internal and external audits shall be conducted in accordance with ASME/NQA-1-1994, Supplement 18S-1.

Appendix A

DDR Form and Instructions for Completion

GE-HITACHI NUCLEAR ENERGY AMERICAS LLC Sheet 1 of __	**DEVIATION DISPOSITION REQUEST** 1. SUPPLIER AND LOCATION

2. PART NAME		3. PART NUMBER	4. DATE INSPECTED
5. PRODUCT	6. MPL NUMBER	7. PROJECT6	8. SUPPLIER JOB NO.

9. IDENTIFY DEVIATING ITEM:

10. DESCRIBE NONCONFORMANCE, PROPOSED DISPOSITION, AND ENGINEERING BASIS:

11. CAUSE OF DEVIATION, ACTION TAKEN TO PRECLUDE RECURRENCE, AND TIME AND POINT OF IMPLEMENTATION:

12. NO. OF SUPPLIER ATTACHMENTS:	13. GEH QC REPRESENTATIVE (QCR) VALIDATION, OR HOW NOTIFIED: DATE	14 SUBMITTAL APPROVAL: DATE

15 GEH DISPOSITION AND JUSTIFICATION (Justification is required for "use as is" or "repair" dispositions):

APPROVED AS PROPOSED ☐
DISAPPROVED ☐
OTHER ☐
NO. OF GHNEA ATTACHMENTS _____

16 DESIGN VERIFICATION DRF LOCATION (Required for "use-as-is" and "repair" dispositions.):

17. GEH APPROVAL SIGNATURES	M/C	COMP	DATE
RESPONSIBLE ENGINEER (RE)			
RESPONSIBLE ENGINEER'S MGR			
LEAD SYSTEM ENGINEER (LSE)			
MATERIALS APPL ENGINEER (MAE)			
PROJECT MANAGER (PM)			
QC ENGINEER (QCE)			
SOURCING			

18. FINAL DISTRIBUTION PQA MASTER FILE

PROCUREMENT QA ☐
SUPPLIER ☐
SOURCING ☐
RE ☐
LSE ☐
MAE ☐
PM ☐
QCE ☐
QCR ☐
OTHERS:

19. OWNER APPROVAL:

	YES	NO
REQUIRED	☐	☐
OBTAINED	☐	☐

20. CHANGE CONTROL DOCUMENTS

ERM/ECN or ECA NO.

FDI NO.

OTHER

21. PO NUMBER/REVISION:

22. DDR NUMBER

23. SUPPLIER QC DATE	GEH QC REPRESENTATIVE DATE

NEO-767 (6/26/96) (See following sheet for instructions)

DDR COMPLETION INSTRUCTIONS

Submit this form only If requirements of a Purchase Order have been deviated i.e. the DDR is to be prepared after the deviating condition exists.

Use Word Processor, Typewriter or black ink ball point pen.

ITEM NO.	INFORMATION REQUIRED
1.	Supplier's name and address.
2. and 3.	Name and identification number of detail part involved. Deviated material must be identified to the part in which it will be used
4.	Date supplier first detected the nonconformance.
5.	Name or description of the product being supplied, as stated on the Purchase Order (PO).
6.	The GEH Master Parts List (MPL) number given on the PO. List each MPL number involved in the request.
7.	Customer's project name and unit number. as assigned by GEH.
8.	Supplier's shop order/job number, if assigned. Identify deviating items.
9.	Identify deviating items: a. Identify applicable serial or unique heat/lot number of equipment and the quantity of each. b. State the document and revision that contains the requirement to be changed, and the section or paragraph number. c. If item has been designated to a specific project and/or is applicable to more than one MPL number and/or part, show this relationship.
10.	Describe nonconformance in "should have been" and "is" terms; propose a disposition giving specific details and engineering basis for the proposal. If of supplier's design, state the effect on reliability, inter- changeability, safety, maintainability, operability and integrity.
11.	For a serious or repetitive deviation, state the probable cause, actions projected/taken to correct the under- lying cause, and when these actions will become effective.
12.	Enter number of supplier attachments to this DDR. Identify each page of attachments with the DDR document number. Sequentially number each page of the attachments.
13.	Signature and date of the GEH Quality Control (QC) Representative validating the accuracy of the description of the nonconformance or if GEH's QC Representative is not available, the means (telephone, TWX, etc.) and date of notification.
14.	Signature, title and date of supplier's QC Manager, Project Engineer or Project Manager.
15.	GE-Hitachi Nuclear Energy Americas LLC disposition will be given here.
16. - 20.	These blocks are for GEH processing.
21.	Enter the number and latest revision of each GEH PO (one PO per DDR) affected by the DDR.
22	Establish a DDR number using in the following format: GEH PO number-sequential number (e.g. 001). The sequence number is the number of DDRs against the GEH PO. Assign a sequential Revision number as appropriate.
23.	Signatures of supplier's QC and the GEH QC Representative attesting that any and all work, on the product required of supplier by the authorized disposition, has been acceptably accomplished.

Supplier to forward DDR to the GEH Sourcing, provide a copy to the GEH QC Representative servicing supplier’s plant.

Normally a copy will be returned to supplier with the GEH disposition. However, if affirmation by supplier QA of work on the product, caused by the disposition of the DDR is required, the original of will be returned for signatures. Signed originals must be returned to Sourcing.

The supplier shall enter the DDR number (and revision number, if any) of those dispositioned as "approved" or "other", in the non-conformance block of the Product Quality Certification (PQC). Attach a copy of the DDR to the PQC that accompanies the product to destination and place a copy in deliverable QA records. However, such reference and attachment shall not be made if subsequent changes applied by PO revision eliminate the deviation.

NOTE: If implementing the disposition of this DDR will cause a price change, the supplier shall obtain Sourcing's authorization prior to implementation.

Appendix B

Supplier Change Request (SCR) Form and Instructions for Completion

GE-Hitachi Nuclear Energy Americas LLC	*SUPPLIER CHANGE REQUEST* Sheet 1 of __

1. SUPPLIER AND LOCATION		2. SUPPLIER JOB NO.
3. PRODUCT	4. PROJECT	5. MPL NO.

6. IDENTIFY REQUESTED CHANGE:

7. PROVIDE BASIS FOR CHANGE REQUEST ALONG WITH BENEFITS AND/OR IMPACT TO GEH:

8. NO. OF SUPPLIER ATTACHMENTS	9. GHNEA PO NUMBER/REVISION:	10. SUPPLIER APPROVAL	DATE

11. GEH DISPOSITION AND JUSTIFICATION:

APPROVED AS PROPOSED ☐
DISAPPROVED ☐
OTHER ☐
FDI NO. _____
NO. OF GEH ATTACHMENTS _____

NEXT PO REVISION NO

12. DESIGN VERIFICATION DRF Number (Required for dispositions of "Approved As Proposed" and "Other")

13. OWNER APPROVAL:

	YES	NO
REQUIRED	☐	☐
OBTAINED	☐	☐

14. GEH APPROVAL SIGNATURES	M/C	COMP	DATE
RESPONSIBLE ENGINEER (RE)			
PROJECT MANAGER (PM)			
PROCUREMENT (PCMT) QC			
Sourcing			

15. FINAL DISTRIBUTION

PROCUREMENT QA ☐
SELLER (Thru Sourcing) ☐
SOURCING ☐
RE ☐
PM ☐
QC ENGINEER ☐
QC REPRESENTATIVE ☐
OTHERS:

16. CHANGE CONTROL DOCUMENTS

ERM/ECN NO:

VPF NO:

OTHER:

SCR NUMBER

S -

NEO-766 (6/26/96) (See following sheet for instructions)

SCR COMPLETION INSTRUCTIONS

If a change in design or QA requirements is desired, submit this form and obtain approval before proceeding or creating a deviation. Use word processor, typewriter or black ink ballpoint pen.

ITEM NO. **INFORMATION REQUIRED**

1. Supplier's name and address.
2. Supplier's shop order/job number, if assigned.
3. Name or description of the product being supplied, as stated on the Purchase Order (PO).
4. Customer's project name and unit number, as assigned by GEH.
5. The GEH Master Parts List (MPL) number, if given on the PO. List each MPL number involved in the request.
6. Identify the required change.
   a. Identify applicable serial or unique heat/lot number of equipment and the quantity of each. State the document and revision that contains the requirement to be changed, and the section of paragraph number.
   b. If item has been designated to a specific project and/or is applicable to more than one MPL number and/or part, show this relationship.
   c. State the proposed date or point of effectivity.
7. Provide the basis, reason, or justification for the change.
   a. If of supplier's design, state the effect on reliability, interchangeability, safety, maintainability, operability and integrity.

   IDENTIFY THE BENEFITS ACCRUING TO GEH IF THE PROPOSED CHANGE IS AUTHORIZED. SEE NOTE BELOW.
8. Enter the number of supplier attachments to this SCR. Identify each page of attachments with the SCR document number. Sequentially number each page of the attachments.
9. Enter the number and latest revision of each GEH PO affected by the SCR.
10. Signature, title, and date of supplier's authorized designee, such as QC Manager, Project Engineer, or Project Manager.
11. GEH disposition will be given here.
12. - 15. These blocks are for GEH processing.
16. Identify change control documents.
   a. Engineering Review Memorandum/Engineering Change Notices (ERM/ECNs) listed in this block are required to be placed on PO prior to release of product for shipment.
   b. Documents identified in this block by Vendor Print File (VPF) number must be revised and received/approved by GEH, as appropriate, prior to release of product for shipment.
   c. Other documents listed must be placed on PO, submitted, or issued, as appropriate to the document, prior to release of the product for shipment.

The supplier is to forward copies of the SCR sheet to the GEH Sourcing, the GEH QC Representative servicing supplier's plant, and retain a copy. Normally, a copy will be returned to the supplier with the GEH disposition.

When requested, the supplier shall demonstrate to a GEH representative that the change has been implemented at the specified point of effectivity.

Changes implemented as authorized by the SCR, must be incorporated by a PO revision issued prior to release for shipment.

NOTE: IF IMPLEMENTING THE DISPOSITION OF THIS SCR WILL CAUSE A PRICE CHANGE, THE SUPPLIER SHALL OBTAIN SOURCING'S AUTHORIZATION PRIOR TO IMPLEMENTING.

Enclosure 3

MFN 10-007

GE Energy Nuclear, "ESBWR Reliability Assurance Program," NEDO-33289, Revision 2, September 2008.

HITACHI

GE Hitachi Nuclear Energy

3901 Castle Hayne Road, Wilmington, NC 28401

NEDO-33289
Revision 2
DRF 0000-0060-1791
Class II
September 2008

Licensing Topical Report

ESBWR Reliability Assurance Program

Principal Author:

Gary Miller

ELECTRONIC COPY

Electronic approvals filed in

EDRF Section 0000-0060-1791

IMPORTANT NOTICE REGARDING THE CONTENTS OF THIS REPORT

Please Read Carefully

The information contained in this document is furnished for the purpose of obtaining NRC approval of the GE Hitachi Nuclear Energy (GEH) ESBWR Certification and implementation. The only undertakings of GEH with respect to information in this document are contained in contracts between GEH and participating utilities, and nothing contained in this document shall be construed as changing those contracts. The use of this information by anyone other than those participating entities and for any purposes other than those for which it is intended is not authorized; and with respect to any unauthorized use, GEH makes no representation or warranty, and assumes no liability as to the completeness, accuracy, or usefulness of the information contained in this document.

Changes From Revision 1

Change	Description
Updated entire document to latest LTR format	Format only; no technical change. Includes addition of change list, list of tables, list of abbreviations and acronyms, and executive summary.
Corrected typographical errors in references, Section 6.	Editorial corrections to close out CAR 46111.
Corrected acronym use.	Editorial only; spelled out all acronyms at first use.
Changed from 3 to 4 phases in Sections 2 and 4 to account for COL applicant and COL holder, and added appropriate text.	Revised to be consistent with response to RAI 17.4-20.
Removed blank pages.	Format only.
Updated TOC to reflect added sections.	Editorial for consistency.

Contents

List of Tables

None

Abbreviations And Acronyms List

Term	Definition
PRA	Probabilistic Risk Assessment
RAP	Reliability Assurance Program
D-RAP	Design Reliability Assurance Program
SSC	Systems, Structures, and Components
COL	Combined Operating License
ITAAC	Inspections, Tests, Analyses and Acceptance Criteria
GEH	GE Hitachi Nuclear Energy
RTNSS	Regulatory Treatment of Nonsafety Systems

ABSTRACT

This document presents the plans for, and the constituents of, the generic Reliability Assurance Program required by NUREG-0800 as part of the ESBWR Design Certification. ESBWR reliability assurance will provide for a high level of equipment reliability that is consistent with the ESBWR Probabilistic Risk Assessment (PRA) and the ESBWR design such that it is preserved throughout the life of the plant. It will also ensure that as the design evolves through ESBWR design certification into initial fuel load and operation, an ESBWR licensee can assure that the reliability estimated in the design certification PRA is preserved.

1. OVERVIEW

1.1 INTRODUCTION

ESBWR reliability assurance is the continuous process of assuring that a high level of equipment reliability, as estimated by the Probabilistic Risk Assessment (PRA), is consistent with the ESBWR design and is preserved throughout the life of the plant. The Design Reliability Assurance Program (D-RAP) is designed to ensure that as the design evolves through ESBWR design certification into initial fuel load and operation, sufficient information is available for an ESBWR licensee to assure that the reliability estimated in the design certification PRA is preserved.

1.2 OBJECTIVES

The objectives of the RAP are to provide reasonable assurance of the following:

- The plant is designed, constructed, and operated consistent with risk-significant PRA assumptions and insights for systems, structures and components (SSCs);
- Risk-significant SSCs will not degrade to an unacceptable level during plant operations;
- The frequency of transients posing challenges to risk-significant SSCs is minimized;
- Risk-significant SSCs will function reliably when challenged.

1.3 USING THIS DOCUMENT

Significant insights into what constitutes an effective D-RAP may be found in NUREG-0800 Section 17.4 (Reference 1). The procedures and performance requirements for implementing the D-RAP are provided in Section 3 of this plan. It is helpful to think of the overall reliability assurance program in the phases described in Section 2 in order to help discern among the reliability program products and procedures. While not specifically part of the D-RAP, Section 4 summarizes the procedures and performance requirements for which the ESBWR licensees will be responsible.

2. RELIABILITY ASSURANCE PROGRAM PHASES

2.1 PHASE I – DESIGN CERTIFICATION

The D-RAP is the first reliability assurance phase. It is developed by the designer to support ESBWR design certification. During this phase, a preliminary, generic PRA model is developed, along with PRA insights and assumptions.

In this phase, preliminary ESBWR design certification PRA information is incorporated into the plant design. The PRA is a generic model, i.e., plant-specific details are not available. The PRA data is based on generic estimates for initiating event frequencies, failure rates, and human error probabilities. The essential elements of the D-RAP for Phase I include:

- A preliminary summary of risk-significant design PRA insights and assumptions (see Reference 2);
- A preliminary list of risk-significant SSCs and the reliability assumed in the design PRA (see Reference 3);
- Inspections, Tests, Analyses and Acceptance Criteria (ITAAC) prepared in accordance with Reference 1 to be used by the licensee to verify that probability assumptions used for the design certification are consistent with the as-built plant (see Reference 4);
- A description of the ESBWR D-RAP (see Reference 5).

During the design phase, key risk-informed information is provided to the system engineer to ensure that it is incorporated into the final system design. The procedures for identifying and prioritizing SSCs are discussed in Section 3. The ESBWR PRA reliability assumptions are described in the design certification PRA (Reference 2).

2.2 PHASE II – COL APPLICANT D-RAP ACTIVITIES

The Combined Operating License (COL) Applicant ensures that the list of risk-significant SSCs is updated with plant-specific information, such as departures from the standard design.

2.3 PHASE III – COL HOLDER D-RAP ACTIVITIES

In this phase, the COL Holder carries forward and refines the products from Phases I and II. The COL Holder completes the ITAAC, and the list of risk-significant SSCs within the scope of the RAP is refined based on plant-specific PRA results and insights. These results are evaluated using a licensee's expert panel to ensure establishment of dominant failure modes as well as recommended operations, maintenance and monitoring strategies.

The design certification PRA model and reliability products are updated to include plant-specific details. The design certification applicant and plant license holder may have joint responsibility for creating an expert panel to review the risk-significant SSC list. The panel evaluates the updated PRA information, in concert with traditional engineering evaluations, sensitivity studies, PRA insights and assumptions, operational experience, and current regulatory requirements. The evaluation provides an updated comprehensive list of risk-significant SSCs. In addition, the

expert panel may use this evaluation to develop reliability assurance strategies for procurement and construction and pre-operational testing.

The PRA model is also updated to contain plant-specific design details and estimated human error probabilities that are based on the development of plant operating procedures. The plant licensee has the responsibility for updating the list of risk-significant SSCs and developing the Maintenance Rule program.

2.4 PHASE IV – OPERATIONS

Phase IV is plant operation following initial fuel load. During the operations phase, the products from Phase III are used to implement the RAP through the plant's Maintenance Rule Program and other processes required under 10CFR 50, such as Quality Assurance, In-Service-Inspection and Testing, and Corrective Action Program.

The ESBWR licensee incorporates recommended operations, maintenance and monitoring strategies into Phase IV of the RAP, to assure that applicable SSCs can be expected to operate throughout plant life with reliable performance that is consistent with the PRA.

The PRA is now a comprehensive (but inexperienced) model. The Operations PRA model and the key RAP products are updated using the plant-specific procedural controls. The RAP is integrated primarily into the Maintenance Rule Program, but some elements may also be included in the Appendix B Program, the Inservice Inspection Program or other risk-informed applications.

3. ESBWR D-RAP IMPLEMENTATION FOR PHASE I

The D-RAP is implemented in a manner consistent with the elements described in Section 17.4 of NUREG-0800 (Reference 1). The D-RAP is described in detail in Section 17.4 of the Tier 2 Design Control Document (Reference 5). An ITAAC for the D-RAP is included in Section 3.6 of the Tier 1 Design Control Document (Reference 4). A list of risk-significant SCCs is provided in Reference 3. The organizational responsibilities, the application of design controls, and the D-RAP procedures described in the Design Control Documents are consistent with the following sections.

3.1 PURPOSE

The purpose of the ESBWR D-RAP described in this document is to implement the design certification RAP in order to provide reasonable assurance that plant safety, in the form of equipment reliability as estimated by the ESBWR PRA, is available from the design phase so that pertinent information related design equipment reliability, as it affects plant safety, can be maintained through the entire plant life.

3.2 SCOPE

The scope of the ESBWR D-RAP includes risk-significant SSCs, both safety-related and nonsafety related, that provide defense-in-depth or have been shown to result in significant improvement in the PRA evaluations. A list of risk-significant SSCs within the scope of the D-RAP is developed during the design certification phase. This information ultimately helps form the basis for the Maintenance Rule program, which in turn ensures that risk-significant SSCs operate throughout plant life with reliable performance that is consistent with the PRA.

3.3 DESIGN ORGANIZATION

The GE ESBWR Engineering Section is an integrated design and engineering organization that is responsible for formulating and implementing the D-RAP. The Manager, ESBWR Engineering, is responsible for the design and licensing of the ESBWR, and for development of the D-RAP.

The ESBWR Engineering organization is responsible for the ESBWR design analysis and PRA engineering that is necessary to support development of the D-RAP. PRA personnel are directly involved with the design organization and keep the design staff cognizant of risk-significant items, program needs, and project status. PRA personnel participate in the design change control process, which includes providing RAP related inputs in the design process.

3.4 DESIGN CONTROLS

ESBWR design control procedures provide guidance for developing reliability assurance. The overall GE ESBWR engineering design procedural controls are also applied to the D-RAP. These procedures provide guidance on the design process, control of design changes, and storage and retrieval controls.

Design change control procedures define the process for evaluating design changes in engineering controlled documents to ensure that the total effect is considered before a change is approved. The procedure provides authority for a change and identifies the pertinent interfaces and organizations responsible for these interfaces, including PRA review, and provides accurate and traceable records of a change.

The documentation procedure establishes the requirements and responsibilities for the preparation, approval, and issue of documents controlled by the engineering design organizations. The quality assurance records procedure provides requirements for quality assurance record retention. The self-assessment, corrective action and audits procedure specify the responsibilities for performing self-assessments; internal audits of the engineering organization; and prompt identification, documentation, and corrective actions on conditions that are adverse to quality.

3.5 D-RAP PROCEDURES FOR PHASE I

The ESBWR D-RAP procedure or procedures contain, but may not be limited to, the program purpose, scope, limitations, bases, responsibilities, the procedures used to implement the D-RAP, as well as any self-assessment and corrective actions methods and program record keeping requirements for the program.

The reliability assurance procedures developed for the ESBWR D-RAP are consistent with the performance requirements provided in this section. Procedures provide for corrective actions when the requirements are not met.

In addition to the standard engineering design processes and quality controls, specific guidance is necessary to implement an effective D-RAP. The D-RAP procedures describe the processes for identifying and prioritizing risk significance, maintaining design and PRA reliability assumptions consistent for risk-significant SSCs, and monitoring program effectiveness. D-RAP procedures are used to develop the Phase I products such that the risk-significant SSC reliability assumed in the design certification PRA in incorporated into the design of the ESBWR can be carried through fuel load and into operation.

During the design phase, procedures provide instructions for developing and documenting ESBWR design certification PRA risk insights and assumptions. Procedures require that these risk-significant PRA insights and assumptions be compared with the evolving ESBWR design.

Design phase procedures require that a list of risk-significant SSCs be developed. Preliminary lists are developed based on the generic ESBWR PRA information available as the design evolves during the design certification phase. As the design progresses, the list of risk significant SSCs is updated using methods that apply the best information from PRA results with defense-in-depth principles and pertinent operating experience. Procedures provide for an expert panel with collective knowledge and experience in operations and maintenance processes. This expert panel may be used as an option to evaluate this design certification information during the design phase, but is not required.

4. ESBWR RAP IMPLEMENTATION FOR PHASES II, III AND IV

4.1 SCOPE

The COL Applicant and COL Holder are responsible for implementing Phases II, III and IV of the RAP, respectively. Licensees use the Phase I products as inputs to implement these phases.

Licensee procedures describe the processes used to translate risk insights and the list of risk-significant SSCs from Phase I into strategies for reliability assurance. This involves confirming the dominant failure modes of risk-significant SSCs and their effects on safety functions. Specific operations and maintenance strategies to address the dominant failure modes are identified so that equipment performance is consistent with the PRA.

4.2 PHASE II III AND IV PROCEDURES

Licensee procedures contain instruction for engineers to evaluate the design of a component, train or system to identify dominant failure modes and their effects. Inputs may include PRA importance analysis, root cause analysis, failure modes and effects analysis, and review of operating experience.

Equipment performance information, including vendor manuals, ASME Section XI, technical specifications, Regulatory Treatment of Non-Safety Systems (RTNSS), and other regulatory requirements may be reviewed to identify important safety functions. Licensee procedures provide instructions for engineers to analyze this information to identify dominant failure modes, such as single failures, latent failures not detected by routine monitoring, common cause failures, or failures that could cascade into more significant safety functional failures. This information is incorporated into the baseline and routine design reliability assessments.

4.3 LICENSEE RAP PROCEDURE PERFORMANCE REQUIREMENTS

Licensee procedures describe requirements and instructions for the engineers and the expert panel, collectively, to identify operational reliability assurance strategies for all phases of design and construction that are realistic and achievable. Risk insights may be applied in each phase of development, as indicated by the following examples:

- ESBWR Equipment Procurement and Fabrication
  - Incorporate Risk-Significant Insights into Procurement Specifications, when applicable. Risk-significant components, especially those that are unique to the ESBWR design, are procured with the reliability that is assumed in the PRA. If a component's reliability deviates significantly from the assumed PRA value, it must be evaluated to determine if a PRA model change or a design change is warranted.
- ESBWR Reliability Procedures for Construction
  - Monitor Design Changes. Changes that affect functional characteristics of major components might affect the PRA model.

  - Assess physical layout of SSCs with respect to adverse interactions, fire and flood separation.

- ESBWR Procedures for Pre-Operational Testing
  - Validate risk-significant PRA assumptions by tests, if applicable.
- ESBWR Plant Operations Reliability Procedures
  - Maintenance Rule implementation.
  - Operator training and procedures.
    - Preventive and predictive maintenance (including test and maintenance unavailability used in the PRA model)
  - Surveillance testing.
  - Component performance.
  - Initiating event experience.
  - Human factors.

5. MONITORING AND FEEDBACK (ALL PHASES)

Throughout all phases of the ESBWR RAP, procedures are in place to ensure that processes are established to continuously monitor and refine the elements of the reliability program. These processes include, but are not limited to, design reliability assessments and operations and maintenance reliability assessments.

6. REFERENCES

(1) NUREG-0800, U.S. Nuclear Regulatory Commission Standard Review Plan, Sections 17.4, Reliability Assurance Program (RAP), March 2007

(2) NEDO-33201, ESBWR Probabilistic Risk Assessment

(3) NEDO-33411, ESBWR Risk-Significance of Structures, Systems and Components for the Design Phase of the ESBWR

(4) 26A6641AB, ESBWR Design Control Document/Tier 1

(5) 26A6642BW, ESBWR Design Control Document Chapter 17/Tier2