

1 DRAFT SAFETY EVALUATION BY THE OFFICE OF NUCLEAR REACTOR REGULATION

2  
3 TOPICAL REPORT NEDO-11209, REVISION 9

4  
5 "GE HITACHI NUCLEAR ENERGY QUALITY ASSURANCE PROGRAM DESCRIPTION"

6  
7 GE HITACHI NUCLEAR ENERGY

8  
9 PROJECT NO. 710

10  
11 1.0 INTRODUCTION AND BACKGROUND

12  
13 By letter dated June 30, 2010 (Reference 1), as supplemented by letter dated  
14 December 10, 2010 (Reference 2), GE Hitachi Nuclear Energy (GEH) submitted Topical Report  
15 (TR) NEDO-11209, Revision 9, "GE Hitachi Nuclear Energy Quality Assurance Program  
16 Description [QAPD]," (hereafter referred to as the Quality Assurance Topical Report (QATR)) to  
17 the U.S. Nuclear Regulatory Commission (NRC) for review and approval in accordance with the  
18 provisions of Title 10 of the *Code of Federal Regulations* (10 CFR), Section 50.4(b)(7)(ii). GEH  
19 proposed that this updated QATR would replace the current QATR for GEH, which was  
20 approved by the NRC as documented by letter dated March 31, 1989 (Reference 4).

21  
22 2.0 REGULATORY EVALUATION

23  
24 The NRC regulatory requirements related to quality assurance (QA) programs for non-licensees  
25 are set forth in 10 CFR 50.4(b)(7)(ii). This regulation requires that a change to an NRC-  
26 accepted QATR from non-licensees (i.e., architect/engineers, nuclear steam supply system  
27 (NSSS) suppliers, fuel suppliers, constructors, etc.) must be submitted to the NRC. When  
28 requested, the NRC will review the proposed QATR for acceptability to ensure the applicable  
29 requirements of Appendix B to 10 CFR Part 50 will be satisfied.

30  
31 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing  
32 Plants," to 10 CFR Part 50 establishes QA requirements for the design, construction and  
33 operation of structures, systems, and components (SSCs) of the facility. The relevant  
34 requirements of Appendix B to 10 CFR Part 50 apply to all activities affecting the safety-related  
35 functions of those SSCs including their design, purchase, fabrication, handling, shipping,  
36 storage, cleaning, erecting, installing, inspecting, testing, operating, maintaining, repairing,  
37 refueling, and modification.

38  
39 3.0 TECHNICAL EVALUATION

40  
41 3.1 Background

42  
43 The proposed QATR is similar in many respects to previous submittals approved for licensees  
44 in accordance with NUREG-0800, "Standard Review Plan for the Review of Safety Analysis  
45 Reports for Nuclear Power Plants," Section 17.5, "Quality Assurance Program Description

1 [QAPD] – Design Certification, Early Site Permit and New License Applicants” (hereafter  
2 SRP 17.5). The original QAPD was based largely on commitments to the following: (1)  
3 Appendix B of 10 CFR Part 50, (2) Regulatory Guide (RG) 1.28, “Quality Assurance Program  
4 Requirements (Design and Construction),” (3) ANSI N45.2-1971, “Quality Assurance Program  
5 Requirements for Nuclear Power Plants,” and (4) applicable sections of the American Society of  
6 Mechanical Engineers (ASME) Boiler and Pressure Vessel Code.  
7

8 This QATR is based on ASME Nuclear Quality Assurance (NQA) Standard NQA-1-2008,  
9 “Quality Assurance Requirements for Nuclear Facility Applications” and NQA-1a-2009 Addenda.  
10 The QATR is organized into eighteen basic sections corresponding to the quality requirements  
11 delineated in Appendix B to 10 CFR Part 50 and is responsive to both Appendix B, as  
12 applicable, and the regulatory guidance set forth in RG 1.28, Revision 4. GEH considers the  
13 collective requirements of the QATR and Standards NQA-1-2008 and NQA-1a-2009 Addenda  
14 equivalent to the NRC staff guidance in SRP 17.5. SRP 17.5 outlines the NRC staff review of a  
15 standardized QA program and is based on the following documents: (1) ASME Standard NQA-1  
16 (1994 Edition); (2) RG 1.8, “Qualification and Training of Personnel for Nuclear Power Plants;”  
17 (3) RG 1.28, “Quality Assurance Program Requirements (Design and Construction);” (4) RG  
18 1.33, “Quality Assurance Program Requirements (Operation);” and (5) NRC Review  
19 Standard 002, “Processing Applications for Early Site Permits.” The review approach of  
20 SRP 17.5 has previously been used by the NRC staff for evaluating the NQA-1-1994 standard  
21 as the basis for a QA Program.  
22

23 The significant changes to the QA program in the GEH QATR are: (1) a commitment to  
24 NQA-1-2008 and NQA-1a-2009 Addenda (hereafter collectively NQA-1) as the basis for the QA  
25 Program, and (2) other changes made by GEH to allow for the use of new technology and  
26 methods not available in 1989. In the NRC staff’s request for additional information (RAI)-6, the  
27 NRC staff requested that GEH provide a clarification as to whether the proposed QATR will  
28 implement Part II of NQA-1. In its response, GEH stated that Appendix A of the QATR was  
29 revised to clarify that the proposed QATR commits to Part I in its entirety and Part II for those  
30 activities within GEH’s scope as an NSSS supplier as described in contract specific quality  
31 plans.  
32

### 33 3.2 Evaluation

34  
35 The NRC staff evaluated the adequacy of the QATR in describing how the requirements of  
36 Appendix B to 10 CFR Part 50 will be satisfied. The format and content of the QATR were  
37 evaluated in accordance with the guidance of SRP 17.5, which provides a basis for the NRC  
38 staff review of QA programs based on Standard NQA-1-1994. The acceptability of the level of  
39 detail provided by the QATR is in part determined by its adequacy in addressing the acceptance  
40 criteria of SRP 17.5.  
41

#### 42 3.2.1 Format and Content of the QATR

43  
44 The format used for the NRC staff evaluation followed the sequence of the 18 criteria of  
45 Appendix B and corresponding provisions of NQA-1. The QATR provides guidance for  
46 establishing a top-level policy document that defines the quality requirements and assigns major  
47 functional responsibilities. The GEH QATR applies to work involving SSCs for nuclear power  
48 plants and fuel reprocessing plants that prevent or mitigate the consequences of postulated  
49 accidents that could cause undue risk to the health and safety of the public. It is incumbent  
50 upon the client to identify the specific QA requirements that must be met for the scope of  
51 activities.

1 3.2.1.1 Organization  
2

3 The QATR is the top-level policy document that establishes GEH's overall methodology  
4 regarding achievement and assurance of quality. Implementing documents provide more  
5 detailed responsibilities and requirements and define the organizational interfaces involved in  
6 conducting activities within the scope of the QATR. Compliance with the QATR and  
7 implementing documents is mandatory for all GEH employees and contractors performing  
8 activities related to safety.  
9

10 The QATR describes the organizational structure, functional responsibilities, and levels of  
11 authority and interfaces for establishing, executing, and verifying QA program implementation.  
12 GEH services are organized into business groups and functional support groups. This  
13 organizational structure can be categorized in three main elements: Profit & Loss Center (P&L),  
14 Support Organization, and Quality, which all report to the President. The P&L organization is  
15 comprised of several areas with financial responsibility for delivery of products and services.  
16 The support groups facilitate the activities of the P&L. The quality organization is responsible  
17 for providing oversight. In RAI-1 and RAI-2, the NRC staff requested descriptions of the  
18 different groups in Figure 1, "Organizational Structure" and Figure 2, "Functional  
19 Responsibilities," that were not described under the organization description. In its response,  
20 GEH revised the "organization description" and Figure 1 and Figure 2 to be more detailed and  
21 consistent with the use of organizational terminology.  
22

23 The President and Chief Executive Officer (hereafter the "President") of GEH ensures that the  
24 size of the QA Division is commensurate with its duties and responsibilities. Policy, project  
25 instructions, and governing company standards are established to control quality-related  
26 activities. Specific implementing procedures are established to control activities in compliance  
27 with the requirements of the program. In RAI questions 3 and 4, the NRC staff requested that  
28 GEH show the location within its organization of the NQA Manager and the "Specific Quality  
29 Leaders" in Figure 1 and demonstrate how GEH planned to implement a direct line of  
30 communication between the NQA Manager, Specific Quality Leaders, and the President. In its  
31 response, GEH revised the organization description and Figure 1 to be more detailed about how  
32 a direct line of communication will be established with this revised QATR.  
33

34 In establishing its organizational structure, GEH commits to compliance with Appendix B to  
35 10 CFR Part 50, Criterion I, and with NQA-1, Requirement 1. As set forth above, the NRC staff  
36 reviewed the QA measures to be implemented by GEH under this QAPD and concluded that the  
37 controls for the organizational structure meet the guidance in SRP 17.5.  
38

39 3.2.1.2 QA Program  
40

41 GEH has established the necessary measures and governing procedures to implement the  
42 QA Program described in the QATR. GEH policy makes compliance with the program  
43 mandatory for all employees and contractors performing quality-related activities. The QATR  
44 applies to work performed on safety-related SSCs that are within the scope of 10 CFR Part 50,  
45 Appendix B. The program is binding on all companies that have adopted this QATR including  
46 participating organizations, the President, all employees, and contractors whose activities may  
47 influence quality.  
48

49 QA personnel monitor activities affecting quality and evaluate them in accordance with  
50 acceptance criteria to ensure satisfactory performance. These criteria are outlined in the  
51 implementing procedures. The President reviews the overall status and adequacy of the QA

1 Program. Managers review those portions of the program related to their area of responsibility  
2 to ensure effective implementation. These reviews take place at least once each fiscal year or  
3 at least once during the life of the activity whichever is shorter.

4  
5 Personnel working directly or indirectly for GEH are responsible for the achievement of  
6 acceptable quality in their work covered by the QATR. Activities governed by the QA Program  
7 are performed as directed by documented instructions, procedures, and drawings that have a  
8 level of detail appropriate for the activity's complexity and effect on safety. The President  
9 establishes QA policy and objectives.

10  
11 The President has delegated to the QA Manager the responsibility for providing and maintaining  
12 the QA Program policy and direction and for coordinating and verifying its implementation on  
13 projects. Personnel assigned to implement elements of the QA Program shall be capable of  
14 performing their assigned tasks. GEH establishes and maintains formal indoctrination and  
15 training programs for personnel performing, verifying, or managing activities within the scope of  
16 the QA Program to assure that suitable proficiency is achieved and maintained. Quality-related  
17 activities that require qualification of personnel are controlled by written procedures and only  
18 those personnel who have met the requirements are permitted to perform these activities.

19  
20 In establishing its QA Program, GEH commits to compliance with Appendix B to  
21 10 CFR Part 50, Criterion II and NQA-1, Requirement 2. As set forth above, the NRC staff  
22 reviewed the QA measures to be implemented by GEH and concluded that the controls for the  
23 program meet the guidance in SRP 17.5.

#### 24 25 3.2.1.3 Design Control

26  
27 GEH has established the necessary measures and governing procedures to control the design  
28 and design changes of items that are subject to the provisions of the QATR. The engineering  
29 organizations of the companies that have adopted this QATR have overall responsibility for the  
30 control of the design process from its inception to the final result. The design process includes  
31 provisions to control design inputs, outputs, changes, verification, interfaces, organizational  
32 interfaces, and records. Design change control follows the same review process as the original  
33 design. Procedures provide guidance and specify methods for performing design verification.  
34 Design verification reviews are performed by qualified personnel other than those who  
35 performed the original design. Design analyses are required to be sufficiently detailed to permit  
36 design verification without recourse to the originator.

37  
38 In RAI-7, the NRC staff requested that GEH describe the criteria established by the QATR for a  
39 pre-verified computer program. In its response, GEH stated that paragraph 3.4.1 of the QATR  
40 was revised to include the criteria to be implemented by GEH to verify the result of computer  
41 programs used for design analysis. During design reviews, design documents are reviewed  
42 against requirements of the applicable design criteria and/or other supporting documents in  
43 accordance with procedures established by the design organization conducting the reviews.

44  
45 In RAI-8, the NRC staff requested that GEH describe the process to be used if a significant  
46 design change is necessary as a result of an incorrect design. In its response, GEH stated that  
47 paragraph 3.6 was added to the QATR to address this particular situation. Responsibility to  
48 initiate and approve any required design changes is assigned to the same groups or  
49 organizations that reviewed and approved the original design documents. The design change  
50 control procedure requires documentation of the change and approval by the responsible  
51 engineering organization.

1 In establishing provisions for design control, GEH commits to compliance with Appendix B to  
2 10 CFR Part 50, Criterion III and NQA-1, Requirement 3. As set forth above, the NRC staff  
3 reviewed the QA measures to be implemented by GEH and concluded that the controls for  
4 design meet the guidance in SRP 17.5.

#### 5 6 3.2.1.4 Procurement Document Control 7

8 GEH has established the necessary measures and governing procedures to verify that a  
9 statement of the scope of work to be performed and other requirements necessary to ensure  
10 quality are included or referenced in GEH-originated documents for procurement of equipment,  
11 materials, components, and services. GEH procurement documents include information and  
12 requirements such as the following:  
13

- 14 (1) statement of the scope of work, applicable regulatory standards and code requirements,  
15 drawings, test and inspection requirements, and information that describe the items or  
16 services to be furnished;  
17
- 18 (2) reference to the supplier's documented QA Program that has been reviewed and  
19 determined to meet the applicable requirements of Appendix B to 10 CFR Part 50,  
20 consistent with the circumstances of the procurement. Alternately, suppliers may work  
21 to the GEH QA Program and implementing procedures;  
22
- 23 (3) acceptance and/or rejection criteria;  
24
- 25 (4) identification of QA records to be controlled, maintained, retained and/or delivered to  
26 GEH for information, review or approval (retention times and disposition requirements  
27 are specified for records to be retained); and  
28
- 29 (5) provisions for the supplier to submit nonconformances together with their recommended  
30 disposition (use as is, reject, rework, or repair), including the technical justification, to  
31 GEH for review and approval and, if required, recommendation of disposition to the  
32 client.  
33

34 Procurement documents are prepared, reviewed, and approved by the appropriate disciplines  
35 and issued in a sequence of steps prescribed in accordance with standard operating procedures  
36 prior to release for fabrication, construction, or installation of items or performance of services.  
37 A changes and/or revisions to a procurement document are subject to the same level of review  
38 and approval as the original procurement document.  
39

40 In establishing controls for procurement documents, GEH commits to compliance with Appendix  
41 B to 10 CFR Part 50, Criterion IV and NQA-1, Requirement 4. As set forth above, the NRC staff  
42 reviewed the QA measures to be implemented by GEH and concluded that the controls for the  
43 procurement documents meet the guidance in SRP 17.5.  
44

#### 45 3.2.1.5 Instructions, Procedures, and Drawings 46

47 GEH has established the necessary measures and governing procedures to ensure that  
48 activities affecting quality are prescribed and performed in accordance with procedures, work  
49 instructions, or drawings of a type appropriate for the circumstances and include quantitative or  
50 qualitative acceptance criteria to implement the QA Program as described in the QATR. GEH  
51 implementing procedures and/or work instructions are prepared to describe the activity to a level

1 of detail that is based on one or more of the following: the complexity of the task, the need to  
2 ensure consistent and acceptable results, the significance of the item, the work environment, or  
3 worker proficiency and ability.  
4

5 In establishing procedural controls, GEH commits to compliance with Appendix B to  
6 10 CFR Part 50, Criterion V and NQA-1, Requirement 5. As set forth above, the NRC staff  
7 reviewed the QA measures to be implemented by GEH and concluded that the controls for  
8 instructions, procedures, and drawings meet the guidance in SRP 17.5.  
9

#### 10 3.2.1.6 Document Control

11  
12 GEH has established the necessary measures and governing procedures to control the  
13 preparation of, issuance of, and changes to documents that specify quality requirements or  
14 prescribe how activities affecting quality, including organizational interfaces, are controlled to  
15 ensure that correct documents are being employed. The program and implementing  
16 procedures include measures which ensure that documents, including changes, are reviewed  
17 for adequacy and inclusion of quality requirements and approved for release by authorized  
18 personnel. GEH maintains a listing of all controlled documents that identify the current revision.  
19 The list is available to all personnel in order to determine the appropriate document for use.  
20

21 In establishing document controls, GEH commits to compliance with Appendix B to 10  
22 CFR Part 50, Criterion VI, and NQA-1, Requirement 6. As set forth above, the NRC staff  
23 reviewed the QA measures to be implemented by GEH and concluded that the provisions for  
24 the document control program meet the guidance in SRP 17.5.  
25

#### 26 3.2.1.7 Control of Purchased Material, Equipment, and Services

27  
28 GEH has established the necessary measures and procedures to ensure that purchased items  
29 and services are clearly and adequately specified in procurement documents, and that suppliers  
30 are capable of producing items and furnishing services that conform to procurement document  
31 requirements. Controls shall provide for the following, as appropriate:  
32

- 33 (1) provisions for supplier evaluation,
  - 34 (2) review of procurement requirements, and
  - 35 (3) surveillance of the supplier.
- 36  
37  
38

39 In establishing a program for the control of items and services, GEH commits to compliance with  
40 Appendix B to 10 CFR Part 50, Criterion VII and NQA-1, Requirement 7 with exceptions or  
41 alternatives. As set forth above, the NRC staff reviewed the QA measures to be implemented  
42 by GEH and concluded that the program for the control of purchased material, equipment, and  
43 services meets the guidance in SRP 17.5.  
44

#### 45 3.2.1.7.1 Evaluation of GEH's QA Program Proposed Clarifications, Exceptions, or 46 Alternatives

47  
48 GEH proposed a revised version of NQA-1, Part I, Requirement 7, Section 600, "Control of  
49 Supplier Nonconformance," paragraph 600(b). GEH rewrote the paragraph to remove the  
50 generalized title of "Purchaser" and customized it to GEH requirements of the QATR.  
51

1 The NRC staff reviewed the proposed revision of Paragraph 600(b) located in the second  
2 paragraph of Section 7.5, "Control of Supplier Nonconformances," of the QATR. The NRC staff  
3 found this alternative acceptable based on the guidance in SRP 17.5, Paragraph II.G.14. This  
4 section states that the "purchaser is required to approve the supplier's recommended  
5 disposition and technical justification for nonconformances." The NRC staff found the GEH  
6 alternative equivalent to the NRC staff guidance.

7  
8 GEH considers 10 CFR Part 50 licensees, Authorized Nuclear Inspection Agencies (AIAs), the  
9 National Institute of Standards and Technology (NIST), or other state and federal agencies,  
10 which may provide items or services to GEH, as not requiring evaluation or audit.

11  
12 The NRC staff determined that neither NQA-1 or SRP 17.5 have requirements or guidance  
13 stating that licensees, an AIA, NIST, or other state and federal agencies providing items or  
14 services, be evaluated or audited. Therefore, the NRC staff determined that GEH's proposal of  
15 not evaluating such entities is acceptable.

16  
17 GEH proposed that when purchasing commercial-grade calibration services from a domestic  
18 calibration laboratory, procurement source evaluation and selection measures do not need to be  
19 performed, provided that certain conditions, as stated in the QATR, Section 7.10, are met. The  
20 NRC staff determined that the QATR wording was equivalent to the guidance in SRP 17.5,  
21 paragraphs II.L.8.a.-i. Therefore, the NRC staff found the GEH alternative equivalent to the  
22 NRC staff's guidance.

23  
24 GEH proposed that requirements for control of commercial-grade items and services will be  
25 established in GEH documents using 10 CFR Part 21 and the guidance of Electric Power  
26 Research Institute NP-5652 as discussed in Generic Letter (GL) 89-02 and GL 91-05.  
27 Dedication is outside the scope of NRC staff guidance provided in SRP 17.5. Subpart 2.14 of  
28 NQA-1 addresses commercial-grade items. GEH proposed controls do not contradict the  
29 requirements in NQA-1 or any NRC staff guidance on commercial-grade dedication. Therefore,  
30 the NRC staff found the proposed alternative equivalent to the NRC staff's guidance.

### 31 32 3.2.1.8 Identification and Control of Materials, Parts, and Components

33  
34 GEH has the necessary measures and governing procedures for the identification and control of  
35 materials, parts, and components to prevent the shipment or use of incorrect or defective items.  
36 This includes controls for consumable materials and items with a limited shelf life. The  
37 identification of items is maintained throughout fabrication, erection, installation, and use, such  
38 that the item can be traced to its documentation, consistent with the item's effect on safety.

39  
40 Identification is maintained throughout the life of the product, component, part, or item.  
41 Identification is accomplished using heat numbers, part numbers, serial numbers, or other  
42 appropriate means. The identification is located either on the item or on records traceable to  
43 the item. Locations and methods of identification are selected so as not to affect the function or  
44 quality of the item.

45  
46 In establishing provisions for identification and control of items, GEH commits to compliance  
47 with Appendix B to 10 CFR Part 50, Criterion VIII and NQA-1, Requirement 8. As set forth  
48 above, the NRC staff reviewed the QA measures to be implemented by GEH and concluded  
49 that the controls for the identification and control of materials, parts, and components meet the  
50 guidance in SRP 17.5.

51

1 3.2.1.9 Control of Special Processes  
2

3 GEH has established the necessary measures and governing procedures to ensure that special  
4 processes such as welding, heat treating, and nondestructive examination are controlled.  
5 These provisions include ensuring that special processes are accomplished by qualified  
6 personnel using qualified procedures and equipment. Special processes are performed in  
7 accordance with applicable codes, standards, specifications, criteria, or other established  
8 requirements. Special processes are those where the results are highly dependent on the  
9 control of the process, the skill of the operator, or both, and for which the specified quality  
10 cannot be readily determined by inspection or test of the final product.  
11

12 In establishing measures for the control of special processes, GEH commits to compliance with  
13 Appendix B to 10 CFR Part 50, Criterion IX and NQA-1, Requirement 9. As set forth above, the  
14 NRC staff reviewed the QA measures to be implemented by GEH and concluded that the  
15 controls for special processes meet the guidance in SRP 17.5.  
16

17 3.2.1.10 Inspection  
18

19 GEH has established the necessary measures and governing procedures to implement  
20 inspections that ensure items, services, and activities affecting safety meet established  
21 requirements and conform to documented instructions, procedures, and drawings. Types of  
22 inspections may include, but are not limited to: source, in process, final, receipt, maintenance,  
23 modification, in-service and operations. Inspections are carried out by properly qualified  
24 personnel independent of those who performed or directly supervised the work. Inspection  
25 results are documented by the inspector and reviewed by authorized personnel qualified to  
26 evaluate the inspection.  
27

28 In establishing inspection requirements, GEH commits to compliance with Appendix B to  
29 10 CFR Part 50, Criterion X and NQA-1, Requirement 10. As set forth above, the NRC staff  
30 reviewed the QA measures to be implemented by GEH and concluded that the controls for  
31 inspection activities meet the guidance in SRP 17.5.  
32

33 3.2.1.11 Test Control  
34

35 GEH has established the necessary measures and governing procedures to demonstrate that  
36 items subject to the provisions of the QATR will be tested for qualifying, demonstrating, or  
37 ensuring the quality of procured items or services. The GEH test program includes provisions  
38 for ensuring that prerequisites and suitable environmental conditions are met, adequate  
39 instrumentation is available and used, appropriate tests and equipment are used, and  
40 necessary monitoring is performed. Test results are documented and evaluated by the  
41 responsible organization to assure that the test requirements have been satisfied.  
42

43 Additionally, GEH has established and implemented provisions to ensure that computer  
44 software used in applications affecting safety is prepared, documented, verified, tested, and  
45 used such that the expected output is obtained and configuration control is maintained.  
46

47 In establishing test control requirements, GEH commits to compliance with Appendix B to  
48 10 CFR Part 50, Criterion XI and NQA-1, Requirement 11. As set forth above, the NRC staff  
49 reviewed the QA measures to be implemented by GEH and concluded that the test control  
50 requirements meet the guidance in SRP 17.5.  
51

1 3.2.1.12 Control of Measuring and Test Equipment

2  
3 GEH has established the necessary measures and governing procedures to control the  
4 calibration, maintenance, storage and use of measuring and test equipment. The procedures  
5 cover equipment such as indicating and actuating instruments and gauges, tools, reference and  
6 transfer standards, and nondestructive examination equipment. Measuring and test equipment  
7 are calibrated at prescribed intervals whenever the accuracy of the measuring and test  
8 equipment is suspect, or prior to use. This activity is controlled by an approved procedure that  
9 requires adequate documentation of calibration.

10  
11 In establishing a measuring and test equipment calibration program, GEH commits to  
12 compliance with Appendix B to 10 CFR Part 50, Criterion XII and NQA-1, Requirement 12. As  
13 set forth above, the NRC staff reviewed the QA measures to be implemented by GEH and  
14 concluded that the controls for measuring and test equipment meet the guidance in SRP 17.5.

15  
16 3.2.1.13 Handling, Storage, and Shipping

17  
18 GEH established the necessary measures and governing procedures to control the handling,  
19 storage, packaging, shipping, clearing, and preservation of items to prevent inadvertent damage  
20 or loss and to minimize deterioration. Items are appropriately marked and labeled during  
21 packaging, shipping, handling and storage to identify, maintain and preserve the item's integrity  
22 and indicate the need for special controls. Special controls (such as containers, shock  
23 absorbers, accelerometers, inert gas atmospheres, specific moisture content levels and  
24 temperature levels) are provided when they are required to maintain acceptable quality.

25  
26 In RAI-9, the NRC staff requested GEH to describe the controls they have in place to minimize  
27 the deterioration of items under special environmental conditions. In its response, GEH stated  
28 that Paragraph 13.3 of the QATR was revised to include controls that will be implemented under  
29 special environmental conditions to minimize deterioration of items.

30  
31 In establishing provisions for handling, storage, and shipping, GEH commits to compliance with  
32 Appendix B to 10 CFR Part 50, Criterion XIII and NQA-1, Requirement 13. As set forth above,  
33 the NRC staff reviewed the QA measures to be implemented by GEH and concluded that the  
34 controls for handling, storage, and shipping meet the guidance in SRP 17.5.

35  
36 3.2.1.14 Inspection, Test, and Operating Status

37  
38 GEH has established the necessary measures and governing procedures to identify the  
39 inspection and test status of individual items and for indicating the operating status of  
40 equipment, such as valves and switches. Implementing procedures specify the authority for the  
41 application and removal of these status indicators. In RAI-10, the NRC staff requested GEH to  
42 clarify if the scope of the QATR will establish requirements to control temporary modifications,  
43 such as temporary bypass lines, electrical jumpers, lifted electrical leads, and temporary trip  
44 point settings. In its response, GEH stated that the QATR is not intended to include these  
45 requirements because independent verification of temporary modifications is applicable to  
46 operating plants and is outside of GEH's scope as an NSSS supplier. The inspection and test  
47 status is maintained through the use of physical location, status indicators (such as tags,  
48 markings, shop travelers, stamps, and inspection records), or other suitable means.

49  
50 In establishing measures for control of inspection, test, and operating status, GEH commits to  
51 compliance with Appendix B to 10 CFR Part 50, Criterion XIV and NQA-1, Requirement 14. As

1 set forth above, the NRC staff reviewed the QA measures to be implemented by GEH and  
2 concluded that the controls for the inspection, test, and operating status meet the guidance in  
3 SRP 17.5.

#### 4 5 3.2.1.15 Nonconforming Materials, Parts, or Components 6

7 GEH has established the necessary measures and governing procedures to control items that  
8 do not conform to specified requirements and to prevent inadvertent test, installation, or use.  
9 GEH's controls provide for identification, documentation, evaluation, segregation when practical,  
10 disposition of nonconforming items, and notification to affected organizations. Nonconforming  
11 items are identified by marking, tagging, or other methods not detrimental to the item, on the  
12 item, the container, or the package containing the item. Nonconformance evaluation and  
13 disposition are defined in implementing procedures. Personnel performing evaluations to  
14 determine a disposition are qualified to:

- 15 (1) demonstrate competence in the specific area they are evaluating,
- 16 (2) possess an adequate understanding of the requirements, and
- 17 (3) access pertinent background information.

18  
19  
20  
21  
22 Nonconformances to design requirements dispositioned "use-as-is" or "repair" are subject to  
23 design control measures commensurate with those applied to the original design.

24  
25 In establishing provisions for nonconforming material, parts, or components, GEH commits to  
26 compliance with Appendix B to 10 CFR Part 50, Criterion XV and NQA-1, Requirement 15. As  
27 set forth above, the NRC staff reviewed the QA measures to be implemented by GEH and  
28 concluded that the controls for handling nonconforming material, parts, or components meet the  
29 guidance in SRP 17.5.

#### 30 31 3.2.1.16 Corrective Action 32

33 GEH has established the necessary measures and governing procedures to promptly identify,  
34 control, document, classify, and correct conditions adverse to quality (CAQs). Implementing  
35 procedures ensure that appropriate actions are initiated following the determination of CAQs in  
36 accordance with regulatory requirements. GEH procedures require personnel to identify known  
37 CAQs in a timely manner so that corrective actions are adequately documented and not  
38 inadvertently nullified by subsequent actions. Reports of conditions that are adverse to quality  
39 are analyzed to identify trends in quality performance. Significant conditions and trends adverse  
40 to quality are reported to the appropriate level of management.

41  
42 In establishing corrective action requirements, GEH commits to compliance with Appendix B to  
43 10 CFR Part 50, Criterion XVI and NQA-1, Requirement 16. As set forth above, the NRC staff  
44 reviewed the QA measures to be implemented by GEH and concluded that the controls for  
45 corrective action meet the guidance in SRP 17.5.

#### 46 47 3.2.1.17 QA Records 48

49 GEH has established the necessary measures and governing procedures to ensure that  
50 sufficient records of items and activities affecting quality are developed, reviewed, approved,  
51 issued, used, and revised to reflect completed work. The provisions of such procedures

1 establish the scope for the records retention program and include requirements for records  
2 administration, including receipt, preservation, retention, storage, safekeeping, retrieval, and  
3 final disposition.

4  
5 Additionally, GEH has established the necessary provisions for the generation, distribution, use,  
6 maintenance, storage, and disposition of quality records in electronic media. GEH procedures  
7 identify the acceptable media on which electronic records are created and stored.

8  
9 In establishing a QA records program, GEH commits to compliance with Appendix B to 10 CFR  
10 Part 50, Criterion XVII, NQA-1, Requirement 17, Generic Letter 88-18, and RIS 2000-18. As set  
11 forth above, the NRC staff reviewed the QA measures to be implemented by GEH and  
12 concluded that the controls for QA records meet the guidance in SRP 17.5.

#### 13 14 3.2.1.18 Audits

15  
16 GEH has established the necessary measures and governing procedures to verify compliance  
17 with QA Program requirements, to verify that performance criteria are met, to determine the  
18 effectiveness of the program, and to provide a comprehensive independent evaluation of  
19 activities and procedures covered by this QATR. GEH utilizes a system of planned audits and  
20 surveillances to verify compliance and assess the effectiveness of all aspects of GEH's program  
21 and implementing procedures. Audits are performed in accordance with written procedures or  
22 checklists by qualified personnel who do not have direct responsibility for performing the  
23 activities being audited. An audit schedule is documented at the beginning of each year to  
24 document the planned, periodic coverage of internal functions performing quality-related  
25 activities and evaluation of the performance of suppliers.

26  
27 In RAI-11, the NRC staff requested that GEH describe the QA measures used to ensure that  
28 audits of covered activities within the scope of the QATR will be completed at least once per  
29 year or at least once during the life of the activity. In its response, GEH stated that  
30 Paragraph 18.3.1 of the QATR was revised to address this requirement by adding the following  
31 sentence: "Activities with durations of less than one year are audited at least once during the  
32 life of the activity." GEH's audit schedule is reviewed periodically and revised to ensure that  
33 coverage is current.

34  
35 In establishing an audit program, GEH commits to compliance with Appendix B to  
36 10 CFR Part 50, Criterion XVIII, NQA-1, Requirement 18 and RIS 2000-18. As set forth above,  
37 the NRC staff reviewed the QA measures to be implemented by GEH and concluded that the  
38 controls for the audit program meet the guidance in SRP 17.5.

#### 39 40 4.0 CONCLUSION

41  
42 The NRC staff evaluated GEH's QATR (Reference 5) submittal and the supplemental  
43 correspondence. The NRC staff concludes that GEH's QA Program description, including  
44 alternatives, adequately addresses the requirements of Appendix B to 10 CFR Part 50 and is  
45 acceptable.

46

1 5.0 REFERENCES

- 2
- 3 1. Letter from GEH to NRC, MFN 10-181, "Revised Version of the GE Hitachi, Nuclear  
4 Energy, Topical Report NEDO 11209, entitled 'GE Hitachi Nuclear Energy Quality  
5 Assurance Program Description,'" dated June 30, 2010. ADAMS Accession No.  
6 ML101830319.  
7
- 8 2. Letter from GEH to NRC, MFN 10-354, "Response to NRC RAIs on GE Hitachi Nuclear  
9 Energy Topical Report NEDO-11209, Revision 9," dated December 10, 2010. ADAMS  
10 Accession No. ML103480313.  
11
- 12 3. Letter from NRC to GEH, "Request for Additional Information Re: GE-Hitachi Nuclear  
13 Energy (GEH) Topical Report NEDO-11209, Revision 9, 'GE Hitachi Nuclear Energy  
14 Quality Assurance Program Description' (TAC No.4483)," dated November 10, 2010.  
15 ADAMS Accession No. ML103090076.  
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- 17 4. Letter from NRC to GE Nuclear Energy, "Acceptance of Amendment 8 to General  
18 Electric Company (GE) QA Topical Report," dated March 31, 1989. ADAMS Accession  
19 No. ML022810092.  
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- 21 5. TR NEDO-11209, Revision 9, "GE Hitachi Nuclear Energy Quality Assurance Program  
22 Description," dated December 9, 2010. ADAMS Accession No. ML103480314.  
23

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27 Date: July 26, 2011