

1 OFFICE OF NUCLEAR REACTOR REGULATION

2 DRAFT SAFETY EVALUATION FOR GE HITACHI NUCLEAR ENERGY

3 PROPOSED REVISION 16 TO TOPICAL REPORT, NEDO-11209A, REVISION 15

4 "GE HITACHI NUCLEAR ENERGY QUALITY ASSURANCE PROGRAM DESCRIPTION"

5 (EPID: L-2020-TOP-0042)

6
7 1.0 INTRODUCTION

8
9 By letter dated July 29, 2020 (Agencywide Documents Access and Management System
10 (ADAMS) Accession No. ML20211L779), GE Hitachi Nuclear Energy (GEH) submitted for the
11 U.S. Nuclear Regulatory Commission (NRC) staff's review and approval the proposed
12 Revision 16 to NEDO-11209A Revision 15, "GE Hitachi Nuclear Energy Quality Assurance
13 Program Description," in accordance with Title 10 of the *Code of Federal Regulations* (10 CFR)
14 paragraph 50.4(b)(7)(ii). GEH is also a 10 CFR Part 71, "Packaging and Transportation of
15 Radioactive Material," licensee holder and utilizes the same quality assurance (QA) program
16 description (QAPD) to meet the requirements of 10 CFR Part 71. The GEH QAPD provides an
17 overview of the program controls applied to quality related items and activities at GEH. GEH
18 proposed that Revision 16 would replace the current Revision 15 QAPD, in its entirety. The
19 changes included in Revision 16 include updating the QAPD to be based on American Society
20 of Mechanical Engineers (ASME) Nuclear Quality Assurance (NQA)-1-2015, "Quality Assurance
21 Requirements for Nuclear Facility Application," dated February 20, 2015, updated to reflect new
22 organization structure, updates to more recent documents, and editorial and clarification
23 changes.

24
25 2.0 REGULATORY EVALUATION

26
27 The Commission's regulatory requirements related to QA programs for non-licensees are set
28 forth in 10 CFR 50.4(b)(7)(ii). This regulation requires that a change to an NRC-accepted
29 QAPD from non-licensees (i.e., architect/engineers, nuclear steam system suppliers, fuel
30 suppliers, constructors, etc.) must be submitted to the NRC. The NRC will review the proposed
31 QAPD for acceptability to ensure the applicable requirements of Appendix B to 10 CFR Part 50
32 will be satisfied.

33
34 Appendix B, "Quality Assurance Criteria for Nuclear Power Plants and Fuel Reprocessing
35 Plants," to 10 CFR Part 50 establishes QA requirements for the design, fabrication,
36 construction, and testing of structures, systems, and components (SSCs) of the facility. The
37 pertinent requirements of Appendix B to 10 CFR Part 50 apply to all activities affecting the
38 safety-related functions of SSCs and include designing, purchasing, fabricating, handling,
39 shipping, storing, cleaning, erecting, installing, inspecting, testing, operating, maintaining,
40 repairing, refueling, and modifying.

41
42 3.0 TECHNICAL EVALUATION

43
44 NUREG-0800, "Standard Review Plan for the Review of Safety Analysis Reports for Nuclear
45 Power Plants," Section 17.5, "Quality Assurance Program Description - Design Certification,
46 Early Site Permit and New License Applicants," Revision 1, dated August 2015 (ADAMS

1 Accession No. ML15037A441), which provides acceptance criteria for QAPDs. SRP
2 Section 17.5 is based on ASME Standard NQA-1-2008 Edition and the NQA-1a-2009 Addenda,
3 as supplemented by additional regulatory and industry guidance for nuclear operating facilities.
4 In addition, the NRC staff used Regulatory Guide (RG) 1.28, "Quality Assurance Program
5 Criteria (Design and Construction)," Revision 5, dated October 2017, endorses the use of
6 NQA-1-2015 with exceptions and clarifications, within. The GEH QAPD, Revision 16, is based
7 on NQA-1-2015 and the exceptions and clarifications noted in RG 1.28, Revision 5.

8
9 The format used for the NRC staff's evaluation followed the sequence of the 18 criteria of
10 Appendix B and corresponding provisions of NQA-1-2015. The QAPD provides guidance for
11 establishing a top-level policy document that defines the quality requirements and assigns major
12 functional responsibilities. The GEH QAPD applies to work involving SSCs for nuclear power
13 plants and fuel reprocessing plants that prevent or mitigate the consequences of postulated
14 accidents that could cause undue risk to the health and safety of the public. In Part I,
15 "Introduction," GE Reuter Stokes was removed from the list of companies affiliated and
16 applicable to the GEH QAPD.

17 18 3.1 Organization

19
20 In Part II, "QAPD Details," Section 1.0, "Organization," GEH made changes to personnel and
21 organizational titles and reporting structure. In Section 1.10, "Commitment," GEH commits to
22 compliance with Appendix B to 10 CFR Part 50, Criterion I, "Organization," and NQA-1-2015
23 Edition, Requirement 1.

24
25 The NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 1.0 and
26 concluded that the organizational changes in the QAPD continue to meet the guidance in SRP
27 Section 17.5, and Appendix B to 10 CFR Part 50, Criterion I, "Organization."

28 29 3.2 Quality Assurance Program

30
31 In Part II, Section 2.0, "Quality Assurance Program," GEH made minor changes to the
32 discussion on review and approval of subsequent issues. In Section 2.9, "Commitment," GEH
33 commits to compliance with Appendix B to 10 CFR Part 50, Criterion II, "Quality Assurance
34 Program," and NQA-1-2015 Edition, Requirement 2.

35
36 The NRC staff reviewed Section 2.0 of the GEH QAPD, and the measures documented and its
37 commitment. The NRC staff finds the changes to the QAPD continue to meet the guidance in
38 SRP Section 17.5 and the requirements in Appendix B to 10 CFR Part 50, Criterion II, "Quality
39 Assurance Program."

40 41 3.3 Design Control

42
43 In Part II, Section 3.0, "Design Control," GEH made changes to add clarity and remove
44 duplication of information. In Section 3.10, "Commitment," GEH commits to compliance with
45 Appendix B to 10 CFR Part 50, Criterion III, "Design Control," and NQA-1-2015 Edition,
46 Requirement 3. In addition, GEH commits to compliance with NQA-1-2015, Subpart 2.7 for
47 establishing requirements for computer program design control.
48

1 The NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 3.0 and
2 concluded that the changes in the QAPD continue to meet the guidance in SRP Section 17.5,
3 and Appendix B to 10 CFR Part 50, Criterion III, "Design Control."
4

5 3.4 Procurement Document Control 6

7 In Part II, Section 4.0, "Procurement Document Control," GEH added controls for software
8 errors in procurement documents. In Section 4.5, "Commitment," GEH commits to compliance
9 with Appendix B to 10 CFR Part 50, Criterion IV, "Procurement Document Control," and
10 NQA-1-2015 Edition, Requirement 4.
11

12 The NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 4.0 and
13 concluded that the changes in the QAPD continue to meet the guidance in SRP Section 17.5,
14 and Appendix B to 10 CFR Part 50, Criterion IV, "Procurement Document Control."
15

16 3.5 Instructions, Procedures, and Drawings 17

18 In Part II, Section 5.0, "Instructions, Procedures, and Drawings," GEH made no modifications to
19 this section except to update its commitment. In Section 5.4, "Commitment," GEH commits to
20 compliance with Appendix B to 10 CFR Part 50, Criterion V, "Instructions, Procedures, and
21 Drawings," and NQA-1-2015 Edition, Requirement 5.
22

23 The NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 5.0 and
24 concluded that the changes in the QAPD continue to meet the guidance in SRP Section 17.5,
25 and Appendix B to 10 CFR Part 50, Criterion V, "Instructions, Procedures, and Drawings."
26

27 3.6 Document Control 28

29 In Part II, Section 6.0, "Document Control," GEH made no modifications to this section except to
30 update its commitment to reflect the use of NQA-1-2015 Edition. In Section 6.5, "Commitment,"
31 GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion IV, "Document
32 Control," and NQA-1-2015 Edition, Requirement 6.
33

34 The NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 6.0 and
35 concluded that the changes in the QAPD continue to meet the guidance in SRP Section 17.5,
36 and Appendix B to 10 CFR Part 50, Criterion VI, "Document Control."
37

38 3.7 Control of Purchased Material, Equipment, and Services 39

40 In Part II, Section 7.0, "Control of Purchased Material, Equipment, and Services," GEH changed
41 the title of Source Acceptance to Source Verification. In Section 4.5, "Commitment," GEH
42 commits to compliance with Appendix B to 10 CFR Part 50, Criterion VII, "Control of Purchase
43 Material, Equipment, and Services," and NQA-1-2015 Edition, Requirement 7. In addition,
44 GEH added requirement for the calibration or a test laboratory to be accredited to
45 ISO/IEC 17025:2017 or 2005.
46

47 The NRC staff notes that the proposed GEH QAPD has already been approved to use the
48 Nuclear Energy Institute (NEI) Technical Report NEI 14-05A, Revision 1, "Guidelines for the
49 Use of Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory
50 Calibration and Test Services," dated August 2014 (ADAMS Accession No. ML14245A391), in

1 NRC staff safety evaluation for GEH QAPD, Revision 12, dated June 6, 2016 (ADAMS
2 Accession No. ML161138A359).

3
4 The NRC staff is currently completing its review of Revision 1 to NEI 14-05A submitted to the
5 NRC by NEI on February 20, 2020 (ADAMS Accession No. ML20054C066). The revision
6 provides clarification guidance for the use of the International Laboratory Accreditation
7 Cooperation (ILAC) process and the use of the 2017 edition of ISO/IEC 17025.

8
9 It is expected that when the NRC approval is completed, GEH will incorporate all limitations and
10 conditions documented in the revision to NEI-14-05 and the associated NRC staff's safety
11 evaluation.

12
13 The NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 7.0 and
14 concluded that the changes in the QAPD continue to meet the guidance in SRP Section 17.5,
15 and Appendix B to 10 CFR Part 50, Criterion VII, "Control of Purchased Material, Equipment,
16 and Services."

17 18 3.8 Identification and Control of Materials, Parts, and Components

19
20 In Part II, Section 8.0, "Identification and Control of Materials, Parts, and Components," GEH
21 made no modifications to this section except to update its commitment. In Section 8.6,
22 "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion VIII,
23 and NQA-1-2015 Edition, Requirement 8.

24
25 The NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 8.0 and
26 concluded that the changes in the QAPD continue to meet the guidance in SRP Section 17.5,
27 and Appendix B to 10 CFR Part 50, Criterion VIII, "Identification and Control of Materials, Parts,
28 and Components."

29 30 3.9 Control of Special Processes

31
32 In Part II, Section 9.0, "Control of Special Processes," GEH made no modifications to this
33 section except to update its commitment to reflect the use of NQA-1-2015 Edition. In
34 Section 9.6, "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50,
35 Criterion IX, and NQA-1-2015 Edition, Requirement 9.

36
37 The NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 9.0 and
38 concluded that the changes in the QAPD continue to meet the guidance in SRP Section 17.5,
39 and Appendix B to 10 CFR Part 50, Criterion IX, "Control of Special Processes."

40 41 3.10 Inspection

42
43 In Part II, Section 10.0, "Inspection" GEH made no modifications to this section except to update
44 its commitment to reflect the use of NQA-1-2015 Edition. In Section 10.6, "Commitment," GEH
45 commits to compliance with Appendix B to 10 CFR Part 50, Criterion X, "Inspection," and
46 NQA-1-2015 Edition, Requirement 10.

47
48 The NRC staff reviewed the changes to the QA measures to be implemented by GEH in QAPD
49 Section 10.0 and concluded that the changes in the QAPD continue to meet the guidance in
50 SRP Section 17.5, and Appendix B to 10 CFR Part 50, Criterion X, "Inspection."

1 3.11 Test Control

2
3 In Part II, Section 11.0, "Test Control," GEH made modifications and reorganized statements
4 related to software testing based on the commitment to NQA-1-2015 Subpart 2.7. In
5 Section 11.6, "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50,
6 Criterion XI, "Test Control," and NQA-1-2015 Edition, Requirement 11. In addition, GEH added
7 "In establishing requirements for computer program test procedures and test records, GEH
8 commits to compliance with NQA-1-2015, Subpart 2.7."
9

10 The NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 11.0
11 and concluded that the changes in the QAPD continue to meet the guidance in SRP
12 Section 17.5, and Appendix B to 10 CFR Part 50, Criterion XI, "Test Control."
13

14 3.12 Control of Measuring and Test Equipment

15
16 In Part II, Section 12.0, "Control of Measuring and Test Equipment," GEH made no
17 modifications to this section except to update its commitment to reflect the use of NQA-1-2015
18 Edition. In Section 12.6, "Commitment," GEH commits to compliance with Appendix B to
19 10 CFR Part 50, Criterion XII, "Control of Measuring and Test Equipment," and NQA-1-2015
20 Edition, Requirement 12.
21

22 The NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 12.0
23 and concluded that the changes in the QAPD continue to meet the guidance in SRP
24 Section 17.5, and Appendix B to 10 CFR Part 50, Criterion XII, "Control of Measuring and Test
25 Equipment."
26

27 3.13 Handling, Storage, and Shipping

28
29 In Part II, Section 13.0, "Handling, Storage, and Shipping," GEH made no modifications to this
30 section except to update its commitment to reflect the use of NQA-1-2015 Edition. In
31 Section 13.6, "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50,
32 Criterion XIII, "Handling, Storage, and Shipping," and NQA-1-2015 Edition, Requirement 13.
33

34 The NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 13.0
35 and concluded that the changes in the QAPD continue to meet the guidance in SRP
36 Section 17.5, and Appendix B to 10 CFR Part 50, Criterion XIII, "Handling Storage, and
37 Shipping."
38

39 3.14 Inspection, Test, and Operating Status

40
41 In Part II, Section 14.0, "Inspection, Test, and Operating Status," GEH made no modifications to
42 this section except to update its commitment to reflect the use of NQA-1-2015 Edition. In
43 Section 14.3, "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50,
44 Criterion XIV, "Inspection, Test and Operating Status," and NQA-1-2015 Edition,
45 Requirement 14.
46

47 The NRC staff reviewed the changes to the QA measures to be implemented by GEH in QAPD
48 Section 14.0 and concluded that the changes in the QAPD continue to meet the guidance in
49 SRP Section 17.5, and Appendix B to 10 CFR Part 50, Criterion XIV, "Inspection, Test, and
50 Operating Status."

1 3.15 Nonconforming Material or Components

2
3 In Part II, Section 15.0, "Nonconforming Material or Components," GEH made no modifications
4 to this section except to update its commitment to reflect the use of NQA-1-2015 Edition. In
5 Section 15.5, "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50,
6 Criterion XV, "Nonconforming, Material or Components," and NQA-1-2015 Edition,
7 Requirement 15.

8
9 The NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 15.0
10 and concluded that the changes in the QAPD continue to meet the guidance in SRP
11 Section 17.5, and Appendix B to 10 CFR Part 50, Criterion XV, "Nonconforming Material or
12 Components."

13
14 3.16 Corrective Action Program

15
16 In Part II, Section 16.0, "Corrective Action," GEH made a minor grammatical change to this
17 section and updated its commitment to reflect the use of NQA-1-2015 Edition. In Section 16.5,
18 "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion XVI,
19 "Corrective Action," and NQA-1-2015 Edition, Requirement 16.

20
21 The NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 16.0
22 and concluded that the changes in the QAPD continue to meet the guidance in SRP
23 Section 17.5, and Appendix B to 10 CFR Part 50, Criterion XVI, "Corrective Action."

24
25 3.17 Quality Assurance Records

26
27 In Part II, Section 17.0, "Quality Assurance Records," GEH made modifications to
28 Section 17.7.4 related to indexing information necessary to retrieve the record to this section
29 and updated its commitment to reflect the use of NQA-1-2015 Edition. In Section 17.8,
30 "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion XVII,
31 "Quality Assurance Records," and NQA-1-2015 Edition, Requirement 17, and RG 1.28,
32 Revision 5.

33
34 The NRC staff reviewed the changes to the QA measures to be implemented by GEH in QAPD
35 Section 17.0 and concluded that the changes in the QAPD continue to meet the guidance in
36 SRP Section 17.5, and Appendix B to 10 CFR Part 50, Criterion XVII, "Quality Assurance
37 Records."

38
39 3.18 Audits

40
41 In Part II, Section 18.0, "Audits," GEH made modifications to this section to reflect the changes
42 in NQA-1-2015 and the regulatory positions in RG 1.28, Revision 5. In addition, GEH made
43 changes to update its commitment to reflect the use of NQA-1-2015 Edition. In Section 18.7,
44 "Commitment," GEH commits to compliance with Appendix B to 10 CFR Part 50, Criterion XVIII,
45 and NQA-1-2015 Edition, Requirement 18 and RG 1.28, Revision 5.

46
47 The current revision QAPD, Revision 15 requires the following for internal audits:

48
49 Internal audits of organizations and activities are conducted prior to placing a
50 facility in operation and at least once a year subsequently. Once Activities have

1 been established, internal audits are conducted to ensure all GEH Quality
2 Assurance (QA) program elements are evaluated for each functional area within
3 a period of two years. Activities with durations of less than one year are audited
4 at least once during the life of the activity.
5

6 The proposed change in GEH QAPD, Revision 16 requires the following for internal audits:
7

8 Prior to placing a licensed facility into operation – All applicable QA program
9 elements are audited at least once each year or at least once during the life of
10 the activity, whichever is shorter.
11

12 After placing a licensed facility into operation – All applicable QA program
13 elements for each functional area shall be audited within a period of two years.
14 For well-established activities, the period may be extended one year at a time
15 beyond the two-year interval based on the results of an annual evaluation of the
16 applicable functional area and objective evidence that the functional area
17 activities are being satisfactorily accomplished. However, the internal audit
18 interval shall not exceed a maximum of four years.
19

20 Activities not related to a licensed facility or other support activities – All
21 applicable QA program elements shall be audited at least once each year or at
22 least once during the life of the activity, whichever is shorter. This interval may
23 be extended up to two years based on the results of an annual evaluation and
24 objective evidence that the activities are being satisfactorily accomplished in
25 accordance with the applicable QA program elements.
26

27 The NRC staff reviewed the changes related to internal audits. Based on GEH's experience in
28 the nuclear industry, the NRC staff finds GEH has a well-established audit program. The NRC
29 staff determined the GEH's proposed changes in internal audit frequency for internal audits is in
30 alignment with current NRC staff guidance and is therefore acceptable.
31

32 The NRC staff reviewed the QA measures to be implemented by GEH in QAPD Section 18.0
33 and concluded that the changes in the QAPD continue to meet the guidance in SRP
34 Section 17.5, and Appendix B to 10 CFR Part 50, Criterion XVIII, "Audits."
35

36 4.0 CONCLUSION 37

38 The NRC staff used the acceptance criteria in NUREG-0800, Section 17.5, as the basis for
39 evaluating the acceptability of the changes to the GEH QAPD, Revision 16, in conformance with
40 the applicable portions of 10 CFR Part 71, and Appendix B to 10 CFR Part 50. The NRC staff
41 concludes that GEH QAPD, NEDO-11209, Revision 16, follows the NRC guidance contained
42 within and conforms to the format of NUREG-0800, Section 17.5, complies with Appendix B to
43 10 CFR Part 50 requirements for the QA program and, therefore, is acceptable.
44

45 5.0 REFERENCES 46

- 47 1. Safety Evaluation of GEH Quality Assurance Topical Report, NEDO-11209, Revision 12,
48 Quality Assurance Program Description, dated June 6, 2016 (ADAMS Accession
49 No. ML16138A359).
50

- 1 2. Final Safety Evaluation of NEI 14-05, "Guidelines for the Use of Accreditation in Lieu of
2 Commercial Grade Surveys for Procurement of Laboratory Calibration and Test Services,
3 Revision 1," dated February 9, 2015 (ADAMS Accession No. ML14322A535).
4
- 5 3. NEI submittal Revision 1 to Technical Report NEI 14-05A, "Guidelines for the Use of
6 Accreditation in Lieu of Commercial Grade Surveys for Procurement of Laboratory
7 Calibration and Test Services," dated February 20, 2020 (ADAMS Accession
8 No. ML20054C066).
9
- 10 4. Safety Evaluation of GEH Quality Assurance Topical Report, NEDO-11209, Revision 15,
11 Quality Assurance Program Description, dated May 20, 2020 (ADAMS Accession
12 No. ML20140A322).
13
- 14 5. Regulatory Guide 1.28, "Quality Assurance Program Criteria (Design and Construction),"
15 dated October 27, 2020 (ADAMS Accession No. ML17207A293).
16
- 17 6. NUREG-0800, Standard Review Plan for the Review of Safety Analysis Reports for Nuclear
18 Power Plants: LWR Edition, Section 17.5 Revision 1, "Quality Assurance Program
19 Description – Design Certification, Early Site Permit and New License Applicants,"
20 August 2015 (ADAMS Accession No. ML15037A441).
21
- 22 7. American Society of Mechanical Engineers (ASME) NQA-1-2015, "Quality Assurance
23 Requirements for Nuclear Facility Applications," dated February 20, 2015.

24
25 Principal Contributor: A. Keim

26
27 Date: December 1, 2020