**GE Hitachi Nuclear Energy**

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MFN 16-076

Docket Number: 72-01

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U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Director, Division of Spent Fuel Management
Office of Nuclear Material Safety and Safeguards
Washington, DC 20555-0001

**Subject: Response to Request for Additional Information for the Review of the GE Hitachi Nuclear Energy, Morris Operation, Topical Report NEDE-31559, "GE Hitachi Nuclear Energy Quality Assurance Plan Morris Operation," (CAC No. L25119)**

References:

1. Letter from Marlone Davis (NRC) to Jerald G. Head (GEH), Subject: Request for Additional Information for the Review of the GE Hitachi Nuclear Energy, Morris Operation, Topical Report NEDE-31559, "GE Hitachi Nuclear Energy Quality Assurance Plan Morris Operation," (CAC No. L25119), MFN 16-077, September 29, 2016.
2. Letter from Jerald G. Head (GEH) to Document Control Desk (NRC), Subject: Change Evaluation for Revision 3 of the GE Hitachi Nuclear Energy, Morris Operation, Topical Report NEDE-31559, "GE Hitachi Nuclear Energy Quality Assurance Plan Morris Operation," MFN 16-029, May 13, 2016.

This letter transmits the GE Hitachi Nuclear Energy (GEH) response to the Nuclear Regulatory Commission (NRC) Request for Additional Information (RAI) in Reference 1. Enclosure 1 presents the changes that will be made when GEH publishes the accepted (-A) version of NEDE-31559 following receipt of the NRC Safety Evaluation.

The following statement made in Reference 2 remains applicable:

> Please note that the change evaluation indicates that in Section 8.4.1 of NEDE-31559 Revision 3, the text in the last sentence was changed from “Section 10.0” to “Section 7.0”; however, GEH has observed that this change was not made in Revision 3 of NEDE-31559; this change will be made as part of the creation of the accepted (-A) version of NEDE-31559 Revision 4.

If you have any questions regarding this letter, please contact Rich Augi at 910-819-6366.

Sincerely,

Jerald G. Head
Senior Vice President Regulatory Affairs

Commitments: No additional commitments are made in this response.

Enclosure:

1. Response to NRC Request for Additional Information (RAI) – Non-Proprietary Information – Class I (Public)

cc: Mark Lombard, NRC NMSS
Marlone Davis, NRC
Anthony McFadden, GEH
Franklin Partney, GEH
Emily Martin, GEH
Peter Yandow, GEH
Tammy Orr, GEH
Mark Elliot, GEH
PLM Specification 003N1259 R2

Enclosure 1

MFN 16-076

Response to NRC Request for Additional Information (RAI)

Non-Proprietary Information – Class I (Public)

**NRC RAI**

The NRC staff has also approved NEDE-31559, GE Hitachi Nuclear Energy Quality Assurance Plan-Morris Operation," under docket number 71-0004 for limited Part 71 activities. As a part of this review, the NRC staff identified that GEH Nuclear Energy deleted reference to Part 71 and stated, in part, that any activities related to 10 CFR Part 71 shall be performed per topical report GEH Quality Assurance Plan Description (QAPD) NEDO-11209A. Therefore, if the NRC approves the changes made to NEDE-31559, then the Quality Assurance Program (QAP) Approval applicable to 10 CFR Part 71 packaging and transportation activities occurring at the Morris Facility would void the conditions of the NRC approved QAP under docket number 71-0004 without reasons for such changes.

Clarify how the proposed changes to NEDE-31559 would affect Parts 71 and 72 activities conducted under docket number 71-0004 and the intent to establish, maintain, and execute a quality assurance program satisfying each of the applicable criteria of subparts H and G, for Parts 71 and 72, respectively.

The staff requests this information to determine compliance with 10 CFR 71.105 and 10 CFR 72.140(d).

**GEH Response**

The Part 72 Subpart G provisions are currently included in the proposed Revision 3 of NEDE-31559 as they were in the approved Revision 2 of NEDE-31559. Regarding the Part 71 Subpart H provisions, GEH has determined that these provisions should be included in Revision 3 with appropriate notes. The changes are summarized in the table below and illustrated in the revised pages immediately following this RAI response, with all changes shown in revision mode.

Note there are a few changes identified in this response that are not directly related to the RAI response. These instances are noted in the table.

**Summary of Changes to be made to Revision 3**

| Section | Summary of Change |
|---|---|
| Policy Statement | Changed the name to the current Vice President, Emily Martin<br>(Not Related to RAI) |
| Section 1 | |
| 1.4.4 | Added text to clarify Quality activities and responsibilities.<br>(Not Related to RAI) |
| 1.4.5 | Changed QA to Quality consistent with the current organization<br>(Not Related to RAI)<br>Deleted Item (i) regarding 10 CFR Part 71 activities |
| Figure 1 | Modified to reflect the proper location of the Quality organization<br>(Not Related to RAI) |

| Section | Summary of Change |
|---|---|
| Section 2 | |
| 2.2.1 | Added 10 CFR Part 71 Subpart H to the list of regulations to which the Morris QAP complies. |
| 2.2.5 | Added this new section to specify the limitations associated with the Morris 10 CFR Part 71 limited use license. |
| Section 3 | |
| 3.1 | Added a note clarifying that the Morris Facility has no authorization for design activities related to 10 CFR Part 71. |
| Section 4 | |
| 4.2.2 | Added 10 CFR 71 Subpart H to the listed Regulatory Requirements |
| Section 13 | |
| 13.5.4 | Deleted this section pertaining to the use of NEDO-11209-A for any 10 CFR Part 71 activities. |

## POLICY STATEMENT

This Quality Assurance Plan is the top-level policy document that establishes the manner in which quality is to be achieved and presents GEH Morris' overall philosophy regarding achievement and assurance of quality. Implementing procedures assign more detailed responsibilities and requirements, and define the organizational interfaces involved in conducting activities within the scope of the Quality Assurance Program. Compliance with the Quality Assurance Plan and implementing procedures is mandatory for personnel associated with implementation of the GEH Morris Quality Assurance Program. These activities shall be performed in compliance with the requirements of the Code of Federal Regulations (CFR), the applicable Nuclear Regulatory Commission (NRC) Facility Operating Licenses, regulatory guidance documents and applicable laws and regulations of the state and local governments.

~~Jon Ball~~**Emily Martin**, Vice President, Global Supply Chain

GE Hitachi Nuclear Energy

Date

- Radiation Safety which includes radiation safety, safety, security and radioactive material shipping and receiving.

1.4.2 The Environmental Health and Safety and Procurement Administrator (EHSPA) is responsible for compliance to all applicable OSHA and internal EHS standards.

1.4.3 The Operations and Maintenance Coordinator (OMC) is responsible for operations and maintenance overview, projects, contracts, and site engineering. The OMC is also responsible for operator certification, operations plans, and schedules.

1.4.4 Quality is responsible for establishing overall quality programs and for assuring that quality-related activities are performed in accordance with these programs. Quality is organizationally independent of the operating functions and has been delegated authority and responsibility to identify and evaluate quality problems; to recommend and assure implementation of corrective actions; and to stop work and control further processing, delivery, installation or utilization of nonconforming items until proper disposition is established. **Quality verifies activities affecting the functions that are important to safety have been correctly performed via checking, auditing and inspection. Quality has direct access to levels of management necessary to perform the responsibilities listed.**

1.4.5 Certain activities are delegated to GEH Wilmington ~~QA~~**Quality**, Sourcing, and Engineering. These activities are conducted per the applicable requirements of the NRC approved GEH Quality Assurance Program Description NEDO-11209-A. The delegated activities are summarized as follows:

(a) Qualification of suppliers
(b) Supplier evaluation and audits
(c) Procurement document review and issuance
(d) Source inspection
(e) Engineering calculations
(f) Engineering activity verification
(g) Administration and maintenance of quality-related software
(h) Internal audits
~~(i) 10 CFR Part 71 activities (if required)~~

1.4.6 Personnel can perform functions that they are qualified for, but are outside their primary area of responsibility. When this occurs, they shall report to the manager or supervisor responsible for the function; i.e., when personnel perform quality control activities they report to Quality.

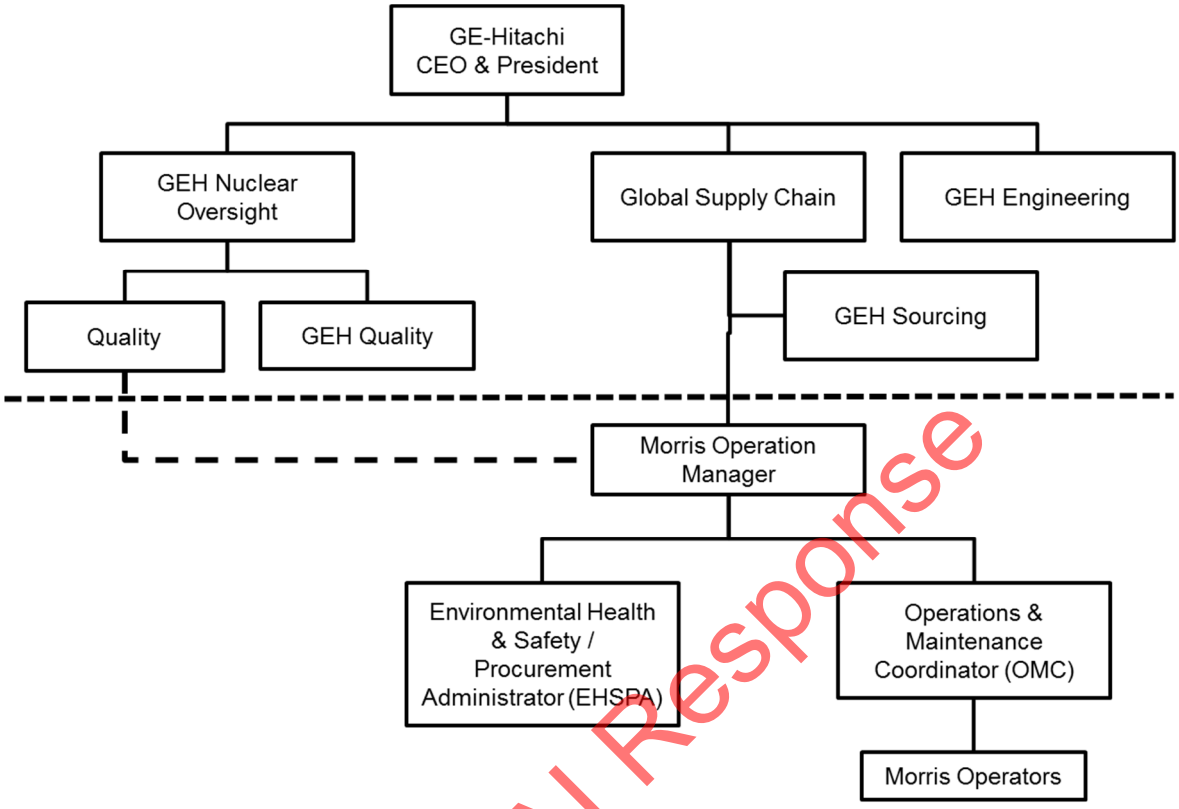


**FIGURE 1: MORRIS OPERATION ORGANIZATION**

(Operations below dotted line are represented at GEH Morris)

# 2.0 QUALITY ASSURANCE PROGRAM

## 2.1 Purpose

To establish requirements to plan, manage, control and implement this QAP.

## 2.2 General

2.2.1 MO's QAP complies with the Code of Federal Regulations, Title 10, Part 72, Licensing Requirements for the Storage of Spent Fuel in an Independent Spent Fuel Storage Installation (ISFSI), **10 CFR Part 71, Subpart H** and 10 CFR Part 21.

2.2.2 MO's Quality Program is implemented with written methods established in MO procedures or instructions.

2.2.3 The MO Quality Program described in this document shall apply to the following structures, systems and components that are determined to be important to safety per 10 CFR 72.122:

- Fuel storage basin-concrete walls, floors, and expansion gate,
- Fuel storage basin-stainless steel liner,
- Fuel storage system, including baskets and supporting grids,
- Unloading pit doorway guard,
- Filter cell structure,
- Fuel Storage Basin building,
- Fuel Basket Grapple,
- Fuel Grapple,
- Fuel Basin Crane,
- Fuel Handling Crane,
- Cask Crane,
- Spent Fuel Cladding.

Other items are normally excluded from the scope of this document, but may be included to meet specific project requirements. Depending on project scope or service, this QAP may be applied in its entirety, or any portion thereof may be applied, as determined by Quality.

**2.2.4** Activities affecting quality are documented and accomplished under controlled conditions.

~~2.2.4~~**2.2.5 MO holds a limited use license for 10 CFR Part 71 activities. These activities are limited to: procurement, maintenance, repair and use.**

## 2.3 Responsibilities

2.3.1 The Manager, Global Supply Chain is responsible for providing the organization structure for the implementation of this QAP.

2.3.2 The Manager, MO is responsible for implementing activities in accordance with the requirements of this QAP, including program documentation, maintenance, and enforcement.

## 3.0 DESIGN CONTROL

### 3.1 General

3.1.1 Engineering activities including engineering calculations, verification activities and administration and maintenance of quality-related software are to be performed under the GEH QAPD NEDO-11209-A.

**3.1.2** Engineering activities on structures, systems and components as described in Section 2.2.3 will be treated as safety related per NEDO-11209-A.

**NOTE: MO has no authorization for design activities related to 10 CFR Part 71.**

# 4.0 PROCUREMENT DOCUMENT CONTROL

## 4.1 Purpose

To describe measures to assure applicable regulatory requirements, design bases and other requirements necessary to assure quality are included in procurement documents.

## 4.2 General

4.2.1 The Materials and Service Request (MSR) is classified to reflect the quality level of the procurement.

4.2.2 The MSR, drawings, specifications and other accompanying documents are reviewed for quality requirements by Quality. These requirements may include:

- Standard or Specification, as appropriate.
- Supplier on Approved Supplier List.
- Regulatory Requirements (i.e. 10CFR21, 10CFR72 Subpart G, **10CFR71 Subpart H**).
- Provisions for Source Inspection.
- Documentation Requirements.
- Quality or Non-Quality designation.
- Where the MSR is for a structure, system or component as defined in Section 2.2.3, the supplier shall certify the material was furnished under a quality program approved by GE-Hitachi Nuclear Energy (GEH) and shall record their quality manual identification and revision number on their certification documentation. The supplier shall be required to incorporate appropriate QA Program requirements in subtier procurement documents.
- Personnel and procedure qualification records.
- Specific quality clauses.
- Other quality-related records.

4.2.3 To the extent necessary, procurement documents require vendors to provide a QA program consistent with requirements of this QAP.

4.2.4 Revisions to MSRs shall list requirements that have been changed and shall be subject to the same preparation, review, approval and other processing required for the initial document. Specific non-quality related revisions, such as price changes or cancellation may be processed by Sourcing. Sourcing personnel cannot add, alter or delete technical or quality requirements after review and approval of the MSR.

4.2.5 Purchase Orders (POs) issued by an approved MSR can only be revised by issuing a revised MSR.

4.2.6 On POs which specify source inspection, the supplier is required to grant MO and/or the customer the right of access to the supplier's shop to inspect products, processes, testing and quality records related to the PO.

### 13.5 Implementation

13.5.1 Requirements for cleaning, marking, packaging, preservation, shipping, storage and handling are incorporated in Operations and Maintenance documents. These requirements are reviewed and approved by appropriate management.

13.5.2 Operations and Maintenance implements these tasks by development and/or use of detailed procedures.

13.5.3 Specific procedures for irradiated fuel handling and storage are developed in accordance with the QAP.

~~13.5.4 Any activities related to 10 CFR Part 71 shall be performed per the GEH QAPD NEDO-11209-A.~~