UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

November 24, 2021

Mr. Mark Soler
Vice President of Quality
Holtec International
1 Holtec Blvd.
Camden, NJ 08104

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION FOR REVIEW OF THE HOLTEC INTERNATIONAL QUALITY ASSURANCE MANUAL REVISION 15

Dear Mr. Soler:

By letter dated July 31, 2020, Holtec International submitted an application for approval of a revised quality assurance (QA) program under Title 10, *Code of Federal Regulations* (10 CFR) Part 71.

In connection with the staff's review, we need the information identified in the enclosure to this letter. We request that you provide this information by January 31, 2022. Inform us at your earliest convenience, if you are not able to provide the information by that date.

Please reference Docket No. 71-784 in future correspondence related to this request. The staff is available to clarify these questions, and if necessary, to meet and discuss your proposed responses. If you have any questions regarding this matter, please contact Matthew Learn at Matthew.Learn@nrc.gov or Marlone Davis at Marlone.Davis@nrc.gov.

Sincerely,

Earl Love, Acting Chief
Inspections and Operations Branch
Division of Spent Fuel Management
Office of Nuclear Material Safety
and Safeguards

Docket No.: 71-784

Enclosure:
Request for Additional Information

SUBJECT: REQUEST FOR ADDITIONAL INFORMATION FOR REVIEW OF THE HOLTEC INTERNATIONAL QUALITY ASSURANCE MANUAL REVISION 15
DATE: November 24, 2021

Docket No.: 71-784

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Request for Additional Information Holtec International
Docket No. 71-784
Holtec International Quality Assurance Manual Proposed Revision 15

By submittal dated July 31, 2020, Holtec International requested approval of the Holtec International Quality Assurance Manual (HQAM) Proposed Revision 15. This request for additional information (RAI) identifies information needed by the U.S. Nuclear Regulatory Commission (NRC) staff in connection with its review of the HQAM. The requested information is listed by chapter number and title in the applicant's HQAM. NUREG 2216, "Standard Review Plan for Transportation Packages for Spent Fuel and Radioactive Material," was used by the staff in its review of the application.

Each individual RAI describes information needed by the staff for it to complete its review of the submittal and to determine whether the applicant has demonstrated compliance with the regulatory requirements.

**Table of Contents**

TOC Revise page numbers to remove typographical errors.

**Part 1 Introduction - Section 1 - General**

I-1 Revise the following statement, it appears to contain a typographical error.

"Applicable subparts from Part 2 of ASME NQA-1-2015 Part 1 as listed in each section within this HQAM and with exceptions/clarifications as listed in the applicable section of this HQAM."

This information is needed to determine compliance with 10 CFR 71.101, 71.105.

**Part 2 – Section 2 – Program**

2-1 Describe measures to ensure that lead auditor qualifications as committed to and described in American Society of Mechanical Engineers (ASME) NQA-1-2015 meet the NRC's exceptions to ASME NQA-1-2015 provided in Regulatory Guide (RG) 1.28, "Quality Assurance Program Criteria (Design and Construction)" Revision 5.

RG 1.28, Revision 5 endorses, with certain clarifications, exceptions, and regulatory positions ASME NQA-1 2015. RG 1.28 provides the following exception to ASME-NQA-1.

> "Prospective lead auditors**, with comparable industry experience** [emphasis added], may satisfy the lead auditor qualification requirement of participating in a minimum of five QA audits within a period of 3 years prior to the date of qualification by alternatively **demonstrating the ability to properly implement the audit process, effectively organize and report results, and participate in at least one nuclear audit**

**within the year preceding the date of qualification, subject to review and acceptance by the responsible QA organization** [emphasis added]."

This information is needed to determine compliance with 10 CFR 71.105.

**Part 2 – Section 4 – Procurement Document Control**

4-1 Describe measures to ensure requirements for adequate quality is required in the documents for procurement of material, equipment, and services by contractors or subcontractors.

10 CFR 71.109 states in part that, "the licensee, certificate holder, and applicant for a CoC shall establish measures to assure that adequate quality is required in the documents for procurement of material, equipment, and services, whether purchased by the licensee, certificate holder, and applicant for a CoC or by its **contractors or subcontractors** [emphasis added]."

This information is needed to determine compliance with 10 CFR 71.109.

**Part 2 – Section 7 - Control of purchased material, equipment, and services**

7-1 Clarify the specific "Company requirements" the Company will utilize to determine if the scope and adequacy of third-party audits or surveys that are used are adequate to establish supplier qualification.

The HQAM Section 7.1 States that, "The Company may utilize audits and commercial grade surveys conducted by outside organizations for supplier qualification provided that the scope and adequacy of the audits or surveys meet Company requirements."

This information is needed to determine compliance with 10 CFR 71.115.

7-2 Please provide additional clarification on when a commercial grade supplier is or is not required to be on the AVL.

The HQAM Section 7.1 States, "Suppliers of items or services which will be dedicated by the Company from commercial to safety significant status are not required to be on the AVL."

This information is needed to determine compliance with 10 CFR 71.115.

7-3 Define or provide examples of "exigent condition" discussed in HQAM Section 7.1 and 7.2.

This information is needed to determine compliance with 10 CFR 71.115.

7-4 Please provide additional detail on the decision-making process based on the below-mentioned criteria for whether a remote audit can be performed.

The HQAM states “The Company must first assess whether a remote audit can be performed such that a thorough and complete evaluation of the supplier’s QA Program and its implementation can be made. Consideration must be given to the following:

a) complexity and type of item or service being provided by the supplier;
b) the Company’s familiarity with the supplier;
c) the supplier’s ability and willingness to support a remote based audit;
d) do exigent conditions exist such that it is not possible to be at the supplier’s facility.

This information is needed to determine compliance with 10 CFR 71.115 and 71.137.

7-5 Describe the actions that will be taken within the procurement process to ensure that the vendor is able and willing to support the necessary source surveillance / source verification methods when a procurement is placed with a vendor and the possibility of exigent conditions affecting the procurement process exist.

The HQAM states that, “Consideration must be given to the following: … c) the supplier’s ability and willingness to support a remote based audit…”

The information is needed to determine compliance with 10 CFR 71.109 and 71.115.

7-6 Clarify or qualify the following statement: “the remote aspect cannot change how the audit is performed.”

Performing a remote audit inherently changes how an audit is performed as no auditors are physically at the facility.

The information is needed to determine compliance with 10 CFR 71.115 and 71.137.

7-7 Describe the audit planning process to ensure the following is achieved.

The HQAM states, that, “The remote aspect of the audit cannot change how the audit is performed, how objective evidence is selected and what activities are observed. The control of the audit and the selection of necessary objective evidence must be done by the audit team in order to retain true independence and assure that a thorough and complete audit is performed.”

The information is needed to determine compliance with 10 CFR 71.115 and 71.137.

7-8 Describe the process for evaluating the effectiveness of a particular, proposed remote technology (e.g., computer, phone, camera, etc.) in allowing the auditor to “direct” and “see” the necessary objective evidence that is to be observed. Additionally, describe how a determination as to whether sufficient “visual clarity and mobility“ and “audio” has been established for witnessing the performance of a particular activity.

The HQAM states that, “The audited entity must be able to support remote real time observation of the performance of activities that are required to be observed as part of the objective evidence to support implementation of the QA Program. This includes the technological capabilities to provide sufficient visual clarity and mobility as well as audio. Such activities to be observed may include, but not be limited to welding, inspection, machining, material processing, testing, etc. In addition, observation requirements may include real time verification of such things as calibration stickers affixed to M&TE, nonconformance tags appropriately attached to applicable items, item traceability markings, etc.”

The information is needed to determine compliance with 10 CFR 71.115, 71.129, 71.131, 71.137.

7-9 Please provide information on any special personnel qualifications that may be associated with performance of a remote audit.

This information is needed to determine compliance with 10 CFR 71.137.

7-10 Please identify limitations with auditor familiarity with the facility. For example, at least one auditor has previously been to the facility or as an alternative, the auditors may consult with the auditors from previous assessments. Further clarify whether a remote audit may be performed for the first audit of the facility.

This information is needed to determine compliance with 10 CFR 71.137.

**Part 2 - Section 13 – Handling, storage, and shipping control**

13-1 Revise the following statement to eliminate the word “minimize” and add “prevent.” “The Company has established the necessary measures and governing procedures to control the handling, storage, packaging, shipping, cleaning, and preservation of items to prevent inadvertent damage or loss, and to **minimize** deterioration.“

10 CFR 71.127 requires that measures be established to prevent deterioration. Specifically, 10 CFR 71.127 states that, “the licensee, certificate holder, and applicant for a CoC shall establish measures to control, in accordance with instructions, the handling, storage, shipping, cleaning, and preservation of materials and equipment to be used in packaging to **prevent** damage or deterioration.”

This information is needed to determine compliance with 10 CFR 71.127.

**Part 2 – Section 15 – Nonconforming materials, parts or components**

15-1 Describe the measures to control materials, parts, or components that do not conform to the licensee's requirements to prevent their **inadvertent use or installation.**

10 CFR 71.131 requires that the licensee, certificate holder, and applicant for a CoC shall establish measures to control materials, parts, or components that do

not conform to the licensee's requirements to prevent **their inadvertent use or installation** [emphasis added].

The HQAM states the following: “Controls are provided to address conditional release of nonconforming items for use on an at-risk basis prior to resolution and disposition of the nonconformance, including maintaining identification of the item and documenting the basis for such release” and “Nonconformances are corrected or **resolved prior to relying on the item to perform its intended safety function**.” [emphasis added].

This information is needed to determine compliance with 10 CFR 71.131.

**Part 2- Section 16 – Corrective Action**

16-1 Describe measures that ensure that the identification of the significant condition adverse to quality, **the cause of the condition, and the corrective action taken** [emphasis added] must be documented and reported to appropriate levels of management in accordance with 10 CFR 71.133.

10 CFR 71.133 states that, “the identification of the significant condition adverse to quality, **the cause of the condition, and the corrective action taken** [emphasis added] must be documented and reported to appropriate levels of management.” The HQAM states that, “Significant conditions adverse to quality and significant adverse trends are documented and reported to responsible management.” The HQAM does not indicate that the cause of the condition and the corrective action are reported to appropriate levels of management.

This information is needed to determine compliance with 10 CFR 71.133.

**Part 2 – Section 17 – Quality Assurance Records**

17-1 Describe measures to ensure that managing quality assurance records in electronic media as committed to and described in ASME NQA-1-2015 meet the NRC’s exceptions to ASME NQA-1-2015 provided in Regulatory Guide 1.28, Revision 5.

RG 1.28, Revision 5 endorses, with certain clarifications, exceptions, and regulatory positions ASME NQA-1 2015. RG 1.28 provides the following exception to ASME-NQA-1:

> (1) For the management of electronic records, appropriate controls on quality assurance include the following:
>
> > (a) No deletion or modification of records unless authorized pursuant to the record retention rule
> > (b) Redundancy (system backup, dual storage, etc.) is provided
> > (c) Legibility is required of each record
> > (d) Records media are properly maintained
> > (e) Inspections to ensure no degradation of records
> > (f) Records are acceptably converted into any new system before the old system is taken out of service

The Nuclear Information and Records Management Association (NIRMA) technical guides (TGs), as listed below, provide guidance to establish the appropriate quality controls that incorporates the implementation of enterprise content management systems, web-based technologies, and higher capacity LAN/WAN networks. The NRC approves for use the 2011 versions of the NIRMA TGs.

(a) NIRMA TG 11, "Authentication of Records and Media".
(b) NIRMA TG 15, "Management of Electronic Records.
(c) NIRMA TG 16, "Software Configuration Management and Quality Assurance"; and
(d) NIRMA TG 21, "Electronic Records Protection and Restoration".

This information is needed to determine compliance with 10 CFR 71.135.

**Part 2 – Section 18 – Audits**

18-1 Clarify that the HQAM takes exceptions to ASME NQA-1-2015, Part 1, Requirement 18.

The HQAM states that "the Company commits to compliance with NQA-1, Part 1, Requirement 18. No exceptions," however ASME NQA-1-2015, Part 1 Requirement 18 Section 200, states that, "A grace period of 90 days may be applied to scheduled audits and annual evaluations of supplier performance." It appears an exception to this requirement is taken in HQAM Section 7.1, "A grace period not to exceed 25 percent of the audit or survey interval shall be allowed under exigent conditions with the following requirements."

This information is needed to determine compliance with 10 CFR 71.137.

18-2 Describe measures to ensure that internal audits committed to and described in ASME NQA-1-2015 meet the NRC's exceptions to ASME NQA-1-2015 provided in Regulatory Guide 1.28, Revision 5.

RG 1.28, Revision 5 endorses, with certain clarifications, exceptions, and regulatory positions ASME NQA-1 2015. RG 1.28 provides the following exception to ASME-NQA-1-2015:

"Applicable elements of an organization's QA program should be audited at least once each year or at least once during the life of the activity, whichever is shorter. In determining the scope of the audit, an evaluation of the activity being audited may be useful. The evaluation may include results of previous QA program audits and the results of audits from other sources, including the nature and frequency of identified deficiencies and any significant changes in personnel, the organization, or the QA program."

ASME NQA-1-2015, Requirement 18, Section 201.3 states the following:

> "201.3 Suppliers and Other Nuclear Support Organizations. All applicable quality assurance program elements shall be audited at least once each year or at least once during the life of the activity, whichever is shorter. **This interval may be extended up to 2 yrs. based on the results of an annual evaluation and objective evidence that the activities are being satisfactorily accomplished in accordance with the applicable quality assurance program elements** [emphasis added]."

This information is needed to determine compliance with 10 CFR 71.137.