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August 28, 2019

72-1014

Christian Araguas, Chief, Inspection and Operations Branch
Division of Spent Fuel Management
Office of Nuclear Material Safety and Safeguards

U.S. Nuclear Regulatory Commission
ATTN: Document Control Desk
Washington, DC 20555-0001

Subject: Reply to a Notice of Violation

Reference(s): [1] U.S. Nuclear Regulatory Commission Follow-Up Inspection Report No. 07201014/2019-201 and Notice of Violation

Dear Mr. Araguas:

This letter provides Holtec's response as required in the above referenced Notice of Violation [1].

Violation:

10 CFR 72.48(d)(1) requires, in part, that the licensee and certificate holder shall maintain records of changes in the facility or spent fuel storage cask design, of changes in procedures, and tests and experiments made pursuant to paragraph (c) of this section. These records must include a written evaluation, which provides the bases for the determination that the change does not require a CoC amendment pursuant to paragraph (c)(2) of this section.

Contrary to the above, Holtec's 72.48 evaluations failed to (1) demonstrate that an estimation of gouge sizes was achieved through any identified methodology and (2) compare the estimated gouge sizes to acceptance criteria for minimum wall thickness, as identified in ASME Section III (or Section XI).

Holtec Response:

Holtec does not contest the violation. However, Holtec would like to take the opportunity to provide a perspective on the technical aspects prior to discussing the actions taken. For the change evaluated by the two 72.48s cited in the inspection report, the technical justification relied in part on a simple formula that is ubiquitous in the ASME Code. Our engineers had considered the logic based on the formula to be essentially self-evident, considering it to implicitly underpin their notion of a sound *engineering judgement*. Thus, even though ASME Section III is the underlying structural basis of the HI-STORM UMAX system, the specific details or the ASME Section III

IE08
NM5526
NM55



paragraph was not quoted in the change or the evaluation. Nevertheless, it is understood that *explicit documentation to support engineering judgement* is the NRC's expectation. Our instruction to the preparers and reviewers of safety documentation has been accordingly updated. Thus, in addition to revising the affected documents to provide the needed information, Holtec has been providing training to the personnel who prepare engineering change documents, and also correspondingly updated internal procedures to assure appropriate actions in the future. Most of this has already been completed, the one outstanding action still in progress is expected to be completed by the end of September.

To address the NRC's specific requests in Reference [1]:

- 1) The reason for the violation, or, if contested, the basis for disputing the violation or severity level

As stated above, Holtec does not contest the violation. The cause of the violation is lack of specificity in our procedural guidance documents. The involved engineers had used engineering judgement as the basis for the conclusion and believed that such conclusion would be concurred by those with a general knowledge of the ASME Code.

- 2) The corrective steps that have been taken and the results achieved
- 3) The corrective steps that will be taken to avoid further violations
- 4) Your plan and schedule for completing short and long term corrective actions
- 5) The date when full compliance will be achieved

Questions 2 through 5 are all addressed by the following list of corrective actions and actions to prevent recurrence and the dates of completion / planned completion.

- a) Revise Engineering Change Order ECO-5021-42 and corresponding 72.48 – 7/19/2019
- b) Revise ECO-5021-39 and corresponding 72.48 – 7/26/2019
- c) Provide training to technical disciplines on ECO justification expectations – 7/31/2019
- d) Update Holtec Standard Procedure HSP-100501 to include guidance on the technical rigor needed for ECO justification – 8/13/2019
- e) Complete a new review of HSP-321 including the desktop instruction area in order to identify any areas where additional details or guidance may be warranted in order to prevent future noncompliant conditions – 9/30/2019



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We trust the above response would meet with your approval. If there are any additional questions, we would be pleased to provide supplemental information. I can be reached at 856-797-0900 ext. 3619, m.soler@holtec.com (email) .

Sincerely,

Mark Soler

Digitally signed by Mark Soler
DN: cn=Mark Soler, o, ou,
email=m.soler@holtec.com, c=US
Date: 2019.08.28 06:55:59 -04'00'

Mark Soler
Vice President of Quality,
Holtec International

cc: (via email)
Mike Layton (USNRC)
Chris Regan (USNRC)
John McKirgan (USNRC)