July 24, 2008

Dr. Stefan Anton, Director
Technical Services and Licensing
Holtec International
Holtec Center
555 Lincoln Drive West
Marlton, NJ 08053

SUBJECT: RESUBMITTAL OF THE HOLTEC INTERNATIONAL HI-STAR 180 PACKAGE APPLICATION (DOCKET NUMBER 71-9325)

Dear Mr. Anton:

We have received your letter of July 7, 2008, indicating Holtec International's (Holtec's) intent to resubmit the HI-STAR 180 package design (for Certificate of Compliance No. 9325). U.S. Nuclear Regulatory Commission (NRC) staff agrees that a new submittal is appropriate in this case, given the status of the current application. As stated in our letter of June 12, 2008, NRC staff identified significant issues during its current review, and consequently suspended its review of the most recent application. In addition, during a public meeting between Holtec and NRC staff on June 27, 2008, it became clear that Holtec is still in the design stages of this project. Specifically, model design and validation are ongoing; materials testing and characterization are ongoing; and basket design is evolving. As NRC noted in its acknowledgement letter of October 11, 2007, "[i]n general, no additional changes to the application will be allowed except for those minor changes that result in responding to an RAI [request for additional information]. Additional changes, supplements, or enhancements may be treated as a new application." The changes necessary to the application go beyond the minor changes that could normally result from an RAI. Therefore, as you stated in your letter of July 7, 2008, your plan to provide a revised submittal would be the most effective next step, and would facilitate the most efficient review. As stated in our letter to you of June 12, 2008, and discussed during our public meeting of June 27, 2008, NRC staff has therefore closed its review of the current application, has closed the review Technical Assignment Control number (TAC), and awaits your future resubmittal as described.

Before Holtec transmits the resubmittal, NRC staff recommends the following actions to ensure an effective and efficient review: Note that any resubmitted application will include acceptance review and development of a review schedule.

1. The resubmitted application should be a complete, high-quality, stand-alone document.
2. The resubmitted application should address the open technical issues from the NRC letter of June 12, 2008.
   a. Note that there are additional issues beyond the materials and structural issues discussed in the June 27, 2008, meeting. These issues are listed in the referenced letter (ML081650206), and include concerns regarding the thermal evaluation, the shielding evaluation, the criticality evaluation, containment, operating procedures, and the acceptance criteria and maintenance program.

b. Note also, that the open technical issues are not necessarily complete. The open technical issues represent concerns across the technical areas in the application, but do not represent a complete RAI. The review was suspended when it became clear that the application did not provide technical information in sufficient detail to enable the staff to complete its review.
c. Addressing only the open technical issues is not sufficient to ensure a complete, quality application. Holtec should look at the package application holistically to determine what needs to be included.

3. Provide sufficient characterization of Metamic HT's structural materials properties to allow NRC staff to make a determination as to the material's adequacy for the application.
4. Adequately benchmark the structural modeling codes used, and provide sufficient characterization to allow NRC staff to determine whether the HI-STAR 180 package can perform its safety function from the perspective of structural behavior.
5. Finally, considering the history of the Holtec HI-STAR 180 application and review process, NRC staff encourages Holtec to conduct a sufficiency review of the application before Holtec resubmits it. Certification of application sufficiency could be performed by the respective owners group, peer review, or another independent review group. Such external, objective expertise would help to ensure that the application is complete, high-quality, and technically adequate.

In the public meeting of June 27, 2008, Holtec indicated its intent to resubmit its application in the third quarter of calendar year 2008. NRC staff encourages Holtec to take the necessary time to be sure that the application is high quality, and to resubmit the application once it is complete, rather than focusing on an application schedule at this time. NRC staff also recommends a pre-application meeting. Please refer to Docket Number 71-9325 in future correspondence related to this action. If you have any questions regarding our review, or to schedule the pre-application meeting, please contact me, or Jennifer Davis of my staff at BJennifer.Davis@nrc.gov, or (301) 492-3371.

Sincerely,

/RA/

Eric Benner, Chief
Licensing Branch
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety
and Safeguards

Docket No. 71-9325

b. Note also, that the open technical issues are not necessarily complete. The open technical issues represent concerns across the technical areas in the application, but do not represent a complete RAI. The review was suspended when it became clear that the application did not provide technical information in sufficient detail to enable the staff to complete its review.
c. Addressing only the open technical issues is not sufficient to ensure a complete, quality application. Holtec should look at the package application holistically to determine what needs to be included.

6. Provide sufficient characterization of Metamic HT's structural materials properties to allow NRC staff to make a determination as to the material's adequacy for the application.
7. Adequately benchmark the structural modeling codes used, and provide sufficient characterization to allow NRC staff to determine whether the HI-STAR 180 package can perform its safety function from the perspective of structural behavior.
8. Finally, considering the history of the Holtec HI-STAR 180 application and review process, NRC staff encourages Holtec to conduct a sufficiency review of the application before Holtec resubmits it. Certification of application sufficiency could be performed by the respective owners group, peer review, or another independent review group. Such external, objective expertise would help to ensure that the application is complete, high-quality, and technically adequate.

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Sincerely,

/RA/
Eric Benner, Chief
Licensing Branch
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Docket No. 71-9325
Closes out TAC L24076

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