Second Request for Additional Information
Holtec International
Docket No. 71-9375
HI-STAR ATB 1T Package

By letter dated February 6, 2017, Holtec International (Holtec) submitted an application for Certificate of Compliance No. 9375, Revision No. 0, for the Model No. HI-STAR ATB 1T package. By letter dated April 14, 2017, Holtec responded to a request for supplemental information (RSI) letter dated March 21, 2017. The application was accepted for review on May 10, 2017. By letter dated December 8, 2017, Holtec partially responded to the first request for additional information (RAI) letter dated August 9, 2017, and completed its responses by letter dated April 2, 2018.

This second request for additional information (RAI) identifies information needed by the U.S. Nuclear Regulatory Commission staff (the staff) in connection with its review of the HI-STAR ATB 1T package application to confirm whether the applicant has demonstrated compliance with regulatory requirements.

The requested information is listed by chapter number and title in the package application. NUREG-1609, "Standard Review Plan for Transportation Packages for Radioactive Material," was used for this review.

Chapter 1 – General Information

1-1 Clarify the location of the elastomeric seals in the package.

Detail FG on Sheet 3 of Drawing 9786 indicates a general region where the elastomeric seals (BOM 7) are located in the flange (BOM 2). However, it is unclear where the seals are located relative to the flange itself.

The applicant's response to RAI 2-13, dated August 9, 2017, indicates that the elastomeric seals are located at 1.25 inches from the edge of the flange. Knowing the location of the seals with respect to the flange is important to demonstrate that containment requirements have been met, and that the package description is complete.

This dimension is critical, and should be depicted on the licensing drawings, since the applicant has recognized that the seal region experiences inelastic deformations, which may challenge sealing and containment of the package (see RAI 4-1).

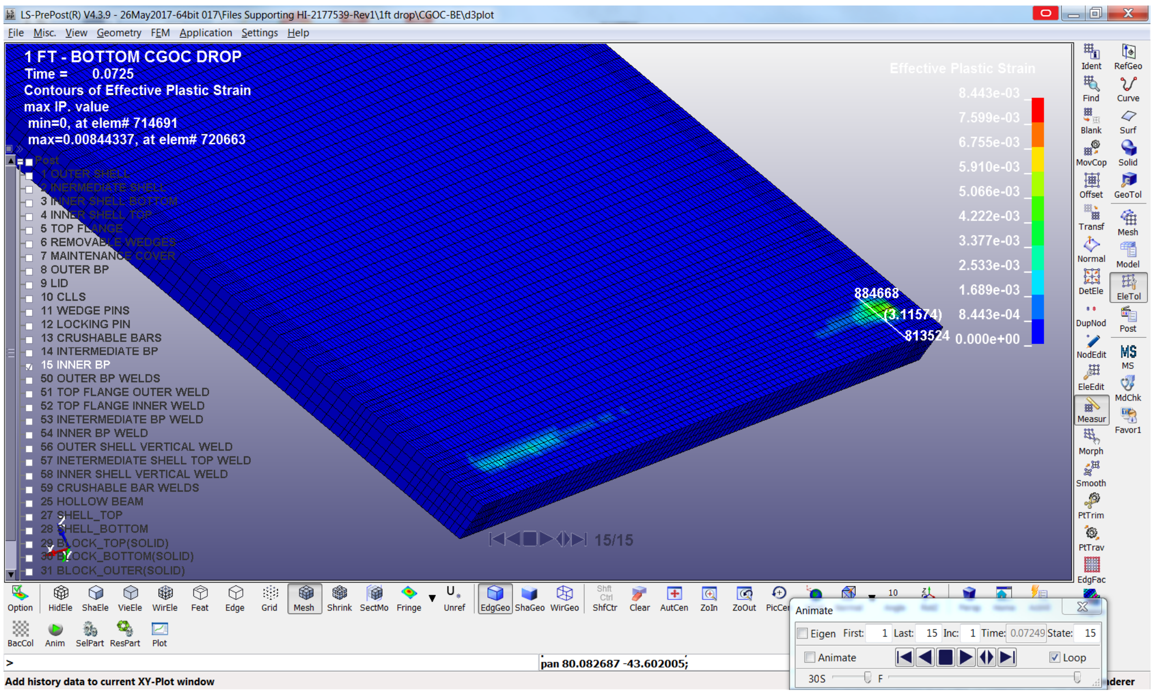
This information is needed by the staff to determine compliance with 10 CFR 71.33.

Chapter 2 – Structural and Materials Evaluation

2-1 Clarify how the components in the containment boundary will not exceed ASME Section III NB values for normal conditions of transport (NCT).

RAI 2-14, dated August 9, 2017, requested the applicant to confirm that stress limits within the lid of the ATB 1T package do not exceed the values set forth by ASME for the 1-ft bottom end drop simulation for NCT conditions. However, the LS-DYNA simulations show that the inner base plate (and other components that are also part of the containment boundary) also undergo plastic deformation, as shown in the Figure below for the 1-ft NCT Bottom CG over corner drop. Specifically, there is inelastic strain 3 inches away from the edge of the part on the surface.

Since inelastic deformations indicate that ASME stress levels are exceeded, the applicant shall (i) reconfirm that all containment boundary components do not exceed stress intensity values, according to ASME Section III NB, for all NCT drop and penetration simulations, and (ii) update tables and calculations in the application, as necessary.



This information is needed by the staff to determine compliance with 10 CFR 71.71(c)(7).

2-2 Explain and justify the parameters used to model concrete in LS-DYNA for the ¼ scale prototype.

In response to RAI 2-9 dated August 9, 2017, the applicant stated that “the essential characteristics of the target, viz., the concrete thickness, its compressive strength, the top HY Armor 80 steel material and its thickness, are obtained from SNL”, and that “the concrete material model used in the LS-DYNA ¼-scale drop simulations is consistent with the one used for numerous other dry storage applications including HI-STORM FW, HISTORM 100. Specifically, the concrete pad behavior is characterized using the same LS-DYNA material model (i.e., MAT_PSEUDO_TENSOR or MAT_016) as for the end drop and tipover analyses of the HI-STORM 100 storage cask and the tipover analysis of the HI-STORM FW storage overpack”.

While the modeling approach has been used in other applications, Holtec has not demonstrated that this modeling approach is applicable to the site conditions found at

Sandia National Laboratories. Specifically, the applicability of the parameters used in the LS-DYNA model of the concrete properties, as cited in *Witte, M., et al., "Evaluation of Low-Velocity Impacts Tests of Solid Steel Billet onto Concrete Pads, and Application to Generic ISFSI Storage Cask for Tipover and Side Drop", Lawrence Livermore National Laboratory, UCRL-ID-126295, Livermore, California, March 1997"*, to those found at the Sandia test site, has not been made. Billet drop tests were performed on a concrete pad alone at LLNL, while the target at Sandia incorporates a steel plate on top of a concrete mass

The applicant shall justify that the parameters used in the *MAT_PSEUDO_TENSOR* model for the ATB 1T package are representative of the concrete properties used at the Sandia site.

This information is needed by the staff to determine compliance with 10 CFR 71.71(c)(7), 71.73(c)(1), and 71.73(c)(3).

2-3 Clarify the material properties cited in Tables 2.2.1A and Table 2.2.1B of the application.

Values reported in Tables 2.2.1A and Table 2.2.1B of the application for the yield strengths of SA-240 304 material appear to be inconsistent ((26.7 ksi and 30 ksi at 150^{o}F, respectively) while the applicant claims to ensure that better than minimum material values can be expected from the material (Table 2.2.1B).

Confirm which values are correct and update the application, and any calculations, as necessary.

This information is needed by the staff to determine compliance with 10 CFR 71.33(a)(5).

2-4 Clarify the material properties used for the trunnions on the drawings.

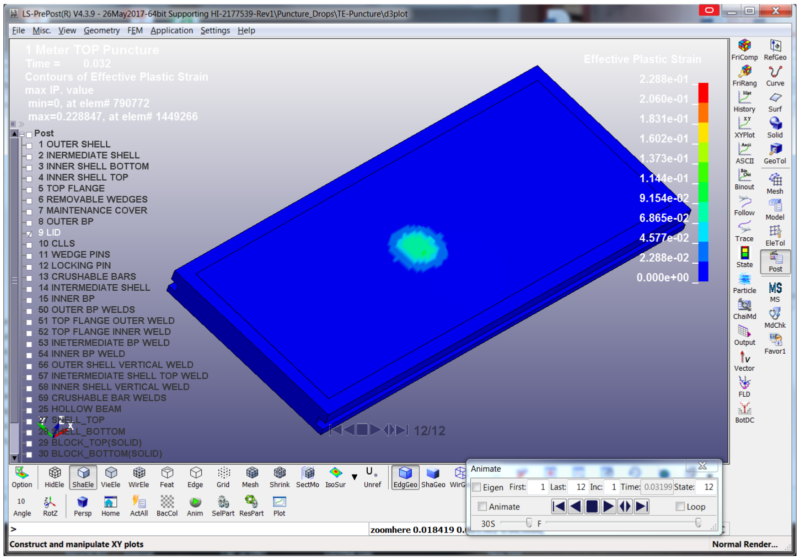
The licensing drawings do not indicate the material used to construct the trunnions, only that they must meet a minimum yield (106.3 ksi) and ultimate strength of 140 ksi (see flag note 5, sheet 1 of 5, on Drawing No. 9786). However, lifting results (Table 2.5.1) are based on a specific material (SA-182 FXM-19).

Clarify the safety factors in Table 2.5.1, as they are not based on the minimum material properties specified on the licensing drawings. Revise any related calculations using the material properties specified on the licensing drawings, as necessary, and update the application.

This information is needed by the staff to determine compliance with 10 CFR 71.45(a) and 10 CFR 71.33(a)(5).

2-5 Clarify the effective plastic strain reported for the top end puncture simulation.

Table 8.3 of the report, "Drop Analysis of the HI-STAR ATB 1T Transport Package" indicates that the maximum strain in the lid is 14.13%. However, from the files submitted, the maximum effective plastic strain is reported to be as high as 22.9%, as shown below on staff's plot using the applicant's model.



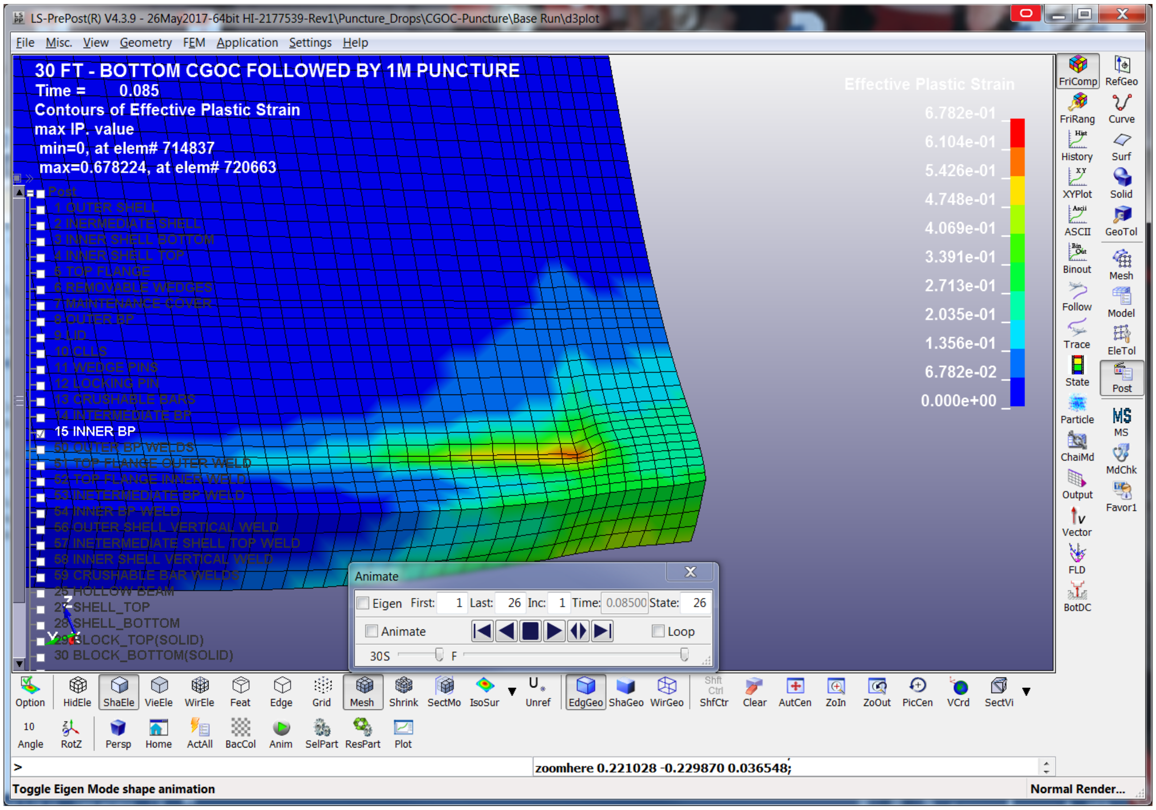
Verify this value, and others like this one in similar tables of this report, ensure all values in the application match the values in the models, and update the tables as necessary.

This information is needed by the staff to determine compliance with 10 CFR 71.73(c)(3).

2-6 Clarify the effective plastic strain reported for the containment base plate and containment weld for the CG over corner followed by puncture simulation for hypothetical accident conditions (HAC).

The applicant indicates there is an effective plastic strain of 40% for the containment base plate (BOM 1) and of 35% for the adjoining containment weld. However, from the files submitted, the maximum effective plastic strain is reported to be as high as 67.8% for the containment base plate and 57.1% for the adjoining containment weld, respectively. Table 2.4 shows the allowables for the material which are exceeded in this case. Both of these effective plastic strain values exceed the values tabulated in Table 8.3 of the application.

Verify that these values are correct and revise the application, and any supporting calculations, as necessary. Note that all simulations should be re-examined and the application updated, as necessary.



This information is needed by the staff to determine compliance with 10 CFR 71.73(a), 10 CFR 71.73(c)(1), and 10 CFR 71.73(c)(3).

2-7 Clarify the location of peak effective plastic strains and related numerical singularities as reported in the application.

Note (3) of Table 2.7.2 and Table 8.3 of the application and the drop analysis report, respectively, state that peak “effective strain accounting for triaxiality factor excludes the hot spots (points of numerical singularity)”, as recommended by paragraph FF-1142 from ASME BPVC Section III – Appendices. Note 45 in paragraph FF-1142 states: “Not applicable to points of numerical singularity in the finite element model as justified in the final Design Report”. This is related to containment components (baseplate in this case), and the applicant shall address numerical singularities using the strain based acceptance criteria.

Clarify:

(a) How the location of the “numerical singularity” is determined, as it can contain peak effective plastic strains above the allowable strain limit?

(b) What are the corresponding elements of the peak effective plastic strain being reported in the containment baseplate and the containment baseplate weld? It is unclear which elements are specifically being used for the peak effective plastic strains being reported and the ensuing through thickness effective plastic strains.

(c) Why the effective plastic strain for elements 720468 and 721135 (50.03% and 49.47%, respectively), in the containment baseplate, after completion of Simulation 9, are larger than the peak effective plastic strain of 40%? Justify how the argument of a “numerical singularity” can be made for element 720468, which has a peak effective plastic strain of 50.03% after accounting for triaxiality, as defined in Appendix B of the “Drop Analysis of the HI-STAR ATB 1T Transport Package” report.

This information is needed by the staff to determine compliance with 10 CFR 71.73(a), 10 CFR 71.73(c)(1), and 10 CFR 71.73(c)(3).

2-8 Verify that closure of the package is maintained during drop simulations by justifying the statement: “element erosion is not enough to cause any of the components to dislodge or shift position”.

In response to RAI 2-6, dated August 9, 2017, the applicant stated that: “Per the updated drop simulations, the closure lid locking wedges (BOM 9 and 10) and the wedge blocks (BOM 11) experience very limited element erosion and only during the top down CGOC drop. The element erosion is not enough to cause any of the components to dislodge or shift position. Therefore, the use of standard (non-eroding) surface-to-surface contact elements is adequate for the closure lid locking wedges and wedge blocks, and it has no adverse effect on the results”.

It is unclear how standard non-eroding surface-to-surface contact elements are justified when elements in these closure components are clearly eroding, as represented in the simulations for the closure lid locking wedges (BOM 9 and 10), and the cask wedge blocks.

This information is needed by the staff to determine compliance with 10 CFR 71.71(c)(7), 71.73(c)(1), and 71.73(c)(3).

2-9 Clarify the values used to model identical materials in the LS-DYNA drop simulation files

The licensing drawings state that BOM items 9-11, 29, 43, and 45 are made of Nitronic 50 (SB637-N07718). LS-DYNA simulations indicate that there are two different materials used to model these components, MID 2 and 3. These materials models are similar, but have different strain rate values and scale factors.

Staff is concerned that Holtec simulations may be producing erroneous results since the material models used are not consistent. Holtec has to provide material data supporting Nitronic 50 strain rates used in the simulations. Holtec has to clarify why these material values are different for the same material and update the LS-DYNA simulations and results, as necessary.

This information is needed by the staff to determine compliance with 10 CFR 71.71(c)(7), 71.73(c)(1), and 71.73(c)(3).

2-10 Clarify the stress limit values used to describe Nitronic 50 material, SB637-N07718, as reported in the application.

Table 2.2 of the application tabulates stress limits (such as 2 times Sm for bending) for SB-637 N07718 material as coming from ASME NB-3220. However, the values cited do not appear to come from this section of the code. Some of the values appear to come from Section II, Part D, Subpart 1, Table 4, via subparagraph NB-3232.1. Stress limits for this material should come from Part D Mandatory Appendix 2 for materials other than bolting (Tables 2A and 2B) to determine the appropriate Sm value.

It appears that the applicant is using the wrong stress limits (ASME limits) for this material, and as such, the reported safety factors/margin are most likely bigger (non-conservative, as a result). The applicant needs to revise or explain these values with respect to safety margins, clarify and/or justify the stress limits in Table 2.1.4 for this material, and revise the application, as well as the report HI-2177539, and any calculations that utilize this table, as necessary.

This information is needed by the staff to determine compliance with 10 CFR 71.31(c).

2-11 Confirm that the packaging coatings and consumable chemical products are non-flammable.

Section 2.2.7 of the application mentions that the cask closure system lubricants and hydraulic fluid are non-flammable. However, it does not specify whether the coatings, adhesives, and lubricants on secondary packaging are non-flammable nor does it provide their auto-ignition temperatures.

Therefore, staff cannot determine whether additional heat source terms should be taken into account in the thermal models.

This information is needed by the staff to determine compliance with 10 CFR 71.43(d).

2-12 Clarify and/or provide additional material property data for SA-182, Grade FXM-19 (Nitronic 50) material and update any related LS-DYNA drop simulations as necessary.

Table 2.1.5, of the application, “Stress Limits for Top Flange Material at Reference Temperature of 150°F (66°C) - Level A Service Condition” and Table 2.2, “Material Properties of Cask Top Flange” do not provide all of the necessary material data needed for the use of Nitronic 50 with the strain based acceptance criteria (SBAC), as outlined in Non-Mandatory appendices EE and FF. Specifically, true stress strain curves, as a function of strain rate and temperature, true uniform strain limits, and true fracture strains should be provided.

True uniform strain limit and true fracture strain requirements can be found in ASME Section III, EE-1220 and EE-1221 of Non-Mandatory Appendix EE – “Strain-based Acceptance Criteria Definitions and Background Information,” and Non-Mandatory Appendix FF – “Strain-based Acceptance Criteria for Energy-limited Events.”

The requested material properties are essential to the performance of those components fabricated from Nitronic 50 for NCT and HAC drop test simulations in LS-DYNA. Staff needs the strain rates for this material, and the applicant models need to be updated using this information. Update all Nitronic 50 material models used by LS-DYNA to simulate package drops for NCT and HAC, and revise any applicable calculations in the application, as necessary.

This information is needed by the staff to determine compliance with 10 CFR 71.31(c), 71.71(c)(7), 71.73(c)(1), and 71.73(c)(3).

Chapter 3 Thermal Evaluation

3-1 Specify the seals' maximum continuous allowable operating temperature and maximum short term allowable operating temperature (24 hours) so that a review of the package containment seal can be performed.

(a) Table 2.2.2 does not provide the continuous and short term maximum allowable operating seal temperatures. The reported allowable seal temperatures should refer to objective measurements rather than referencing the thermal numerical analyses. It is noted that there should be sufficient margin between the seal's normal and accident condition operating temperatures and the allowable temperatures to account for uncertainties and assumptions in the analyses.

(b) Calculation package report HI-2156585 states that the temperature during vacuum drying operation will be similar to that under NCT and will be bounded by the fire accident condition; this text implies that the seal during vacuum drying could have excessive temperatures. The application should clarify that the seal during vacuum drying will not exceed the continuous allowable operating temperature.

This information is needed by the staff to determine compliance with 10 CFR 71.51(a).

3-2 Provide the HAC thermal model results that consider the effect of a puncture test at the seal location, a non-uniform decay heat positioned at the seal, and the change in the package closure lid locker so that a bounding condition at the seals can be analyzed.

Based on the response to RAI 4-2 dated August 9, 2017, it appears that the seal temperatures are near, or very close to, their allowable values. However, the current thermal model did not address conditions that could affect seal temperatures:

(a) The application shows that plastic deformation exists at the seal and closure region after the 1 foot NCT drop and 30 feet HAC drop. Additional plastic deformation is expected in the seal region as a result of the HAC puncture test, where the puncture pin strikes the lid of the package, as suggested by the 1 Meter top puncture simulation that assumed the puncture pin was located towards the center of the lid. Staff believes the testing was not conducted in accordance with 71.73(c)(1) since higher local deformations at HAC could result if the puncture pin had been positioned to strike the package directly over a seal region that already has been plastically deformed, rather than the center of the lid.

(b) Recognizing that the BFA-Tank Cassette is modeled with simplifying assumptions as part of the structural hypothetical accident drop and puncture tests, the thermal input due to the potential for local placement of the source's decay heat at the seal (due to potential failure of the Cassette) was not included. Rather, the package cavity is "… simplified to be a solid volume with uniform heat generation" and internal component temperatures during the thermal accident condition are increased by 160º C from normal conditions. In addition, the calculation for using 160º C was not provided nor was it justified as being bounding for determining the seal temperature.

(c) The revised calculation package HI-2156585 (Section 6.5) indicates that the change in the closure lid locker was not modeled even though it could have an impact on the seal temperature.

This information is needed by the staff to determine compliance with 10 CFR 71.51(a), and 71.73.

3-3 Clarify the boundary conditions used for the thermal model during the hypothetical accident conditions 30 minute fire.

According to the FLUENT model, a mixed thermal boundary condition was applied to the package's external surface. This mixed thermal boundary condition included the convection heat transfer due to the fire, radiative heat transfer input due to the fire with an emissivity of 0.9, and a fire temperature of 1475º F, and heat transfer from the package surface with an emissivity of 0.9 at the package surface temperature.

However, the response to RAI 3-5 stated that a unit absorptivity was adopted. Therefore, the two stated boundary conditions are inconsistent, and it is not certain if the bounding scenario was modeled.

This information is needed by the staff to determine compliance with 10 CFR 71.51(a), and 71.73(c)(4).

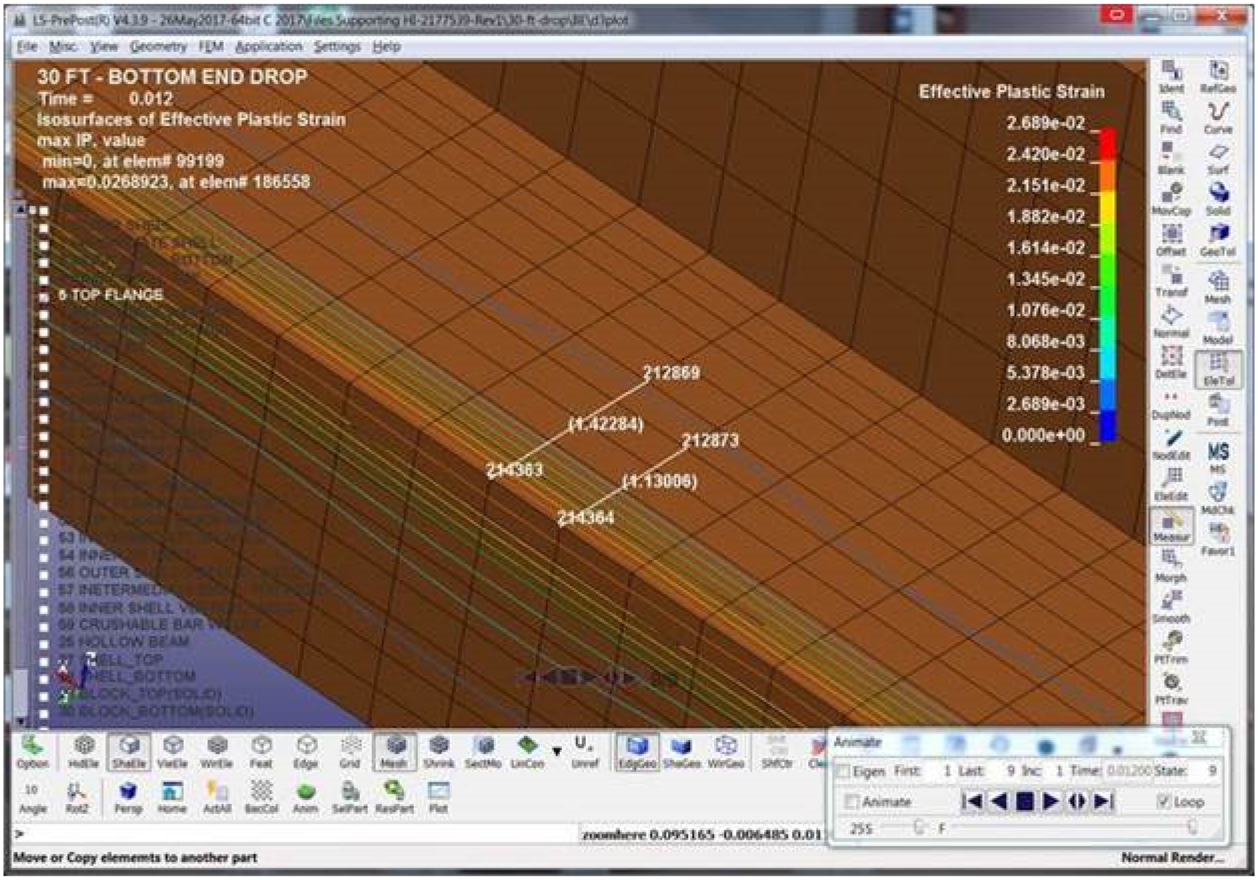
Chapter 4 Containment Evaluation

4-1 Provide evidence that demonstrates the package will meet regulatory release limits during normal conditions and hypothetical accident conditions.

The responses to RAI 2-13 and RAI 4-1 indicate that plastic deformation occurs at the seal and closure region during normal conditions of transport and hypothetical accident conditions. Plastic deformation at the seal and closure region after the 30 ft drop is further shown in the LS-DYNA plot below (seal region of the top flange). However, there was no demonstration that a resulting leakage rate from the package would ensure there would be no loss or dispersal of radioactive contents limited to that described in 71.51(a).

It is also noted that the seal's spring back would not necessarily be sufficient to ensure containment.

This information is needed by the staff to determine compliance with 10 CFR 71.51(a).



4-2 Provide additional discussion on the seal short term temperature tests so that a review of the results can be performed.

As provided in the response to RAI 4-2, the Parker report titled “Effects of Short-term Temperature Spike on FF400 Compression Set” briefly described results of FF400 O-rings at 300º C and 320º C. According to Table 1, the Test 1 sample was heated to 200º C for 70 hours and resulted in a 22% compression set. Likewise, Table 1 appears to indicate that the Test 2 sample was heated to 300º C for 70 hours (resulting in a 24% compression set) and the Test 3 sample was heated to 320º C for 70 hours (resulting in a 34% compression set).

However, the “Methods” portion of the report appears to indicate that the 300º C and 320º C test period lasted only one hour (not 70 hours). Likewise, the report was not clear in specifying the exposure period for Test 4 sample and Test 5 sample, which resulted in compression sets of 7% and 9%, respectively.

a) How long were the O-rings exposed to the 300º C and 320º C for Test 2, Test 3, Test 4, and Test 5?
b) What is the difference between the Test 2 and Test 4 samples (both at 300º C) and the Test 3 and Test 5 samples (both at 320º C)?
c) Why do Test 4 and Test 5 sample results have much lower compression sets compared to the Test 2 and Test 3 sample results and which compression set values are considered acceptable?

This information is needed by the staff to determine compliance with 10 CFR 71.51(a), and 71.73

Chapter 5 Shielding Evaluation

5-1 Justify that the package containing fixed surface contamination or CRUD meet the regulatory dose rate limits.

RAI 5-1, dated August 9, 2017 requested that the applicant provide additional information on the allowable contents other than the activated stainless steel or Inconel that are not represented by the analysis within the application. The applicant stated, in its response *"the ceramic mesh screens are not directly activated by the neutron flux in the core. The ceramic mesh screens may have surface contamination present (from contaminated spent fuel pool water), but this is no different from the surface contamination that may be present on other waste content."* This describes the ceramic mesh screens specifically, but does not provide a limit for other materials.

The applicant also added a specific limit for "*maximum permissible Co-60 activity of non-fixed surface contamination*" to Table 7.1.2 of the application. This information however is insufficient to define the contents. For example, CRUD and the ceramic mesh screens from contaminated spent fuel pool water may contain transuranic materials.

The response to the RAI does not address the staff's concern and the content specification is still not clearly and concisely defined. The staff requests that the applicant provide the additional follow-up information:

a) A clarification within the allowable contents description (Section 1.2.2 of the application) that all radioactive contents are activated stainless steel or Inconel and that any other allowable radioactive contents that are not made from stainless steel or Inconel are only contain CRUD and surface contamination. If this is not the case the staff requests that applicant clarify any contents that are not neutron activated stainless steel or Inconel and provide an analysis demonstrating that these contents meet regulatory external dose rates or are bounded by the activated stainless steel/Inconel analyses within Chapter 5 of the application.

b) A discussion on how the specific activity is evaluated for the fixed surface contamination and CRUD. The applicant needs to demonstrate that stainless steel and Inconel bound the self-shielding properties, per mass, of any other contaminated components not made of stainless steel or Inconel (such as mesh filter screens).

c) A shielding analyses to explicitly model components with CRUD and/or surface contamination to demonstrate that the package meets the regulatory dose rate limits. Since fixed surface contamination and CRUD are, by definition, on the surface, the staff finds that the analysis discussed within Chapter 5 of the SAR is not representative as the applicant models a uniformly activated component. This is non-conservative as the analysis assumes that there is activity at the center of a self-shielded component when in reality the activity is toward the surface.

d) A limit for neutron emitting source material. Section 5.2 of the application states: "*Neutron radiation – this source is negligible for activated steel components, and is therefore not considered in the dose analyses.*" Although the primary contribution to external dose from CRUD and surface contamination is from Co-60, transuranic neutron emitting materials are present. The staff requests that the applicant establish a minimum value for neutron emitting material and demonstrate that this amount would be sufficiently low as to not contribute to external dose.

Section 5.5.2, "*Radiation Shielding*" of NUREG-1609, states: "*Confirm that the contents used in the shielding analysis are consistent with those specified in the General Information section of the application. If the package is designed for multiple types of contents, ensure that the contents producing the highest external dose rate at each location are clearly identified and evaluated."*

This information is needed by the staff to determine compliance with 10 CFR 71.47(b)(1), 71.47(b)(2), 71.47(b)(3), and 71.51(a)(2).

5-2 Provide more specific instructions in footnote 4 on Table 7.1.2 of the application for the user to determine the most activated portion of any single waste item.

In RAI 5-4, the staff requested information justifying the uniform distribution of the source. In its response the applicant added a condition to Table 7.1.2 of the application that states: "*The limits for maximum specific activity of contents for each Waste Package Type in Table 7.1.2 have to be met by the most activated portion of any single waste item.*" Because this this statement could be misinterpreted by a user, the applicant needs to revise the footnote to provide more specific instructions that show the user how to determine the "*most activated portion of any single waste item."*

Section 5.5.3.2, "*Material Properties*," of NUREG-1609 states: *"If the shielding model considers a homogenous source region (rather than a detailed heterogeneous model of the contents), ensure that such an approach is justified."*

This information is needed by the staff to determine compliance with 10 CFR 71.47(b)(1), 71.47(b)(2), 71.47(b)(3), and 71.51(a)(2).

5-3 Evaluate HAC dose rates using a bounding model of the bottom BTC (BFA-Tank Cassette) plate or restrict contents so that the source cannot relocate outside the BTC plates.

For the HAC model, the applicant assumed that the 30ft drop of the package would cause the bottom plate to relocate. The applicant assumed that the plate would rotate 45 degrees and expose a section of the contents approximately 300 mm wide. The applicant modeled this by ignoring the rotation and creating a 300 mm missing section of the bottom plate with it fixed in its original location at the bottom of the package. The applicant assumed that the missing volume is filled with contents at the maximum specific activity. In RAI 5-5,the staff requested that the applicant justify that the contents remain within the BTC and BFA-tanks under HAC. In its response, the applicant added some discussion in Section 5.3.1.1.2 of the application and revised the dose rate analysis to add a point source in the amount equivalent to the allowable non-fixed contamination at the missing section of the bottom plate.

Non-fixed contamination is not the only source that could relocate. As discussed in first round RAI 5-5, the contents are not restricted in geometry. Section 1.2.2 of the application states: *"Generally BTCs will not be loaded with segments of exactly the* *same geometry. Segments are not stabilized in the BTC, and will move if the BFA-Tank is upset."* The applicant states on page 5-17 of the application that *"it is assumed that the plate rotates 45 degrees, which exposes a section about 300 mm wide along the entire length of the tank."* Therefore the contents could relocate to outside of the BTC plates. This scenario was not analyzed and the staff finds that the applicant's model is non-conservative. The applicant needs to provide an analyses to determine the dose rate under this scenario and demonstrate that the package meets the regulatory requirements of 10 CFR 71.51(a)(2).

The staff performed a confirmatory evaluation and compared the dose rates with a similar modeling assumption of the bottom BTC plate as done in the application (i.e. in the same location but partially removed) and compared it to a model with the BTC plate rotated by 45 degrees. The staff found that the BTC plate rotated by 45 degrees would result in a significant increase in HAC dose rates that exceed the limit in 10 CFR 71.51(a)(2). The staff's model assumed that the contents with maximum specific activity relocated to the other side of the plate (see Figure 5-3-1 below).

In addition, Section 2.2.8 of the application states that *"the materials used to construct the BFA-Tanks and the BFA-Tank Cassettes, which are loaded inside the HI-STAR ATB 1T transport cask, do not require fracture toughness testing for the following reasons … A relocation of the top or bottom plates of the BFA-Tank Cassette, on the other hand, cannot be entirely ruled out based on geometric considerations. Therefore, as described in Section 5.3.1.1.2, a sensitivity study has been performed in Chapter 5 to determine the external dose rate at 1-meter assuming that roughly one quarter of the BTC bottom plate is conservatively removed from the analytical model. As shown in Table 5.4.4, the calculated dose for this extremely conservative geometry is less than the regulatory limit by a factor of almost 2."* However, the staff finds that removing a part of the BTC bottom plate is not conservative as compared to rotating the plate and assuming that source material relocates to the other side based on the staff's calculations.

The applicant needs to either:

- Restrict the contents so that it cannot relocate to the other side of the BTC plates under HAC, or
- Calculate external dose rates under HAC for contents with consideration of the potential content relocation assuming bounding configuration for the bottom BTC plate and justify the modeling assumptions are bounding.

Section 5.5.3.1, "Configuration of Source and Shielding," of NUREG-1609 states: *"Ensure that any changes in configuration (e.g., displacement of source or shielding, reduction in shielding) resulting under normal conditions of transport or hypothetical accident conditions have been included, as appropriate."*

This information is needed by the staff to determine compliance with 10 CFR 71.51(a)(2).

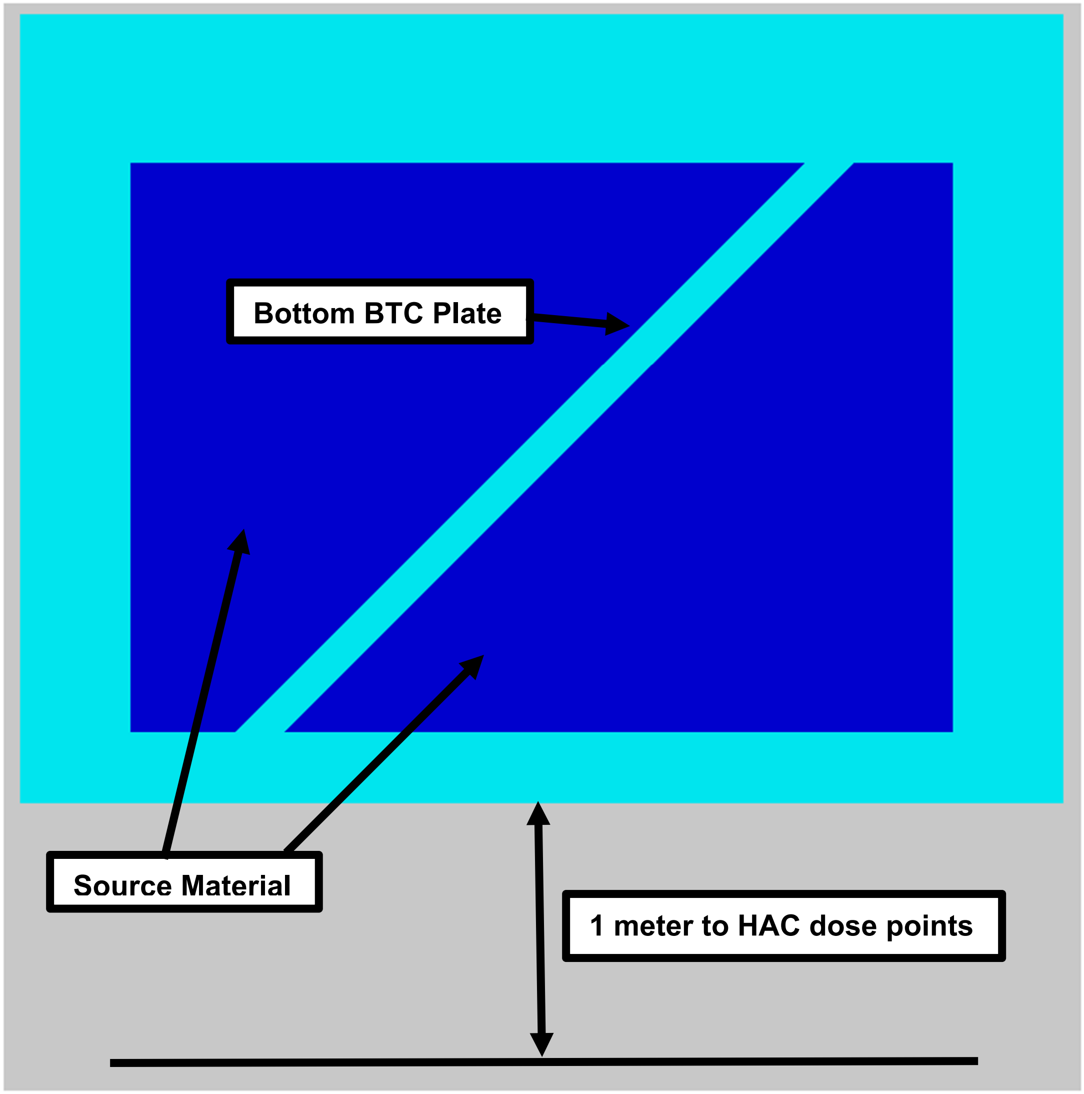


Figure 5-3-1: HAC Model of ATB-1T with Rotated BTC bottom plate

Chapter 8 Acceptance Tests and Maintenance Program Evaluation

8-1 Provide acceptance criteria to ensure the seals (that have been removed from the CLLS) do not have an excessive compression set that could affect seal performance.

As part of the response to RAI 8-4, dated August 9, 2017, Table 8.2.1 and Section 8.2.4(v) of the revised application state the seals that have been removed from the CLLS will be visually inspected to ensure that the seal "projects past the plane of the top seating surface of the seal groove". This criterion may not be sufficient because O-ring performance is dependent on having sufficient size and flexibility to deform within the groove when pressurized.

This information is required by the staff to determine compliance with 10 CFR 71.43(d)(f), and 71.51(a).

8-2 Explain the rationale for not replacing a prequalified gasket in Note 2b in Table 8.1.1.

The response to RAI 8-5, dated August 9, 2017, indicated that Note 2 was added to Table 8.1.1. However, the rationale for Note 2b ("i.e. the prequalified gasket was never replaced") is not clear for the staff. Therefore, staff is unable to evaluate whether the operation/maintenance of the ITS component will result in the appropriate sealing that will meet 10 CFR 71.51.

This information is required by the staff to determine compliance with 10 CFR 71.51(a).

8-3 Clarify that the Level III Specialist described in Section 8.1.4 is trained for the leak testing examination method.

The revised language in Section 8.1.4 mentions the role of the American Society for Nondestructive Testing (ASNT) Level III Specialist but does not specify that the individual is to be trained in the leak testing examination method.

This information is required by the staff to determine compliance with 10 CFR 71.51(a).

8-4 Clarify the number of BFA Tanks and BTCs planned for shipment in the HI-STAR ATB 1T package, their manufacturers along with their respective QA programs, as directly related to this quality assurance program exemption request. Clarify if Holtec has sampled "as-built" BFAs and BTCs from each manufacturer.

BFA Tanks and BTCs were fabricated by multiple suppliers that individually developed their own inspection plans to comply with the KBM regulations. Holtec has not provided sufficient information, directly applicable to this exemption request, on (i) the number of manufactured tanks and cassettes, (ii) their manufacturers, (iii) the provisions that appropriate quality standards were indeed included in the design and manufacturing documents of the BFAs and BTCs, and (iv) the manufacturers' control of deviations to those quality standards.

Holtec must provide documented evidence that the final "as-built" BTC or BTA, to be shipped in the ATB 1T package, conforms to the design requirements and licensing drawings specified in the NRC Certificate of Compliance.

This information is required by staff to demonstrate compliance with 10 CFR 71.107.

8-5 Provide a documented reconciliation of the Swedish Radiation Safety Authority (SSM) regulations to the requirements of 10 CFR 71 Subpart H.

The KBM document provided by Holtec does not appear to satisfy provisions and criteria applicable to the materials procurement and fabrication of the BFAs and BTCs. The applicant shall implement appropriate criteria in a graded approach for important to safety components, such as BFAs and BTCs.

This information is required by staff to demonstrate compliance with 10 CFR 71.101.

8-6 Document the number of manufactured BFAs and BTCs that were sampled and justify Holtec's basis for reviewing a sample of fabrication drawings of the BFA-Tanks and BTCs as well as other fabrication and manufacturing documents from the non-Holtec and non-NRC approved QA program fabricators.

Holtec has not reconciled the KM Quality Regulations to 10 CFR 71 Subpart H and has not provided objective evidence of quality, as furnished by the manufacturers through either inspection at the manufacturer's facilities or examination of the manufactured BFAs and BTCs to ensure compliance with KM Quality Regulations.

This information is required by staff to demonstrate compliance with 10 CFR 71.115.

8-7 Provide a translation of Enclosure B "Inspection and Test Reports". Provide a Certificate of Compliance and Component Completion Record for each BFA and BTC manufactured according to KM Quality Regulations attesting that the packages conform to 10 CFR 71 (as reconciled) and to the ATB-1T NRC CoC conditions.
Holtec has provided a document written in a foreign language for staff's review. As such, neither staff nor the applicant can attest of documentary evidence that the manufactured BFAs and BTCs conform to the procurement specifications nor can assure that specific requirements were identified for the purchased materials before fabrication.

This information is required by staff to demonstrate compliance with 10 CFR 71.115.

8-8 Provide a Certificate of Conformance by the Manufacturers to certify that the systems were manufactured according to KM Quality Regulations and that there were no manufactured defects on any of their components.
Holtec has not provided evidence that measures were taken to control materials or parts that did not conform to the design requirements of the BFAs or BTCS to prevent their use in case of defects.

This information is required by staff to demonstrate compliance with 10 CFR 71.131.

8-9 Define and clarify design and fabrication record retention responsibilities.

The certificate holder shall maintain sufficient records to describe activities affecting quality. The BFAs and BTCs were not manufactured under an NRC approved QA program and Holtec has not provided justification that instructions, procedures, drawings, and personnel qualifications required by 10 CFR 71.111 were established in a record retention program consistent with regulations.

This information is required by staff to demonstrate compliance with 10 CFR 71.135.

8-10 Specify 10 CFR 21 reporting responsibility.

Holtec has not attested that their current exemption request will still permit the NRC staff to inspect fabrication records and manufacturing facilities of the BFAs or BTCs. Holtec shall assume 10 CFR 21 reporting responsibility for those Important to Safety components.

This information is required by staff to demonstrate compliance with 10 CFR 21.31.