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Sent: Monday, March 18, 2013 12:10 PM
To: Allen, William
Cc: Bob Vaughan; Flagg, Michael Afton
Subject: Initial Response to RAI
Attachments: CTR 2013-04 SAFKEG HS Response Matrix to the 1st RAI v3.docx

Hello Chris

Attached to this email is our very initial response to the RAI questions. Those that are highlighted are those that we feel we need to seek further NRC guidance/advice. These responses are very much draft so please excuse the short responses and any mistakes with the grammar these will be corrected and improved prior to formal issue.

Thank you,
Sarah

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**SAFKEG HS Response Matrix to the First Request for Additional
Information (RAI) from the Nuclear Regulatory Commission**

Title	SAFKEG HS Response Matrix to the First Request for Additional Information (RAI) from the Nuclear Regulatory Commission	Number	CTR 2013/04
		Issue	A
		File Reference	CTR 2013-04 SAFKEG HS Response Matrix to the 1st RAI.docx
Compiled		Checked	
	S Marshall		RA Vaughan
Approved		Date	22 nd March 2013
	RA Vaughan		
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Reference Number	NRC Comment	Croft Response
Drawing Review		
1.1	Provide the height of Item 2 on both drawing 1C-5945 and 1C-5946. The height of these items must be clearly identifiable to ensure that the as manufactured overall package height is the overall package height used in the analyses by which the package is certified. This information is necessary to satisfy the requirements in 10 CFR 71.33(a)(5).	Drawing edited to provide package height.
1.2	Identify the correct item to be tightened in note 1 on drawing 0C-5942. Note 1 on drawing 0C-5942 identifies the packaging outer cork will be tightened to 23 + 1 Nm. However, studs, washers, etc., are not used to secure the outer cork during fabrication of the packaging. This information is necessary to satisfy the requirements in 10 CFR 71.33(a)(5).	Drawing corrected to clarify correct torque.
1.3	Provide all dimensions necessary to fabricate the items on drawing 0C-5943. The packaging components shown on drawing 0C-5943 have surfaces which are machined on an angle. However, no angular dimensions are provided on the drawing and the dimensions provided are insufficient to determine at what angle the surfaces should be machined. This information is necessary to satisfy the requirements in 10 CFR 71.33(a)(5).	Drawing has been updated.
1.4	Modify proposed Drawing No. 1C-5940 to include the proposed CoC drawings for the inserts. The inserts are part of the package and drawings have been provided for them. Also, the inserts are relied upon for shielding and other functions. Thus, for completeness, Drawing No. 1C-5940 should include the drawings for the inserts. This information is needed to confirm compliance with 10 CFR 71.31(a) and 71.33(a).	Drawing has been updated to include the CoC for the inserts.
1.5	Include the following information on the proposed CoC Drawing Nos. 2C-6173, 2C-6174, and 2C-6176: a. The thickness of the magnetic cap in the lid (tungsten inserts). b. The dimensions of the cut out portions of the lid and base. c. The thickness of the lid and the base. d. The dimensions of the optional HS-48x124-PTFE liner.	Information included.

Reference Number	NRC Comment	Croft Response
	<p>e. Confirm the appropriateness of the specified drawing tolerance for the steel insert thickness.</p> <p>The inserts are part of the package and appear to be relied on for shielding in the analyses. These dimensions are important to define the shielding present in the package. The applicant should ensure the shielding analyses are either consistent with or bounding for the package dimensions including these insert features. The tolerance specified in the drawings (± 1 mm), particularly for the steel insert in Drawing No. 2C-6176, appears to be too large of a tolerance considering the apparent thickness of the insert top, base and walls. The drawings should specify a tolerance that is appropriate for these dimensions of the insert.</p> <p>This information is needed to confirm compliance with 10 CFR 71.33(a), 71.47, and 71.51.</p>	
General Information Review		
1.6	Revise the application to address the following items:	
a	Section 1.2.1.2 heading incorrectly identifies the keg model number as 3979.	Heading corrected.
b	Section 1.2.1.2 lists side wall thicknesses of the containment vessel (CV) that are two times larger than the proposed certificate of compliance (CoC) drawings.	Section 1.2.1.2 lists the thickness of the inner cork. No CV wall thicknesses are discussed in this section.
c	Replace "affected" (i.e., impacted) with "effected" (i.e., made/created) in the second sentence of the third paragraph in Section 1.2.1.3.	Affected replaced as requested.
d	Modify the application to acknowledge that the contents include materials that emit non-negligible amounts of neutrons as can be seen by a comparison of the activity limits determined in Appendix A to CTR 2011/01 and the activity limit for the same nuclides in Tables 1-4-7 and 1-4-8.	editorial (in progress)
e	Modify all references (i.e., figures, drawings, SAR text, etc.) to the stainless steel insert to indicate the insert cavity height is actually 149 mm.	editorial (in Progress)
f	Revise Column 5 of Tables 1-4-1 through 1-4-8 to show a "<1" for those contents with an A2 value that is unlimited since it is impossible to have an unlimited number of A2 values of a material with an A2 value that is unlimited.	Tables edited as required.

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g	Ensure drawing titles in the table in Section 1.3.3 and on CoC Drawing No. 1C-5940 are correct (e.g., there is no Safkeg-LS or CV design no. 3987 in the proposed CoC drawings).	Drawings and tables edited as requested.
h	Replace "...line intensity of 0.852" with "...line energy of 0.852" in the second paragraph of Section 5.3.1.	Edited as requested.
i	Revise the heading of the third column in Table 5-4 to read "neutrons/sec."	Edited as requested.
j	The description of the source location for tungsten inserts needs to be consistent throughout the application. The source location at the mid-cavity height is described in Table 5-5 as centered; however, Figure 5-6 shows it as eccentered.	Table 5-5 has been corrected and now lists the mid cavity source location as eccentred.
k	The shielding evaluation demonstrates compliance with dose rate limits; therefore, the safety analysis report should discuss dose rates and not dose.	Edited as requested, dose rates not dose is discussed throughout section 5.
l	The following statement at the end of Section 5.5.4.1.1 conflicts with the results in Table 5-11: "Or when no insert is present when the source is at the centre at the top of the CV cavity."	The text and the table now concur with each other.
m	Delete "..., and the package limits are those given in Table 5-12" from the last sentence of the second paragraph in Section 5.5.4.2 since this is not necessarily true per the tables in Chapter 1.	Changed from package limits to shielding limits so as not to disagree with section 1.
n	Table 5-2 should be labeled as a summary table of maximum dose rates for hypothetical accident conditions, and the regulatory citation should be 10 CFR 71.51(a)(2). This information is needed to confirm compliance with 10 CFR 71.31.	Table 5-2 has been renamed as requested.
1.7	Provide an updated version of PCS 038. The current version of PCS 038 contains editorial errors; e.g., the insert design numbers in Tables 3 thru 10 do not correspond to the design insert numbers in Table 1. It also contains information which conflicts with other information in the application; e.g., Section 5.5 of Revision 1 of the safety analysis report (SAR) identifies the McBend report submitted in response to staff's request for supplemental information as identifying the location which produces the highest dose rate while Section 2.3 of PCS 038 indicates a Serco report identifies the location producing the highest dose rate.	PCS 038 has been updated to correct all the errors.

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	This information is required by the staff to determine compliance with 10 CFR 71.31(a)(1) and 71.31(a)(2).	
1.8	Identify fission products which can be shipped and the allowable quantities. On page 1-11, in Section 1.2.2.1, fission products are mentioned as allowable contents "...within the limits specified in the Table 1-3-7 and Table 1-3-8". However, no fission products are listed in these tables. This information is required by the staff to determine compliance with 10 CFR 71.33(b)(1).	The table numbers in the text have been altered to 1-4-7 and 1-4-8. Both tables include quantities of Pu-239, Pu-241 and U-235.
1.9	Clarify the statements added to Section 1.2.2.1 of the application regarding contents in quantities less than the applicable A ₂ value or modify the statements to provide contents specifications that are applicable to and appropriate for the proposed package design. The intent of the added text about the contents including any isotope in quantities less than the applicable A ₂ value is not clear. Since the limits for some nuclides are less than an A ₂ value, the appropriate limit for non-specified nuclides may also be less than an A ₂ value. In addition, an appropriate sum of ratios of quantities versus limits would be the sum of ratios of non-specified nuclides versus their respective limits (an A ₂ value per the current application) plus the sum of the specified nuclides versus their respective limits in Tables 1-4-1 through 1-4-8. That total may not exceed unity. This information is needed to confirm compliance with 10 CFR 71.33(b), 71.47, and 71.51.	Discuss with NRC
1.10	Identify the conditions under which the optional liner is not used with the stainless steel insert and modify Tables 1-3-3, 1-3-5, 1-3-7, and 1-3-8 to capture these conditions as well as changes in mass, content weight, etc. The applicant should also ensure the analyses either address this configuration or bound it. The proposed CoC Drawing No. 2C-6176 indicates that the liner is optional. However, it is not clear that the applicant's evaluations address the condition of a steel insert without the liner present. Also, Tables 1-3-3, 1-3-5, 1-3-7, and 1-3-8 do not clearly specify for which contents this liner is not used. The presence of the liner should be included for those contents items where it is used, such as in the	The liner shall only be used with acidic liquid contents. Section 1, 2, 3, 7 and 8 updated to fully include the liner.

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	descriptions of the insert mass and the maximum weight of CV contents. The applicant's evaluations should be consistent with or bounding for the proposed contents descriptions, including the use (or non-use) of the liner for the stainless steel insert. This information is needed to confirm compliance with 10 CFR 71.33(a), 71.47 and 71.51.	
1.11	Modify the specifications for Tables 1-3-7 and 1-3-8 to be consistent with the contents quantity limits for fissile material in Tables 1-4-7 and 1-4-8. The proposed fissile quantity limits in Tables 1-3-7 and 1-3-8 conflict with those listed in Tables 1-4-7 and 1-4-8. One set of limits should be proposed. This information is needed to confirm compliance with 10 CFR 71.33(b).	The 15g limit for fissile material has been assumed. This limit has now been applied to the contents tables and updated in the SARP.
Structural Review		
2.1	Demonstrate that the justification cited for the negative stress margins exhibited by the containment vessel is reasonably conservative. The justification provided by the applicant for the negative stress margins is as follows: 1) Most of the high stresses are not in the sealing area. 2) The analytical cork model had 1000 times the stiffness of the actual cork. This resulted in a more severe loading condition for the containment vessel. 3) The drop tests indicated no actual change in the containment vessel dimensions, demonstrating no deformation This justification is incomplete for the purposes of rendering a safety determination. Furthermore, the finite element methodology, while expedient, is not consistent with best practices with respect to quasi-static or dynamic analyses. The staff requests, at a minimum, that a sensitivity analysis be performed for a range of cork stiffness such that a trend in containment vessel stresses can be observed with respect to overall damage. The applicant should provide a discussion of the results. Alternatively, the staff prefers a simulation more consistent with an actual drop test which would include an initial velocity equivalent to that of the keg just prior to striking an unyielding surface, with a	Discuss in more detail with the NRC.

Reference Number	NRC Comment	Croft Response
	<p>simulated impact into that surface. The simulation would also be considered a sensitivity study as only one or two simulations would be necessary to demonstrate that the quasi-static methodology used is reasonably accurate. This fully dynamic simulation would allow for realistic material properties to be used for the cork and the results would simulate realistic structural behavior. Absent this type of analysis, staff would consider the testing as the primary means for certification and would disallow much of the finite element analysis in making a safety determination because of flawed or unsubstantiated methodology.</p> <p>This information is necessary to determine compliance with 10 CFR 71.71 and 10 CFR 71.73.</p>	
2.2	<p>Identify how the gaps between the steel and depleted uranium (DU) are maintained.</p> <p>Drawing No. 1C-5946, Rev. A, "Containment Vessel (CV) Body," shows a gap between the machined CV Shield, DU, and the stainless steel (ASTM A511, TY MT304L) CV outer wall. However, it is not clear how this gap is maintained. See Section X-X and Detail A.</p> <p>This information is needed to ensure compliance with 10 CFR 71.33.</p>	Under review
2.3	<p>Explain the use of "or equivalent" in the Bill of Materials.</p> <p>Drawing No. OC-5942, Rev. A, Keg Design No. 3977, material section allows equivalent material to be used in lieu of specified material specifications for item 15, keg closure washer and item 17, fuse plug.</p> <p>This information is needed to ensure compliance with 10 CFR 71.127.</p>	Wording or equivalent has been removed.
Thermal Review		
3.1	<p>Clarify why the application states that the maximum calculated temperatures are all within the acceptable temperature limits for the package components.</p> <p>Table 3-2 of Report CTR 2008/11 summarizes the temperatures under normal conditions of transport (NCT). However, the seals and cork reported temperatures are above the temperature limits specified in this table.</p> <p>This information is needed to determine compliance with 10 CFR Part 71.71.</p>	O-ring seals are tested to 180°C for 1000 hours and 225°C for 24 hours. Table 3-2 has been corrected and the tests have been added to section 8. The correct operating temperatures have been added for the cork.
3.2	Clarify what the temperature limit is for the cork material.	Same as point above

Reference Number	NRC Comment	Croft Response
	Table 3-2 of Report CTR 2008/11 provides two limits: 140 and 160°C. If the limit is 140°C, then the reported maximum temperature is above the specified limit. However, if the limit is 160, then the reported maximum temperature is below the specified limit. See also RAI 3.1. This information is needed to determine compliance with 10 CFR Part 71.71.	
3.3	Clarify what the values provided in the last column of Table 3-3 of Report CTR 2008/11 represent. Table 3-3 of Report CTR 2008/11 provides a summary of package temperatures for hypothetical accident conditions (HAC). However, the last column of this table does not provide a definition of the values provided in this table. This information is needed to determine compliance with 10 CFR Part 71.73.	The title of the last column has been altered to clarify the values provided.
3.4	Assuming that the last column of Table 3-3 of Report CTR 2008/11 provides allowable temperature limits, explain why the shielding insert seal is above the specified limit. Table 3-3 of Report CTR 2008/11 provides a maximum temperature of 218°C for the shielding insert seal during HAC. This calculated temperature is above 200°C (assuming this is the temperature limit). See also RAI 3.3. This information is needed to determine compliance with 10 CFR 71.73.	See answer to 3.1.
3.5	Demonstrate that it is realistic or conservative to assume linear temperature dependence in the thermal conductivity and specific heat of depleted uranium. Table 3-5 of Report CTR 2008/11 provides only two values for the thermal conductivity and specific heat for depleted uranium. More data are needed to assess the assumed linear behavior of the thermal conductivity with temperature. This information is needed to determine compliance with 10 CFR 71.71 and 71.73.	Attached are two pages from: 'ATOMIC ENERGY Technical Data Sheets: Properties of Substances in SI units', UDC 53, 1980. They show that both the thermal conductivity and specific heat of uranium vary linearly with temperature over a wide temperature range. The assumption of linear variation between 38°C and ~200°C (the range experienced in our calculations) is therefore valid.
3.6	Explain where in Table 3-2 of Report CTR 2008/11 it is shown that during NCT a margin of 4°C is predicted for the containment seal. Table 3-2 of Report CTR 2008/11 shows that the reported	Same as point 3.1

Reference Number	NRC Comment	Croft Response
	temperatures for the seals and the cork are above the temperature limits specified in the table. See also RAI 3.1. This information is needed to determine compliance with 10 CFR 71.71.	
3.7	Correct reference to Figures 27 and 28 of Report AMEC/6335/001. Page 13 of Report AMEC/6335/001 states Figure 27 shows how the lid seal temperatures for the cork and air-filled gap models vary with time during the NCT transient simulations and Figure 28 shows how the containment vessel lid seal temperatures for the cork and air-filled gap models vary with time during the HAC fire test simulations. It appears the correct figures should be Figures 28 and 29. This information is needed to determine compliance with 10 CFR 71.71 and 71.73.	We confirm there is a typo in AMEC report AMEC/6335/001 the references to Figures 27 and 28 on Page 13 should indeed be Figures 28 and 29. Do we have to correct this report?
3.8	Clarify which analysis represents a realistic or bounding case to consider when performing the thermal evaluation of the package for the two following cases: gaps filled with air or gaps filled with cork material. Page 13 of Report AMEC/6335/001 states a study was conducted to investigate the influence of the air gaps on the numerical predictions. The report also states that the main effect of having the various air gaps in the model filled with cork rather than air is slightly to enhance the efficiency of heat transfer from the containment vessel to the keg's outside surface in the case of the NCT simulation, and in the opposite direction in the case of the HAC fire test simulation. However, Figures 28 and 29 of the thermal analysis report show that higher seal temperatures are predicted when the gaps are filled with air for both NCT and HAC. The applicant should justify why it is acceptable to assume all gaps are filled with cork material. This information is needed to determine compliance with 10 CFR 71.71 and 71.73.	The model used within the FEA analysis contains the air gaps as detailed in section 2.3.4. The gaps were not filled with cork in the model used to determine the package temperatures. As such this leads to the highest possible temperatures of the seal and CV. The discussion regarding air gaps vs cork was added due to an NRC question asked during the LS review that felt air gaps lead to a lower temperature of the seals. As discussed in section 6 of the report AMEC/6335/001, a model containing air gaps provides the highest temperatures of the containment seal and containment vessel cavity.
Containment Review		
4.1	Clarify the following discrepancies between the values calculated for D on page 2 of Calculation sheet 2012/04, issue A. In doing the containment review under NCT, the applicant calculated the value for D in reference case (a) to be 1.0×10^{-4} cm. Staff	The reference cases are taken from the ANSI N14.5-1997 standard and the results obtained are checked against the results given in that standard. Both of the diameters and Lu match that provided in the ANSI standard. Therefore the diameter of hole given in this report is

Reference Number	NRC Comment	Croft Response
	calculated the value for D to be 1.63×10^{-4} cm. In reference case (b), the applicant calculated the value for D to be 1.0×10^{-4} cm. Staff calculated the value for D to be 1.81×10^{-4} cm. This information is needed to confirm compliance with 10 CFR 71.51(a)(1).	correct according to the ANSI standard.
4.2	Clarify the following discrepancies between the values calculated for D on page 3 of Calculation sheet 2012/05, issue A. In doing the containment review under HAC, the applicant calculated the value for D in the case of Krypton-79 to be 1.1×10^{-4} cm. Staff calculated the value for D to be 1.40×10^{-4} cm. This information is needed to confirm compliance with 10 CFR 71.51(a)(1).	The value D is taken from CTR 2012/04, this calculation sheet determines the maximum diameter under leak tight conditions. The value of D is then used in the calculation to determine the maximum activity that may be shipped. D does not vary in this calculation. The calculation of D in CTR 2012/04 has been checked and the calculation verified against the ANSI standard.
Shielding Review		
5.1	<p>Modify the shielding evaluation to derive the shielding-based quantity limits from analyses for the most limiting dose rate location(s) for the package, accounting for dose rates at the package surface and at 1 meter from the package for the following two scenarios.</p> <p>a. The source is located at the top of the CV or insert cavity and next to the cavity wall, the steel insert's liner is not present, with the detectors located so that the DU thickness is minimized, accounting for the cut out in the insert lid in models with the insert present.</p> <p>b. The source is in the same location as in 5.1.a for the steel insert (or no insert present), the insert liner is not present, and the detectors are positioned so that the total packaging material thickness is minimized between the source and the detectors, accounting for the cut out in the insert lid in the model.</p> <p>Based upon the results of above scenarios, modify the limits of the proposed contents in Chapter 1 as necessary.</p> <p>It is not clear from the applicant's shielding evaluation that the highest dose rate locations have been identified and used to determine the maximum allowable contents. The current evaluation includes analyses that utilize large amounts of DU shielding. However, dose rates may be greater where the DU shielding between the detector and the source is at a minimum; e.g., a detector located on the side of the</p>	Discuss with NRC

Reference Number	NRC Comment	Croft Response
	<p>package above the CV lid. For the steel insert, or no insert present, the point source is positioned axially above the thickest part of the CV side DU shield, when the liner is not used. Thus, staff expects (and the AMEC/SF6652/001 report indicates) that the dose rates on the package side surface at the same axial position as the source are more limiting than those analyzed by the applicant. Additionally, the insert lids have portions of reduced thickness per the proposed CoC drawings. The analysis should also include this reduction of shielding material and the presence of any gaps between the CV lid and flange/cavity wall.</p> <p>This information is needed to confirm compliance with 10 CFR 71.47 and 71.51.</p>	
5.2	<p>Justify the neutron source energy used to calculate the maximum activity limits for neutron dose rates that meet the 10 CFR Part 71 dose rate limits.</p> <p>The applicant calculated activities assuming a mono-energetic neutron source from the nuclides evaluated in the four tables in Appendix A to CTR 2011/01, "Safkeg-HS 3977A: Package Activity Limits Based on Shielding." However, the neutrons are generated from spontaneous fission and have multiple energy spectra. The applicant should justify why a single energy is sufficient and address the different energy spectra of the neutrons emitted from the analyzed nuclides.</p> <p>Alternatively, the applicant should calculate the dose rates and the maximum allowable nuclide activities using the appropriate energy spectra for the nuclides. Also, based upon the conversion factor units listed in IAEA Safety Series No. 37, the correct conversion factor is the inverse of that used in the calculations.</p> <p>This information is needed to confirm compliance with 10 CFR 71.33(b), 71.47, and 71.51.</p>	<p>The single energy used is taken from the ICRP 38. This energy is an average energy/probability for the neutrons. Using this energy the dose rate predicted is higher than the actual dose rate.</p> <p>Both neutron emitters Pu-238 and Pu-240 are limited by the heat and mass limit of the package respectively so the actual contents are less than the limit calculated by the shielding calculations.</p> <p>The IAEA dose rate calculation has been corrected so that the neutron rate is divided by the IAEA conversion factor.</p>
5.3	<p>Describe the method for calculating dose rates due to bremsstrahlung, including the following:</p> <p>a. A description of the analysis method, including the equation(s) used, and a justification for the selected method.</p> <p>b. Justification for the selection of the absorber.</p>	<p>a. A description and example calculation was produced however when the spreadsheet was cut and pasted into word it was removed, this has now been included.</p> <p>b. A justification for the selection of the absorber has been added.</p> <p>c. A complete reference for Kaye and Laby is included.</p> <p>d. All of the correct inserts and packaging have been used and are</p>

Reference Number	NRC Comment	Croft Response
	<p>c. The complete reference information for the item simply listed as "Kaye and Laby, 16th Edition."</p> <p>d. Ensure the inserts and the packaging used in the analyses, in this document and in Attachment 2 of Section 1 of the application SAR, are the correct inserts and packaging for this application's proposed package design.</p> <p>e. Account for the progeny of all proposed contents as appropriate. Some tables in Appendix B of CTR 2011/01 only provide very limited information. Either the application, or this CTR 2011/01 report, should describe how dose rates were calculated for bremsstrahlung. This description should include any equations and assumptions used in the method and adequate justification for the method, equations, and assumptions. For example, it is unclear if the applicant has determined some beta emission rates and/or energies need not be considered. Also, it is not clear that selecting the insert material as the absorber material (versus the contents materials or the DU shield), particularly in the case of the steel insert, is appropriate. Where references are used, such as "Kaye and Laby, 16th Edition", these should be complete and their use in the method described. The method should account for bremsstrahlung from the proposed contents and progeny of the proposed contents, as appropriate. Examples of such cases include Y-90 and W-188, the daughters of Sr-90 and Re-188, respectively. Also, the packaging and insert design numbers do not agree between CTR 2011/01 Appendix B, the proposed CoC drawings, and Attachment 2 to Section 1 of the application SAR. Thus, it is not clear that the calculations use the correct inserts and packaging. This information is needed to confirm compliance with 10 CFR 71.47 and 71.51.</p>	<p>correctly referenced in the tables in Appendix B.</p> <p>e. Y-90 and Sr-90 should be assessed using the unity rule which would limit the amount of Y-90 present and hence Sr-90.</p> <p>Discuss with NRC</p>
5.4	<p>Provide model figures for the inserts that include the appropriate dimension and material information.</p> <p>The shielding evaluation relies on the inserts; however, no model figures are provided and only limited model information for the base of the inserts is provided in the application. Information is needed with respect to the entire insert (not just the base) since it is not clear the base is where dose rates are the most limiting. See RAI 5.1.</p>	<p>Model figures are provided for the inserts.</p>

Reference Number	NRC Comment	Croft Response
	This information is needed to confirm compliance with 10 CFR 71.47 and 71.51.	
5.5	<p>Justify the model dimensions for the depth of the M12 hole in the containment vessel lid and the DU intersection thickness. The model figure (Drawing No. 1C-5997) shows the M12 hole is 31 mm deep versus the CoC drawing (Drawing No. 1C-5945) depth of 37 mm. The model figure (Drawing No. 1C- 5999) shows the DU intersection dimension as 47.05 mm versus the CoC drawing (Drawing No. 1C-5946) dimension of 45.7 mm. The model should be consistent with or bounding for the package. The M12 hole may represent a streaming path and differences in the steel thickness may be sufficient to have a significant increase in dose rates above this location on the package surface. The DU shielding dimensions can have significant impacts on dose rates too.</p> <p>This information is needed to confirm compliance with 10 CFR 71.35(a), 71.47, and 71.51.</p>	A small grub screw has been included which is screwed into the M12 hole once the lifting eye is removed. This ensures that the worst case conditions were assessed within the AMEC shielding report.
5.6	<p>Modify the application to demonstrate compliance with an appropriate set of regulatory dose rate limits as required by 10 CFR 71.35(a). The applicant provides a shielding evaluation and analyzes for dose rates to meet the limits for a non-exclusive use shipment. However, in response to the staff's request for supplemental information, the applicant modified the evaluations to discuss shipment under exclusive use without providing the appropriate supporting evaluations. Instead, as indicated by text in Section 5.2.1, the applicant leaves it up to the package user for determining whether the package design is to be used under exclusive use or non exclusive use whereas the applicant has only evaluated the design for non-exclusive use. The applicant must demonstrate that the package meets the appropriate limits for the proposed contents. The current application evaluates the package for non-exclusive use shipment only. Additionally, the staff notes that the surface of the package must still meet the 200 mrem/hr (2 mSv/hr) limit in 10 CFR 71.47 since there is nothing in the evaluation regarding an enclosure, or the package being shipped in a closed vehicle, or the package being fixed in position with respect to the vehicle sides.</p> <p>This information is needed to confirm compliance with 10 CFR</p>	Discuss with NRC

Reference Number	NRC Comment	Croft Response
	71.35(a).	
5.7	<p>Modify the neutron shielding calculation to address neutron production by means of alpha-neutron reactions in the contents or propose a condition that prohibits inclusion of boron and beryllium. The applicant's shielding analysis only addresses neutron sources from spontaneous fission. Neutrons may also be produced by other means, such as alpha-neutron reactions. The application should address this type of neutron source for all appropriate proposed contents and their progeny and the associated dose rates. Alternatively, since most significant production of neutrons by this means involves boron or beryllium, the applicant should propose a condition that prohibits these elements from being in the contents. Consideration of this type of reaction may also be necessary for contents in the steel insert with the liner present due to the fluorine in the liner.</p> <p>This information is needed to confirm compliance with 10 CFR 71.47 and 71.51.</p>	<p>We don't have Boron or Beryllium on the contents list and B and Be are not produced as daughters. The PTFE insert is limited to liquids only so there is no F for neutron production. Require NRC clarification to help identify where the issue arises.</p>
5.8	<p>Determine activity limits for the proposed contents from a shielding evaluation that includes contribution to dose rates from gamma, neutron and bremsstrahlung radiation, as applicable, from the proposed nuclides and their progeny.</p> <p>CTR 2011/01 includes calculations for neutron and bremsstrahlung dose rates in its appendices. However, it is not clear from the application that the calculated activity limits for the proposed nuclide contents account for the contributions to the package dose rates from these radiation types. The calculated activities appear to be based on gamma dose rates alone, whereas the combination of gammas, neutrons and bremsstrahlung to dose rates should be considered, as applicable, in determining the nuclide activities that result in dose rates at the regulatory limits. The contributions from progeny for each of these radiation types should also be addressed as part of these activity limits. The activity limits in Tables 1-4-1 through 1-4-8 should be updated as necessary.</p> <p>This information is needed to confirm compliance with 10 CFR 71.47 and 71.51.</p>	<p>Discuss with NRC</p>

Reference Number	NRC Comment	Croft Response
5.9	<p>Modify the shielding analysis to account for the progeny of the proposed nuclide contents, addressing the following:</p> <ul style="list-style-type: none"> a. Calculate dose rates with the proposed activity limit for each nuclide as the nuclide activity at the decay time that maximizes dose rates from the nuclide and its progeny. b. Include the progeny of Ra-224. c. Ensure that the Ra-226 progeny include At-218 to ensure correct progeny and amounts are used in the analysis. d. Clarify that the Cs-137 calculations account for Ba-137m. <p>The application accounts for progeny of proposed nuclides for which the applicant determined the progeny impact the dose rates. However, it appears that the proposed activity limits for the nuclides are without progeny present and those activities are then decayed to an optimum build in of the progeny. The application does not prevent loading a package with contents that have been prepared at higher activity levels that are then decayed to meet the proposed limits at the time of loading, meaning that the activities of the contents and their progeny exceed those considered in the analyses (especially for contents with short half-lives). Thus, the applicant should consider the proposed activity as the activity of the proposed nuclide contents with progeny present at the decay time that maximizes the dose rates and ensure that dose rates for this condition do not exceed the regulatory limits. As noted in other RAI questions, contributions of neutrons and bremsstrahlung should be accounted for, as applicable. Further, staff evaluations indicate that the progeny of Ra-224 may also significantly impact dose rates and should be accounted for. The proposed contents activity limits in Chapter 1 should be modified as necessary. This information is needed to confirm compliance with 10 CFR 71.47 and 71.51.</p>	<ul style="list-style-type: none"> a. This has been done and is explained in the Shielding Report. We used the exposure rate tool in Microshield which decays the nuclides and the daughters and provides the time at which the highest dose occurs, taking into account daughters. Microshield is then run at the decay time which provides the highest dose rate. The appropriate print outs have been included with this RAI response. b. The progeny of Ra-224 have been included on the table and were included in the Microshield calculation as shown in the attached Microshield printout. c. All the Ra-226 progeny have been included as shown on the attached Microshield print out. Table 5-3 has been corrected to include At-218 d. Ba-137m has been included in the Cs-137 calculations as shown in the attached Microshield print out. Cs-137 has been added to Table 5-3
5.10	<p>Address the uncertainties associated with the proposed shielding method, including quantitative evaluations, and demonstrate that the package still meets the regulatory dose rate limits.</p> <p>The proposed shielding method proposes contents limits that are derived from calculations of the activities that result in the dose rates at the regulatory limits. In other words, the activities are back-calculated</p>	<p>Discuss with the NRC.</p>

Reference Number	NRC Comment	Croft Response
	<p>from the regulatory dose rate limits. This is an acceptable approach. However, the uncertainties in the shielding method need to be addressed to ensure the dose rate limits will in fact be met by the proposed package design. The applicant has provided some qualitative arguments which note some conservatisms in the method. However, staff's evaluation of the uncertainties and conservatisms indicates that the uncertainties are much greater than the conservatisms. Thus, it is not clear that the package with the proposed contents will meet the regulatory dose rate limits. One option is to reduce the proposed contents quantities to account for the uncertainties not compensated by the conservatisms. Also, some items the applicant identified as conservatisms may not be conservatisms. For example, if sources that are effectively point sources can be shipped in the package, modeling sources as point sources is not necessarily conservative. Additionally, the DU shield density in the MicroShield model does not account for the 2% Mo alloying specification in the proposed CoC drawings and thus, appears to be non-conservative. The uncertainties include the use of ICRP 51 fluxto-dose rate conversion factors (DCF's). This information is needed to confirm compliance with 10 CFR 71.47 and 71.51.</p>	
5.11	<p>Modify the shielding evaluation to adequately justify the use of ICRP 51 DCFs and address the items described in the following, or modify the evaluation to use the ANSI/ANS-6.1.1-1977 DCFs. The DCFs in ICRP 51 are for calculating effective dose equivalent (EDE) as well as organ dose equivalents and rates. These differ from the dose rate quantities in 10 CFR Part 71 which are dose equivalent rates that are in line with the dose (rate) quantities calculated with the ANSI/ANS-6.1.1-1977 DCFs. Furthermore, compliance with the limits at time of shipment is by measurement. EDE is not a measurable quantity. Thus, the applicant should use the ANSI/ANS-6.1.1-1977 DCFs in its shielding evaluation. The current application attempts to consider use of the ICRP 51 DCFs as a source of uncertainty. This may be acceptable if the uncertainties are adequately addressed in the application. See RAI 5.10. Depending on the gamma</p>	Discuss with the NRC

Reference Number	NRC Comment	Croft Response
	<p>energies, the uncertainties in dose rates could be significant. For example, the dose rates calculated for Ac-225 and its progeny with the ICRP 51 DCFs resulted in dose rates that are about 15% less than those calculated with the ANSI/ANS standard DCFs. Thus, dose rates for this nuclide and its progeny may be under-predicted by about 15%. In addition, the applicant has provided a table which lists several sets of the ICRP 51 DCFs and their values in the application. It is not clear which set is used. Additionally, a comparison of DCFs from ICRP 51 Table 2 indicates that the DCFs in the table provided by the applicant are shifted by one row versus the gamma energy. For example, the Anterior-Posterior DCF for 10.0 MeV should be 24.7 and for 0.010 MeV should be 0.062. This information is needed to confirm compliance with 10 CFR 71.47 and 71.51.</p>	
5.12	<p>Justify the material selection for calculating the buildup in the MicroShield models and confirm whether or not the same material is used for all proposed contents and therefore all gamma energies. The DU shield is used to calculate the buildup factors in the sample input files provided with the application. However, it is not clear that this material is used for the calculations for all the proposed contents. Also, depending on the contents, the steel outside the DU shield may be thick enough to significantly influence buildup. Appropriate materials should be used to determine the buildup. In some cases the buildup material may be different (e.g. this may be true for the analyses requested in RAI 5.1). This information is needed to confirm compliance with 10 CFR 71.47 and 71.51.</p>	<p>Depleted Uranium has been used as the build up factor for all of the nuclides. Discuss with the NRC.</p>
5.13	<p>Confirm the material properties used in the MicroShield models for tungsten. Table 5-8 of the application indicates that the material in the model for the tungsten shield includes iron and nickel; however, the sample output file in CTR 2011/01 only shows tungsten without these alloying elements. The application should accurately describe the input used in the calculations. The differences in the model materials from the actual materials may add uncertainties to the analyses that should be addressed. See RAI 5.10.</p>	<p>The Microshield model would only include Tungsten and wouldn't have alloying elements however the density has been adjusted to obtain the same result as the MCBEND report. This reduction in density</p>

Reference Number	NRC Comment	Croft Response
	This information is needed to confirm compliance with 10 CFR 71.47 and 71.51.	
5.14	<p>Modify the shielding analyses for NCT and HAC conditions to address impacts due to thermal concerns regarding the packaging components' seals and the impacts of the structural tests.</p> <p>As discussed in RAIs 3.1 and 3.4, some of the seals (e.g., insert seals) in the package appear to exceed the allowable limits. This could mean that some contents may be able to migrate to other areas of the package, such as the CV cavity. The current shielding analyses do not account for this condition. Also, the structural test results indicate there are dimensional changes to the package due to the NCT and HAC tests (see Table 11 of CTR 201 0/02). For example, the NCT and HAC puncture tests result in deformations of several millimeters in the keg body. The current shielding analyses rely on nominal dimensions for an as-designed package. The shielding analyses should include the impacts of dimensional changes from these tests. Since the shielding method is to back calculate allowable contents limits from the regulatory dose rate limits, the proposed contents limits in Chapter 1 should be adjusted as necessary.</p> <p>This information is needed to confirm compliance with 10 CFR 71.47 and 71.51.</p>	<p>With regards to the seals see responses to 3.1.</p> <p>Discuss with NRC</p>
Criticality Review		
6.1	<p>Revise the application to clarify the limits on fissile material to be shipped in the Safkeg-HS 3977A.</p> <p>Tables 1-4-7 and 1-4-8 report activity limits corresponding to masses greater than the fissile material limits in the fissile exemptions in 10 CFR 71.15, and the general licenses in §71.22 and §71.23. Revise the application to reduce the fissile material activity limits to those corresponding to the fissile exemptions and fissile material general licenses, and clarify which exemption or general license is applicable to each content type.</p> <p>This information is needed in order to ensure that the package design meets the fissile material requirements in 10 CFR Part 71.15, 71.22, and 71.23.</p>	Tables 1-4-7 and 1-4-8 have been edited to limit the fissile material to less than 15 g.
Operations Review		

Reference Number	NRC Comment	Croft Response
7.1	<p>Include a statement similar to the following at the beginning of Chapter 7: "The user's procedures must comply with the operations descriptions in this chapter."</p> <p>The applicant states that the package user's procedures must ensure compliance with 10 CFR Part 71, Subpart G, and other regulations. The package user's procedures must also be in compliance with the package operations as they are described in Chapter 7 of the application. Also note that references to 10 CFR Part 20 may be more pertinent than references to 10 CFR Part 835.</p> <p>This information is needed to ensure compliance with 10 CFR 71.87.</p>	Statement added and the CFR reference has been updated as suggested.
7.2	<p>Change references to drawings in Sections 1.3.2 and 1.3.3 to references to the CoC drawings.</p> <p>A package user must use a package that is in compliance with the CoC and licensing drawings incorporated by reference into the CoC. The model drawings do not meet this criterion.</p> <p>This information is needed to confirm compliance with 10 CFR 71.87.</p>	All references to the licensing drawings have been updated to section 1.3.3.
7.3	<p>Clarify Section 7.1.1, steps 7 and 11 to explain what things are being matched.</p> <p>Steps 7 and 11 include a statement to check body and lid model/serial numbers to ensure they match for the CV and the keg respectively. It is not clear that this means that these numbers need to match the shipping documentation for each item or that the number on the lid needs to match the number on the body.</p> <p>This information is needed to confirm compliance with 10 CFR 71.87.</p>	The check has been clarified to make it clear the serial number marked on the lid is matched to that marked on the body.
7.4	<p>Address the following items in Chapter 7:</p> <p>a. Identify which cork components are checked in Section 7.1.1, step 15, and if only some of the cork components are checked, explain why.</p> <p>b. Change references to tables and sections in Chapter 1 of the SAR for contents and insert specifications in Section 7.1.2, steps 2, 3, and 4 to reference the CoC. The CoC will include the necessary specifications and conditions regarding the allowable contents and the inserts to be used with the contents.</p> <p>c. Section 7.1.3, step 2 should specify the particular steps from Section 7.1.1 that are to be followed.</p> <p>d. Modify Section 7.1.3, step 7 to indicate that the radiation survey</p>	<p>a. Identified cork components that are checked on loading</p> <p>b. The references have been altered</p> <p>c. Added the required steps to this section</p> <p>d. Added the gamma and neutron radiation survey</p> <p>e. Added requirement 10 CFR 20.1906 as requested</p> <p>f. Added a point to cover the decontamination of the insert and corrected the regulations references.</p> <p>g. Added the gamma and neutron radiation survey as requested.</p>

Reference Number	NRC Comment	Croft Response
	<p>includes both a neutron and a gamma dose rate survey for applicable contents since some contents (parents and/or progeny) are significant neutron emitters for the proposed allowable activities.</p> <p>e. Add compliance with 10 CFR 20.1906 to the list of requirements included at the beginning of Section 7.2.</p> <p>f. Modify Section 7.3, step 1 to ensure the contamination survey includes the internal and external surfaces of the insert (and the insert liner for the steel insert) and that the acceptance criterion is that non-fixed contamination does not exceed the limits in 49 CFR 173.428(d) (or the more stringent levels of 10 CFR 71.87 and 49 CFR 173.443, which are for external package surfaces). The language of this step is not clear as written.</p> <p>g. Include a step in Section 7.3 for a radiation survey (gamma and neutron as applicable) to ensure dose rates meet the limits of 49 CFR 173.428(a) for empty packages.</p> <p>This information is needed to confirm compliance with 10 CFR 71.31(c) and 71.87.</p>	
7.5	<p>Justify that the acceptance criteria for ensuring the insert in Section 7.1.2, step 6 is appropriately sealed is sufficient to ensure the radioactive contents remain within the insert under NCT and HAC conditions for all contents.</p> <p>The package operations for loading the contents indicate the insert is tightened hand tight. In addition, for liquid contents, a bubble method test is performed. The acceptance criterion for this test is no visible stream of bubbles. The shielding evaluation assumes all contents remain in the insert. However, it is not clear that an insert sealed in the stated manner will prevent powders, gases, or liquids from escaping the insert and entering the CV cavity as well as gaps between the CV cavity/flange and CV lid. If the applicant cannot justify the current sealing method and acceptance criterion, either modify the sealing method and acceptance criterion to ensure the contents remain in the insert, or modify the shielding analysis to account for the contents getting out of the insert. Modifications to the shielding analysis would need to consider contents migrating into the gaps between the CV lid and CV body and for any shifting of the DU shield due to the gaps</p>	Need to include the drop tests we have conducted.

Reference Number	NRC Comment	Croft Response
	between the DU shield and the CV base and flange. This information is needed to ensure compliance with 10 CFR 71.47, 71.51, and 71.87(a), (b), (d), (f), and (j).	
7.6	Clarify why a step ensuring the contents to be loaded are authorized in the CoC was not included within Section 7.1.1 "Preparation for Loading" of the SAR. In reviewing the Package Operations section, this statement was not defined within the applicant's procedures within the Preparation for Transport section. This information is needed to confirm compliance with 10 CFR 71.87.	The requirement that the contents shall meet the CoC is included in section 7.1.2 when loading of the contents is discussed. Section 7.1.1 just discusses the preparation of the package for transport.
7.7	Clarify the meaning of "invert" in step 15 of Section 7.1.1 "Preparations for Loading"; i.e., identify if the keg liner and the liner welds are visually inspected for indications of corrosion; i.e., scale, discoloration, etc. An air gap exists between the encased cork and the stainless steel vessel. Temperature inversions may allow water to form between the encased cork and the stainless steel. Over time, this could cause the stainless steel vessel to corrode especially if there are slight fabrication imperfections. This information is needed to ensure compliance with 10 CFR 71.87(f).	Inversion of the keg has been clarified. Added a requirement to check the keg liner for corrosion.
7.8	Clarify if the inner cork is removed during unloading operations. Although Step 3 of Section 7.3 states that the inner cork is to be placed inside the keg body, there is no step in Section 7.2 which either removes the inner cork from the keg or removes the inner cork from around the CV after the CV is removed from the keg. This information is needed to ensure compliance with 10 CFR 71.87(f).	There is no requirement to remove the inner cork however there is no issue should the customer chose to remove it. Section 7.3 just ensures that should the cork have been removed it is replaced correctly. A note has been added in the text to help clarify this point)
Maintenance Review		
8.1	Change the following references from references to sections, table, figures, or drawings in the SARP/application to references to the CoC or drawings in the CoC: a. The reference to drawings in Section 1.3.2 of the SARP on page 8-1 (just before Section 8.1). b. The reference in Section 8.1.1 to drawings in Section 1.3.3. c. The reference in Section 8.1.3 to Section 1 of the SARP. d. The reference in Section 8.1.4 to Section 1 of the SARP. e. The reference in Section 8.1.5.5 to section 1.3.3.	For other SARs with regards to the type of sections mentioned here they reference sections in the SAR they don't reference drawings on the CoC. Text has been added to make clear these are the drawings referenced in the CoC. Discuss with NRC.

Reference Number	NRC Comment	Croft Response
	<p>f. The reference in Section 8.1.5.6 to section 1.3.3.</p> <p>g. The reference in Section 8.2 (on page 8-5) to Section 1 of the SARP.</p> <p>h. The reference in Section 8.2.3.2, Item 8 to Section 1 of the SARP.</p> <p>i. The reference in Section 8.2.3.3, Item 8 to Section 1 of the SARP.</p> <p>j. The reference in Section 8.2.3.4, Item 2 to Section 1 of the SARP.</p> <p>k. The reference in Section 8.2.3.5, Item 6 to Section 1 of the SARP.</p> <p>l. The reference in Section 8.2.5.3 to Section 1.3.2.</p> <p>Important specifications and conditions for the package and its use should be included in the CoC and items incorporated into it by reference. For example, the package must meet the specifications in the drawings incorporated in the CoC (referred to as the CoC drawings). Usually manufacturing drawings have significant amounts of detail that are more than what is necessary for the purposes of a CoC drawing or a condition of the CoC.</p> <p>The staff recommends that the applicant consider the information in NUREG/CR-5502, "Engineering Drawings for 10 CFR Part 71 Package Approvals," and SFST-ISG-20, "Transportation Package Design Changes Authorized Under 10 CFR Part 71 Without Prior NRC Approval," in developing the drawings and other specifications (such as in Chapters 7 and 8 of the application) that will be incorporated into the CoC. This information is needed to confirm compliance with 10 CFR 71.85 and to assure that the maintenance program is adequate to assure the package performance meets the requirements of 10 CFR Part 71, Subparts E and F, during its service life.</p>	
8.2	<p>Modify the second sentence of the first paragraph in Section 8.1 of the application to include: "and in compliance with the requirements and descriptions in this Section."</p> <p>The acceptance tests must comply with the requirements and descriptions for acceptance tests that are provided in Section 8.1 of the</p>	Text edited as requested.

Reference Number	NRC Comment	Croft Response
	application since this part of the application is incorporated into the CoC. The text should clearly state this requirement. This information is needed to confirm compliance with 10 CFR 71.85.	
8.3	Modify Section 8.1.5.6 to identify all characteristics of the DU shield to be verified and where these characteristics can be found. Section 8.1.5.6 indicates drawing 1C-5946 identifies the chemical composition and the minimum density of the DU shield. Drawing 1C-5946 also identifies the required fracture toughness for the DU shield, but Section 8.1.5.6 does not reference this characteristic. In addition, drawing 1C-5945 identifies the chemical composition, minimum density, and required fracture toughness of the DU shield. However, this drawing is not referenced in Section 8.1.5.6. Section 8.1.5.6 should identify all characteristics of the DU shield which must be verified and the location(s) of these characteristics. This information is needed to confirm compliance with 10 CFR 71.85.	A reference to drawing 1C-2945 has been added along with the fracture toughness test.
8.4	Justify that the currently proposed DU shielding acceptance testing in Section 8.1.5.6 is sufficient to ensure the fabricated shield meets the required specifications and will perform as designed, or propose a different test with an acceptance criterion that will ensure proper shield component fabrication. Section 8.1.5.6 states the DU density will be verified by means of a water displacement method and the component will be visually inspected to check the DU surface. Section 2.1.4 states the density test is performed after machining. It is not clear that these tests are sufficient to verify the adequacy of the fabricated DU shield components. A water density test may show that the overall density of the DU meets the required minimum, but it does not verify a uniform density of the DU. Additionally, a water displacement test will not identify cracks or voids within the DU shield component. A non-destructive volumetric examination method such as radiography or ultrasonic, with an acceptance criterion based on a standard, is a more certain way to ensure that the DU shield components meet the required specification. This information is needed to confirm compliance with 10 CFR 71.85.	Discuss with NRC
8.5	Justify the acceptance criteria for defects in the keg outer shell, such	

Reference Number	NRC Comment	Croft Response
	<p>as dents and defects that remove material up to the depths and thicknesses specified in step 3 of Section 8.2.3.2.</p> <p>Step 3 of Section 8.2.3.2 specifies depths of dents, abrasions and scratches which are acceptable. It is not clear that these acceptable defects are supported by the application evaluations. For example, the shielding evaluation relies upon dimensions and thicknesses which are based on a package at the time of fabrication. The requirements are that NCT dose rates meet the limits specified in 10 CFR 71.47. Thus, the limits/criteria for acceptable defects should be modified to be those which are supported by the current evaluations, or the evaluations should be modified to consider a package with these defects. For example, in the case of the shielding evaluation, these defects would represent additional uncertainty in the method that may result in the dose rates for the currently proposed contents exceeding the limits in 10 CFR 71.47.</p> <p>This information is needed to confirm compliance with 10 CFR 71.47 and to ensure that the package performance meets the requirements of 10 CFR Part 71, Subparts E and F, during its service life.</p>	
8.6	<p>Modify the following:</p> <ul style="list-style-type: none"> a. Section 8.2.3.3, Item 1 to clarify the statements about matching of serial numbers. b. Section 8.2.3.5, Item 1 to clarify the statements about matching of serial numbers. c. Section 8.2.3.5 to include any needed maintenance for the liner for the stainless steel insert . d. Table 8-1 to include a summary of the maintenance for the inserts (and the stainless steel insert's liner) described in Section 8.2.3.5. <p>It is not clear from the current descriptions whether the serial numbers of the CV (or the insert) body and lid are verified to match each other (i.e., the lid number must match the body number) or they are verified to (and must) match the serial numbers in the documentation for each packaging. It appears that some maintenance should be performed on the stainless steel insert liner components. Finally, Table 8-1 should include a summary of the maintenance requirements for the inserts and their individual components as is done for the other</p>	<ul style="list-style-type: none"> a. Clarified the statement regarding matching of the serial numbers. b. Clarified the statement regarding matching of the serial numbers. c. Maintenance information added d. Insert information added to the table

Reference Number	NRC Comment	Croft Response
	package components. This information is needed to confirm compliance with 10 CFR 71.31(c) and 10 CFR 71.87(b) and to ensure that the package performance meets the requirements of 10 CFR Part 71, Subparts E and F, during its service life.	