SAFKEG-HS 3977A

SAR Update Matrix for Inclusion of Liquid Mo-99 to be shipped in a Split Lid Containment vessel

Title	SAFKEG-LS 3977A SAR Update Matrix for Inclusion of Liquid Mo-99 to be shipped in a Split Lid Containment vessel	Number	CTR 2016/08
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Contents

1 Notes on methodology and content

This Update Matrix (CTR 2016/08) details the changes in the SAFKEG-HS 3977A SAR in updating from Rev 6 to Rev 9.

The update to SAR Rev 7 is to allow Mo-99 in liquid form to be carried in a new steel insert, as listed in Contents Type 8. In order to facilitate handling of Mo-99 a split lid CV has been introduced.

This Update Matrix (CTR 2016/08) provides the following.

- Justification for the changes in the SAFKEG-HS 3977A SAR in updating from Rev 6 to Rev 7
- Details of SAR changes - List of all changes to the SAR - Table 1
- Question and Response Matrix Table – Table 2 and Table 3
- List of SAR page changes [Appendix B]

This document (CTR 2016/08) includes responses to the NRC questions made to revision 8 of the SAR therefore it fully documents all issues including any questions and responses for the entire SAR update.

2 Justification for the changes in the SAFKEG-HS 3977A SAR in updating from Rev 6 to Rev 7

Croft wishes to add liquid Mo-99 to the approved contents of the HS 3977A package. In order to carry Mo-99, the contents type 8 has been changed to liquid Mo-99. The contents listed in the original application as Contents Type 8 are no longer proposed for this package. The liquid Mo-99 will be carried in a new steel insert, which will be located inside a tungsten liner. Due to handling requirements for the Mo-99 a split CV lid has also been introduced to allow the handing of the Mo-99 bottles at the loading and unloading facilities.

3 Changes Made to SAR from Rev 8 to Rev 9

Changes have been made to the SAR in response to the NRC questions. The product bottle has been defined along with the temperature of the contents and the hydrogen generation rates. Clarifications have also been added to the text in sections 4, 5, 7 and 8. Table 2 provides the questions asked by the NRC and the responses provided by Croft.

4 Changes Made to SAR from Rev 9 to Rev 10

Changes have been made to the SAR in response to the NRC questions. Clarifications have been provided regarding the determination of the Mo-99 contents MNOP and HAC pressure in the containment vessel. Table 3 provides the questions asked by the NRC and the responses provided by Croft.

5 SAR Changes

This table contains notes on all the SAR Page Changes and supporting Document Changes for Rev 7 (from Rev 6).

Table 1 Summary of SAR Page Changes and Supporting Document Changes for Rev 7

Summary of SAR Page Changes and Supporting Document Changes for Rev 7			
SAR Page	**Location**	**Change**	**Reason for Change**
Chapter 0 - Contents			
All pages	Header	Page Rev status amended to Rev 7 All changes are shown in red and sidelined.	Changes required solely to record the current issue status of SAR pages and references.
Page 0-2	Date box	Date amended	Update.
Page 0-5	Documents in section 1.3.3	Licensing drawings added to include the split CV lid, new stainless steel insert and tungsten liner.	These drawings are required to provide the manufacturing details for the HS package used to ship the Mo-99 contents. Although a full set of drawings are provided the keg, cork and containment vessel body are identical to the current approved drawings.
Chapter 1 - General Information			
Page 1-2	Section 1.2.1.1	The split CV lid details added to the general description of the package.	Addition of Mo-99 contents requires a new split CV lid design.
Page 1-3	Section 1.2.1.3	A description of the split CV lid was added to the CV description.	Addition of Mo-99 contents requires a new split CV lid design.
Page 1-3a	Section 1.2.1.4	Extra figures listed in text.	An extra figure demonstrating the containment boundary of the split CV lid has been added to the SAR.
Page 1-3a and 1-4	Section 1.2.1.5	Extra figures listed in text.	An extra figure demonstrating the radiation shielding of the split CV lid has been added to the

Summary of SAR Page Changes and Supporting Document Changes for Rev 7			
SAR Page	**Location**	**Change**	**Reason for Change**
			SAR.
Page 1-4	Section 1.2.1.6	Extra figures listed in text.	An extra figure demonstrating the energy absorbing features of the split CV lid package has been added to the SAR.
Page 1-5	Figure 1-1a	Title of figure changed.	To clarify that this figure shows the standard CV lid.
Page 1-5a	Figure 1-1b	Addition of figure.	This figure presents the package with the split CV lid.
Page 1-6	Figure 1-1c	Title changed to 1-1c from 1-1b.	Allows the addition of new figures
Page 1-7	Figure 1-2a	Title of figure changed.	To clarify that this figure shows the standard CV lid.
Page 1-7a	Figure 1-2b	Addition of figure.	This figure presents the split CV lid.
Page 1-8	Figure 1-2c	Title changed to 1-2c from 1-2b.	Allows the addition of new figures.
Page 1-9	Figure 1-3a	Title of figure changed.	To clarify that this figure shows the standard CV lid.
Page 1-9a	Figure 1-3b	Addition of figure.	This figure presents the split CV lid.
Page 1-10	Figure 1-4a	Title of figure changed.	To clarify that this figure shows the standard CV lid.
Page 1-10a	Figure 1-4b	Addition of figure.	This figure presents the split CV lid.
Page 1-11	Section 1.2.2.1	Text added to demonstrate that the standard CV lid will be used for all contents types, apart from Type 8, which will be carried in the split lid containment vessel.	Contents Type 8 is the liquid Mo-99 contents. A Split CV lid is required to handle these contents.
Page 1-12	Section 1.2.2.2	Extra figures listed in text.	An extra figure has been added to illustrate the new insert and liner design.
Page 1-12	Table 1-1	New insert and tungsten liner added to table.	A new insert and liner were required to carry the liquid Mo-99 contents.

Summary of SAR Page Changes and Supporting Document Changes for Rev 7			
SAR Page	**Location**	**Change**	**Reason for Change**
Page 1-13a	Figure 1-5d	Addition of figure.	This figure provides an illustration of the new insert and tungsten liner.
Page 1-14	Table 1-2	Contents Type 8 altered. CV lid arrangement added to table.	A user would like to carry Mo-99 therefore the contents category was altered from the unlicensed solid contents to liquid Mo-99. The table was expanded to clarify that only the Mo-99 may be shipped with a split CV lid.
Page 1-22	Table 1-3-8	The contents description and requirements altered to liquid Mo-99.	A user would like to carry Mo-99 therefore the contents category was altered from the unlicensed solid contents to liquid Mo-99. The special form fissile material has been removed from the SAR because these contents are not approved by the NRC.
Page 1-33	Table 1-4-8	The contents limits were altered to liquid Mo-99.	A user would like to carry Mo-99 therefore the contents category was altered from the unlicensed solid contents to liquid Mo-99. The special form fissile material has been removed from the SAR because these contents are not approved by the NRC.
Page 1-34	Section 1.2.3	Contents Type 8 added to the liquid contents listed in section 1.2.3.	Mo-99 has been added as an approved liquid contents.
Page 1-34	Section 1.2.4	The addition of the split CV lid general arrangement drawing.	The addition of Mo-99 requires a split CV lid to provide suitable handling of the contents. Therefore the drawing has been added.
Page 1-37	Section 1.3.3	Title to 1.3.3.1 altered to include standard CV lid design and section 1.3.3.2 added to list out the added drawings including the split CV lid, new steel insert and tungsten liner.	Addition of liquid Mo-99 contents. The Mo-99 user requires a split CV lid to load and unload the product. To simplify drawings a new set has been produced however the keg, CV body and cork are identical for both designs.
Chapter 2 - Structural Evaluation			

Summary of SAR Page Changes and Supporting Document Changes for Rev 7			
SAR Page	**Location**	**Change**	**Reason for Change**
Pages 2-1 to 2-3	Section 2.1.1	New drawing numbers for the Mo-99 contents are added to the relevant sections. A description of the split CV lid has been added along with the new insert and tungsten liner.	Addition of liquid Mo-99 contents requires a split CV lid, new insert and tungsten liner.
Page 2-3a	Section 2.1.2	Clarification that the tests were carried out using the standard CV lid.	The loading on the CV lid is worst case for the standard lid, therefore the results bound the results of the split CV lid.
Pages 2-18 to 2-19	Table 2-10	Updated the O-ring materials to Fluoroelastomer.	Corrected an error identified during review. The O-rings were altered during the last RAI process. While the drawings were correctly updated, the SAR contained this error.
Pages 2-18 to 2-19	Table 2-10	New insert and tungsten liner added to table.	The addition of insert and liner in order to carry Mo-99 liquids.
Page 2-21	Section 2.2.3	Corrected O-ring material.	Corrected an error identified during review. The O-rings were altered during the RAI process. While the drawings were correctly updated, the SAR contained this error.
Page 2-24	Table 2-15	The tungsten liner has been added to the matrix. The O-ring material has been corrected.	The tungsten liner has been added due to the inclusion of Mo-99. The O-ring material has been corrected. The O-rings were altered during the RAI process. While the drawings were correctly updated, the SAR contained this error.
Page 2-25	Section 2.3.1	Drawing numbers added to text.	This ensures the split CV lid drawings are included in the SAR.
Page 2-26	Section 2.3.2	Drawing numbers added to text. The leakage test on manufacture of the insert has been added to section.	This ensures the split CV lid drawings are included in the SAR. The leakage testing of the inserts has always been carried out however it wasn't included in this

Summary of SAR Page Changes and Supporting Document Changes for Rev 7			
SAR Page	**Location**	**Change**	**Reason for Change**
			section, it has now been added for completeness.
Page 2-27	Section 2.4.3	Reference to new figure in section 1.	Includes reference to split CV lid figure added in section 1.
Page 2-28	Section 2.6.1.1	Maximum pressure section updated to take into account the pressure generated by Mo-99.	This section is now linked to section 3.3.2 to ensure the correct pressure is presented in section 2.
Page 2-39	Section 2.6.7	Note added to clarify tests were carried out on the standard lid CV along with a description of why this is the worst case test condition.	The addition of Mo-99 necessitates a split lid CV. The loading on the CV lid is worst case for the standard lid, therefore the results bound the results of the split CV lid.
Page 2-47 and 2-47a	Section 2.6.1.2	Discussion added to provide argument that existing testing bounds that of the split CV lid design.	The split lid is being added to the SAR a discussion is required as to why the existing testing covers the split CV lid design.
Page 2-57	Section 2.7.4.1	Altered the maximum pressure to account for the Mo-99 contents	Radiolysis of the Mo-99 solution causes the pressure to rise in the CV above that of the existing contents. Therefore the pressure needed to reflect this, however the pressure of the CV remains within the design pressure.
Chapter 3 - Thermal Evaluation			
Page 3-11	Section 3.3	Inclusion of standard CV lid in the section.	This makes clear the thermal testing was carried out with a standard CV lid.
Page 3-15	Section 3.3.2	Gas generation calculations for liquid Mo-99 added.	The gas generation rates provide the required data to support the inclusion of Mo-99 liquid.
Pages 3-15a and 3-15b	Section 3.3.2	Extra pages added to allow for the text regarding hydrogen generation.	The gas generation rates provide the required data to support the inclusion of Mo-99 liquid.
Page 3-19	Section 3.4.3	Inclusion of hydrogen pressure in the HAC pressure calculation.	This pressure is required to demonstrate the addition of Mo-99 will not increase the pressure

Summary of SAR Page Changes and Supporting Document Changes for Rev 7			
SAR Page	**Location**	**Change**	**Reason for Change**
			above the design pressure.
Page 3-22	Section 3.5.2	Mallinckrodt report added.	This report provides hydrogen generation rates for the MURR Mo-99 liquid.
Chapter 4 - Containment Evaluation			
Page 4-1	Section 4.1	Added standard and split CV lid to text, this includes a new figure which demonstrates the containment boundary of the split CV lid. New drawing numbers added.	Addition of Mo-99 contents requires a new split CV lid design.
Page 4-2	Figure 4-1	Title of figure changed.	To clarify that this figure shows the standard CV lid.
Page 4-2a	Figure 4-2	Figure added.	Figure demonstrates the containment boundary of the split CV lid. Addition of Mo-99 contents requires a new split CV lid design.
Page 4-5	Section 4.3.2	Maximum internal pressure increased to 1100 kPa.	This change to the maximum internal pressure was made during the RAI process on the last certificate application. This section however wasn't updated in accordance with the required change. Therefore this error is corrected during this application.
Chapter 5 - Shielding Evaluation			
Page 5-1	Section 5.1.1	A description of the split CV lid, tungsten liner and new steel insert added to section. Figure references updated.	Addition of Mo-99 contents requires a new split CV lid design, insert and tungsten liner.
Page 5-2	Figure 5-1	Title altered.	This clarifies that this figure is of a standard CV lid.
Page 5-3	Figure 5-2	Figure added.	This figure shows the shielding present for the liquid Mo-99 contents.

Summary of SAR Page Changes and Supporting Document Changes for Rev 7			
SAR Page	**Location**	**Change**	**Reason for Change**
Page 5-5	Figure 5-6	Figure added.	This figure shows the new steel insert design for the Mo-99 contents.
Page 5-8	Section 5.3.1	Addition of shielding report for Mo-99 in a steel insert and tungsten liner.	This provides the shielding data to allow the inclusion of Mo-99 onto the approved contents list.
Pages 5-9 to 5-10	Section 5.4.1	Addition of Mo-99 shielding calculation.	This provides the shielding data to allow the inclusion of Mo-99 onto the approved contents list.
Pages 5-10 to 5-11	Table 5-5	Addition of Mo-99 to the table along with clarification of the CV type used in the calculation.	This provides the shielding data to allow the inclusion of Mo-99 onto the approved contents list.
Page 5-15	Figure 5-10	Figure added.	Demonstrates the source location for the Mo-99 content shielding evaluation.
Page 5-16	Figure 5-11	Figure added	Demonstrates the source location for the Mo-99 content shielding evaluation.
Page 5-17	Figure 5-12	Figure added	Demonstrates the source location for the Mo-99 content shielding evaluation.
Page 5-19	Section 5.4.2	Addition of Mo-99 contents.	Allows the shipment of liquid Mo-99 in the HS package.
Page 5-20	Section 5.5.1	Addition of Mo-99 shielding calculation.	This provides the shielding data to allow the inclusion of Mo-99 onto the approved contents list.
Page 5-20	Section 5.5.2	Addition of Mo-99 shielding calculation.	This provides the shielding data to allow the inclusion of Mo-99 onto the approved contents list.
Page 5-21	Section 5.5.3	Addition of Mo-99 shielding calculation.	This provides the shielding data to allow the inclusion of Mo-99 onto the approved contents list.
Page 5-24	Section 5.5.4.2	Addition of section.	This section discusses the shielding calculations carried out for liquid Mo-99 and the subsequent results.

Summary of SAR Page Changes and Supporting Document Changes for Rev 7			
SAR Page	**Location**	**Change**	**Reason for Change**
Pages 5-24 to 5-25	Table 5-12 and Table 5-13	Addition of Mo-99 shielding calculation results.	This provides the shielding data to allow the inclusion of Mo-99 onto the approved contents list.
Page 5-28	Section 5.5.6	Addition of Mo-99 shielding report to supporting documents list.	Added on this application to allow the addition of Mo-99 to the approved contents list.
Chapter 6 - Criticality Evaluation			
None		None	
Chapter 7 - Operating Procedure			
Pages 7-2 to 7-3	Section 7.1.1	Standard and split CV lid added to title and section. Extra steps added to describe the removal of the split lid. Drawing numbers added for the split CV lid.	Addition of Mo-99 contents requires a new split CV lid design. This section now includes operational requirements for this split lid.
Page 7-4	Section 7.1.2	Standard lid added to title. Clarification added that the standard lid shall only be used with the existing tungsten and steel inserts.	Shielding calculations have only been carried out with the existing inserts and the standard lid, this operational description ensures existing contents will not be loaded with the split lid or new insert.
Pages 7-4 to 7-5	Section 7.1.3	Extra section added.	This section describes the loading of the split CV lid design.
Page 7-5	Section 7.1.4	Standard and split CV lid added to title and section.	Addition of Mo-99 contents requires a new split CV lid design. This section now includes instruction for the preparation of transport for the split lid containment vessel.
Page 7-7	Section 7.2.2	Standard lid added to title.	This ensures the operators remove the contents correctly for the standard lid containment vessel.
Page 7-8	Section 7.2.3	Extra section added.	This section describes the removal of the contents for the split CV lid design.

Summary of SAR Page Changes and Supporting Document Changes for Rev 7			
SAR Page	**Location**	**Change**	**Reason for Change**
Page 7-9	Section 7.3.1	Standard lid added to title.	This ensures the operators remove the contents correctly for the standard lid containment vessel.
Pages 7-10 to 7-11	Section 7.3.2	Extra section added.	This section describes the preparation of an empty package for shipment with the split CV lid design.
Chapter 8 - Acceptance Tests & Maintenance Program			
Page 8-2	Section 8.1.2	Split CV lid drawing numbers added to section.	Addition of liquid Mo-99 contents require the split CV lid, new insert and tungsten liner. The new drawings are therefore added to the section.
Page 8-2	Section 8.1.4	Helium leakage test of lid component clarified for the split CV lid.	The helium leakage test for the lid component is only carried out after machining and not also prior to machining as with the standard lid. This is because the plug is not welded to the lid.
Page 8-3	Section 8.1.5.2	Standard and split lid added to section	This provides clarification these tests are required for both lid designs.
Page 8-3	Section 8.1.5.4	Drawing numbers added to text.	This ensures the split CV lid drawings are included in the SAR.
Page 8-4	Section 8.1.5.5	Drawing numbers added to text.	This ensures the split CV lid drawings are included in the SAR.
Page 8-4	Section 8.1.5.6	Drawing numbers added to text.	This ensures the split CV lid drawings are included in the SAR.
Page 8-4	Section 8.1.6	Inclusion of tungsten liner into the shielding test requirements. Addition of ultrasonic testing of the DU to determine the performance of the DU finished component.	The addition of Mo-99 requires the addition of the tungsten liner for shielding purposes. The ultrasonic test has been added as an alternative to the gamma scan to allow flexibility during manufacture.
Page 8-6	Section 8.2.3.1	Drawing numbers added to text.	This ensures the split CV lid drawings are included in the SAR.

Summary of SAR Page Changes and Supporting Document Changes for Rev 7			
SAR Page	**Location**	**Change**	**Reason for Change**
Pages 8-7a to 8-8	Section 8.2.3.3	Standard and split CV lid added to title and section. Reference to split CV lid drawings added.	Addition of Mo-99 contents requires a new split CV lid design.
Page 8-10	Section 8.2.3.7	Section added.	Addition of the Mo-99 contents requires a new tungsten liner to provide shielding. This section presents the checks to be carried out on the liner during maintenance.
Page 8-11	Table 8-1	Tungsten liner added to table.	Addition of the Mo-99 contents requires a new tungsten liner to provide shielding.

6 NRC Questions and Croft Responses

This section documents all the NRC Questions and Croft Responses.

Table 2 - Question and Response Matrix Table

Q#	Review Question	Croft Response	Changed Item
General Information Review			
1.1	Provide a redacted copy of the Mallinckrodt gas generation calculation. Although the applicant marked the gas generation calculation per the requirements in Title10 of the Code of Federal Regulations (1 0 CFR) 2.390(b)(1)(i)(A), the applicant did not provide a version of the gas generation calculation which can be viewed by the public as required by 10 CFR 2.390(a). This information is necessary to satisfy the requirements in 10 CFR 2.390(b)(1)(i)(B).	This report was originally submitted with the MIDUS SAR. With this submission the whole gas generation report was withheld from the public (ML081770475) we request the same with this application.	
1.2	Identify the maximum mass of Molybdenum-99 (Mo-99) for transport in insert Design No. 4081. Table 1-3-8 in the SAR identifies the maximum mass of contents as 808 grams while Table 2 in PCS 038 identifies the maximum mass of contents as 807 grams. This information is necessary to satisfy the requirements in 10 CFR 71.33(a)(5).	Table 2 in PCS 038 has been updated so the weight matches the weight given in the SAR.	PCS 038
1.3	Clarify the shipping configuration and mass of insert Design No. 4081.	Insert 4081 has been designed to operate in conjunction with the tungsten liner. Therefore it has been included in table 2 of PCS 038.	PCS 038

Q#	Review Question	Croft Response	Changed Item
	Table 1-1 in the safety analysis report (SAR) indicates that the tungsten liner is used in conjunction with insert Design No. 4081 similar to the description of insert Design No.3987. However, Table 2 in PCS 038 only identifies insert Design No. 4081 while the description of insert Design No. 3987 in the same table also includes the PTFE liner. If the shipping configuration for insert Design No. 4081 does not include the tungsten insert, provide the mass of insert Design No. 4081 alone in Table 1-1 of the SAR. This information is necessary to satisfy the requirements in 10 CFR 71.33(a)(5).		
Email C Allen 03/06/16	The amount of depleted uranium shielding shown in drawing 1C-7507 is 49.8 mm. However, the amount of depleted uranium shielding, as stated in safety analysis report section 1.2.1.3, is 45.9 mm.	Section 1.2.1.3 has been updated to quote the correct DU thickness of 49.8 mm	Section 1.2.1.3
Materials Review			
2.1	Identify any significant reaction(s) between the liquid Mo-99 content and the HS-50x85-SS insert and discuss the impact of these reaction(s) on the performance of the package. Drawing No. 2C-7508 identifies the materials of construction for the insert top, and the insert body as SS Type 430, and SS Type 316 respectively. Literature suggests SS 316 is a good material for handling strong bases like sodium hydroxide, which is a main component of the Mo-99 content, below 80 degrees Celsius (^{o}C), up to the limit of solubility. Literature also indicates that the risk of stress corrosion cracking for SS 316 increases if service temperatures exceed 95°C. Table 3-1 identifies the maximum temperature for the shielding insert under normal conditions of transport (NCT) is slightly greater than 80^{o}C and Table	Drawing No. 2C-7508 has been updated so that the lid of the insert is now constructed from ASTM A479/A479M Type 316. The magnetic steel now forms a disc in the lid to allow manipulation of the insert when in a glove box. Therefore the magnetic steel Type 430 is no longer in contact with the contents. Under NCT contents the contents reach a temperature 84.5^{o}C. The contents will remain in the product bottle and therefore will not cause an issue of corrosion with the insert. Under HAC, if product gets out of the bottle it is only in contact with the SS insert for a limited time and the temperature in the CV is only high for the day or so of the HAC thermal cycle. Also there are no welds in the containment vessel and therefore no high stress points for possible stress corrosion.	Drawing 2C-7508

Q#	Review Question	Croft Response	Changed Item
	3-2 indicates that the maximum temperature reached by the shielding insert exceeds 95 °C. In addition, staff could not identify the service characteristics of SS 430 in relation to sodium hydroxide. This information is needed to ensure compliance with 10 CFR 71.43(d).		
2.2	Identify 0-ring materials of construction for the HS-50x85-SS insert within the text of the SAR. Drawing No. 2C-7508 identifies the confinement seal/0-ring as EPM/EPDM. However, silicone is the only insert 0-ring material listed in Table 2-10 and Table 3-2. This information is needed to ensure compliance with 10 CFR 71.33.	Tables 2-10 and 3-2 have been updated to correctly identify EPM/EPDM as the correct O-ring material.	Tables 2-10 and 3-2
Thermal Review			
3.1	Confirm the maximum and minimum allowable temperature range for the Viton GL T containment boundary seal and the shielding insert seal. Table 3-3 lists a maximum allowable Viton GL T 0-ring temperature. Although pages 3-10 and 3-12 in the SAR indicate that -40°C is within the 0-ring minimum temperature, no data (e.g., vendor data sheets) was provided for verification. Similar data should be provided for the EPM/EPDM shielding insert seal. This information is needed to determine compliance with 10 CFR 71.51 and 10 CFR 71.71.	Viton GLT has an allowable temperature range of -40^{o}C to 200^{o}C. Attached to this response is the data vendor sheet for this material. The data sheet for EPM/EPDM is also attached.	
3.2	Confirm that the results from the experimental NCT test and the furnace test on a package with the standard containment vessel lid bound the results for a package with the split lid design.	Section 3.3 has been updated to discuss why the standard lid thermal model bounds the split lid design.	Section 3.3

Q#	Review Question	Croft Response	Changed Item
	Page 3-11 states that the NCT test and furnace test were based on the standard containment vessel lid but the relevance of the test results to the split lid design was not discussed. This information is needed to determine compliance with 10 CFR 71.71 and 10 CFR 71.73.		
3.3	Provide pressure calculations for the containment vessel under NCT that account for the vapor pressure of the Mo-99 liquid mixture at 80 °C. Page 3-15 states that "there is no pressure increase due to vapour pressure of the liquid contents" because the liquid is below the boiling point. However, the vapor pressure of water increases with temperature between loading (presumably at 20 °C) and prior to the boiling point. This information is needed to determine compliance with 10 CFR 71.33(b)(5).	The vapour pressure of the liquid contents at 84^{o}C is this has an absolute pressure of 0.6 bar which is -0.4 barg, therefore this wouldn't affect the gauge pressure which is quoted in the SAR.	
3.4	Confirm that the Mo-99 product bottle/product container has adequate space (i.e., ullage), or other specified provision, for expansion of the liquid during the heat and cold test for NCT and the hypothetical accident conditions (HAC) fire test. It is not clear whether the package systems are adequately designed to accommodate expansion of the liquid Mo-99. This information is needed to determine compliance with 10 CFR 71.33(b)(3) and 10 CFR 71.87(d).	The maximum volume of contents that may be loaded into the Mallinckrodt product bottle is 75 ml. The volume of the product bottle is 110 ml (now added to table 1-3-8), therefore there is an ullage volume of 35 ml. If the liquid heats up from 20^{o}C to 124^{o}C the expansion of the solution would be 6 ml. Therefore sufficient ullage is present in the product bottle.	

Q#	Review Question	Croft Response	Changed Item
3.5	Confirm the gas generation report results bound the gas generated during transport and specify the product bottle material. The materials mentioned in the radiolytic gas generation report ("Radiolytic gas formation in Mallinckrodt produced Mo99 solutions") were SS and glass. Because the product bottle material used during transport is not specified in the application, it is unclear if the gas generation report adequately accounts for the potential radiolysis of the product bottle. For example, plastics have radiolysis generation rates greater than the materials mentioned in the gas generation report. This information is needed to determine compliance with 10 CFR 71.33(b)(5) and 10 CFR 71.43(d).	Table 1-3-8 now includes the product bottle material and an illustration has been included in section one. The product bottle is stainless steel and is similar in design to those used during radiolytic testing.	Table 1-3-8 and Figure 1-6
3.6	Provide radiolysis (i.e., flammable gas concentrations) and pressure calculations that account for NCT temperatures. a. Section 6.1 of the gas generation report ("Radiolytic gas formation in Mallinckrodt produced Mo99 solutions") indicated that the test temperature varied from 28.1 °C to 33.8 °C. However, SAR page 3-15a states the assumed gas temperature is 80.1 °C. This higher temperature would increase the amount of gas/hydrogen generated by radiolysis and would result in a greater pressure within the package. b. The vapor pressure of the liquid should consider the temperature due to self-heating of the Mo-99 content; the decay heat of the radioactive material, if high enough, could cause the content temperature to be greater than the 80^{o}C surrounding air within the containment vessel at NCT. Self-heating should also	The amount of gas generated by radiolysis has been increased by 20% to take into account the increased gas generation rates at 84^{o}C. This is discussed in detail in section 3.3.2 of the SAR. A calculation sheet has also been added to determine the temperature of the contents due to self heating under NCT and HAC. This has increased the temperature of the contents and the pressure calculations for both NCT and HAC have been updated accordingly.	Section 3.3.2, section 3.4.3 and section 3.5.2

Q#	Review Question	Croft Response	Changed Item
	be considered in the pressure calculations for HAC. This information is needed to determine compliance with 10 CFR 71.33(b)(5) and 10 CFR 71.43(d).		
3.7	Clarify if there is a limited transportation period associated with the Mo-99 content. SAR Section 2.6.1.1 generically states that the 7 bar (gauge) pressure is based on a one year period, and SAR Section 3.3.2 indicated a 28-day period for radiolysis associated with the lodine-131 content. However, a transportation time period was not provided for the Mo-99 content. This information is needed to determine compliance with 10 CFR 71.33(b)(5).	It has been clarified in section 3.3.2 that there is no limited transportation period associated with the Mo-99 contents.	section 3.3.2
Containment Review			
4.1	Identify the acceptable pre-shipment leakage test leakage rate. The applicant described the pre-shipment leakage test in SAR Section 7 .1.4 without identifying the acceptable leakage rate. The applicant should identify the acceptable leakage test leak rate per ANSI N14.5 not only for completeness and as an aid to the test personnel, but also to incorporate it by reference in the certificate of compliance. This information is needed to determine compliance with 10 CFR 71.43{f), and 10 CFR 71.51 (a).	The pass rate has been included in section 4 and 7.1.4	Section 4.4.4 and section 7.1.4
Shielding Review			

Q#	Review Question	Croft Response	Changed Item
5.1	Justify the assumption that a 3.5% dose rate increase from the top source due to beta emission is conservative. The applicant provided report AMEC/CRM42622/TN_001 which found there was a 3.5% increase in dose rate associated with the side and bottom sources. The report also assumed a similar dose rate increase for the top source. However, the applicant provided no correlating justification for that assumption. This information is required to determine compliance with 10 CFR 71.47.	• As stated in the Technical Note, AMEC/CRM42622/TN_001 Issue1, the dose-rates arising from the beta sources were calculated with all of the betas emitted at the beta endpoint, 1.2145MeV, rather than using the beta spectrum. • This approach, adopted for simplicity, introduces considerable conservatism into these dose-rates because all betas are emitted at the maximum possible energy. • Thus the result, for the liquid at the side or bottom of the container, that the dose-rates arising from beta sources is at most 3.5% of that arising from gamma sources, is conservative. • The maximum dose-rate arising from gamma sources with the liquid at the top of the container (851microSv/hr) is 72% of the maximum with the liquid at the side of the container (1175microSv/hr). • Thus, for the maximum dose-rate arising from both gamma and beta sources with the liquid at the top of the container to exceed that with the liquid at the side of the container (1214microSv/hr) the dose-rate arising from beta sources would need to be 43% of that arising from gamma sources. This is considered to be incredible given the figure of 3.5% for liquid at the side or bottom of the container, which, as noted above, is itself very conservative. • Thus dose-rates arising from beta sources with the liquid at the top of the container were not calculated explicitly and the 3.5% figure was applied to estimate them. • Unverified calculations have been undertaken to check that this judgement is reasonable: the dose-rate arising from beta sources with the liquid at the top of the container is 3.1% of that arising from gamma sources, thus confirming the original judgement.	
5.2	Explain how the changes in distance from the source to package surface due to denting and buckling from the HAC tests described in AMEC/CRM42622/TN_001 have been determined to alter surface dose rates.	• The NCT and HAC tests, described in CTR 2010/02 Issue A, March 2012, resulted in some denting in the side of the container but no loss of shielding as modelled in the calculations reported in Technical Note	

Q#	Review Question	Croft Response	Changed Item
	The applicant discusses a 5% change in dose rates at the side in Chapter 5, but it is not clear if this was taken into account in the maximum dose rates presented in Tables 5-12 and 5-13. There is further mention of buckling after the top drop but no statement as to whether there is or isn't a change to the distance between the lid and source. While the applicant states that shielding material is not lost, insufficient information was provided to verify that changes in geometry would not also change the external dose rate. This information is necessary to determine compliance with 10 CFR 71.51 (a)(2).	AMEC/CRM42622/TN_001 Issue1 because the shock absorbing material was not included in the model (modelled as void). The distance from the source to the lid or base of the package was unchanged – the skirts were crushed but the lid or base were not dented. • If a dosemeter is placed at the position of the surface before denting then the maximum dose-rates given in Technical Note AMEC/CRM42622/TN_001 Issue1 apply. However, if the dosemeter is placed inside the dent then dose-rates will increase due to closer proximity to the source, even though no shielding as modelled is lost. • After the HAC tests there is an 11mm dent. This has been modelled by simply reducing the distance to the surface. Dose-rates arising from gamma and beta sources were calculated explicitly. The beta source calculation used the beta endpoint as described in the Technical Note. The resulting maximum surface dose-rate on the container is 1362 microSv/hr with 0.4% stochastic uncertainty at the 1 sd level. • After the NCT tests there is a 8mm dent. In that case the maximum surface dose-rate is 1320 microSv/hr with 0.3% stochastic uncertainty. The dose-rate arising from gamma sources was calculated explicitly and that from beta sources estimated from the HAC results.	
5.3	Identify the “cavity” referenced in Tables 5-12 and 5-13. Tables 5-10 and 5-11 provide data for the situation in which the source is positioned at the inside surface of the containment vessel; i.e., no insert. Therefore, it is not clear to staff if the cavity referenced in Tables 5-12 and 5-13 is the insert cavity or the containment vessel cavity. In addition, staff noted that the applicant has duplicate Tables 5-12 and 5-13. One set of tables presents dose rate information for Iodine-131 and one set of tables presents dose rate data for Mo-99.	The insert cavity has been clearly identified in all the tables discussing the I-131 and Mo-99 contents. The tables have also been correctly numbered.	Table 5-12, Table 5-13, Table 5-14, Table 5-15 and Table 5-16

Q#	Review Question	Croft Response	Changed Item
	This information is necessary to determine compliance with 10 CFR 71.47.		
Operations Review			
7.1	Clarify what equipment should be used to handle the containment vessel. Step 5 of Section 7.1.1 recommends a 12 mm eyebolt be used to remove the containment vessel. However, both step 3 of Section 7.2.2 and step 3 of Section 7.2.3 directs the user to install a 12 mm eyebolt to remove the containment vessel from the keg. The language in these instructions is not consistent, and should be revised to assist the user in developing procedures and ensuring the appropriate equipment is available. This information is needed to ensure compliance with 10 CFR 71.87(f).	The wording in section 7.1.1 has been changed so it is now consistent with sections 7.2.2 and 7.2.3 regarding the use of the 12 mm eyebolt.	Section 7.1.1
7.2	Clarify the certification level of the personnel developing/approving the helium leakage rate testing procedures. Although ANSI/ASNT CP-189-2006, "Standard for Qualification and Certification of Nondestructive Testing Personnel", states that a nondestructive testing personnel Level III examiner has the qualifications to develop and approve written instructions for conducting the leak testing, the applicant described the leakage tests in SAR Chapters 7 and 8 without identifying the certification level of the personnel developing/approving the helium leakage rate testing procedures. This information is needed to determine compliance with 10 CFR 71.87(f).	The requirement for a level III examiner to write and approve the leak test procedure has been included in section 8 of the SAR.	Section 8.1.4

Q#	Review Question	Croft Response	Changed Item
7.3	Identify equipment needed to handle the containment vessel shielding plug. Step 8 of Section 7.1.1 states that the shield plug lifting point shall be used to remove the shield plug. Drawing 1 C-7507 indicates the containment vessel shielding plug lifting point is a threaded connection. However, step 8 does not identify what lifting equipment, if any, is need to remove the containment vessel shielding plug. If lifting equipment is required, the loading instructions in Section 7.1.3 should be revised to reference the equipment for loading. This information is needed to ensure compliance with 10 CFR 71.87(f).	The package is loaded and unloaded within the hot cells at Mallinckrodt and also their customers. Each hot cell will require its own method to remove the shielding plug; therefore the exact lifting equipment used cannot be specified in the SAR; however the use of the shielding plug point has been clarified.	Section 7.1.3
7.4	Clarify if the tungsten liner is transported separate from insert Design No. 4081. Step 3 of Section 7.3.2 directs the user to install the containment vessel shielding plug after placing the tungsten liner into the containment vessel. The instructions also identify that loading the insert and payload is optional. Since shielding analysis AMEC/CRM42622/TN_001 assumes insert Design No. 4081 sits within the tungsten liner, the applicant should identify situations in which the tungsten liner is transported separately from insert Design No. 4081. This information is needed to ensure compliance with 10 CFR 71.33(a)(5) and 10 CFR 71.87(f).	When containing Mo-99, the stainless steel insert is always shipped with the tungsten liner present. Section 7.3.2 covers the shipment of the empty package. This usually occurs when the customer returns the empty package to Mallinckrodt. Customers may retain the inserts and bottles however they would be expected to return the tungsten liner so that it can be used for the next shipment.	
7.5	Identify how positive closure of insert Design No. 4081 is ensured. Insert Design Nos. 3982, 3985 and 3987 employ match marks to identify positive closure and ensure the radioactive contents remain inside the insert. Identify how the current design both ensures positive closure	Insert 4081 differs from the other inserts in that it has a positive stop; therefore match marks are not required.	

Q#	Review Question	Croft Response	Changed Item
	of insert Design No. 4081 and ensures the radioactive contents remain inside the insert as assumed in shielding analysis AMEC/CRM42622/TN_001. Alternatively, the applicant should modify both the insert licensing drawing to show match marks and the operating instructions to reference match marks. This information is needed to ensure compliance with 10 CFR 71.33(a)(5) and 10 CFR 71.87(f).		
7.6	Identify the appropriate insert Design number for the split CV lid in Section 7.1.3. Section 7.1.2 provides the appropriate insert Design numbers for the standard lid. There is no corresponding input in Section 7.1.3 for the split CV lid. This information is needed to determine compliance with 10 CFR 71.33.	The appropriate insert design number has been identified in section 7.1.3.	Section 7.1.3
Editorial Issues			
	In addition to the information requests above, staff identified the following editorial items: 1. Mass of steel insert for Mallinckrodt insert should be 1,615 versus 1.615 in PCS 038, 2. References to gaseous shielding limits were deleted in PCS 038, 3. Table 10 is consistently omitted in Sections 1 and 2 of PCS 038, 4. The assumed maximum temperature is missing in the table located on page 3-12, 5. Incomplete sentence in item 2 in Section 7.1.3, and 6. The final unloading instruction in Section 7.2.3 is not numbered.	All editorial issues have been corrected.	

Table 3 - Question and Response Matrix Table For NRC Questions Dated August 8, 2016

Q#	Review Question	Croft Response	Changed Item
Thermal Review			
3.1	Provide the calculation that determines the pressure within the containment boundary during normal conditions of transport (NCT) and hypothetical accident conditions (HAC). The response to RAI 3.6 cites a calculation sheet that presumably shows how the applicant obtained 5.15 bar (gauge) NCT pressure and 8.99 bar (gauge) HAC pressure for the shielding insert. Staff needs to verify the calculation addresses all relevant factors which increase pressure, e.g.; water vapor pressure, temperature changes, the change in moles due to radiolysis, etc. This information is needed to determine compliance with Title 10 of the Code of Federal Regulations (10 CFR) 71.51 (a).	Calculation sheet CS 2016/31 has been attached to the SAR. This demonstrates that all applicable factors have been included in the calculation of pressure in the containment vessel during NCT and HAC.	CS 2016/31, Section 3.3.2, 3.4
3.2	Demonstrate that the HAC pressure accounts for radiolysis associated with higher HAC temperatures. SAR Section 3.3.2 stated that the NCT pressure accounted for radiolysis associated with a higher NCT temperature (84.56 degrees C) compared to the test temperature (28 degrees C). However, SAR Section 3.4.3 did not include a similar explanation (e.g., a 1.2 multiplier factor was used for normal conditions) for HAC. This information is needed to determine compliance with 10 CFR 71.51 (a)(2).	A note has been included in calculation sheet CS 2016/31 as to why the higher rate of hydrogen generation has not been used when determining the pressure under HAC.	CS 2016/31
3.3	Justify the apparent exclusion of water vapor pressure when calculating the containment vessel pressure.	Water vapour pressure has now been included in the pressure calculations.	CS 2016/31, Section 3.3.2

Q#	Review Question	Croft Response	Changed Item
	The response to RAI 3.3 indicated that the increase in vapor pressure from 20 degrees C loading temperature to 80 degrees C would not affect the containment vessel pressure. However, no justification was provided. This information is needed to determine compliance with 10 CFR 71.51 (a)(1).		
3.4	Clarify the HAC package pressure SAR page 3-21 indicated that the maximum pressure at HAC was 10 bar (gauge). However, SAR page 1-11 indicated that the maximum pressure for HAC was 7 bar (gauge). In addition, SAR page 3-21 indicated that the maximum pressure in the containment vessel was 8.99 bar (gauge) whereas SAR page 2-57 stated that the maximum pressure reached during the HAC fire was 7.47 bar (gauge). This information is needed to determine compliance with 10 CFR 71.51 (a)(2).	The pressure has been clarified throughout the SAR	Sections 1.1.2, 2.7.4.1, 3.4.3

Appendix A New or edited SAR pages provided in the SAR at Rev 7

Chapter	Pages
0	0-2 to 0-14
1	1-2 to 1-12, 1-13a , 1-14, 1-22, 1-33 to 1-35, 1-37, 1-38
2	2-1 to 2-5, 2-18 to 2-19a, 2-21, 2-24 to 2-28, 2-39, 2-47, 2-47a, 2-57, 2-58
3	3-11, 3-15, 3-15a, 3-15b, 3-19, 3-22
4	4-1 to 4-2a, 4-5
5	All
7	All
8	8-2 to 8-4a, 8-6, 8-7a, 8-8, 8-10, 8-11

New or edited SAR pages provided in the SAR at Rev 9

Chapter	Pages
0	0-2 to 0-15
1	1-13a, 1-22
2	2-18 to 2-19a
3	3-5 to 3-23
4	4-8
5	5-19, 5-23 to 5-27
7	7-2 to 7-6a and 7-8
8	8-2 to 8-4, 8-5, 8-5a, 8-8 and 8-12

New or edited SAR pages provided in the SAR at Rev 10

Chapter	Pages
0	0-2 to 0-15
1	1-11
2	2-57
3	3-15 to 3-18, 3-21, 3-23
8	8-5, 8-5a

Appendix B New or edited Supporting Documents provided in the SAR at Rev 7

Related SAR Section or Doc	Document Reference		Title
Chapter 1 - General Information			
Documents in Section 1.3.3, Licensing Drawings			
Addition	1C-7500	A	Cover sheet for Safkeg-HS design No. 3977A – Mallinckrodt Version
Addition	0C-7501	A	Safkeg HS design no.3977A – Mallinckrodt Version
Addition	0C-7502	A	Keg Design No.3977 – Mallinckrodt Version
Addition	0C-7503	A	Cork Set for Safkeg HS – Mallinckrodt Version
Addition	1C-7504	A	Containment Vessel Design No 3978 – Mallinckrodt Version
Addition	1C-7505	A	Containment vessel lid – Mallinckrodt Version
Addition	1C-7506	A	Containment vessel body – Mallinckrodt Version
Addition	1C-7507	A	Containment Vessel Plug – Mallinckrodt Version
Addition	2C-7508	A	HS-50x85-SS insert design no 4081
Addition	2C-7509	A	Snap Ring
Addition	2C-7510	A	Tungsten Liner
Documents in Section 1.3.4 Supporting Documents			
Update	PCS 036	F	Package Contents Specification for Safkeg-HS - Package Design No 3977A
Chapter 3 – Thermal			
Documents in Section 3.5.2			
Addition		V2.2	Radiolytic Gas Formation in Mallinckrodt Produced Mo99 Solutions
Chapter 5 – Shielding Evaluation			
Documents in Section 5.5.2			
Addition	AMEC/CRM42622 /TN_001	1	HS Container Shielding Assessment with Mo-99

New or edited Supporting Documents provided in the SAR at Rev 9

Related SAR Section or Doc	Document Reference		Title
Chapter 1 - General Information			
Documents in Section 1.3.3, Licensing Drawings			
Update	1C-7500	B	Cover sheet for Safkeg-HS design No. 3977A – Mallinckrodt Version
Update	0C-7501	B	Safkeg HS design no.3977A – Mallinckrodt Version
Update	2C-7508	B	HS-50x85-SS insert design no 4081
Documents in Section 1.3.4 Supporting Documents			
Update	PCS 036	G	Package Contents Specification for Safkeg-HS - Package Design No 3977A
Chapter 3 – Thermal			
Documents in Section 3.5.2			
Update	CS 2016/27	A	Temperature of Mo-99 Contents in the HS Package

New or edited Supporting Documents provided in the SAR at Rev 10

Related SAR Section or Doc	Document Reference		Title
Chapter 3 – Thermal			
Documents in Section 3.5.2			
New	CS 2016/31	A	Maximum Pressure in Containment Vessel 3978 Under NCT and HAC