SAFKEG-HS 3977A

SAR Update Matrix for Addition of Liquid I-131

Title	SAFKEG-LS 3977A SAR Update Matrix for Addition of Liquid I-131	Number	CTR 2015/17
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1 Notes on methodology and content

This Update Matrix (CTR 2015/17) details the changes in the SAFKEG-HS 3977A SAR in updating from Rev 5 to Rev 6. It has been updated during the NRC review process to include responses to questions from the NRC, thereby it fully documents all changes made during the entire SAR update.

The update to SAR Rev 6 is to allow I-131 in liquid form to be carried in the steel insert, as listed in Contents Type 5. It also allows the correction of minor errors in the SAR and the alteration of the O-ring grooves in the containment vessel.

This Update Matrix (CTR 2015/17) provides the following.

- Justification for the changes in the SAFKEG-HS 3977A SAR in updating from Rev 5 to Rev 6
- Details of SAR changes - List of all changes to the SAR - Table 1
- Question and Response Matrix Table – Tables 2, 3 and 4, this includes all the updates made to the SAR to answer all the questions posed by the NRC.
- List of SAR page changes for both the initial application updating from revision 5 to 6 and the RAI response update revisions [Appendix B]

2 Justification for the changes in the SAFKEG-HS 3977A SAR in updating from Rev 5 to Rev 6

MURR wish to carry liquid I-131 in the stainless steel insert. The update to SAR Rev6 is to allow the inclusion of I-131 to the contents list of contents Type 5. While the SAR is being updated the opportunity is taken, to relax the tolerance on the containment seal the groove sizes and clarify the replacement of damaged keg studs.

3 SAR Changes

This table contains notes on all the SAR Page Changes and supporting Document Changes for Rev 6 (from Rev 5).

Table 1 Summary of SAR Page Changes and Supporting Document Changes for Rev 6

Summary of SAR Page Changes and Supporting Document Changes for Rev 5			
SAR Page or Doc	**Location**	**Change**	**Reason for Change**
Chapter 0 - Contents			
All pages	Header	Page Rev status amended to Rev 6 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	Table	Name amended	Editorial/Update.
Page 0-2	Date box	Date amended	Update.
Page 0-5	Documents in section 1.3.3	The drawings have been updated; the changes made are discussed in Croft change control document M869, attached to this application. The main change of note is the change to the tolerance of the O-ring grooves on the containment vessel lid.	This change is required due to issues experienced during manufacture. The change will not affect containment, indeed the current non conforming units have been pressure and helium leak tested and passed, demonstrating their containment ability.
Chapter 1 - General Information			
Page 1-12	Table 1-1	The mass of the steel insert has been altered along with the maximum mass of the insert plus contents. The final column has been removed from the table	The mass of the steel insert given in the table was incorrect. The final column was removed because this was confusing to users.

Summary of SAR Page Changes and Supporting Document Changes for Rev 5			
SAR Page or Doc	**Location**	**Change**	**Reason for Change**
Page 1-13	Figure 1-5c	Figure 1-5c has been updated.	The design of the steel insert has been altered to accommodate liquid I-131 contents.
Page 1-14	Table 1-2	The title of the steel insert has been altered	The steel insert internal dimensions have altered; this caused the name of the insert to change.
Page 1-19	Table 1-3-6	Leak testing after loading was removed from the table. Name of insert was altered	This is discussed on the page 7-4 line.
Page 1-30	Table 1-4-5	I-131 was added to the liquid contents table	MURR would like to carry liquid I-131 in the HS package.
Page 1-36	Section 1.3.2	Calculation drawing was added for the updated stainless steel insert	To include drawing of the stainless steel insert
Page 1-37	Section 1.3.3	A licensing drawing for the stainless steel insert was added to the drawing list.	The liquid I-131 contents will be contained in the stainless steel insert.
Chapter 2 - Structural Evaluation			
Page 2-25	Section 2.3.2	O-ring test removed	During the original application the O-ring material was changed and therefore this test should have been removed. This error is corrected in this application.
Chapter 3 - Thermal Evaluation			
Page 3-15	Section 3.3.2	Gas generation calculations for liquid I-131 added.	The gas generation rates are provided to allow the inclusion of I-131 liquid.

Summary of SAR Page Changes and Supporting Document Changes for Rev 5			
SAR Page or Doc	**Location**	**Change**	**Reason for Change**
Page 3-15a	Section 3.3.2	Extra page added to allow for the text regarding hydrogen generation.	The gas generation rates are provided to allow the inclusion of I-131 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 I-131 will not increase the pressure above the design pressure.
Page 3-22	Section 3.5.2	MURR report added.	This report provides hydrogen generation rates for the MURR I-131 liquid.
Chapter 4 - Containment Evaluation			
None		None	
Chapter 5 - Shielding Evaluation			
5-3	Figure 5-4	Title altered and drawing updated.	The cavity of the steel insert has been altered causing a change to the title and drawing.
5-5	Table 5-1	Outer surface of the truck added to table.	Added to make clear where the dose point measurement is taken. This was left blank in revision 5
5-6	Section 5.3.1	Addition of shielding report for I-131 in a steel insert	This allows the inclusion of I-131 onto the approved contents list.
5-7	Section 5.4.1	Addition of I-131 shielding calculation.	This allows the inclusion of I-131 onto the approved contents list.
5-8	Section 5.4.1	Addition of I-131 shielding calculation.	This allows the inclusion of I-131 onto the approved contents list.
5-10	Figure 5-6	Change to figure title.	To clarify this figure is for a

Summary of SAR Page Changes and Supporting Document Changes for Rev 5			
SAR Page or Doc	**Location**	**Change**	**Reason for Change**
			tungsten insert
5-10a	Figure 5-7	New figure added.	This figure shows the source locations for the steel insert shielding calculations.
5-11	Section 5.4.1	Addition of the word tungsten.	Clarifies which shielding report is being discussed.
5-12	Section 5.4.2	Addition of I-131 shielding calculation.	Allows MURR to ship liquid I-131.
5-13	Section 5.5.1	Addition of I-131 shielding calculation.	This allows the inclusion of I-131 onto the approved contents list.
5-14	Section 5.5.3	Addition of I-131 shielding calculation.	This allows the inclusion of I-131 onto the approved contents list.
5-16	Section 5.5.4.1.2	Addition of I-131 shielding calculation.	This allows the inclusion of I-131 onto the approved contents list.
5-16a	Table 5-12 and Table 5-13	Addition of I-131 shielding calculation results.	This allows the inclusion of I-131 onto the approved contents list.
5-17	Table 5-14	Addition of I-131 to table	This allows the inclusion of I-131 onto the approved contents list.
5-19	Section 5.5.6	Addition of I-131 shielding report to supporting documents list.	Added on this application to allow the addition of I-131 to the approved contents list.
Chapter 6 - Criticality Evaluation			
None		None	
Chapter 7 - Operating Procedure			
7-4	Section 7.1.2	Leak testing of the insert when	Bubble leak testing an insert with

Summary of SAR Page Changes and Supporting Document Changes for Rev 5			
SAR Page or Doc	**Location**	**Change**	**Reason for Change**
		loading liquids is now prior to loading the contents. This allows leak testing to be carried out without active contents.	loaded radioactive liquid contents presents an unnecessary risk to operators. Leak testing prior to loading demonstrates that the sealing system is effective. The inserts have match marks to ensure that they are correctly closed so there is no mechanism to lead to the contents leaking.
Page 7-4a	Section 7.1.2	Extra page	Accommodating the change on page 7-4 required an extra page.
Chapter 8 - Acceptance Tests & Maintenance Program			
Page 8-7	Section 8.2.3.2	Page Rev status amended to Rev 6 Addition of the use of an equivalent threadlocker Loctite 263 to position the studs. Allow the replacement of any damaged keg closure studs	Loctite 270 is difficult to source in the US so we have allowed the use of Loctite 263. Loctite 263 has the same properties as Loctite 270. The keg studs can be replaced if damaged in accordance to section 8.2.3.2 (8), however MURR requested that we clarified the replacement of studs by adding this extra sentence.
Page 8-7a		Page Rev status amended to Rev 6 Extra page added	Accommodates the change added in point 4

4 NRC Questions and Croft Responses

This section is provided to document all NRC Questions and Croft Responses. The updates required in Table 2 are made to Rev 7 of the SAR and update it to Rev 8. The updates discussed in Table 3 are made to Rev 9 of the SAR and update it to Rev 10. The updates discussed in Table 4 are made to Rev 11 of the SAR and update it to Rev 12.

Table 2 - Question and Response Matrix Table

Q#	Review Question	Croft Response	Changed Item
1.1	Revise Drawing No. 2C-6176 as necessary to identify under what conditions the PTFE liner is optional. Although Note 3 on Drawing No. 2C-6176 states that the PTFE liner is optional, the safety analysis report (SAR) change pages provided with the application do not identify instances where the stainless steel liner is used without the PTFE liner. In addition, in reviewing historical documents associated with this package, staff determined that Croft previously addressed this question during the initial issuance of certificate of compliance 71-9338 and stated "…[t]he liner shall be used for all contents types carried in the stainless steel insert…" (ADAMS accession number ML13114A172). This information is necessary to satisfy the requirements in 10 CFR 71.33(a)(5).	The liner is not optional it shall always be present. The optional wording has been removed from the drawing.	Drawings 2C-6176 and 1C-5940
1.2	Identify the correct mass of the stainless steel insert. Table 1-3-5 states the stainless steel insert mass is 730 g and Table 1-1 states the stainless steel insert mass is 1451 g. This information is necessary to satisfy the requirements in 10 CFR 71.33(a)(5).	The correct mass is 1451g, table 1-3-5 has been corrected accordingly.	Table 1-3-5

Q#	Review Question	Croft Response	Changed Item
3.1	Review all units to ensure that they are correct for the parameters they represent and revise as necessary. Page 3-15 of the Safety Analysis Report (SAR) in a free volume of 216.4°C along with heating of the gases on loading this would lead to a MNOP of 2.23 bara. The units used for both volume and pressure are incorrect. The staff needs to verify that adequate units are used for the parameters they represent. This information is needed to determine compliance with 10 CFR 71.71.	^{o}C amended to cm^{3}. The pressure calculation has been reviewed and corrected to reflect the correct pressure in barg.	Section 3.2.2
3.2	Provide detailed calculations, as well as all assumptions used in these calculations, which demonstrate that the heating from hydrogen ignition is negligible. Page 3-15a of the SAR states that the heating created by ignition of all of the hydrogen generated over 28 days would be negligible compared to the heating of the package by the decay of I-131. However, the assumed initial temperature and pressure of both the containment vessel and associated contents are not provided. In order to assess both the accuracy of this statement and the adequacy of the containment system if hydrogen ignition occurred, staff needs to review the detailed calculations and all assumptions which substantiate this statement. Identify the maximum temperature and pressure of the containment vessel and associated contents due to hydrogen ignition with the detailed calculations. This information is needed to determine compliance with 10 CFR 71.71.	Detailed calculation provided with this RAI response.	Section 3.5.2
3.3	Identify the gamma energy used in the hydrogen generation analysis and prove it bounds all expected values. On Page 10 of 13 of the Hydrogen Generation Analysis, the applicant states that I-131 decays emitting beta particles with an average energy of 0.19 MeV and gammas with an average energy of 0.364 MeV. However, the gamma energy value used	The statement “with an average energy of 0.364 MeV” reflects the actual energies used in the MCNP calculation to determine the fraction of energy deposited in the vial. The model used the five most prominent I-131 emission energies: 0.080 MeV (2.6%), 0.284 MeV (6.1%), 0.364 MeV (81.7%), 0.637 MeV (7.2%), 0.773 (1.8%).	

Q#	Review Question	Croft Response	Changed Item
	in the analysis is less than the average energy of 0.364 MeV. Since the average gamma energy is higher than the value used in the analysis, staff needs to determine if the hydrogen generation rate is under predicted by the applicant. This information is needed to determine compliance with 10 CFR 71.71.	Regarding the risk-based assessment of the use of this average, were we to change the model and assume that the energies from the gamma peaks were 25% stronger than initially modeled, this would give us an assumed energy of 0.455 MeV. Incorporating this into the model and multiplying this by the absorption fraction, we then find 0.455 MeV * 0.045 = 0.0205 MeV of energy deposited into the system. Using the assumption that every single beta particle is absorbed by the system at 0.19 MeV, the assumed energy deposited per disintegration is 0.2105 MeV vs. 0.206 MeV, a change of 2.21%. When combined with the other conservatisms built into the model, we regard the use of 0.364 MeV as appropriate	
4.1	Provide the basis for the new O-ring groove dimensions. The staff needs to verify the acceptability of the proposed containment system relaxed O-ring groove dimensions; therefore, the applicant should provide the basis for their choice of new O-ring groove dimensions, e.g.; manufacturer data sheets. This information is needed to determine compliance with 10 CFR 71.33(a)(5).	The depth of the groove remains unchanged and this is the vital performance characteristic regarding sealing. The fact that the groove width can now be 0.2mm wider than before makes no difference. The minimum fill ratio of the O-ring in the groove remains the same i.e. because the groove width can't be any less than that previously approved (old groove mouth width 2.9±0.1mm, new groove mouth width 2.9+0.3/-0.1mm).	

Q#	Review Question	Croft Response	Changed Item
4.2	Clarify the material used for the containment vessel O-ring and justify removal of the O-ring test from Section 2.3.2 of the SAR. The applicant proposes to remove an O-ring test from page 2-25 of the SAR because, as the applicant states on page five of "SAR Update Matrix for Addition of Liquid I-131" (ADAMS Accession No. ML15351A333), the O-ring material was changed during the original application and this test should have been removed. The applicant states they are correcting this error. However, Drawing 1C-5944, Issue C, identifies the containment seal material as Fluoroelastomer (Base material Viton GLT) while page 2-19 of SAR Revision 5 states that the containment seal material is Ethylene Propylene Rubber. Consequently, the staff needs clarification on the containment seal material and the basis for the removal of the O-ring test in Section 2.3.2 of the SAR. This information is needed to determine compliance with 10 CFR Part 71.33(a)(5).	The containment seal is Fluoroelastomer (base material Viton GLT). This material was chosen in preference to EPM due to its performance at high temperatures. The test in section 2.3.2 of the SAR allowed for EPM O-rings to be tested in situ at 150^{o}C for 1000 hours and 200^{o}C for 24 hours, to demonstrate the EPM batch used was suitable. However during the review process the EPM was changed to Fluoroelastomer (base material Viton GLT) which is shown to function at 205^{o}C and therefore didn't require this test. The references to EPM were erroneously left in the text and should have been removed at revision 5 of the SAR. All references to EPM were removed in revision 7 of the SAR.	

Q#	Review Question	Croft Response	Changed Item
5.1	Clearly identify the location of maximum dose rate resulting from the 3D Monte Carlo evaluations and the correlating Microshield evaluation. The values in Table 5-6 do not correspond to the expected thicknesses shown in the drawings in reference AMEC/SF6652/001 even if the evaluation were to be at a point on the outer radial surface of the package at the same elevation of the point source. Therefore, it is not clear that the slab thicknesses used in the Microshield evaluation correspond to the location of maximum dose rate, described as “just above the top steel annulus” in reference AMEC/CRM37327/TN_001. This location is at an elevation above the containment vessel, and both Rev. 5 and Rev. 6 of the SAR state that Microshield calculations were only run at the location of highest dose. The application also states that the Microshield evaluation used nominal thicknesses. However, it is not clear if the Microshield evaluation occurred in either the radial direction from the point source, the vertical direction from the point source, or if another path was used to determine the slab thickness in the Microshield evaluation. This information is required to determine compliance with 10 CFR 71.47.	The Microshield calculations were completed using the slab thicknesses through the bottom of the package in the vertical direction. During the NRC assessment it was clear this was not the location of the maximum dose rate. Therefore further Monte Carlo evaluations were carried out to determine the location of the highest dose rate, which was. As described in CTR 2013/09, “Uncertainties associated with the proposed shielding calculation method for the SAFKEG-HS 3977A Package”, a correction factor was then applied to the Microshield results to take into this into account when calculating dose rates for each nuclide. Therefore the Microshield evaluation will not correspond directly with the MCBEND calculations. Text has been added to section 5 to clearly demonstrate how the dose rates were calculated using the factors applied to the Microshield calculations.	Sections 5.3.1, 5.4.1 and 5.5.2
7.1	Identify how flammable and combustible gases will be purged from the containment vessel prior to content removal. The hydrogen gas generation analysis report submitted in support of the application postulates that hydrogen gas could escape from the product container into the containment vessel. Therefore, if a flammable and combustible atmosphere exists inside the containment vessel and does not ignite during transit, the unloading procedures need to address how the package recipient will safely remove the contents. This information is needed to ensure compliance with 10 CFR 71.87(f).	We have identified a minimum volume to be used for unloading. This will ensure the hydrogen remains below 5% concentration.	Section 7.2.2

Q#	Review Question	Croft Response	Changed Item
8.1	Clarify when damaged keg closure studs (Item 16 on the Bill of Materials) and hardware (nuts and washers) will be replaced. Section 8.2.3.2 indicates that damaged keg closure studs will be replaced according to drawing 0C-5942. However, it is unclear from this drawing and section 8.2.3.2 what procedure or criteria will be invoked for stud and/or hardware replacement. This information is needed to determine compliance with 10 CFR 71.87(b).	Section 8.2.3.2 has been reworded to clarify the criteria for stud replacement and correctly reference drawing 0C-5942.	Section 8.2.3.2

Table 3 – Second Question and Response Matrix

Q#	Review Question	Croft Response	Changed Item
3.1	Perform a gas generation calculation that demonstrates hydrogen and other flammable gases comprise less than 5% by volume of the total gas inventory within any confined volume. Alternatively, provide adequate justification that a higher value will not result in a hydrogen ignition event or that the consequences from such an event are negligible and do not pose any risk to public safety. Page 3-15a of the Safety Analysis Report predicts a hydrogen concentration is 45% which is much higher than the NUREG-1609 recommended limit. The applicant indicated during a June 81h conference call that this value was generated using very conservative parameters. The applicant should provide a detailed calculation using parameters which are more indicative of the actual parameters for transportation of 1-131; i.e., typical transportation times, actual content amounts presented for transport, etc. The applicant should provide adequate justification for any conservative assumption utilized. Details on how the hydrogen concentration is calculated need to be provided either in the application or in a separate calculation package. The staff needs this information to determine if this package and its contents can be transported safely without undue risk to public health and safety. This information is needed to determine compliance with 10 CFR 71.43(d)	MURR have reviewed their gas generation calculations and produced new calculations with actual parameters of transport	

Table 4 - Third Question and Response Matrix

Q#	Review Question	Croft Response	Changed Item
Telephone conversation 30 Nov 16	Provide information to demonstrate that radiation produced by I-131 will not adversely affect the PTFE insert and therefore cause corrosion of the stainless steel insert.	MURR have produced a report that calculates the dose to the PTFE insert during the shipment of I-131. Over the 10 day shipment period the insert is subjected to a maximum dose of 147 kGy and an averaged dose over the liner of 43 kGy. A search of the literature suggests that PTFE will become brittle if subjected to 50 kGy however some manufacturers indicate that it does not become brittle until 700 kGy. From this information it is clear the PTFE will be affected by the radiation. However the insert is visually checked prior to shipment for any damage. The insert is also maintained annually at which point the insert and liner is visually checked to ensure there is no damage. Therefore any detrimental effects caused by the radiation will be identified and the liner would be replaced.	
Telephone conversation 07 Feb 17	The supporting documentation referenced by the MURR report calculating dose absorbed by the PTFE liner indicates gas generation by the PTFE is possible. This document also mentions that the PTFE may disintegrate to a powder. Please provide information to demonstrate that the gas generation does not cause the contents to exceed the MNOP or design pressure under HAC conditions. Provide information to demonstrate the PTFE will remain effective during the shipment.	A new calculation sheet has been provided, CS 2017/02, which demonstrates the pressure of the CV remains within the allowable limits. Section 3 has been updated to incorporate this information. Regarding the powder issue section 7 has been updated to ensure the PTFE liner is checked prior to shipment. These checks include a visual inspection to ensure PTFE is present and a leak test to ensure the liner will not leak.	3.3.2, 3.4.3 and 7.1.2

Appendix A New or edited SAR pages provided in the SAR

Changes at Rev 6

Chapter	Pages
0	All (0-1 to 0-13)
1	12-14, 19, 30, 36-37
2	25
3	15, 15a, 19
5	3, 5-8, 10-14, 16-19
7	4, 4a
8	7, 7a

Changes at Rev 8

Chapter	Pages
0	All (0-2 to 0-15)
1	19
3	15, 15a, 19, 22
5	8,9, 17, 18, 20
7	7, 7a
8	7

Changes at Rev 10

Chapter	Pages
0	All (0-2 to 0-15)
3	3-15, 3-16, 3-23

Changes at Rev 12

Chapter	Pages
0	0-2, 0-3, 0-11, 0-12, 0-14, 0-15
3	3-15, 3-16, 3-17, 3-20, 3-23
7	7-4, 7-4a

Appendix B New or edited Supporting Documents provided in the SAR

Supporting Documents provided in the SAR at Rev 6

Related SAR Section or Doc	Document Reference		Title
Chapter 1 - General Information			
Documents in Section 1.3.2, Calculational Model Drawings			
Addition	3C-6852	B	HS-55x128-SS Insert Design No.3987 (Construction)
Documents in Section 1.3.3, Licensing Drawings[1]			
Update	1C-5940	G	Cover sheet for Safkeg-HS design No. 3977A (licensing drawing)
Update	0C-5941	E	Keg design no.3977A (licensing drawing)
Update	0C-5942	C	Keg Design No.3977 (licensing drawing)
Update	1C-5945	D	Containment vessel lid (licensing drawing)
Update	1C-5946	E	Containment vessel body (licensing drawing)
Update	2C-6176	D	HS-55x128-SS insert design no 3987 (licensing drawing)
Documents in Section 1.3.4 Supporting Documents			
Update	PCS 036	E	Package Contents Specification for Safkeg-HS - Package Design No 3977A
Chapter 3 – Containment			
Documents in Section 4.5.2			
Addition			Hydrogen Generation Analysis – MURR Technical Note
Chapter 5 – Shielding Evaluation			
Documents in Section 5.5.2			
Addition	AMEC/CRM3732 7/TN_001	1	HS Container Shielding Assessment with I-131

Supporting Documents provided in the SAR at Rev 8

Related SAR Section or Doc	Document Reference	Title
Chapter 1 - General Information		

[1] Information regarding the drawing changes can be found in M869 Issue A attached to this application

Related SAR Section or Doc	Document Reference		Title
Documents in Section 1.3.3, Licensing Drawings[2]			
Update	1C-5940	G	Cover sheet for Safkeg-HS design No. 3977A (licensing drawing)
Update	2C-6176	E	HS-55x128-SS insert design no 3987 (licensing drawing)
Chapter 3 – Thermal			
Documents in Section 3.5.2			
Addition		April 2, 2016	Analysis Of The Possibility Of, And Consequences From, Hydrogen Deflagration And Detonation Resulting From Radiolysis-Produced Hydrogen In An Iodine-131 Radiopharmaceutical Solution

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			
Addition	MURR	July 19, 2016	Additional Contents request for Croft Packaging

Supporting Documents provided in the SAR at Rev 12

Related SAR Section or Doc	Document Reference		Title
Chapter 3 – Thermal			
Documents in Section 3.5.2			
Addition	CS 2017/02	A	Maximum Pressure in Containment Vessel 3978 Under NCT and HAC with I-131 Contents

[2] Information regarding the drawing changes can be found in M896 Issue A attached to this application