Safety Analysis Report
Safkeg–HS Design No. 3977A
Package Docket 71-9338

Application for Approval by the NRC

Applicant: Croft Associates Limited

0.1 SAR REVISION STATUS

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0.2 SUPPORTING DOCUMENT REVISION STATUS

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1C-5999	Issue A	Containment Vessel HS Body Construction
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3C-6851	Issue A	HS-31x114-Tu Insert Design No. 3985 (construction)
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1C-5944	Issue C	Containment vessel design no. 3978 (licensing drawing)
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1C-5946	Issue E	Containment vessel body (licensing drawing)
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SERCO/TAS/002762/01	Issue 1	Compression Testing of Cork
Vectra, L20008/1/R1	Rev 0B	Stress Analysis of Safkeg HS 3977A Containment Vessel
CS 2012/02	Issue A	SAFKEG HS 3977A – Maximum Pressure in CV
CS 2012/03	Issue A	SAFKEG HS 3977A – Package Density
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CS 2012/01	Issue A	SAFKEG HS 3977A – Maximum Temperature of CV Inserts
MURR Report		Hydrogen Generation Analysis – MURR Technical Note
	V2.2	Radiolytic Gas Formation in Mallinckrodt Produced Mo99 Solutions
MURR Report	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**
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CTR2011/01	Issue D	SAFKEG HS 3977A: Package Activity Limits Based on Shielding
CTR2013	Issue C	Uncertainties Associated with the Proposed Shielding Calculation Method for the SAFKEG-HS 3977A Package
AMEC/SF6652/001	Issue 2	Monte Carlo Modelling of Safkeg HS Container
AMEC/CRM37327/TN_001	Issue 1	HS Container Shielding Assessment with I-131
AMEC/CRM37327/TN_001	Issue 1	HS Container Shielding Assessment with Mo-99

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None	-	

Table 1-3-5 CT-5 – Liquid in steel insert (HS-55x128-SS Design No 3987)	
Parameter	**Restrictions**
Contents Type name	CT-5 – Liquid in steel insert
Comments on contents	General use including bulk medical material.
Insert in CV cavity	HS-55x128-SS Design No 3987 (mass 1451g) fitted with a PTFE liner (per drawing 2C-6176)
Maximum quantity of radioactive material	See Table 1-4-5 for maximum quantities of each nuclide.
Maximum mass of radioactive material	905 g
Mixtures of radionuclides	Mixtures of the nuclides are allowed providing that the sum of the proportionate amounts of each nuclide with respect to the quantity allowed does not exceed unity.
Maximum decay heat of radioactive material	5W
Maximum quantity of fissile material	None
Physical form of radioactive material	Liquid, normal form
Chemical form of radioactive material	Salts in solution which may be alkaline or acidic. Acids restricted to HCL, H_2SO_4, HNO_3, of maximum concentration 0.1N.
Pyrophoric contents	Not applicable
Product containers	The radioactive material shall be carried in any convenient product container such as a quartz vial or aluminum capsule. Irradiated items may be carried in plastic or metal can or wrapping to minimize the contamination of the insert.
Location of radioactive material	Within the shielding insert
Maximum weight of contents of the CV	3.26 kg This includes the insert, radioactive material, product containers and any other packing.
Maximum weight of contents of the insert	1,810 g
Loading restrictions	The insert is to be leak tested by the bubble immersion method before shipment. See Section 7.

3.3.2 Maximum Normal Operating Pressure [71.33 (b)(5)]

The MNOP is 7 bar (700 kPa) gauge.

For solid contents emitting 30W, under NCT the maximum temperature of the CV is 163°C and the maximum temperature of the Shielding Insert and air within the CV is 173°C. Assuming the content were loaded at 20°C and a pressure of 1 bar abs, the pressure at the maximum temperature of the Shielding Insert, calculated according to Boyle's and Charles' Laws, would be 1.63 bar (163 kPa) gauge (see Calculation Sheet CS 2012/02),which is well within the design envelope.

With regards to the liquid content the maximum normal operating pressure is calculated using the maximum temperature during NCT, the free volume of the containment vessel cavity and vials and all possible sources of gas generation and gases that are present on loading the containment vessel. For I-131 this includes gases present in the CV on loading, Xe-131 generation and radiolytic decomposition over a 28 day period.

For the I-131, under NCT maximum temperature of the CV is 78°C and the maximum temperature of the Shielding Insert and air within the CV is 80°C. (Section 3.1.3, Table 3-1). There is no pressure increase due to the vapour pressure of the liquid contents (the liquid contents are aqueous with a boiling point of 100°C) as the temperature is < 100°C.

The maximum free volume of the containment vessel cavity is 216.4 cm^3. This corresponds to the free volume that surrounds the insert, the volume around the containment vessel lid up to the seals and the free volume inside the insert and product bottles.

MURR have calculated that each I-131 vial will generate 89 cm^3 of Hydrogen over 28 days as detailed in the technical note listed in section 3.5.2. If 2 vials are shipped this equates to 178 cm^3 of hydrogen. In a free volume of 216.4 cm^3 along with heating of the gases on loading this would lead to a MNOP of 1 barg, which is below the design pressure of 7 barg. The generation of Xe-131 only leads to an increase in pressure of $4x10^{-6}$ bar, therefore it can be neglected from the calculation of the MNOP.

For Mo-99, under NCT the maximum temperature of the CV is 78°C and the maximum temperature of the Shielding Insert and air within the CV is 80°C. (Section 3.1.3, Table 3-1). There is no pressure increase due to the vapour pressure of the liquid contents (the liquid contents are aqueous with a boiling point of 100°C) as the temperature is < 100°C.

The maximum free volume of the containment vessel is 233 cm^3. This corresponds to the free volume inside the insert, product bottle, the free volume that surrounds the insert and the volume around the containment vessel lid up to the seals.

The Mo-99 contents generate hydrogen due to radiolysis. The Mo-99 producer has carried out experiments, to determine the radiolytic gas generation of the Mo-99 solution described in section 1 of this SAR. The results of these experiments are attached in section 3.5.2. From

these experiments a linear fit of the gas formation verses the specific activity of the solution has been determined, which allows the gas formation to be calculated for a specific activity.

For a range of specific activities from 60 Ci/ml to 13.33 Ci/ml (which is the lowest activity the liquid could have with a volume of 75 ml) the gas formation was calculated using the linear fit equation. Using the free volume in the containment vessel and the volume of the solution the pressure was determined at 20°C. It was then assumed this gas would be heated to a peak temperature of 80.1°C. The highest pressure calculated was 4.19 barg for a solution with an activity of 60 Ci/ml and a dispensed product volume of 16.667 ml. This pressure is below the bounding maximum pressure for NCT operating conditions.

The bounding temperatures and pressures for the package are as follows.

NCT Operating Condition	CV
Assumed Max. Temperature	160°C
Max. Pressure	800kPa (8.0 bar) abs
Min. Temperature	-40°C
Min. Pressure	0 kPa (0 bar) abs

The producer of the Mo-99 performed mass spectrometer measurements of the gas samples obtained during the radiolytic gas generation calculations. Of the 2 samples tested the results were 1.8% and 0.8% hydrogen by volume of the pure evolved gas. This is an average of 1.3%, with a 2σ uncertainty of 1.4%. So the concentration of hydrogen in the pure evolved radiolysis product is conservatively estimated to be 2.7% by volume. This is well below 5% by volume and therefore does not constitute a risk of flammability or ignition.

The hydrogen generation calculations for the I-131 contents indicate the hydrogen concentration is 45%. Under normal conditions of transport (NCT) all hydrogen will be trapped in the product container within the insert, and no source for ignition exists. If somehow the product container fails, and the hydrogen escaped into the insert, and then the insert were to leak as well, into the containment vessel, and somehow ignition were to occur, the total energy release would be 966 Joules (231 calories).

The energy content of combustion of evolved hydrogen is negligible compared to the heating of the cask from the decay of I-131. For example, the decay heating rate of 200 Ci of I-131 was previously calculated to be 0.656 watts or 0.656 J/sec which would release 966 Joules of energy in less than one-half hour. Thus, 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. Additional perspective is gained by noting that the spontaneous combustion of all hydrogen produced over 28 days would heat a cup of water 4°C.

These calculations and experiments indicate that hydrogen ignition in the case of I-131 liquid contents is not a credible source of risk to the public, see section 3.5.2.

Figure 3-8 shows the predicted temperature of the inner containment vessel seal during and after the thermal test. The lid seal reaches a maximum temperature of 192°C after 3 ½ hours. A similar maximum temperature is experienced by the depleted uranium shielding this temperature is well below its melting point of 1130°C.

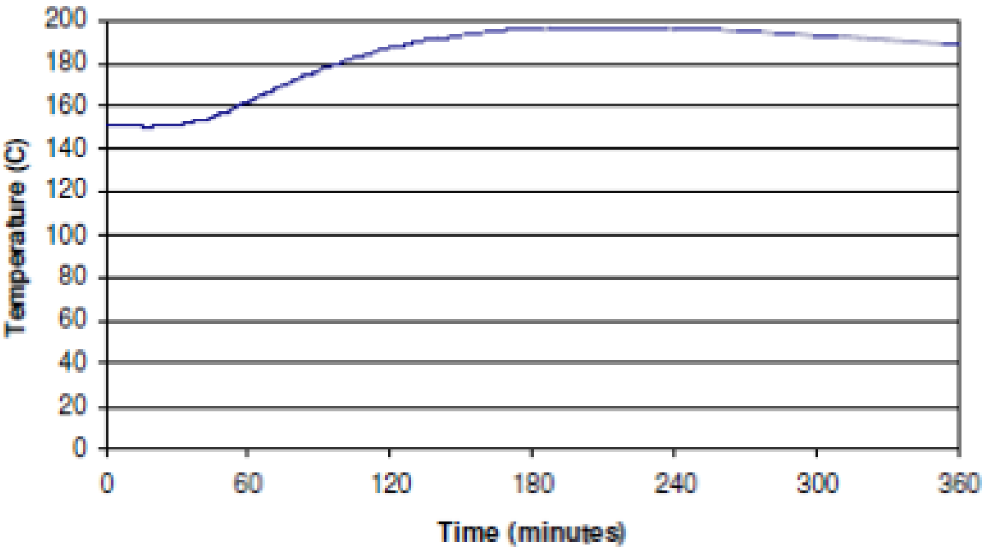

Figure 21 – Predicted Temperature of the Containment Vessel Lid Seal during the Fire Accident – Internal Heat Load of 30W

Figure 3-8 Predicted Temperature of the Containment Vessel Lid Seal during the Fire Test with a 30 W source

The Design Pressure of the CV is 10 bar (1,000 kPa) gauge.

For solid contents emitting 30W, under HAC the maximum temperature of the CV is 208°C and the maximum temperature of the Shielding Insert and air within the CV is 218°C. Assuming the content were loaded at 20°C and a pressure of 1 bar abs, the pressure at the maximum temperature of the Shielding Insert, calculated according to Boyle's and Charles' Laws, would be 1.8 bar (180 kPa) gauge (see Calculation Sheet CS 2012/02 in section 2.12.2), which is well within the design envelope.

For liquid contents emitting 5W, under HAC the maximum temperature of the CV is 132°C and the maximum temperature of the insert is 134 °C (Section 3.1.3, Table 3-1). Assuming the pressure at NCT is calculated as the maximum of 4.19 barg, the pressure at the maximum temperature of the CV, calculated according to Boyle's and Charles' Laws, would be 4.8 bar (138 kPa) gauge. However, the vapour pressure of the liquid contents (the liquid contents are aqueous) would be 2 bar gauge (from steam tables). Therefore the maximum pressure within the CV would be 6.83 bar gauge which is well within the design envelope.

3.5.2 Supporting Documents

Document Reference	Title
AMEC/6335/001	Thermal Analysis of the SAFKEG HS Design
CS 2012/01	SAFKEG-HS 3977A – Maximum temperature of CV inserts
	Hydrogen Generation Analysis – MURR Technical Note
V2.2	Radiolytic Gas Formation in Mallinckrodt Produced Mo99 Solutions
	Analysis Of The Possibility Of, And Consequences From, Hydrogen Deflagration And Detonation Resulting From Radiolysis-Produced Hydrogen In An Iodine-131 Radiopharmaceutical Solution

5.3 Source Specification [71.33 (b)(1)]

5.3.1 Gamma Source

The shielding calculations were carried out using two different shielding models, MCBEND discussed in the attached reports AMEC/SF6652/001, AMEC/CRM37327/TN_001, AMEC/CRM42622/TN_001 and Microshield discussed in the attached reports CTR2011/01 and CTR 2013/09. A MCBEND model was used to determine the location of the point source which caused the highest surface dose rate for the tungsten inserts, and to allow the Microshield model to be validated against the MCBEND reference case (AMEC/SF6652/001). The MCBEND model was also used to determine the maximum surface dose rate for 7.4 TBq of I-131 (AMEC/CRM37327/TN_001) and 1000 Ci of Mo-99 (AMEC/CRM42622/TN_001) in the required stainless steel insert.

The MCBEND tungsten insert calculations were carried out using a 3kCi Cs-137 source in equilibrium with the daughter nuclide Ba-137m, with a gamma energy of 0.662 MeV and line intensity of 0.852.

The Microshield calculations were carried out with a point source using a section through the base of the package for 1 Ci of each nuclide listed in the contents. The gamma decay source data within Microshield version 8.03 is the Grove Library or ICRP 38. The source library chosen for each nuclide was the one that led to the highest surface dose rate. The MCBEND tungsten inserts calculations, demonstrated that the point to use for the highest dose was the side of the package, therefore an adjustment factor was applied to the Microshield results as discussed in Croft Report CTR 2013/09 (section 5.5.6)

For all nuclides the time at which the highest surface dose rate occurred was determined. For the majority of the contents this was at time = 0 however due to daughter products some nuclides had a peak surface dose rate hours, days or years into their life due to the formation of daughter products. Once the point of the decay process which provided the highest dose rate was identified, the nuclide was decayed to this point and the dose rate on the surface of the package determined. Table 5-3 shows all the daughter products that were included in the shielding calculation for applicable nuclides.

The betas and alphas were neglected as shielding source terms as it was assumed they were 100% absorbed into the packaging shielding material and did not contribute to the dose rate on the surface of the package. However, Bremsstrahlung radiation was calculated for all the beta emitters.

Table 5-3 - Daughter Nuclides Included in Shielding Model

Parent Nuclide	Daughter Nuclides
Ac-225	At-217, Bi-213, Fr-221, Pb-209, Po-213, Tl-209
Ac-227	Bi-211, Fr-223, Pb-211, Po-211, Po-215, Ra-223, Rn-219, Th-227, Tl-207
Am-241	Ac-225, At-217, Bi-213, Fr221, Np-237, Pa-233, Pb-209, Po-213, Ra-225, Th-229, Tl-209, U-233
As-77	Se-77m

Cs-137	Ba-137m
Mo-99	Tc-99m, Tc-99
Np-237	Ac-225, At-217, Bi-213, Fr-221, Pa-233, Pb-209, Po-213, Ra-225, Th-229, Tl-209, U-233
Pb-210	Bi-210, Po-210
Pu-238	Bi-210, Bi-214, Pb-210, Pb-214, Po-210, Po-214, Po-218, Pu-238, Ra-226, Rn-222, Th-230, U-234
Pu-239	Ac-227, Bi-211, Fr-223, Pa-231, Pb-211, Po-211, Po-215, Ra-223, Rn-219, Th-227, Th-231, Tl-207, U-235
Pu-240	Ac-228, Bi-212, Pb-212, Po-212, Po-216, Ra-224, Ra-228, Rn-220, Th-228, Th-232, Tl-208, U-236
Pu-241	Ac-225, Am-241, At-217, Bi-213, Fr-221, Np-237, Pa-233, Pb-209, Po-213, Pu-241, Ra-225, Th-229, Tl-209, U-233, U-237
Ra-223	Bi-211, Pb-211, Po-211, Po-215, Rn-219, Tl-207
Ra-224	Rn-220, Po-216, Pb-212, Bi-212, Po-212, Tl-208
Ra-226	Bi-210, Bi-214, Pb-210, Pb-214, Po-210, Po-214, Po-218, Rn-222, At-218
Th-227	Bi-211, Pb-211, Po-211, Po-215, Ra-223, Rn-219, Tl-207
Th-228	Bi-212, Pb212, Po-212, Po-216, Ra-224, Rn-220, Tl-208
U-235	Ac-227, Bi-211, Fr-223, Pa-231, Pb-211, Po-211, Po-215, Ra-223, Rn-219, Th-227, Th-231, Tl-207
W-188	Re-188

5.3.2 Neutron Source

The only contents that emit neutrons are the plutonium Pu-238 and Pu-240 nuclides (limited to solid form). The source strength for each nuclide was taken from ICRP 38 and given in Table 5-4.

Table 5-4 - Neutron Flux

Nuclide	Energy	neutrons/sec
Pu-238	1.927	4.20×10^{-9}
Pu-240	1.915	1.09×10^{-7}

5.4 Shielding Model

5.4.1 Configuration of Source and Shielding

The MCBEND model detailed in the attached report AMEC/SF6652/001 was used to determine the location of a point source which provided the highest surface dose rate for the tungsten inserts. The model was also used to determine the maximum package surface dose rates for I-131 and Mo-99, as discussed in reports AMEC/CRM37327/TN_001 and AMEC/CRM42622/TN_001 respectively.

The 3D model was generated using the calculation drawings in section 1.3.2. The small chamfers and rounding at corners were ignored, except in the vicinity of the containment vessel O-rings. Nuts and bolts were omitted, but the central hole at the top of the containment vessel was included. Very small (< 0.1 mm) air-gaps and voids were ignored, except for the

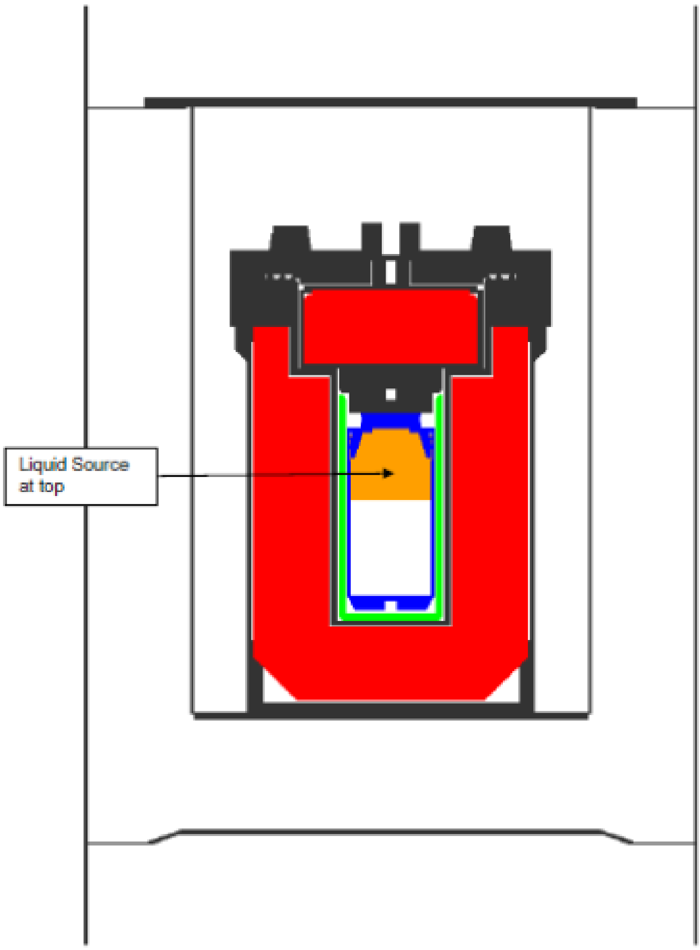

Figure 5-12 - Mo-99 Top Source Location for MCBEND Model for HS Package with stainless Steel Insert, Tungsten Liner and Split Containment Vessel Lid

For the tungsten inserts a Microshield model was built in order to determine the surface dose rate for all the nuclides to be carried. The Microshield calculations were carried out through the base of the package. In this model a point source was used with the shield dimensions taken from the nominal thicknesses, an illustration of the model is provided in Figure 5-8. The cork was modelled as an air gap whereas in reality the density of the cork is 250 kg/m^3. A different model was produced for each tungsten insert to determine the surface dose rates. The thicknesses used for each shield in the different insert models are provided in Table 5-6. The results from the MCBEND calculations showed that a point source located at the top corner of the insert provided the highest dose rate with the dose point taken at the side of the package, to account for this an adjustment factor was applied to the Microshield dose rates, as discussed in Croft report CTR 2013/09.

~~The Microshield model does contain several uncertainties which involved the application of several adjustment factors to the results. These uncertainties and the adjustment factors are discussed in CTR 2013/03 section 5.5.6.~~

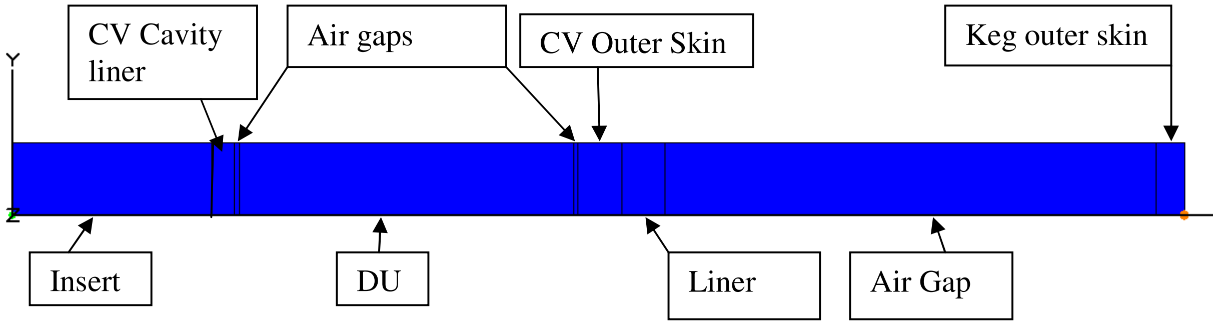

Figure 5-13 - Microshield model (3982 Insert)

Table 5-6 - Summary of Dimensions Used in Microshield Model

Feature	Thickness (cm)			Notes
	3982	3985	3987	
Insert	2.73	1.78	0.18	Tungsten was used for the insert material for 3982 and 3985. Iron was used as the insert material for 3987
CV cavity liner	0.31	0.31	0.31	Iron was used for this material in Microshield
air gap	0.07	0.07	0.07	
CV shield	4.6	4.6	4.6	Depleted uranium
Air gap	0.06	0.06	0.06	
CV outer skin	0.6	0.6	0.6	Iron was used for this material in Microshield
3977 Cavity liner	0.6	0.6	0.6	Iron was used for this material in Microshield
Outer Cork liner	6.75	6.75	6.75	Cork was assumed to be

Table 5-8 - Shielding Material Properties in Microshield

Material	Density (g/m^3)	Elemental Compostion	Mass Fraction
Iron	7.86	Fe	1
Depleted Uranium	17.93	U	1
Tungsten	17.23	W	1
Air	0.0012	N O	0.77 0.23

5.5 Shielding Evaluation

5.5.1 Methods

The MCBEND model was used to determine the location of a point source that causes the highest dose rate on the surface of the package for the tungsten inserts. It was also used to calculate the maximum package surface dose for 1-131 and Mo-99 in the stainless steel inserts. The model also provided a reference case with which to validate the Microshield model. The Microshield model was then used to determine all the surface dose rates for the contents in the tungsten inserts.

MCBEND is a Monte Carlo radiation transport code. The calculations have been carried out using the latest version of MCBEND, version 10A_RU1. The code and data are maintained to a level of quality assurance consistent with the standards of the ANSWERS Software Service. This ensures that reference versions of the code, data libraries and test data are held, and that updating and archiving of the code and data are strictly controlled.

Microshield is a photon/gamma shielding and dose assessment program. It was validated using the output from the MCBEND code for the 3000 Ci Cs-137 contents.

5.5.2 Input and Output Data

The input and output data for the MCBEND shielding calculations are reported in AMEC/SF6652/001, AMEC/CRM37327/TN_001 and AMEC/CRM42622/TN_001 (Section 5.5.2).

The input and output data for the MicroShield shielding calculations is reported are CTR 2011/01 (Section 5.5.2). The Microshield model does contain several uncertainties which involved the application of several adjustment factors to the results. These uncertainties and the adjustment factors are discussed in CTR 2013/03 section 5.5.6.

7.2.1 Receipt of Package from Carrier

1) Confirm that the package is the one identified on the accompanying documentation. Any special requirements of the receiving organization shall be fulfilled.

2) The exterior of the package shall be checked for damage that may have occurred during shipment. Damaged packages shall be handled in accordance with the user's facility procedures for handling packages that may not be in a safe condition.

3) The radiation and contamination levels on the outer surface of the keg shall be monitored. If, at any stage of unloading, levels of radiation or contamination are detected above those permitted, then the appropriate action shall be taken to safeguard personnel, and to rectify the situation. Radiation level limits are specified in 10 CFR 71.47 and 49 CFR 173.441. The maximum level of removable radioactive contamination on the package surface is specified in 10 CFR 71.87(i) and 49 CFR 173.443.

4) The security seals shall be checked to ensure they are intact. If NOT intact investigate the cause and follow internal procedures. No further disassembly of the package shall be attempted until the situation has been resolved.

7.2.2 Removal of Contents for a Standard CV Lid

1) The security seals, keg closure nuts, washers, and keg lid shall be removed. The opened top of the keg shall be monitored

2) The top cork shall be removed.

3) Remove the shielding screw from the top of the containment vessel and fit a 12 mm diameter eyebolt. Using this eyebolt lift the containment vessel from the keg. The containment vessel shall be monitored for contamination as it is removed from the cork body.

4) The containment vessel closure screws and the lid shall be removed.

5) If the containment vessel lid is not readily released, as may occur if the containment vessel was loaded at a lower atmospheric pressure, gently jack the lid from the containment vessel body using 2 jacking screws fitted in the jacking holes on the containment vessel lid. The jacking screws should be left in the containment vessel lid withdrawn to be flush with the lid top surface.

6) The containment vessel shall be monitored while the lid is removed. If the containment vessel is carrying liquid I-131 it shall be opened in a glove box or hot cell, or be mated up with a glove box or hot cell with a volume of at least 3400 cm^3. This ensures that the hydrogen generated during shipment will remain below a concentration of 5% during unloading of the package.

7) A silicone sponge rubber disc and the insert shall be removed from the containment vessel.

8.2.3.2 Keg

1) The model/serial numbers of the keg assembly (keg body and keg lid) shall be checked to be ensure that the number marked on the body matches that on the lid: where the model/serial numbers of the keg assembly (body and lid) do not match, these assemblies shall be removed from service.

2) The keg name plate shall be checked for legibility of the nameplate information.

3) The keg outer shell shall be visually checked for unacceptable defects. Unacceptable defects are dents; cracking of welded joints; penetration of the keg skin; or abrasion or scratches that reduces the thickness of the keg below its licensed dimensions, including tolerances, as shown in the general arrangement drawings in the Certificate of Compliance.

4) The keg closure studs shall be checked for tightness of fit in the keg top flange and damage (i.e. stripped or distorted). A die nut (thread class 6g) shall be used to clear any tight threads. The closure studs shall be checked that they are positioned in accordance with drawing 0C-5942. If the stud is loose or the height is incorrect, the stud shall be removed, cleaned, and repositioned using Loctite 270 or Loctite 263. If any keg closure studs are damaged they shall be removed and replaced with studs that meet the requirements of drawing 0C-5942, and positioned using Loctite 270 or Loctite 263 in accordance with drawing 0C-5942.

5) The keg lid seal and respective groove shall be checked for visible damage such as splits or cuts in the lid seal and scratches in the lid seal groove. The lid seal shall fit correctly into the seal groove. The lid seal shall be replaced as necessary; there is no requirement for periodic replacement.

6) The keg, keg lid, and keg closure nuts shall fit up freely. Any damaged nuts or washers shall be replaced according to drawing 0C-5942.

7) The fuse plug and spring washer shall be visually inspected for presence in the keg and damage and wear. A damaged or missing fuse plug or washer shall be replaced according to the specifications in drawing 0C-5942.

8) Non-conforming components shall be rejected and controlled for rework, or scrapped and replaced. Components that are reworked or replaced shall meet the specifications given in the general arrangement drawings in the Certificate of Compliance.

9) The inspection results and any necessary replacement or repairs, shall be recorded in the package maintenance records.