

**CERTIFICATE OF COMPLIANCE
FOR RADIOACTIVE MATERIAL PACKAGES**

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2. PREAMBLE

- a. This certificate is issued to certify that the package (packaging and contents) described in Item 5 below meets the applicable safety standards set forth in Title 10, *Code of Federal Regulations*, Part 71, "Packaging and Transportation of Radioactive Material."
- b. This certificate does not relieve the consignor from compliance with any requirement of the regulations of the U.S. Department of Transportation or other applicable regulatory agencies, including the government of any country through or into which the package will be transported.

3. THIS CERTIFICATE IS ISSUED ON THE BASIS OF A SAFETY ANALYSIS REPORT OF THE PACKAGE DESIGN OR APPLICATION

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| a. ISSUED TO (<i>Name and Address</i>)
Croft Associates Limited
Building F4, Culham Science Centre
Culham, Abingdon
Oxfordshire, OX14 3BD, United Kingdom | b. TITLE AND IDENTIFICATION OF REPORT OR APPLICATION
Croft Associates Limited application dated
September 29, 2012, as supplemented. |
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4. CONDITIONS

This certificate is conditional upon fulfilling the requirements of 10 CFR Part 71, as applicable, and the conditions specified below.

5.

(a) Packaging

- (1) Model No.: 3977A
- (2) Description

The Model No. 3977A is a package for the transport of radioisotopes used in a wide range of therapeutic and diagnostic applications and research. The packaging consists of an outer stainless steel keg and an inner containment vessel surrounded by insulating cork packing. There are four specific inserts, designated as Shielding Insert Design Nos. 3982, 3985, 3987 and 4081, authorized for use in the Model No. 3977A. The outer keg provides impact and thermal protection. Containment is provided by the containment vessel. Shielding is provided by the containment vessel and shielding inserts.

The keg has a stainless steel outer shell and a stainless steel liner, between which insulating cork is fitted. The keg lid is attached to the body by eight stainless steel studs and nuts, with a single O-ring weather seal. An inner cork liner is fitted between the keg liner and the top and sides of the containment vessel, consisting of a cork body and cork top, with no cork between the bottom of the containment vessel and the keg liner.

The containment vessel consists of a body and lid. The body has a stainless steel outer wall, base, and flange/cavity wall. The flange/cavity wall is welded to the outer wall to form a cavity into which DU shielding is placed. The DU shielding thickness is approximately 46 mm at the base of the CV and 47.6 mm along the side of the CV except at the top where the lid seats. The DU shielding thickness at the top is 22.5 mm thick. After the DU shielding is installed, the base is then welded to the outer wall. There are two CV lid configurations: a standard configuration and a split lid configuration. For the standard CV lid, the stainless steel lid shielding casing, with 45.9 mm of DU inside, is welded to the

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5.(a) (2) Description (Continued)

stainless steel CV lid top. For the split CV lid, a shielding plug, composed of 49.8 mm of DU enclosed within a stainless steel body and a stainless steel top, sits within the CV and a stainless steel CV lid is installed. Both the standard and the split lid are secured by eight, M-10x1.5x20, alloy steel recessed hexagon socket head cap screws. The containment vessel is sealed by two concentric fluoroelastomer O-rings, and the lid is equipped with a leak test port.

There are four shielding inserts designed for use in the Model No. 3977A packaging. Design No. 3982, HS-12x95-Tu, is a tungsten insert with inner cavity size of 12 mm diameter by 95 mm height. The approximate mass of the insert is 9.2 kg. Design No. 3985, HS-31x114-Tu, is a tungsten insert with inner cavity size of 31 mm diameter by 114 mm in height. The approximate mass of the insert is 7.9 kg. Shielding insert Design Nos. 3982 and 3985 are only used with the standard CV lid arrangement. The third shielding insert, Design No. 3987, HS-55x128-SS, is a stainless steel insert with inner cavity size of 55 mm diameter by 128 mm height. A titanium liner shall be employed with the HS-55x128-SS insert. The approximate mass of the insert is 1.8 kg with a liner installed. The fourth shielding insert, Design No. 4081, is only used with the split CV lid arrangement. Design No. 4081, HS-50x85-SS, is a stainless steel insert with inner cavity size of 50 mm diameter by 85 mm height. Design No. 4081 is used in conjunction with a snap ring, which attaches the shielding insert to the shielding plug associated with the split CV lid design, and a tungsten liner which provides additional shielding from the radioactive material transported.

The radioactive material shall be enclosed in a convenient product container such as a quartz vial, aluminum capsule or stainless steel bottle. Irradiated items may be carried in a plastic can, a metal can or wrapping to minimize the contamination of the insert.

The approximate dimensions and mass of the package are:

Overall package outer diameter	424 mm
Overall package height	585 mm
Containment vessel outer diameter	200 mm
Containment vessel height	302.5 mm
Containment vessel cavity inner diameter	65.8 mm
Containment vessel cavity inner height	157.1 mm
Maximum package mass	163 kg

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(3) Drawings

Packaging which employs a standard lid is constructed and assembled in accordance with Croft Associates Limited Drawing Nos:

1C-5940, Rev. H	Cover Sheet for Safkeg HS Design No. 3977A (Licensing Drawing)
0C-5941, Rev. E	SAFKEG HS Design No. 3977A (Licensing Drawing)
0C-5942, Rev. C	Keg Design No. 3977 (Licensing Drawing)
0C-5943, Rev. B	Cork Set for Safkeg HS (Licensing Drawing)
1C-5944, Rev. C	Containment Vessel Design No. 3978 (Licensing Drawing)
1C-5945, Rev. D	Containment Vessel Lid (Licensing Drawing)
1C-5946, Rev. E	Containment Vessel Body (Licensing Drawing)
2C-6920, Rev. A	Silicone Sponge Rubber Disc (Licensing Drawing)

Packaging which employs a split lid is constructed and assembled in accordance with Croft Associates Limited Drawing Nos:

1C-7500, Rev. C	Cover Sheet for Safkeg HS Design No. 3977A – Mallinckrodt Version (Licensing Drawing)
0C-7501, Rev. C	SAFKEG HS Design No. 3977A – Mallinckrodt Version (Licensing Drawing)
0C-7502, Rev. A	Keg Design No. 3977 – Mallinckrodt Version (Licensing Drawing)
0C-7503, Rev. A	Cork Set for Safkeg HS – Mallinckrodt Version (Licensing Drawing)
1C-7504, Rev. A	Containment Vessel Design No. 3978 – Mallinckrodt Version (Licensing Drawing)
1C-7505, Rev. A	Containment Vessel Lid – Mallinckrodt Version (Licensing Drawing)
1C-7506, Rev. A	Containment Vessel Body – Mallinckrodt Version (Licensing Drawing)
1C-7507, Rev. A	Containment Vessel Plug – Mallinckrodt Version (Licensing Drawing)

The shielding inserts are constructed and assembled in accordance with Croft Associates Limited Drawing Nos:

2C-6173, Rev. D	HS-12 x 95-Tu Insert Design No. 3982 (Licensing Drawing)
2C-6174, Rev. D	HS-31 x 114-Tu Insert Design No. 3985 (Licensing Drawing)
2C-6176, Rev. F	HS-55X128-SS Insert Design No. 3987 (Licensing Drawing)
2C-7508, Rev. C	HS-50 x 85-SS Insert Design No. 4081 (Licensing Drawing)
2C-7509, Rev. B	Snap Ring
2C-7510, Rev. A	Tungsten Liner

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5.(b) Contents

(1) Type and form of material

Solid material must have a melting point greater than 250 °C and must not be volatile below 250 °C.

- (i). Solids, normal or special form material, as limited in Table 1, within insert Design No. 3982. All contents may be shipped as individual elements or compounds except for Cs, Hg, I, Na, and P. Cs, Hg, I, Na, and P contents must be shipped as compounds.
- (ii). Solids, normal or special form material, as limited in Table 2, within insert Design No. 3985. All contents may be shipped as individual elements or compounds except for Cs, Hg, I, Na, and P. Cs, Hg, I, Na, and P contents must be shipped as compounds.
- (iii). Gases, normal form material, as limited in Table 3, within insert Design No. 3985 as individual elements. The product container shall be a quartz vial sealed by fusing or aluminum capsules.
- (iv). Liquids, normal form, as limited in Table 4, within insert Design No. 4081 as sodium molybdenate in a matrix solution of NaNO₃ 1M and NaOH 0.2M (Na₂MoO₄ [NaNO₃ 1M/NaOH 0.2M]). The product container shall be stainless steel.
- (v). Liquids, normal form, as limited in Table 5, within insert Design No. 3987 as either alkali or acidic salt solutions. For acidic salt solutions, only HCl, H₂SO₄ and HNO₃ solutions of 0.1 N are allowed. The product container shall be a quartz vial or aluminum capsule wrapped in LDPE or similar material with equivalent radiation resistance.

(2) Maximum quantity of material per package

Decay heat not to exceed 30 watts per package for both solid and gaseous contents. Decay heat not to exceed 5 watts per package for liquid contents. Mixtures of nuclides are allowed providing the sum of the proportionate amounts of each nuclide with respect to the quantities shown in the respective table does not exceed unity. The contents include the progeny of the radionuclides listed in Tables 1 through 4; however, the quantities in the tables are for the listed radionuclides without progeny present (i.e., at the time of loading, only the radionuclides explicitly listed in the table may be present up to the quantities shown in the tables).

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5.(b) (2) (continued)

(i) For the contents described in 5(b)(1)(i):

Total mass of contents and insert not to exceed 9.3 kg. Maximum mass of radioactive material is 45 g.

TABLE 1

Radionuclide	Maximum TBq	Radionuclide	Maximum TBq	Radionuclide	Maximum TBq
Ac-225	2.51E+00	I-131	3.26E+02	Re-186	1.56E+02
Ac-227	7.24E-01	In-111	4.25E+02	Re-188	7.25E-01
Ac-228	4.28E-01	Ir-192	1.81E+02	Rh-105	8.12E+02
Am-241	3.51E-01	Ir-194	2.05E+00	Se-75	4.61E+02
As-77	7.90E+02	Lu-177	1.03E+03	Sm-153	6.12E-01
Au-198	2.56E+02	Mo-99	5.27E+01	Sr-89	1.22E+01
Ba-131	1.88E+02	Na-24	2.63E-02	Sr-90	1.73E+00
C-14	7.20E+00	Np-237	1.17E-03	Tb-161	1.61E+01
Co-60	2.38E-01	P-32	5.58E+00	Th-227	1.01E+01
Cs-131	6.71E+03	P-33	2.44E+03	Th-228	6.79E-02
Cs-134	7.05E+00	Pb-203	5.20E+02	Tl-201	1.45E+03
Cs-137	1.44E+02	Pb-210	8.04E+00	W-187	2.24E+01
Cu-67	6.91E+02	Pd-109	2.96E+02	W-188	6.43E-01
Hg-203	3.57E+01	Ra-223	6.83E+00	Y-90	1.73E+00
Ho-166	2.04E+00	Ra-224	8.86E-02	Yb-169	4.42E+02
I-125	3.19E+03	Ra-226	9.91E-02	Yb-175	1.11E+03
I-129	2.93E-04				

Note: Boron and beryllium shall not be loaded with the contents in Table 1.

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5.(b) (2) (continued)

(ii) For the contents described in 5(b)(1)(ii):

Total mass of contents and insert not to exceed 8.6 kg. Maximum mass of radioactive material is 345 g.

TABLE 2

Radionuclide	Maximum TBq	Radionuclide	Maximum TBq	Radionuclide	Maximum TBq
Ac-225	5.47E-01	I-131	3.26E+02	Re-186	2.66E+01
Ac-227	1.63E-01	In-111	4.25E+02	Re-188	2.61E-01
Ac-228	9.30E-02	Ir-192	1.81E+02	Rh-105	8.12E+02
Am-241	7.92E-01	Ir-194	4.83E-01	Se-75	4.61E+02
As-77	7.90E+02	Lu-177	1.03E+03	Sm-153	5.71E+02
Au-198	5.69E+01	Mo-99	9.56E+00	Sr-89	2.59E+00
Ba-131	3.06E+01	Na-24	6.38E-03	Sr-90	4.15E-01
C-14	5.52E+01	Np-237	8.97E-03	Tb-161	3.70E+00
Co-60	4.68E-02	P-32	1.25E+00	Th-227	2.09E+00
Cs-131	6.71E+03	P-33	2.44E+03	Th-228	1.67E-02
Cs-134	1.32E+00	Pb-203	5.20E+02	Tl-201	1.45E+03
Cs-137	1.58E+02	Pb-210	1.66E+00	W-187	4.28E+00
Cu-67	6.91E+02	Pd-109	4.81E+01	W-188	2.19E-01
Hg-203	5.58E+02	Ra-223	2.07E+00	Y-90	4.15E-01
Ho-166	4.60E-01	Ra-224	2.19E-02	Yb-169	4.42E+02
I-125	3.19E+03	Ra-226	2.34E-02	Yb-175	1.11E+03
I-129	2.24E-03				

Note: Boron and beryllium shall not be loaded with the contents in Table 2.

(iii) For the contents described in 5(b)(1)(iii):

Total mass of contents and insert not to exceed 8.6 kg. Maximum mass of radioactive material is less than one gram. Maximum volume of contents, including the product container material and packing, is less than 10 cc.

TABLE 3

Radionuclide	Maximum TBq	Radionuclide	Maximum TBq
Kr-79	1.15E+01	Xe-133	1.04E+03

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5.(b) (2) (continued)

(iv) For the contents described in 5(b)(1)(iv):

Total mass of contents and insert not to exceed 4.9 kg. Maximum mass of radioactive material is 0.8 kg. Maximum specific activity shall be less than 60 Ci/ml and the maximum volume shall be 75 ml.

TABLE 4

Radionuclide	Maximum TBq
Mo-99	3.7E+01

(v) For the contents described in 5(b)(1)(v):

Total mass of contents and insert not to exceed 3.6 kg. Maximum mass of radioactive material is 0.9 kg.

TABLE 5

Radionuclide	Maximum TBq
I-131	7.4E+00

6. For the contents described in 5(b)(1)(v), the shipment period begins when the containment vessel is closed and must be completed within 10 days.

7. In addition to the requirements of Subpart G of 10 CFR Part 71:

- (a) New O-ring seals must be installed in insert Design No. 4081 and insert Design No. 3987 prior to each shipment of the contents described in 5(b)(1)(iv) and 5(b)(1)(v).
- (b) The package shall be prepared for shipment and operated in accordance with the Package Operations in Section 7.0 of the application, as supplemented.
- (c) The package must meet the Acceptance Tests and Maintenance Program in Section 8.0 of the application, as supplemented.

8. The package authorized by this certificate is hereby approved for use under the general license provisions of 10 CFR 71.17.

9. Revision No. 2 of this certificate may be used until March 31, 2019.

10. Expiration date: March 31, 2024.

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REFERENCES

Croft Associates Limited application dated September 29, 2012.

Supplements dated: December 20, 2012; April 23, September 20, November 21, and 28, December 13, 16, and 17, 2013; January 6, 10, 27, and 31, and February 11, 2014; December 14, 2015; and March 21, May 23, July, 6, September 9, and October 27, 2016; January 26, March 22, and May 12, 2017.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION



Ilka T. Berrios, Acting Chief
Spent Fuel Licensing Branch
Division of Spent Fuel Management
Office of Nuclear Material Safety
and Safeguards

Date: March 28, 2019

SAFETY EVALUATION REPORT

Docket No. 71-9338
Model No. 3977A
Certificate of Compliance No. 9338
Revision No. 3

SUMMARY

By letter dated February 11, 2019, as supplemented March 27, 2019 (Agency Documents Access and Management System (ADAMS) Accession Nos. ML19042A202 and ML19087A044 respectively), Croft Associates Ltd. requested renewal of Certificate of Compliance No. 9338 for the Model No. 3977A package. The certificate has been renewed for a five year term.

CONCLUSION

By application dated February 11, 2019, Croft Associates Ltd., requested renewal of Certificate of Compliance No. 9338 for the Model No. 3977A package. Croft Associates Ltd. did not request any changes to the package design or authorized contents. The staff reviewed the documents referenced in the certificate and determined that the documentation was available and complete. The staff also reviewed the operating and maintenance procedures for the package and found them to be adequate. The certificate of compliance is revised to update the revision number, remove unnecessary change bars, and make editorial changes.

The certificate has been renewed for a five year term that expires on March 31, 2024. This change does not affect the ability of the package to meet the requirements of Title 10 of the *Code of Federal Regulations* Part 71, "Packaging and Transportation of Radioactive Material."

Issued with Certificate of Compliance No. 9338, Revision No. 3, on March 28, 2019.