

**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

- a. ISSUED TO (*Name and Address*)
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
July 30, 2009, as supplemented.

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.: 3979A
- (2) Description

The Model No. 3979A 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 three specific inserts authorized for use in the Model No. 3979A, designated as Shielding Insert Design Nos. 3983, 3984, and 3986. The outer keg provides impact and thermal protection. Containment is provided by the containment vessel. Shielding is provided by the containment vessel and shielding insert.

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 8 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

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

the lead shielding is cast. The base is then welded to the outer wall. The containment vessel lid top and lid shielding casing are stainless steel, with 22 mm of lead cast inside. The containment vessel lid is secured by eight, M-10x1.5x20, alloy steel recessed hexagon socket head cap screws. The containment system is sealed by two concentric ethylene propylene rubber O-rings, and the lid is equipped with a leak test port.

There are three Shielding Inserts designed for use in the Model No. 3979A packaging. Design No. 3983, LS-31x73-Tu, is a tungsten insert with inner cavity size of 31 mm diameter by 73 mm height. The approximate mass of the insert is 4.9 kg. Design No. 3984, LS-12x65-Tu, is a tungsten insert with inner cavity size of 12 mm diameter by 65 mm in height. The approximate mass of the insert is 5.8 kg. The third design, Design No. 3986, LS-50x103-SS, is a stainless steel insert with inner cavity size of 50 mm diameter by 103 mm height. The approximate mass of the insert is 1.0 kg.

The radioactive material may be enclosed 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.

The approximate dimensions and mass of the package are:

Overall package outer diameter	424 mm
Overall package height	483 mm
Containment vessel outer diameter	175 mm
Containment vessel height	204 mm
Containment vessel cavity inner diameter	65 mm
Containment vessel cavity inner height	109 mm
Maximum package mass	65 kg

(3) Drawings

The packaging is constructed and assembled in accordance with Croft Associates Limited Drawing Nos:

1C-6040, Rev. H	Cover Sheet for Safkeg LS Design No. 3979A (Licensing Drawing)
0C-6041, Rev. C	SAFKEG LS Design No 3979A (Licensing Drawing)
0C-6042, Rev. F	Keg Design No. 3979 (licensing Drawing)
0C-6043, Rev. C	Cork Set for Safkeg LS (Licensing Drawing)
1C-6044, Rev. F	Containment Vessel Design No. 3980 (Licensing Drawing)
1C-6045, Rev. E	Containment Vessel Lid (Licensing Drawing)
1C-6046, Rev. E	Containment Vessel Body (Licensing Drawing)

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5.(a) (3) Drawings (Continued)

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

2C-6171, Rev. C LS-12x65-Tu Insert Design No. 3984 (Licensing Drawing)
 2C-6172, Rev. C LS-31x73-Tu Insert Design No. 3983 (Licensing Drawing)
 2C-6175, Rev. D LS-50X103-SS Insert Design No. 3986 (Licensing Drawing)

5.(b) Contents

(1) Type and form of material

Solid material must have melting point greater than 250° C.

- (i) Solid, normal form material, as limited in Table 1, within insert Design No. 3984.
- (ii) Solid, normal form material, as limited in Table 2, within insert Design No. 3983.
- (iii) Solid, normal form material, as limited in Table 3, within insert Design No. 3986.
- (iv) Krypton-79, and Xenon-133 gas, as limited in Table 4, within insert Design No. 3983.
- (v) Solid, normal form material or solid sealed sources that meet the requirements of special form radioactive material, as limited in Table 5, within insert Design No. 3986.

(2) Maximum quantity of material per package

Decay heat not to exceed 10 watts per package. The contents may include fissile materials provided the mass limits of 10 CFR 71.15, 71.22, or 71.23 are not exceeded. 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.

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

Total mass of contents and insert not to exceed 5.8 kg. Maximum mass of radioactive material, is 30 g.

TABLE 1

Radionuclide	Maximum TBq	Radionuclide	Maximum TBq	Radionuclide	Maximum TBq
Ac-225	1.22E-01	I-131	1.34E+00	Re-188	5.74E-01
Ac-227	8.38E-01	In-111	1.42E+02	Rh-105	2.71E+02
Ac-228	1.07E-02	Ir-192	9.60E-01	Se-75	1.54E+02
Am-241	3.90E+00	Ir-194	2.58E-01	Sm-153	1.90E+02

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Radionuclide	Maximum TBq	Radionuclide	Maximum TBq	Radionuclide	Maximum TBq
As-77	1.95E+02	Lu-177	3.43E+02	Sr-89	1.07E+02
Au-198	2.33E+00	Mo-99	2.80E-01	Sr-90	1.62E+01
Ba-131	4.52E-01	Na-24	7.80E-04	Tb-161	3.19E+02
C-14	4.80E+00	Np-237	7.80E-04	Th-227	1.79E+00
Co-60	2.28E-03	P-32	1.90E-02	Th-228	2.53E-03
Cs-131	2.24E+03	P-33	8.15E+02	Tl-201	4.84E+02
Cs-134	2.24E-02	Pb-203	1.45E+01	W-187	1.96E-01
Cs-137	1.42E-01	Pb-210	8.40E+01	W-188	6.02E-01
Cu-67	2.30E+02	Pd-109	1.73E+02	Y-90	8.76E-03
Hg-203	1.86E+02	Ra-223	8.46E-01	Yb-169	1.47E+02
Ho-166	2.42E-01	Ra-224	3.33E-03	Yb-175	3.69E+02
I-125	1.06E+03	Ra-226	3.62E-03		
I-129	1.95E-04	Re-186	1.38E+02		

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

Total mass of contents and insert not to exceed 5.3 kg. Maximum mass of radioactive material, is 200 g.

TABLE 2

Radionuclide	Maximum TBq	Radionuclide	Maximum TBq	Radionuclide	Maximum TBq
Ac-225	8.35E-02	I-131	6.71E-01	Re-188	3.55E-01
Ac-227	4.70E-01	In-111	1.42E+02	Rh-105	2.71E+02
Ac-228	6.90E-03	Ir-192	4.30E-01	Se-75	1.54E+02
Am-241	1.13E+01	Ir-194	1.66E-01	Sm-153	1.90E+02
As-77	7.84E+01	Lu-177	3.43E+02	Sr-89	6.64E+01
Au-198	1.32E+00	Mo-99	1.52E-01	Sr-90	6.89E+00
Ba-131	2.56E-01	Na-24	5.66E-04	Tb-161	2.99E+02
C-14	3.20E+01	Np-237	5.20E-03	Th-227	1.01E+00
Co-60	1.53E-03	P-32	1.35E-02	Th-228	1.86E-03
Cs-131	2.24E+03	P-33	8.15E+02	Tl-201	4.84E+02
Cs-134	1.29E-02	Pb-203	7.34E+00	W-187	1.01E-01
Cs-137	7.09E-02	Pb-210	5.60E+02	W-188	3.72E-01
Cu-67	2.30E+02	Pd-109	1.73E+02	Y-90	6.41E-03
Hg-203	1.86E+02	Ra-223	4.74E-01	Yb-169	1.47E+02
Ho-166	1.66E-01	Ra-224	2.44E-03	Yb-175	3.65E+02
I-125	1.06E+03	Ra-226	2.54E-03		
I-129	1.30E-03	Re-186	7.21E+01		

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5.(b)(2) (continued)

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

Total mass of contents and insert not to exceed 2.5 kg. Maximum mass of radioactive material, is 800 g.

TABLE 3

Radionuclide	Maximum TBq	Radionuclide	Maximum TBq	Radionuclide	Maximum TBq
Ac-225	2.08E-02	I-129	5.20E-03	Ra-226	6.81E-04
Ac-227	5.40E-02	I-131	5.03E-02	Re-186	6.93E+00
Ac-228	1.41E-03	In-111	1.42E+02	Re-188	6.02E-02
Am-241	1.13E+01	Ir-192	2.10E-02	Rh-105	1.48E+01
As-77	2.85E+00	Ir-194	3.35E-02	Se-75	1.28E+00
Au-198	7.61E-02	Lu-177	3.43E+02	Sm-153	3.15E+01
Ba-131	2.31E-02	Mo-99	1.70E-02	Sr-89	1.06E+01
Bi-210	2.74E-02	Na-24	1.79E-04	Sr-90	8.94E-01
C-14	1.28E+02	Np-237	2.08E-02	Tb-161	1.69E+01
Co-60	3.68E-04	P-32	2.20E-02	Th-227	1.16E-01
Cs-131	2.24E+03	P-33	8.15E+02	Th-228	5.96E-04
Cs-134	1.62E-03	Pb-203	5.70E-01	Tl-201	4.84E+02
Cs-137	5.85E-03	Pb-210	2.39E+02	W-187	8.88E-03
Cu-67	7.67E+01	Pd-109	1.50E+01	W-188	6.31E-02
Hg-203	6.03E+01	Po-210	1.18E+01	Y-90	6.02E-03
Ho-166	4.46E-02	Ra-223	5.46E-02	Yb-169	5.06E+01
I-125	1.06E+03	Ra-224	7.83E-04	Yb-175	2.56E+00

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

Total mass of contents and insert not to exceed 5.3 kg. Maximum mass of contents; i.e., radioactive material, is 429 g. Maximum volume of contents, including the material of the gas container, is 10cc.

TABLE 4

Radionuclide	Maximum TBq	Radionuclide	Maximum TBq
Kr-79	2.00E-01	Xe-133	3.45E+02

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5.(b)(2) (continued)

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

Total mass of contents and insert not to exceed 2.5 kg. Maximum mass of radioactive material, is 800 g.

TABLE 5

Radionuclide	Maximum TBq	Radionuclide	Maximum TBq	Radionuclide	Maximum TBq
Pu-238	1.14E+01	Pu-240	6.72E+00	U-235	Note 1
Pu-239	Note 1	Pu-241	Note 1		

Note1: Fissile material must meet the mass limits and conditions of 10 CFR 71.15, "Exemption from classification as fissile material," or of the general license in 10 CFR 71.22 or 71.23. For shipment under the general license for fissile material, 10 CFR 71.22, and plutonium-beryllium special form material, 10 CFR 71.23, package contents are limited to no more than a Type A quantity of radioactive material.

5.(c) Criticality Safety Index

For the contents described in 5(b)(1)(v), as limited in 5(b)(2)(v), the criticality safety index must be calculated in accordance with the provisions of 10 CFR 71.22 or 71.23, as appropriate, and rounded up to the first decimal place. Criticality safety index is not required for material meeting the mass limits and conditions of 10 CFR 71.15.

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

- (a) The package shall be prepared for shipment and operated in accordance with the Package Operations in Section 7.0 of the application.
- (b) The package must meet the Acceptance Tests and Maintenance Program in Section 8.0 of the application.

7. Air transport of plutonium is not authorized.

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 April 30, 2017.

10. Expiration date: April 30, 2021.

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REFERENCES

Croft Associates Limited application dated July 30, 2009.

Supplements dated: October 15, 2009; March 31, and, September 30, 2010; April 19, and September 5, 2012; April 20, July 17, and December 17, 2015; January 21, and March 10, 2016.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION



Steve Ruffin, Acting Chief
Spent Fuel Licensing Branch
Division of Spent Fuel Management
Office of Nuclear Material Safety
and Safeguards

Date: April 7, 2016

SAFETY EVALUATION REPORT

Docket No. 71-9337
Model No. 9379A
Certificate of Compliance No. 9337
Revision No. 3

SUMMARY

By application dated December 17, 2015 (Agency Document Access Management System (ADAMS) Accession No. ML15352A023), as supplemented January 21, and March 10, 2016 (ADAMS Accession Nos. ML16033A082 and ML16075A363 respectively), Croft Associates Ltd. requested renewal of Certificate of Compliance (CoC) No. 9337 for the Model No. 3979A shipping package. Croft Associates Ltd. also requested an editorial change be made to the certificate of compliance and provided revised safety analysis report pages. The certificate has been renewed for a five year term.

CONCLUSION

By application dated December 17, 2015 (ADAMS Accession No. ML15352A023), as supplemented January 21, and March 10, 2016 (ADAMS Accession Nos. ML16033A082 and ML16075A363 respectively), Croft Associates Ltd. requested renewal of CoC No. 9337 for the Model No. 3979A shipping package. Although Croft Associates Ltd. did not request any changes to the package design or authorized contents, they did provide updated safety analysis (SAR) pages with their renewal request. Croft stated that the updated SAR pages reflected changes which should have been made prior to initial issuance of CoC 9337, but were inadvertently omitted. Staff reviewed the submitted changed SAR pages and confirmed that only changes requested by staff during the initial review of the package had been made. Staff also reviewed the documents referenced in the certificate and determined that the documentation was available and complete. Staff reviewed both the operating and maintenance procedures. Although staff determined that the operating instructions were adequate, staff determined that a portion of the maintenance procedures had been inadvertently deleted from the SAR and requested the information from the applicant. Croft Associates subsequently provided the updated maintenance instructions and staff determined the updated maintenance instructions to be adequate.

The certificate 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, 2021. This change does not affect the ability of the package to meet the requirements of 10 CFR Part 71.

Issued with Certificate of Compliance No. 9337, Revision No. 3, on April 7, 2016.