

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

- | | |
|---|---|
| <p>a. ISSUED TO (<i>Name and Address</i>)</p> <p>Croft Associates Limited
Building F4, Culham Science Centre
Culham, Abingdon
Oxfordshire, OX14 3BD, United Kingdom</p> | <p>b. TITLE AND IDENTIFICATION OF REPORT OR APPLICATION</p> <p>Croft Associates Limited application dated
July 30, 2009, as supplemented.</p> |
|---|---|

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.

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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
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.

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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, as supplemented.

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. 4 of this certificate may be used until December 31, 2022.

10. Expiration date: April 30, 2026.

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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; February 21, November 9, and November 22, 2021.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

**Yaira K. Diaz-
Sanabria**

Digitally signed by Yaira K. Diaz-
Sanabria

Date: 2021.12.21 17:43:46 -05'00'

Yaira K. Diaz Sanabria, Chief
Storage and Transportation Licensing Branch
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

Date: December 21, 2021





UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

SAFETY EVALUATION REPORT

Docket No. 71-9337
Model No. 3979A
Certificate of Compliance No. 9337
Revision No. 5

SUMMARY

On November 9, 2021 (Agencywide Documents Access and Management System (ADAMS) Accession No. ML21314A014), as supplemented on November 22, 2021 (ADAMS Accession No. ML21326A260), Croft Associates Ltd. (Croft) submitted an amendment request to revise Certificate of Compliance No. 9337 for the Model No. 3979A package. The applicant proposed revisions to the acceptance tests for the O-ring seal.

The U.S. Nuclear Regulatory Commission's (NRC's) staff reviewed the application using the guidance in NUREG-2216, "Standard Review Plan for Spent Fuel Dry Storage Systems and Facilities." Based on the statements and representations in the application, as supplemented, and the conditions listed in the certificate of compliance, the staff concludes that the package meets the requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71.

3.0 THERMAL

The objective of the NRC's thermal evaluation is to ensure that the applicant has adequately evaluated the thermal performance of the transportation package design. Croft requested a change to the acceptance tests in Chapter 8, Acceptance Tests and Maintenance Programs," to revise the temperature for O-Ring seal test to ensure material performance at temperature.

In Section 3.2.2 of the safety analysis report (SAR), the applicant described a set of critical characteristic tests (discussed in Section 8.3.2 of the SAR) for the O-ring material to provide assurance that reducing the temperature from 150 °C to 130 °C for the 1000-hour temperature test was acceptable to continue to meet the acceptance criterion for the O-ring and maintain containment during normal conditions of transport (NCT).

The applicant also described in Section 3.2.2 of the SAR that the temperature reduction from 150 °C to 130 °C for the 1000-hour temperature test is justified in Croft Report No. CTR 2021/22, "3979A O-ring NCT Test Temperature Reduction - SARP Impact," with confirmatory testing reported from the testing conducted by Croft, described in Croft Report No. CTR 2021/24, "LS 3979A (3980) O-ring Seal Thermal Tests." The applicant described in Croft Report No. CTR 2021/22 that the maximum NCT O-ring temperature in the SAR was 116.4 °C, which is below the 130 °C test temperature. The staff confirmed that the maximum containment vessel cavity temperature for NCT with insolation was 116.4 °C, as described by the applicant in Table 3-2 of the SAR. The applicant also described in CTR 2021/24 that there is sufficient O-ring compression resilience after 1000 hours at 130 °C to remain leaktight (1×10^{-7} reference cubic centimeter per second (ref-cm³/s)) acceptance criterion.

Based on the staff's review of the applicant's confirmatory testing, the applicant's justification for reducing the temperature on the O-ring NCT 1000-hour temperature test, and the contents of

Section 3.2.2 of the SAR, the staff finds the change in temperature for the O-ring NCT 1000 hour temperature test to be acceptable, and the Croft Model No. 3979A design continues to meet the requirements of 10 CFR 71.51(a)(1) and 71.71 for NCT.

4.0 CONTAINMENT EVALUATION

The objective of the review is to verify that the containment performance for the Croft Model No. 3979A package satisfies the containment requirements of 10 CFR Part 71. The applicant is proposing a temperature reduction for the NCT O-ring 1000-hour temperature test that is specified in Chapter 8 of the SAR from 150 °C to 130 °C while maintaining the American National Standards Institute (ANSI) N14.5, "American National Standard for Radioactive Materials – Leakage Tests on Packages for Shipment," leaktight acceptance criterion.

Since the applicant did not change the containment design/function of the package, which will still be tested to leaktight criteria, consistent with ANSI N14.5, the NRC staff finds that the safety and regulatory compliance conclusions remain unchanged, thus the 3979A package remains in compliance with 10 CFR Part 71 containment criteria.

8.0 ACCEPTANCE TESTS AND MAINTENANCE PROGRAM

The objective of the NRC' review is to verify that the acceptance tests for the packaging, as documented in the application, meet the requirements of 10 CFR Part 71, to ensure that the package is fabricated in accordance with the design approved by the NRC.

In Section 8.1.5.2 of the SAR, the applicant stated that one inner and one outer O-ring shall be removed from each manufacturing batch and tested to ensure that the O-ring remain leaktight after 1000 hours at 130 °C. In addition, the applicant stated that after a set of the O-rings have been held at 130 °C for 1000 hours, the test rig would be cooled to room temperature, and helium leak tested to the leaktight acceptance criterion.

Based on the staff's review of the applicant's confirmatory testing and the contents of Section 8.1.5.2, the staff finds the change in temperature for the O-ring NCT 1000-hour temperature test to be acceptable, and the Croft Model No. 3979A design continues to meet the requirements of 10 CFR 71.51(a)(1) and 71.71 for NCT.

CONDITIONS

The CoC includes the following condition(s) of approval:

Condition 6 was revised to state that the package must meet the Acceptance Tests and Maintenance Program in Section 8.0 of the application, as supplemented.

Condition 9 was revised to authorize use of Revision No 4 of the certificate until December 31, 2022.

The References were updated to include the application and supplement for this amendment.

CONCLUSIONS

Based on the statements and representations contained in the application, as supplemented, and the conditions listed above, the staff concludes that the design has been adequately

described and evaluated, and the Model No. 3979A package meets the requirements of 10 CFR Part 71.

Issued with Certificate of Compliance No. 9337, Revision No. 5.