NRC FORM 618
(8-2000)
10 CFR 71

U.S. NUCLEAR REGULATORY COMMISSION

CERTIFICATE OF COMPLIANCE
FOR RADIOACTIVE MATERIAL PACKAGES

1 a. CERTIFICATE NUMBER	b. REVISION NUMBER	c. DOCKET NUMBER	d. PACKAGE IDENTIFICATION NUMBER	PAGE	PAGES
9310	7	71-9310	USA/9310/B(U)-96	1 OF	4

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)*

Best Theratronics
413 March Road
Ottawa, Ontario
Canada K2K 0E4

b. TITLE AND IDENTIFICATION OF REPORT OR APPLICATION

Best Theratronics application dated July 29, 2019, 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. F-431 Transport Package

(2) Description

The Model No. F-431 Transport Package is designed to transport Cesium-137 in either special form or RAMCO-50 non-special form sealed sources. The F-431 Transport Package consist of the following components: (1) the overpack which provides impact and thermal protection; (2) either the Gammacell-1000 irradiator (GC-1000), or the Gammacell-3000 irradiator (GC-3000) which provides shielding protection; and (3) the radioactive contents in either special form or RAMCO-50 non-special form sealed sources which provide containment.

The F-431 Transport Package is a stainless-steel cylindrical package with a 1,067-millimeter (mm) [42-inch (in.)] outside diameter and a height of 1,283 mm (50.5 in.) that is placed on a removable mild steel skid. The maximum weight of the package is 2,270 kilograms (kg) [5,000 pounds (lb.)].

The overpack consists of nested cylindrical shells. The shells are made from stainless steel and the volume between the shells is filled with rigid foam. This foam provides insulation during an accidental fire. Vent holes, plugged with material designed to melt in a fire, are provided between the shells to prevent pressure buildup and allow a pathway for escape of gases from foam during an accidental fire.

5.(a)(2) continued

The GC-1000 and the GC-3000 are lead-shielding casks each with a source cavity. The package contents may consist of up to eight Cesium-137 special form sealed sources or RAMCO-50 non-special form sealed sources (provided Condition 5.(b)(1)(ii) is met) inside a source holder, within the source cavity. The maximum total activity of Cesium-137 is 113 tera-Becquerels (TBq) [3,050 Curies (Ci)]. The following are the features of the GC-1000 and GC-3000:

Irradiator Model	Rated Capacity	Diameter*	Height*	Lead Thickness*	Steel Shell Thickness*	Weight*
GC-1000	113 TBq (3,050 Ci)	457 mm (18 in.)	610 mm (24 in.)	150 mm (6 in.)	9.5 mm (0.375 in.)	1,054 kg (2,324 lb)
GC-3000	113 TBq (3,050 Ci)	457 mm (18 in.)	610 mm (24 in.)	110 mm (4.35 in.)	9.5 mm (0.375 in.)	1,091 kg (2,404 lb)

* Nominal Values

The approximate dimensions and weights of the package are as follows:

Package outside diameter	1,067mm (42 in.)
Package height	1,283 mm (50.5 in.)
Cavity diameter	559 mm (22 in.)
Cavity height	813 mm (32 in.)
Removable skid	1,118 mm (44 in.) x 1,003 mm (39.5 in.) x 203 mm (8 in.)
Overpack weight	1,044 kg (2,300 lbs.)
Contents weight (max.)	1,225 kg (2,700 lbs.)
Maximum package weight	2,270 kg (5,000 lbs.)

(3) Drawings

The packaging is constructed in accordance with the Best Theratronics drawing F643101-001, "F-431/GC-1000/3000 Transportation Package Information Drawing," Sheet 1, Revision K, and Sheet 2, Revision F.

(b) Contents

(1) Type and form of material

(i) Cesium-137 as a sealed source which meets the requirements of special form radioactive material. The sealed sources consist of the following special form sources: C-378, C-1000, C-1001, C-3000, C-3001, C3100, or ISO-1000.

5.(b) continued

(ii) Cesium-137 as the RAMCO-50 non-special form sealed source, provided the following conditions are met:

a. Source must conform to the specifications given in Figure 4.8 of the Safety Analysis Report and sealed source registry Certificate No. NR-0880-S-804-S.

b. Source must have been shown to not be leaking within six months prior to shipment.

c. Source must not have been damaged during its service in the GC-1000.

(2) Maximum quantity of material per package

113 TBq (3,050 Curies)

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

(a) The package must be prepared for shipment and operated in accordance with the Operating Procedures in Chapter 7 of the application.

(b) Each packaging must be acceptance tested and maintained in accordance with the Acceptance Tests and Maintenance Program in Chapter 8 of the application.

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

8. Transport by air of fissile material is not authorized.

9. Revision No. 6 of this certificate may be used until November 30, 2020.

10. Expiration date: November 30, 2024.

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REFERENCES

Best Theratronics application dated July 29, 2019.

Supplement dated: November 5, 2019.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Daniel Doyle, Acting Chief
Storage and Transportation Licensing Branch
Division of Fuel Management
Office of Nuclear Material Safety
and Safeguards

Date: 11/26/2019

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

SAFETY EVALUATION REPORT
Docket No. 71-9310
Model No. F-431 Transport Package
Certificate of Compliance No. 9310
Revision No. 7

SUMMARY

By application dated May 23, 2019 (Agencywide Documents Access and Management System [ADAMS] No. ML19150A567), as supplemented on June 25, 2019 (ADAMS Accession No. ML19177A354), July 29, 2019 (ADAMS Accession No. ML19329A531), and November 5, 2019 (ADAMS Accession No. ML19312A446), Best Theratronics Ltd. (the applicant) requested the renewal of Certificate of Compliance (CoC) No. 9310, for the Model No. F-431 transport package. The applicant also requested to remove "MDS Nordion" in Gammacell-1000 and Gammacell-3000 from the "Description" section of the certificate, since the package can transport these types of gammacells from other manufacturers (ADAMS Accession No. ML19312A446).

The applicant did not request any changes to the package design or its authorized contents. The certificate has been renewed for a five-year term.

EVALUATION

The staff reviewed the applicant's requests to renew the CoC the Model No. F-431 and to remove "MDS Nordion" from the "Description" section of the certificate related to Gammacell-1000 and Gammacell-3000. Per the applicant's request dated November 5, 2019, these gammacells have been, through the years, "manufactured at the same facility" under the same name but different owners such as the following:

1) AECL (Atomic Energy of Canada Limited),

2) Nordion International,

3) MDS Nordion, and

4) Currently, Best Theratronics.

The Model No. F- 431 package is used to transport all these gammacell units (ADAMS Accession No. ML19312A446). Therefore, the removal of the phrase "MDS Nordion" does not affect the performance of the package.

In terms of the renewal, the staff reviewed the documents referenced in the CoC and determined that the documentation was available and complete. Given the number of supplements in the certificate for the Model No. F-431, the staff requested a consolidated application for this renewal. The staff verified that the information in the supplements listed in

Revision 6 of CoC No. 9310 was incorporated into the consolidated application (ADAMS Accession Nos. ML19177A354 and ML19329A531).

Based on the application and its supplements, the staff finds that the information provided by the applicant is adequate and the package continues to meet the requirements of Title 10 of the *Code of Federal Regulations* (10 CFR) Part 71.

CONDITIONS

The following conditions of the CoC were revised or added to the certificate:

1) In Condition No. 1.b., the revision No. of the certificate was increased to 7.

2) Condition 3.b. has been revised as follows:

   Best Theratronics application dated July 29, 2019, as supplemented.

3) Condition 5.(a)(2) has been revised to deleted the phrase "MDS Nordion."

4) Condition 5.(a)(3) has been revised as follows to reflect different revision Nos. of the drawings:

   The packaging is constructed in accordance with the Best Theratronics drawing F643101-001, "F-431/GC-1000/3000 Transportation Package Information Drawing," Sheet 1, Revision K, and Sheet 2, Revision F.

5) Condition No. 9 has been added to allow using Revision 6 of the CoC until November 30, 2020.

6) Condition No. 9 was renumbered as Condition No. 10 and revised to reflect the new certificate expiration date.

The "REFERENCES" section has been updated to include the date of the last consolidated application submitted by the applicant for the renewal request (i.e., July 29, 2019) and the supplement requesting the removal of "MDS Nordion" from the "Description" of the certificate.

CONCLUSION

The certificate has been renewed for a five-year term, which expires on November 30, 2024. Based on the statements contained in the application, and the conditions listed above, the staff concludes that the changes to the certificate indicated by the applicant do not affect the ability of the package to meet the requirements of 10 CFR Part 71.

Issued with Certificate of Compliance No. 9310, Revision No. 7,
on 11/26/2019.