U.S. Department
of Transportation
Pipeline and
Hazardous Materials
Safety Administration

East Building, PHH-23
1200 New Jersey Avenue Southeast
Washington, D.C. 20590

COMPETENT AUTHORITY CERTIFICATION FOR A TYPE B(U) RADIOACTIVE MATERIALS PACKAGE DESIGN CERTIFICATE USA/9290/B(U)-96, REVISION 8

This certifies that the radioactive material package design described has been certified by the Competent Authority of the United States as meeting the regulatory requirements for a Type B(U) packaging for radioactive material as prescribed in the regulations of the International Atomic Energy Agency[1] and the United States of America[2].

1. Package Identification - MDS Nordion Model No. F-430/GC-40 Transport Package.

2. Package Description and Authorized Radioactive Contents - as described in U.S. Nuclear Regulatory Commission Certificate of Compliance No. 9290, Revision 7 (attached).

3. General Conditions -

   a. Each user of this certificate must have in his possession a copy of this certificate and all documents necessary to properly prepare the package for transportation. The user shall prepare the package for shipment in accordance with the documentation and applicable regulations.

   b. Each user of this certificate, other than the original petitioner, shall register his identity in writing to the Office of Hazardous Materials Technology, (PHH-23), Pipeline and Hazardous Materials Safety Administration, U.S. Department of Transportation, Washington D.C. 20590-0001.

   c. This certificate does not relieve any consignor or carrier from compliance with any requirement of the Government of any country through or into which the package is to be transported.

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[1] "Regulations for the Safe Transport of Radioactive Material, 1996 Edition (Revised), No. TS-R-1 (ST-1, Revised)," published by the International Atomic Energy Agency(IAEA), Vienna, Austria.

[2] Title 49, Code of Federal Regulations, Parts 100-199, United States of America.

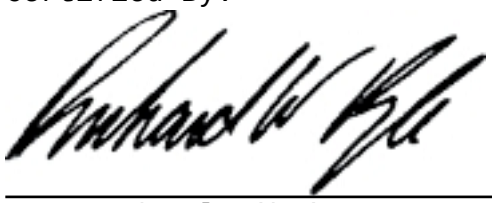
d. Records of Quality Assurance activities required by Paragraph 310 of the IAEA regulations[1] shall be maintained and made available to the authorized officials for at least three years after the last shipment authorized by this certificate. Consignors in the United States exporting shipments under this certificate shall satisfy the applicable requirements of Subpart H of 10 CFR 71.

4. Marking and Labeling - The package shall bear the marking USA/9290/B(U)-96 in addition to other required markings and labeling.

5. Expiration Date - This certificate expires on February 28, 2017.

This certificate is issued in accordance with paragraph 808 of the IAEA Regulations and Section 173.471 of Title 49 of the Code of Federal Regulations, in response to the April 05, 2012 petition by Best Theratronics Ltd., Ottawa, Ontario, and in consideration of other information on file in this Office.

Certified By:



Dr. Magdy El-Sibaie
Associate Administrator for Hazardous Materials Safety

Apr 20 2012
(DATE)

Revision 8 - Issued to endorse U.S. Nuclear Regulatory Commission Certificate of Compliance No. 9290, Revision 7.

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
9290	7	71-9290	USA/9290/B(U)-85	1	OF	3

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

MDS Nordion application dated February 20, 2003, 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-430/GC-40 Transport Package

(2) Description

The Model No. F-430/GC-40 Transport package is designed to transport MDS Nordion's Gammacell-40 (GC-40) irradiator containing cesium-137 sealed sources in special form. The F-430 overpack provides impact and thermal protection for the radioactive contents. Containment is provided by the special form sealed source and shielding is provided by the GC-40 irradiator body.

The F-430 is stainless steel cylindrical package with a 50" diameter and a height of 50" that is placed on a removable mild steel skid. The maximum weight of the package is 7000 pounds. The maximum weight of the GC-40 contents is 3835 pounds.

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.

The package contents consist of a Cesium-137 sealed source contained within an MDS Nordion GC-40 irradiator (upper or lower heads). The GC-40 is a research irradiator with lead shielding and a lead filled source drawer.

5.(a)(2) (continued)

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

Package outside diameter	50 inches
Package height	50 inches
Cavity diameter	36 inches
Cavity height	35.25 inches
Removable skid	50 inches x 50 inches x 8 inches (height)
Overpack weight	2640 pounds
Contents weight	3835 pounds
Maximum package weight	7000 pounds

(3) Drawings

The packaging is constructed in accordance with the Best Theratronics drawings F643001-001, Rev. P, sheet 1 of 3, and F643001-001, Rev. H, sheet 2 of 3, and F643001-001, Rev. B, sheet 3 of 3.

(b) Contents

(1) Type and form of material

Cesium-137 as a sealed source which meet the requirements of special form radioactive material.

(2) Maximum quantity of material per package

2,000 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. Expiration date: February 28, 2017.

REFERENCES

MDS Nordion application dated February 20, 2003.

Supplements dated: July 21, August 25, and December 18, 2003; January 16, July 16, July 21, and July 23, 2004; April 21, and October 30, 2006; February 27 (Best Theratronics), March 31 (MDS Nordion), 2009, October 7, 2011 (Best Theratronics), October 21, 2011, February 15, and March 9, 2012.

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

Christine Lipa, Acting Chief
Licensing Branch
Division of Spent Fuel Storage and Transportation
Office of Nuclear Material Safety
and Safeguards

Date: April 4, 2012

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

SAFETY EVALUATION REPORT
Docket No. 71-9290
Model No. F-430 Transportation Package
Certificate of Compliance No. 9290
Revision No. 7

SUMMARY

By application dated October 21, 2011, and as supplemented February 15, and March 9, 2012, Best Theratronics requested an amendment to Certificate of Compliance No. 9290, for the Model No. F-430 transportation package. Based on the statements and representations in the application, the staff agrees that these changes do not affect the ability of the package to meet the requirements of 10 CFR Part 71.

GENERAL INFORMATION

Best Theratronics requested the ability to ship both the original design of the package and a modified design which includes additional security features to the content of the package. These minor changes to the payload, a Gammacell-40 (GC-40) irradiator, include a GC-40 without a shipping tube but with new shipping plates and an additional large socket head cap screw. During the review, staff discovered a typographical error in the maximum weight of contents listed in the certificate of compliance which has been corrected. The weight listed was higher than the maximum design weight listed in the Safety Analysis Report (SAR). As the maximum design weight exceeds any weight that the package would typically expect during shipment, staff does not believe that this error would have led to any situation where a shipment greater than the design weight would have occurred.

STRUCTURAL EVALUATION

The F-430 package was submitted with a revised design that provides a more robust mechanism to prevent unauthorized access. While the F-430 overpack itself remains unchanged, the GC-40 irradiator was modified to incorporate the new security features.

The original design included shipping plates attached to the shielding heads. These shipping plates are fitted within a counterbore within the shielding head and are fastened with four 3/8-inch fastening screws. The function of the shipping plates is to retain the irradiated source within a source drawer and to retain a shipping tube also used to physically block the source drawer from movement within its cavity.

Since the new design features made it impractical to utilize the shipping tube, the shipping heads were modified to accept a single 1/2-inch cap screw in addition to the four 3/8-inch fastening screws. This larger screw is used to secure the source drawer to a single shipping plate to prevent movement. This new method of securing the source drawer is used in conjunction with the drawer interlock bar at the opposite end of the bore containing the source drawer.

Review of the steel bracing for both the upper and lower heads of the GC-40 shows that the structural response of the F-430 package under normal conditions of transport (NCT) and hypothetical accident conditions (HAC) will not change, therefore, the conclusions of the previous safety evaluation are still valid.

THERMAL EVALUATION

The package consists of a main body and inner lid and outer lid. The main materials of the packaging are 304L stainless steel and rigid polyurethane foam. The F-430 package provides thermal protection for the radioactive contents and containment is provided by the sealed sources. Except for changes to the payload device, the thermal design of the F-430 package is unchanged and the heat generated by the payload is unchanged. The thermal evaluation of this amendment is still bounded by the original analysis of internal heat generation of 100 W.

The thermal analysis of the F-430 under NCT and HAC was presented in SAR IN/TR-1608/1645 and remains valid in SAR IN/TR-6088. The staff accepts the previous thermal analysis of the F-430 package, approved by the NRC with significant safety margin for NCT and HAC, because there are no changes in decay heat limit, packaging components, and packaging material properties. The staff has reviewed the F-430 transportation package description and payload description and has reasonable assurance that the F-430 transportation package satisfies the thermal requirements of 10 CFR Part 71.

SHIELDING EVALUATION

The objective of this review is to verify that the package design meets the external radiation requirements of 10 CFR Part 71 under NCT and HAC. The applicant proposed a modification to the allowable package contents for ensuring the radioactive source in the contents remains secured in its position (and secured from unauthorized access) within the GC-40 heads. The GC-40 upper and lower heads, together with their Cs-137 special form sources (2000 Ci maximum), constitute the allowable package contents. The package will be used to ship the currently approved contents in addition to contents that have the proposed modification for securing the source.

Staff reviewed the proposed amendment with respect to impacts on the shielding capabilities. Based on the results of the structural review (see "Structural Evaluation" above), the staff finds that the source will remain secured in its location and thus the shielding capabilities of the package will be maintained. Although the shielding design of the package (the GC-40 is relied on for shielding) did not change, the applicant modified the licensing drawings to include additional dimensions to adequately characterize the shielding design of the package and to provide dimensional tolerances. These additional dimensions include the lead thickness in the source drawer, which is relied on for shielding along the axis of the source drawer tube in the GC-40 heads. This dimension applies to the lead in the source drawer on both sides of the source. The staff finds that there were no other changes to the package features that impact shielding. The staff finds that the licensing drawings and the package operations in Chapter 7 of the application have been appropriately modified to adequately describe the package's shielding design and to account for the change to the contents. Thus, the staff finds there is reasonable assurance that the package will continue to meet the external radiation requirements of 10 CFR Part 71.

PACKAGE OPERATIONS

Staff reviewed the changes to the operating procedures and finds that the applicant adequately incorporated changes in the procedures related to the shipping tube, shipping plates, and socket head cap screw.

CONDITIONS

The following changes have been made to the certificate of compliance:

Condition No. 5(a)(2), "Description," has been updated with the correct contents weight.

Condition No. 5(a)(3), "Drawings," has been updated to reference the updated drawings which include changes resulting from the additional security feature.

The References section has been updated to include this revision request.

CONCLUSION

Based on the statements and representations contained in the application, the staff concludes that these changes do not affect the ability of the package to meet the requirements of 10 CFR Part 71.

Issued with Certificate of Compliance No. 9290, Revision No. 7 on
April 4, 2012.

U.S. Department
of Transportation

**Pipeline and
Hazardous Materials
Safety Administration**

**East Building, PHH-23
1200 New Jersey Avenue SE
Washington, D.C. 20590**

CERTIFICATE NUMBER: USA/9290/B(U)-96, Revision 8

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