East Building, PHH-23
1200 New Jersey Avenue Southeast
COMPETENT AUTHORITY CERTIFICATION Washington, D.C. 20590
FOR A TYPE B(U)

RADIOACTIVE MATERIALS PACKAGE DESIGN CERTIFICATE USA/0587/B(U)-85, REVISION 3

REVALIDATION OF CANADIAN COMPETENT AUTHORITY CERTIFICATE CDN/2067/B(U)-85

This certifies that the radioactive material package design described is hereby approved for use within the United States for import and export shipments only. Shipments must be made in accordance with the applicable regulations of the International Atomic Energy Agency¹ and the United States of America².

- 1. <u>Package Identification</u> Gammacell 40 MK3 Irradiator, (Shipped in the 20WC-5 Overpack, Serial Nos. 1A, 1B, 2A, 2B, 3A, 3B).
- 2. <u>Package Description and Authorized Radioactive Contents</u> as described in Canada Certificate of Competent Authority CDN/2067/B(U)-85, Revision 6 (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.

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.

CERTIFICATE USA/0587/B(U)-85, REVISION 3

- d. Records of Quality Assurance activities required by Paragraph 310 of the IAEA regulations¹ 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. <u>Marking and Labeling</u> The package shall bear the marking USA/0587/B(U)-85 in addition to other required markings and labeling.
- 5. Expiration Date This certificate expires on February 29, 2016.

This certificate is issued in accordance with paragraph 817 of the IAEA Regulations and Section 173.473 of Title 49 of the Code of Federal Regulations, in response to the February 23, 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

Mar 15 2012

(DATE)

Revision 3 - Issued to revalidate Canadian Certificate of Competent Authority No. CDN/2067/B(U)-85, Revision 6, and to extend the expiration date.



Canadian Nuclear Safety Commission Commission canadienne de sûreté nucléaire

Canadian Certificate No. CDN/2067/B(U)-85 (Rev. 6)

Issue Date Feb-22-2012

Expiry Date Feb-29-2016

CNSC File 30-A2-175-0

Certificate **Transport Package Design**

The transport package design identified below is certified by the Canadian Nuclear Safety Commission pursuant to paragraph 21(1)(h) of the Nuclear Safety and Control Act and Section 7 of the Packaging and Transport of Nuclear Substances Regulations, and to the 1985 Edition (As Amended 1990) of the IAEA Regulations for the Safe Transport of Radioactive Material.

REGISTRATION OF USE OF PACKAGES

All users of this authorization shall register their identity in writing with the Canadian Nuclear Safety Commission prior to the first use of this authorization and shall certify that they possess the instructions necessary for preparation of the package for shipment.

PACKAGE IDENTIFICATION

Designer:

Best Theratronics

Make/Model:

Gammacell 40 MK3 Irradiator, (Shipped in the 20WC-5 Overpack, Serial Nos. 1A,

1B, 2A, 2B, 3A, 3B)

Mode of Transport: Air, Sea, Road, Rail

IDENTIFICATION MARK

The package shall bear the competent authority identification mark "CDN/2067/B(U) - 85".

PACKAGE DESCRIPTION

The Gammacell 40 MK3 Irradiator, as described on Drawing Nos. C104002-071 (Issue C) and C104002-098 (Issue C), consists of two steel-encased, 152 mm thick lead-shielded source heads. Each head is completely wrapped within Kaowool thermal insulation encased in polyethylene sheet. Each wrapped head is installed in the cavity of a USDOT specification 20WC-5 package as shown on Drawing No. C104010-010 (Issue D). The containment system for each source head consists of the source capsule, the source drawer, the shipping end plate and spacer, and the steel-encased lead-shielded body. There are two packages (upper and lower head respectively) in each shipment.

An illustration of the package is shown on attached Drawing No. GC-40-MK3, (Rev. 4).

Any modification to the package design must be submitted to the Canadian Nuclear Safety Commission for approval prior to implementation.



Canadian Nuclear Safety Commission de sûreté nucléaire

Commission canadienne

Canadian Certificate No.	Issue Date	Expiry Date	CNSC File
CDN/2067/B(U)-85 (Rev. 6)	Feb-22-2012	Feb-29-2016	30-A2-175-0

The configuration of the package is as follows:

Shape: Drum

Mass: 1740 kg Length: n/a

Width: n/a

Shielding:

Lead

Outer Casing: n/a

Height:

1041 mm

Diameter:

1306 mm

AUTHORIZED RADIOACTIVE CONTENTS

The package is authorized to contain a maximum of 148 TBq (4,000 Ci) of Cesium 137 in the form of cesium chloride compressed powder pellets contained within two MDS Nordion C161 Type 8 or Reviss Type R6100 (MDS Nordion C-440) double-walled welded stainless steel capsules (one capsule in each irradiator head) meeting the requirements for special form radioactive material.

OUALITY ASSURANCE

Quality assurance for the design, manufacture, testing, documentation, use, maintenance and inspection of the package shall be in accordance with:

- Best Theratronics Specification No. IN/TS 1268 GC40E+ (E), "Technical Specification Gammacell 40E+ Radiation Shield Assembly"
- Best Theratronics Document No. 5.05-QA-01(2)*, "Radioactive Material Transport Package Quality Plan"
- Best Theratronics Document No. IN/IM 2548 F000(3), "Transport Package Maintenance Overview Procedure"
- Packaging and Transport of Nuclear Substances Regulations
- IAEA Regulations
- * or latest current revision

SHIPMENT

The preparation for shipment of the package shall be in accordance with:

Best Theratronics Document No. IN/PP 0272 GC40MK3, (Issue 11), "Preparation for Shipment of the





Canadian Nuclear Safety Commission

Commission canadienne de sûreté nucléaire

Canadian Certificate No.	Issue Date	Expiry Date	CNSC File
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CDN/2067/B(U)-85 (Rev. 6)	Feb-22-2012	Feb-29-2016	30-A2-175-0
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GC-40, GC-40E and GC-40E+ in the GC-40 MK3 Transport Package (20WC-5)"

- Packaging and Transport of Nuclear Substances Regulations
- IAEA Regulations

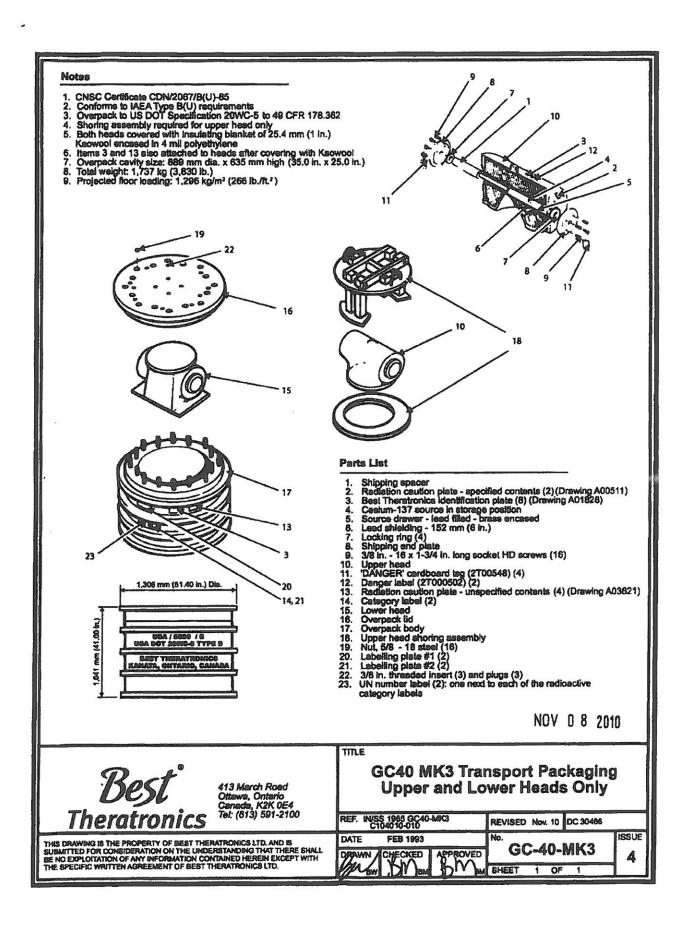
This certificate does not relieve the consignor from compliance with any requirement of the government of any country through or into which the package will be transported.

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Designated Officer pursuant to paragraph 37(2)(a)

of the Nuclear Safety and Control Act





U.S. Department of Transportation

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

Pipeline and Hazardous Materials Safety Administration

CERTIFICATE NUMBER: USA/0587/B(U)-85, Revision 3

ORIGINAL REGISTRANT(S):

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