71-9310

Best® Theratronics

413 March Road
Ottawa, Ontario
Canada K2K 0E4
Tel: 613-591-2100

June 8, 2015

Licensing Section
Spent Fuel Project Office
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

Re: Amendment for transport package F431, certificate USA/9310/B(U)-96

Dear Sir/Madam,

On behalf of Best Theratronics Ltd., I am requesting an amendment to the F431 transport package, certificate number USA/9310/B(U)-96. The amendment request is to add a new Cs137 sealed source model, the C3100, as authorized radioactive contents.

Best Theratronics Ltd has recently developed the C3100, Cs137 sealed source model. The C3100 source model has been certified as Special Form Material by the CNSC, certificate CDN/0035/S-96 (see attached).

The C3100 source model is made as a direct replacement to the C3001 source model currently used in the Gammacell (GC) 1000 and 3000 blood irradiators. The device certificate for the GC1000 and GC3000 (NR-1307-D-102-S) has been recently revised to include this new source model (see attached). The C3100 is identical to the C3001 in both outer dimensions and allowable activity contents.

There are absolutely no changes to the designs of the GC1000 or GC3000 to incorporate the C3100 source model. The C3001 can be replaced directly with the C3100. The GC construction, dimensions, and weight remain unchanged and as such, there is no change to the F431 safety analysis report.

Payment for the amendment will be provided by credit card. Please contact Gwen McCaffrey 613-591-2100 ext: 2595 for details.

Thank you for your consideration of this matter. I believe the above information will prove satisfactory. However, if you have any questions or require further information please feel free to contact me.

NMSS01

Sincerely,

Richard Wassenaar, PhD, MCCPM
Director of Compliance and RSO

Canadian Certificate No.: **CDN/0035/ S -96 (Rev. 0)**
Issue Date: **Nov-19-2014**
Expiry Date: **Nov-30-2019**
CNSC File: **30-B5-1-2**

Certificate

CDN/0035/ S -96 (Rev. 0)

Special Form

The special form radioactive material 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 1996 Edition (Revised) of the IAEA *Regulations for the Safe Transport of Radioactive Material.*

CAPSULE IDENTIFICATION

Designer:	**Best Theratronics**
Make/Model:	**C3100**

CAPSULE DESCRIPTION

The C3100 capsule, as shown on Best Theratronics Drawing No. G143101-001 (Issue 5), consists of two sealed stainless steel inner capsules further encapsulated in a stainless steel capsule.

An illustration of the capsule is shown on attached Drawing No. C3100 (Issue A).

The configuration of the capsule is as follows:

Shape:	**Cylinder**	Shielding:	**n/a**
Mass:	**0.3 kg**	Outer Casing:	**Stainless Steel**
Length:	**271.5 mm**	Height:	**n/a**
Width:	**n/a**	Diameter:	**17.58 mm**

AUTHORIZED RADIOACTIVE CONTENTS

This capsule is authorized to contain not more than 56.25 TBq of Cs-137 in the form of pressed or tamped Cs-137 chloride powder within two inner encapsulations.

QUALITY ASSURANCE

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

- Best Theratronics Document No. 5.05-QA-02 (2)*, "Sealed Source Quality Plan"
- Best Theratronics Document No. IN/TS 2578 C000 (C), "Technical Specification for Sealed Sources"
- Best Theratronics Document No. IN/TS 2714 C000 (C), "Technical Specification for Sealed Sources Containing Cs-137"
- Packaging and Transport of Nuclear Substances Regulations
- IAEA Regulations
- * or latest current revision

S. Faille
Designated Officer pursuant to paragraph 37(2)(a) of the Nuclear Safety and Control Act

NOTES

Revision 0: November 19, 2014. New Certificate.

Security-Related Information
Figure Withheld Under 10 CFR 2.390

Best® Theratronics

413 March Road
Ottawa, Ontario
Canada, K2K 0E4
Tel: (613) 591-2100

TITLE

C3100 Source Capsule

REF. IN/SS 6120 C3100 G143101-001	REVISED Aug 2014	DC31114
DATE August 2014	No: C3100	ISSUE A
DRAWN GW / CHECKED / APPROVED AC	SHEET 1 OF 1	

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-1307-D-102-S DATE: May 15, 2015

DEVICE TYPE: Gamma Irradiator

MODEL: Gammacell 1000-A, B, C, or D and
Gammacell 1000 Elite-A, B, C, D, Type I or Type II and
Gammacell 3000 Elan-A, B, C, Type I or Type II

DISTRIBUTOR:	Best Theratronics Ltd. 7643 Fullerton Road Springfield, VA 22153
MANUFACTURER:	Best Theratronics Ltd. 413 March Road Ottawa, Ontario Canada K2K 0E4
SEALED SOURCE MODEL DESIGNATION:	Isomedix RAMCO-50 or ISO-1000 MDS Nordion C-1000, C-3000 Best Theratronics C-1001, C-3001, Best Theratronics C-378 **Best Theratronics C3100**

ISOTOPE:	MAXIMUM ACTIVITY:
Cesium-137	3,264 curies (120.8 TBq)

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (J) Gamma Irradiator, Category I

CUSTOM DEVICE: ____YES ___X___NO

DEVICE TYPE: Gamma Irradiator

DESCRIPTION:

The Gammacell 1000, 1000 Elite, and 3000 Elan are fully self-contained irradiators. The weight range for the Gammacell 1000 and 1000 Elite is 2500 to 2800 lbs (1134 to 1270.1 kg). The weight range for the Gammacell 3000 Elan is 3000 to 3300 lbs (1360.8 to 1496.9 kg). Each unit contains a sample chamber with a built-in turntable which provides dose uniformity for the sample when rotating. The A, B, C, D, Type I, and Type II designations refer to the various configurations of sources which can be provided with each unit. Doubly encapsulated sources are fixed in a source holder designed specifically according to the unit and source selected. The source holder, with sources installed, is inserted into the source cavity of the unit and a cover is either bolted or fully welded in place to prevent access. The various source configurations allowed are described later in this document.

The Gammacell 1000 measures 24 inches wide by 24 inches in length by 65 inches in height (60.96 cm wide by 60.96 cm length and 165.1 cm in height). The sample chamber accepts beakers up to 8 inches (20.3 cm) in height and 3 inches (7.6 cm) in diameter (0.25 gallon (0.96 liter) capacity). The sample chamber is introduced into the radiation field by manually turning the rotor 1800 by means of a lever. Irradiation of the sample will continue until the sample chamber is returned to the 'load'-'unload' position.

In October of 1988, AECL divided a portion of its source and device production between two separate entities (Theratronics International Limited and Nordion International, Inc.). At that time only the Gammacell 1000 was being manufactured. AECL ceased all manufacture, distribution and servicing of the Gammacell 1000 irradiators and Nordion International, Inc., took over the manufacturing and servicing responsibilities-for these devices. The Gammacell 1000 is no longer supplied as a new unit.

The Gammacell 1000 Elite is an updated version of the Gammacell 1000. Operation of the unit has been mechanized in order to simplify operation and provide more precise irradiation. The

DEVICE TYPE: Gamma Irradiator

DESCRIPTION (Cont.):

unit is housed in a fire resistant cabinet which measures 30 inches to 33 inches wide by 26 inches to 32 inches length by 56 inches to 63 inches in height (76.2 to 83.82 cm wide by 66 cm to 81.3 cm in length and 142.2 to 160 cm in height). Access to the sample chamber is gained by opening a door in the cabinet. An interlock system prevents operation of the unit when the door is open. The manual lever which was used to introduce the sample chamber to and from the radiation field has been replaced by a DC motor. This motor is controlled by digital DC components which are programmed from a control panel on the cabinet face. From this control panel the unit can be programmed to rotate a sample into the radiation field for a prescribed time and automatically return it to the 'load'-'unload' position. A DC battery backup has been added which, when input power is lost, will complete the current programmed cycle; however no additional cycles will be initiated until power is restored. The backup battery is continuously recharged while input power is available.

The Gammacell 3000 Elan is essentially similar to the Gammacell 1000 Elite. Only differences between the two will be discussed. The sample chamber of the Gammacell 3000 Elan has been enlarged to accommodate sample beakers of up to 0.69 gallon (2.6 liter) capacity. As a consequence of this, radiation shielding was slightly reduced. In order to compensate for the reduced shielding, secondary shielding constructed of lead is bolted onto the rear and side of the existing radiation shield at the time of installation.

The C-1000 and C-3000 sources are manufactured by Westinghouse Hanford Co., USA for the exclusive use in the Gammacell 1000 Elite and Gammacell 3000 Elan research irradiators. The sources are not registered by the NRC under any other name or manufacturer. These sources are similar in design and construction. Both are doubly encapsulated using 316L stainless steel capsules with fusion welded end caps and contain cesium-137 pellets in the form of pressed cesium chloride powder.

DEVICE TYPE: Gamma Irradiator

DESCRIPTION (Cont.):

Nominal activity for the C-1000 is 600 Ci (22.2 TBq) +20%, -10%, and for the C-3000 is 1,270 Ci (47.0 TBq) +20%, -10%. Nominal capsule wall thickness for both sources is 0.035 inches (0.89 mm).

The C-1001 and C-3001 sources are manufactured by Reviss Services Ltd. (formerly AEA Technology QSA, Inc., Amersham Corporation) for the exclusive use in the Gammacell 1000 Elite and Gammacell 3000 Elan research irradiators. The sources are not registered by the NRC under any other name or manufacturer. These sources are similar in design and construction to the C-1000 and C-3000. The only significant differences between the C-1001 and the C-1000 sources and the C-3001 and C-3000 sources is that the C-1001 and C-3001 contain cesium-137 encapsulated in three inner capsules instead of a single capsule and the nominal wall thickness of the C-1001 and C-3001 sources is 0.039 inches (1.0 mm) as compared to 0.035 inches (0.89 mm). All sources are doubly encapsulated using 316L stainless steel with fusion welded end caps and contain cesium-137 in the form of cesium chloride powder. Nominal activity for the C-1001 is 590 Ci (21.9 TBq) with a maximum activity of 810 Ci (30.0 TBq) and for the C-3001 nominal activity is 1,270 Ci (47.0 TBq) with a maximum activity of 1,620 Ci (60.0 TBq).

The inner capsule of the Model C-1000 measures 9.840 inches in length by 0.375 inches in diameter (25.0 cm by 0.953 cm) and is sealed by fusion weld at each end by 0.250 inches thick by 0.317 inches in diameter (0.635 cm by 0.805 cm) end caps. The outer capsule measures 10.690 inches in length by 0.500 inches in diameter (27.15 cm by 1.27 cm) and is sealed by fusion weld at each end by 0.375 inches thick by 0.442 inches in diameter (0.953 cm by 1.12 cm) end caps.

Each of the inner capsules of the Model C-1001 measures maximum 3.47 inches in length by 0.406 inches in diameter (8.805 cm by 1.03 cm) and is sealed by fusion weld at each end by 0.075 inches thick by 0.328 inches in diameter (0.19 cm by 0.834 cm) end caps. The outer capsule measures 10.690 inches in length by

DEVICE TYPE: Gamma Irradiator

DESCRIPTION (Cont.):

0.50 inches in diameter (27.15 cm by 1.28 cm) and is sealed by fusion weld at each end by 0.114 inches thick by 0.427 inches in diameter (0.290 cm by 1.084 cm) end caps.

The inner capsule of the Model C-3000 measures 9.840 inches in length by 0.562 inches in diameter (24.9 cm by 1.43 cm) and is sealed by fusion weld at each end by 0.250 inches thick by 0.50 inches in diameter end caps (0.64 cm by 1.28 cm). The outer capsule measures 10.690 inches in length by 0.687 inches in diameter (27.15 cm by 1.75 cm) and is sealed by fusion weld at each end by 0.375 inches thick by 0.630 inches in diameter end caps (0.95 cm by 1.60 cm).

Each of the inner capsules of the Model C-3001 measures maximum 3.467 inches in length by 0.593 inches in diameter (8.8065 cm by 1.5065 cm) and is sealed by fusion weld at each end by 0.075 inches thick by 0.513 inches in diameter end caps (0.19 cm by 1.31 cm). The outer capsule measures 10.690 inches in length by 0.687 inches in diameter (27.15 cm by 1.74 cm) and is sealed by fusion weld at each end by 0.114 inches thick by 0.618 inches in diameter end caps (0.29 cm by 1.56 cm).

RAMCO-50 source is constructed of 316L stainless steel and contains cesium-137. ISO-1000 source is constructed of 304L stainless steel and contains cesium-137. The ISO-1000 or the RAMCO-50 sealed sources for GC-1000 or GC-3000 models are no longer manufactured.

The Model C-378 sealed source is manufactured for exclusive use in the Gammacell 1000 Elite and Gammacell 3000 Elan research irradiators. The sources are not registered by the NRC under any other name or manufacture. The Model C-378 sealed source is an over-encapsulation of the ISO-1000 approved sealed source with an additional outer shell of 316L stainless steel. The maximum activity for each Model C-378 cesium-137, source is 550 curies (20.4 TBq).

DEVICE TYPE: Gamma Irradiator

DESCRIPTION (Cont.):

The outer capsule has a maximum length of 10.993 inches (279.22 mm), a maximum diameter of 0.632 inches (16.05 mm) with a 0.025 inches (0.64 mm) wall thickness. The C-378 is produced by inserting an active used leak tested ISO-1000 capsule into the C-378 body with one end cap already welded into place. The final end cap is then inserted and fusion welded. The manufacturer provides a one year warranty for the C-378 source. However, the manufacturer expects the physical and working life of the source to be unlimited.

The Model C3100 sealed source is manufactured for exclusive use in the Gammacell 1000 Elite and Gammacell 3000 Elan research irradiators. Sealed source model C3100 is a direct replacement for the C3001 source model. Model C3100 sources contain cesium-137 in the form of cesium chloride. The maximum activity for each C3001 source capsule is 1520.3 Ci (56.25 TBq) of cesium-137.

The C3100 source capsule consists of two sealed 316L stainless steel inner capsules further encapsulated in a 316L outer stainless steel capsule. Each inner capsule has a length of 4.667 inches (118.55 mm) and a diameter of 0.506 inches (12.85 mm), with an inner wall thickness of 0.041 inches (1.05 mm). The outer capsule has a maximum length of 10.689 inches (271.5 mm), a maximum diameter of 0.692 inches (17.58 mm), with a wall thickness of 0.039 inches (1 mm). The thickness of the end caps is 0.375 inches (9.525 mm). Caps are press fit into position and fusion welded. Model C3100 sealed sources have a recommended working life of 15 years. However, the recommended working life may be extended by Best Theratronics based on inspection and technical assessment.

The sources are installed into source holders designed specifically for each source type. The source holder, with sources installed, is then inserted into the source cavity of the unit and a cover plate is welded over the cavity to prevent access to the sources. The sources are installed according to the activity requested by the customer. Table 1 shows the

DEVICE TYPE: Gamma Irradiator

DESCRIPTION (Cont.):

allowable configurations for the sources loaded with maximum activity for each model.

Table 1

Gammacell	Number of sources	Max. Activity (Ci)
1000	2, 4, 6, or 8 RAMCO-50 sources	3264.0
	1, 2, 3, or 4 ISO-1000 sources	2880.0
1000 Elite	1, 2, 3, or 4 ISO-1000 sources	2880.0
	Any combination of C1000/C1001, C3000/C3001**/C3100**, or C378 sources, up to 3 sources	3048.0
3000 Elan	Any combination of C1000/C1001, C3000/C3001**/C3100**, or C378 sources, up to 3 sources	3048.0

DEVICE TYPE: Gamma Irradiator

LABELING:

The devices are labeled in accordance with the requirements of Section 20.1901, 10 CFR Part 20 and with the requirements of ANSI N433.1-1977, "Safe Design and Use of Self Contained, Dry Source Storage Gamma Irradiators (Category I)." The labels are affixed to the exterior of the unit by screws and contain the radiation symbol, isotope, activity, model number, serial number, name of manufacturer, and the words "CAUTION-RADIOACTIVE MATERIAL".

The following information is engraved on the C-1000, C-3000, C-1001, and C-3001 sources:

For the C-1000
NII
Cs137B
XXXX (Serial Number)
Radiation Symbol
or
Radioactive

For the C-3000
NII
Cs137C
XXXX (Serial Number)
Radiation Symbol
or
Radioactive

For the C-1001
NII or MDSN or BTL
Cs137E
C1001
XXXX (Serial Number)
Radioactive

For the C-3001
NII or MDSN or BTL
Cs137F
C3001
XXXX (Serial Number)
Radioactive

For the C3100
BTL
C3100
XXXX (Serial Number)
Cs137
Radiation Symbol
or
Radioactive

DEVICE TYPE: Gamma Irradiator

LABELING (Cont.):

The following is engraved on the outer surface of the C-378 sources:

MDSN or BTL
Cs137G
C378
XXXX (Serial Number)
RADIOACTIVE

DIAGRAMS:

Attachments 1 through **6**.

CONDITIONS OF NORMAL USE:

The Gammacell 1000, Gammacell 1000 Elite, and the Gammacell 3000 Elan are low dose rate irradiators designed to irradiate biological or other samples requiring low dose rate, (e.g., blood and blood components to eliminate small lymphocytes, sprout stimulation of seeds and tubers, non-sporulating bacteria and molds -- pasteurization and sterilizations, viruses, polymerization, etc.). The irradiators would be located in laboratory environments and will be used only by personnel trained in radiation safety.

PROTOTYPE TESTING:

The manufacturer claims that the devices comply with ANSI N433.1-1977. The Gammacell 1000 has been in use for over 15 years without any reported problems. The Gammacell 1000 Elite and 3000 Elan are essentially similar to the Gammacell 1000 and for this reason the manufacturer claims they are expected to perform with comparable reliability.

The RAMCO-50 and ISO-1000 sealed sources have passed special form tests conducted by the manufacturer, Oak Ridge National Laboratory. The C-1000 and C-3000 sealed sources have passed special form tests conducted by the manufacturer and have been tested to and received a rating of 77E65546 as per ANSI N542-

DEVICE TYPE: Gamma Irradiator

PROTOTYPE TESTING (Cont.):

1977. The C-1001 and C-3001 sealed sources have passed special form tests conducted by Amersham Corporation.

The C-378 sealed sources have passed special form tests performed by MDS Nordion and have achieved a rating of 96E64334(5)as per ANSI N43.6-1997. MDS Nordion subjected this sealed source model to a bend test to satisfy ISO 2919.1999(E) requirements.

The Model C3100 sealed sources were tested to IAEA special form requirements by Best Theratronics and have achieved an ISO 2919:2012 E65646 classification.

EXTERNAL RADIATION LEVELS:

MDS Nordion reported that the Gammacell 1000 has an average dose rate less than 0.5 mrem/hr (5 μSv/hr) at 1.97 inches (5 cm) from its surface when loaded with maximum activity.

The Gammacell 1000 Elite is self-shielded and can be safely operated in an existing lab environment. The manufacturer claims that with the secondary shielding installed the Gammacell 3000 Elan can be safely operated in an existing lab environment as well. When loaded with maximum activity the external radiation levels for these devices in the transient condition have been calculated by Nordion to be no greater than 5.0 mrem/hr (50 μSv/hr) at 1.97 inches (5.0 cm) from the accessible surface of the unit and 0.5 mrem/hr (5 μSv/hr) at 39.4 inches (100 cm) from the accessible surface of the unit.

With the devices in the "in use" or "not in use" condition the external radiation levels have been calculated by Nordion to be no greater than 1.0 mrem/hr (10 μSv/hr) at 1.97 inches (5 cm) from the accessible surface of the unit and 0.05 mrem/hr (0.5 μSv/hr) at 39.4 inches (100 cm) from the accessible surface of the unit.

DEVICE TYPE: Gamma Irradiator

QUALITY ASSURANCE AND CONTROL:

Best Theratronics maintains a quality assurance and control program **(QA/QC)** which has been deemed acceptable for licensing purposes by NRC **and is ISO 9001:2008 certified. The manufacture of Model C3100 sealed source is covered by Best Theratronics' QA/QC program.** A copy of the program is on file with the NRC.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The irradiators and sources shall be distributed only to persons specifically licensed by the NRC or an Agreement State.
- Handling, Storage, Use, Transfer, and Disposal: To be determined by the licensing authority.
- The irradiators shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.
- REVIEWER NOTE: The secondary shielding for the Gammacell 3000 Elan must be installed at the time of delivery to the user's facility and prior to the initial use of the device. This installation must be performed by Best Theratronics or persons specifically licensed by the NRC or an Agreement State to perform service on this device.
- **The Model C-1000, C-1001, C-3000, C-3001, C-378, and C3100 sealed sources are approved by the NRC for use in the Gammacell 1000 and Gammacell 3000 Series irradiators. These sources are not registered on a separate certificate.**
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A DEVICE
(AMENDED IN ITS ENTIRETY)

DEVICE TYPE: Gamma Irradiator

SAFETY ANALYSIS SUMMARY:

This certificate supersedes NR-0220-D-102-S. MDS Nordion has transferred the manufacture and distribution of these devices to Best Theratronics. The quality control programs remain the same and the technical capability to administer these programs has not been changed. The transfer is limited to the name change, no changes were made in the design, fabrication, or operating procedures.

The Gammacell 1000 was deemed acceptable for licensing purposes in 1979. At that time, the device was manufactured by Isomedix, Inc. and distributed by AECL.

The Gammacell 1000 Elite was deemed acceptable for licensing purposes in 1990. The unit has a simplified operation from that of the Gammacell 1000. The cavity door has been equipped with an interlock to prevent the sample chamber from rotating when the door is open. This reduces the risk of hand injuries and radiation exposure. The unit is more stable due to a lower center of gravity and larger base. No significant changes were made to the source housing as compared to the Gammacell 1000.

The Gammacell 3000 Elan is identical to the Gammacell 1000 Elite in operation and essentially similar in design. Slight changes in the sample chamber, source cavity, rotor and exterior appearance were made for the Gammacell 3000 Elan. These changes do not affect the safety of the device and do not significantly change the radiation profile of the unit. Since the Gammacell 1000 and Gammacell 1000 Elite were deemed acceptable for licensing and that the changes made do not affect the safety of the device, the Gammacell 3000 Elan is deemed acceptable for specific licensing purposes.

The C-1000 source is essentially similar to the ISO-1000 source. The C-3000 source is identical in construction to the C-1000 source, but with a slightly larger diameter and a higher activity. The C-1000 source has been subjected to tests sufficient to receive an ANSI N542-1977 rating of 77E65546 and by comparison the C-3000 source has received the same rating.

DEVICE TYPE: Gamma Irradiator

SAFETY ANALYSIS SUMMARY(Cont.):

For these reasons the C-1000 and C-3000 sources are deemed acceptable for use in the Gammacell 1000 Elite and Gammacell 3000 Elan.

The C-1001 source is essentially similar to the C-1000 source and the C-3001 source is essentially similar to the C-1001 source. The C-1001 and C-3001 sources are expected to be able to withstand similar conditions to the C-1000 and C-3000 sources.

The C-378 has an additional encapsulation of ISO-1000 approved source with a leak tested single outer shell. The C-378 sealed source has passed special form tests performed by MDS Nordion and have been tested to and achieved a rating of 96E64334(5) as per ANSI N43.6-1997.

The Model C3100 sealed source is a direct replacement of the Model C-3001 sealed source. The C3100 sealed source has passed special forms test performed by Best Theratronics and has been tested to and achieved an ISO 2919 classification of E65646. Based on our review of the information and test results provided by Best Theratronics we conclude that the Model C3100 sealed source is acceptable for licensing purposes when used in the Gammacell 1000 and Gammacell 3000 Series irradiators. Furthermore, we conclude that the Model C3100 source would be expected to maintain its integrity for normal and accidental conditions of use which might occur during uses specified in this certificate.

We **continue to** conclude that these devices and sources would be expected to maintain their containment integrity for normal conditions of use specified in this certificate.

DEVICE TYPE: Gamma Irradiator

REFERENCES:

The following supporting documents for the Gammacell 1000 research irradiator are hereby incorporated by reference and are made a part of this registry document.

- Isomedix, Inc. letters dated May 9, 1980 and June 11, 1980 with enclosures thereto.

- ORNL letter dated June 18, 1980. Atomic Energy of Canada, Ltd. letter dated June 2, 1983 with enclosures thereto.

The following supporting documents for the Gammacell 1000 Elite research irradiator are hereby incorporated by reference and are made a part of this registry document.

- Atomic Energy of Canada, Ltd. letter dated August 20, 1986 with enclosures thereto.

- Nordion International, Inc. letters dated December, 8, 1988 and April 11, 1990 with enclosures thereto.

The following supporting documents for the Gammacell 3000 Elan research irradiator, C-1000, and C-3000 sources are hereby incorporated by reference and are made a part of this registry document.

- Nordion International, Inc. letters dated September 5, 1991, September 24, 1991, November 4, 1991, December 17, 1991 and December, 20, 1991 with enclosures thereto.

- Nordion International, Inc. facsimile received November 22, 1991. MDS Nordion, Inc., letters dated September 25, 1997, and January 13, 1998, with enclosures thereto.

DEVICE TYPE: Gamma Irradiator

REFERENCES (Cont.):

The following supporting documents for the C-1001 and C-3001 sources are hereby incorporated by reference and are made a part of this registry document.

- Nordion International, Inc. letters dated June 4, 1993, and March 18, 1993, with enclosures thereto.
- Amersham Corporation's letter, in support of Nordion's application, dated December 16, 1992, with enclosures thereto.
- MDS Nordion, Inc., letters dated September 25, 1997, and January 13, 1998, with enclosures thereto.
- MDS Nordion letter dated December 14, 2001, requesting name and address change.MDS Nordion letter dated September 18, 2003, and electronic mail dated November 24, 2003, with enclosures thereto.

The following supporting documents for the C-378 sources are hereby incorporated by reference and are made a part of this registry document.

- MDS Nordion letters dated May 23, 2002, and September 16, 2002, with enclosures thereto.
- Best Theratronics letter dated March 20, 2008, with enclosures thereto.
- Best Theratronics letter and e-mail dated September 9, 2010, with enclosures thereto.
- Best Theratronics letters dated June 28, 2011, with enclosures thereto.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A DEVICE
(AMENDED IN ITS ENTIRETY)

DEVICE TYPE: Gamma Irradiator

REFERENCES (Cont.):

- Best Theratronics letters dated November 17, 2011, and April 27, 2012, with enclosures thereto.
- Best Theratonics emails dated April 27, 2012, with enclosures thereto.

The following supporting documents for the C3100 sources are hereby incorporated by reference and are made a part of this registry document.

- **Best Theratonics letters dated December 3, 2014 (ML15005A339), March 26, 2015 (ML15090A673), April 24, 2015 (ML15117A055), and May 1, 2015 (ML15124A003), with enclosures thereto.**

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

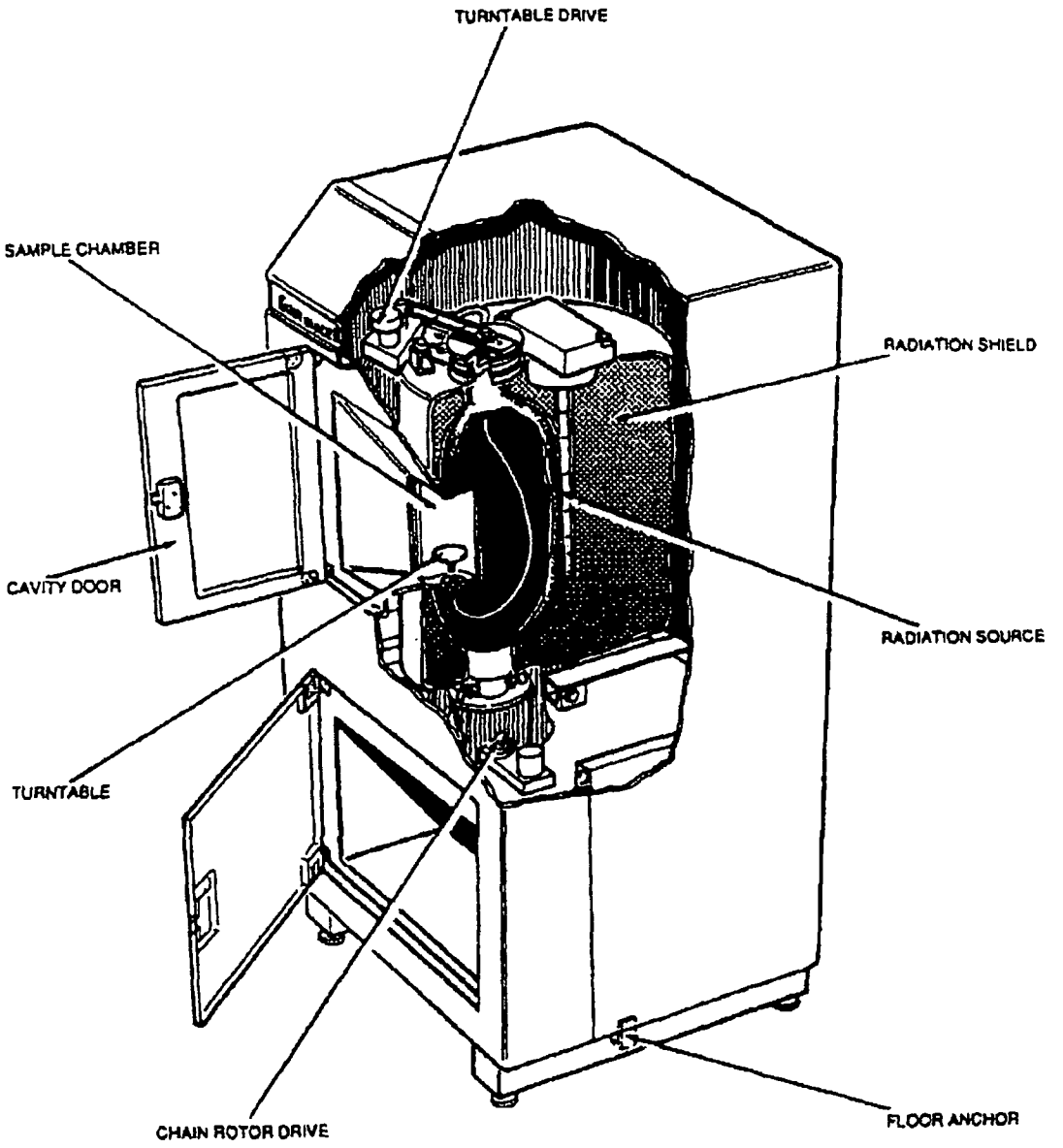
Date: May 15, 2015 Reviewer: Tomas Herrera
Tomas Herrera

Date: May 15, 2015 Concurrence:
Lymari Sepulveda

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-1307-D-102-S DATE: May 15, 2015 ATTACHMENT: 1 of 6

DEVICE TYPE: Gamma Irradiator



Model Gammacell 1000 Elite

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-1307-D-102-S DATE: May 15, 2015 ATTACHMENT: 2 of 6

DEVICE TYPE: Gamma Irradiator

Security-Related Information
Figure Withheld Under 10 CFR 2.390

Model Gammacell 3000 Elan

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-1307-D-102-S DATE: May 15, 2015 ATTACHMENT: 3 of 6

DEVICE TYPE: Gamma Irradiator

Security-Related Information
Figure Withheld Under 10 CFR 2.390

C-3000 Source Capsule **C-3001 Source Capsule**

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-1307-D-102-S DATE: May 15, 2015 ATTACHMENT: 4 of 6

DEVICE TYPE: Gamma Irradiator

Security-Related Information
Figure Withheld Under 10 CFR 2.390

ISO-1000 Source Capsule

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-1307-D-102-S DATE: May 15, 2015 ATTACHMENT: 5 of 6

DEVICE TYPE: Gamma Irradiator

Security-Related Information
Figure Withheld Under 10 CFR 2.390

C-378 Source Capsule

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-1307-D-102-S DATE: May 15, 2015 ATTACHMENT: 6 of 6

DEVICE TYPE: Gamma Irradiator

Security-Related Information Figure Withheld Under 10 CFR 2.390

C3100 Source Capsule