

12/3/2014

Materials Licensing Section
U.S. Nuclear Regulatory Commission
Region III
2443 Warrenville Road STE 210
Lisle, Illinois 60532-4352

Lic. No. 24-02490-03
Docket No. 030-02308

Dear Sir or Madam,

We are writing to request an amendment to our material license number 24-02490-03 at SSM DePaul Health Center. We would like to include Yttrium-90(Y-90) microspheres as MDS Nordion, Inc. Model Therasphere manufactured by Nordion(Canada) Inc. We request authorization for maximum possession limits of 4 Ci(148 GBq).

The Y-90 TheraSphere microsphere will be used at SSM DePaul Health Center and ordered and administered only by the Authorized users qualified. Specifically, we request to add Dr. Robert M. Fischer MD as Authorized User(35.1000) for Therapeutic administration of Y-90 TheraSphere microspheres.

Following the guidance on Microsphere Brachytherapy Sources and Devices Revised June 2012, Dr. Robert M. Fischer MD will attend and complete the supervised hand-on cases training provided by the vendor, Nordion-TheraSphere. Besides, Nordion-TheraSphere will provide Proctoring for the first three cases that will be conducted at SSM DePaul Health Center.

SSM DePaul Health Center will keep all commitments to be in compliance with the NRC Guidelines and requirements for radiation safety.

Also we have enclosed the Material License from Nordion(Canada) Inc.

Should you have any questions, please contact Joseph Pekala, Lead CNMT, for SSM DePaul Health Center at 314-447-5981.

Sincerely,



Ronald Palmer, M.D.
Radiation Safety Officer

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SSM HEALTH CARE — ST. LOUIS INCLUDES

Cardinal Glennon Children's Medical Center • DePaul Health Center • St. Clare Health Center • St. Joseph Health Center
St. Joseph Health Center — Wentzville • St. Joseph Hospital of Kirkwood • St. Joseph Hospital West • St. Mary's Health Center

Through our exceptional health care services, we reveal the healing presence of God.

MATERIALS LICENSE

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

<p>Licensee</p> <p>1. Nordion (Canada) Inc.</p> <p>2. 447 March Road Ottawa, Ontario, Canada K2K 1X8</p>	<p>In accordance with the letter dated November 22, 2010,</p> <p>3. License number 54-28275-02MD is amended in its entirety to read as follows:</p> <hr/> <p>4. Expiration date October 31, 2014</p> <hr/> <p>5. Docket No. 03030793 Reference No.</p>	
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Iodine 125</p> <p>B. Yttrium 90</p> <p>C. Iodine 125</p> <p>D. Yttrium 90</p> <p>E. Iodine 125</p> <p>F. Iodine 131</p> <p>G. Samarium 153</p> <p>H. Iodine 123</p> <p>I. Rubidium 82</p> <p>J. Strontium 82</p>	<p>7. Chemical and/or physical form</p> <p>A. Sealed sources (AECL/Nordion Model C-324/C-236 or C-235/C-236)</p> <p>B. Glass microspheres (MDS Nordion, Inc. Model TheraSphere)</p> <p>C. Any (Iotrex as part of the GliaSite RTS System)</p> <p>D. Any</p> <p>E. Any</p> <p>F. Any</p> <p>G. Any</p> <p>H. Any</p> <p>I. Any</p> <p>J. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. Not to exceed 3 curies per source</p> <p>B. Not to exceed 540 millicuries per administration set</p> <p>C. Not applicable</p> <p>D. Not applicable</p> <p>E. Not applicable</p> <p>F. Not applicable</p> <p>G. Not applicable</p> <p>H. Not applicable</p> <p>I. Not to exceed 150 millicuries per generator</p> <p>J. Not to exceed 150 millicuries per generator</p>

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number

54-28275-02MD

Docket or Reference Number

03030793

Amendment No. 09

K. Strontium 85

K. Any

K. Not to exceed 750 millicuries
per generator

9. Authorized use:

- A. Pursuant to 10 CFR 32.74, the licensee is authorized to distribute the licensed material described in Items 6.A. and 7.A. of this license to persons licensed pursuant to 10 CFR Part 35.500, or under equivalent licenses of any Agreement State.
- B. and C. Pursuant to 10 CFR 32.74, the licensee is authorized to distribute the licensed material described in Items 6.B, 7.B., 6.C. and 7.C. of this license to persons licensed pursuant to 10 CFR Part 35.1000, or under equivalent licenses of any Agreement State.
- D. through G. Pursuant to 10 CFR 32.72, the licensee is authorized to distribute the licensed material described in Items 6 and 7 of this license to persons licensed pursuant to 10 CFR 35.100, 35.200, 35.300 or under equivalent licenses of any Agreement State.
- H. Pursuant to 10 CFR 32.72, the licensee is authorized to distribute the licensed material described in Items 6 and 7 of this license to persons licensed pursuant to 10 CFR 35.100, 35.200 or under equivalent licenses of any Agreement State.
- I. through K. Pursuant to 10 CFR 32.72, the licensee is authorized to distribute the licensed material described in Items 6 and 7 of this license to persons licensed pursuant to 10 CFR 35.200 or under equivalent licenses of any Agreement State.

CONDITIONS

10. The licensee may distribute material from 447 March Road, Ottawa, Ontario, Canada and 4004 Westbrook Mall, Vancouver, British Columbia, Canada.
11. This license does not authorize possession or use of licensed material.
12. Notwithstanding 10 CFR 32.72 (a)(4)(ii) the licensee may label I-131 monoclonal antibody product in accordance with their letter dated November 24, 2005.

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
54-28275-02MDDocket or Reference Number
03030793

Amendment No. 09

13. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

- A. Application dated February 22, 1994
- B. Letter dated September 14, 1994
- C. Letter dated September 26, 1994
- D. Letter dated October 31, 1995
- E. Letter dated March 27, 1996
- F. Letter dated April 3, 1996
- G. Letter dated August 14, 2001
- H. Letter dated September 20, 2001
- I. Letter dated November 7, 2001
- J. Letter dated May 6, 2004
- K. Letter dated November 24, 2005 (ML05342050)
- L. Letter dated January 4, 2010 (ML100082108)



For the U.S. Nuclear Regulatory Commission

Date March 9, 2011

By

Dennis R. Lawyer
Commercial and R&D Branch
Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Wednesday, March 9, 2011 10:49:26

DePaul Health Center
Radiology Department-3rd Floor
12303 DePaul Drive
Bridgeton, MO 63044

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XX DEC-04-14 ST. LOUIS MO 631 RETURN SERVICE REQUESTED

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