



nordion
SCIENCE ADVANCING HEALTH

Br. 1

September 11, 2017

Penny Lanzisera, Licensing Assistance Team
Division of Nuclear Materials Safety Branch
U.S. Nuclear Regulatory Commission, Region 1
2100 renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

SUBJECT: Submitting Revised Lead-Pot Label for TheraSphere Distributed Under
NRC License No. 54-28275-02MD 03030793

Dear Ms. Lanzisera,

TheraSphere is currently distributed in the United States by Nordion under NRC Materials License No. 54-28275-02MD. This letter is to inform the NRC that the reference on compliance found on the Lead-Pot label is in process of being revised.

The revised reference on compliance has been approved by the NRC's Office of Material Safety, State, Tribal, and Rulemaking Programs and a revised Sealed Source and Device Registration will imminently be issued by that program.

DETAILS:

The current TheraSphere Lead-Pot label references compliance with various sections of 10 CFR Part 35, namely 35.57, 35.400 and 35.500. The references are historical and are not necessarily indicative of the full or current compliance requirements. Nordion wishes to revise the reference on the Lead-Pot label. The current and revised wordings are provided below.

REC'D IN LAT.

600884

NM59/RGN1 MATERIALS-002



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Current Wording

The U.S. Nuclear Regulatory Commission has approved distribution of TheraSphere to persons licensed to use byproduct material identified in 35.57, 35.400 and 35.500, as appropriate and to persons who hold an equivalent license issued by an Agreement State.

Revised Wording

The U.S. Nuclear Regulatory Commission has approved distribution of TheraSphere to persons licensed to use byproduct material under Title 10 of the Code of Federal regulations Part 35 as appropriate and to persons who hold an equivalent license issued by an Agreement State.

A copy of the revised Lead-Pot label is appended to this letter.

Thank you for your consideration of this matter. Should you have any questions, please do not hesitate to contact me by telephone (613) 592-3400 ext. 2108 or by fax (613) 592-2006 or by email: Luc.Desgagne@nordion.com.

Sincerely,

Luc Desgagné
Senior Licensing Coordinator
Licensing & Compliance
Nordion (Canada) Inc.

Encl:

Label proof for TheraSphere Commercial Dose
Label proof for TheraSphere Clinical Dose



APPLICATION FOR MATERIALS LICENSE

Estimated burden per response to comply with this mandatory collection request: 4.3 hours. Submittal of the application is necessary to determine that the applicant is qualified and that adequate procedures exist to protect the public health and safety. Send comments regarding burden estimate to the FOIA, Privacy and Information Collections Branch (T 5 F53), U.S. Nuclear Regulatory Commission, Washington, DC 20555-0001 or by e-mail to InfoCollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NE08-10202, (3150-0120), Office of Management and Budget, Washington, DC 20503. If a means used to impose an information collection does not display a currently valid OMB control number, the NRC may not conduct or sponsor, and a person is not required to respond to, the information collection.

INSTRUCTIONS: SEE THE CURRENT VOLUMES OF THE NUREG-1556 TECHNICAL REPORT SERIES ("CONSOLIDATED GUIDANCE ABOUT MATERIALS LICENSES") FOR DETAILED INSTRUCTIONS FOR COMPLETING THIS FORM: http://www.nrc.gov/reading_rm/doc_collections/nuregs/staff/nc1556/. SEND TWO COPIES OF THE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

MATERIALS SAFETY LICENSING BRANCH
DIVISION OF MATERIAL SAFETY, STATE TRIBAL AND RULEMAKING PROGRAMS
OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION
WASHINGTON, DC 20555-0001

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS:

IF YOU ARE LOCATED IN:

ALABAMA, CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, FLORIDA, GEORGIA, KENTUCKY, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, NORTH CAROLINA, PENNSYLVANIA, PUERTO RICO, RHODE ISLAND, SOUTH CAROLINA, TENNESSEE, VERMONT, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA,

SEND APPLICATIONS TO:

LICENSING ASSISTANCE TEAM
DIVISION OF NUCLEAR MATERIALS SAFETY
U.S. NUCLEAR REGULATORY COMMISSION REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION REGION II
2443 WARRENVILLE ROAD, SUITE 210
LISLE IL 60532-4352

ALASKA, ARIZONA, ARKANSAS, CALIFORNIA, COLORADO, HAWAII, IDAHO, KANSAS, LOUISIANA, MISSISSIPPI, MONTANA, NEBRASKA, NEVADA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, OREGON, PACIFIC TRUST TERRITORIES, SOUTH DAKOTA, TEXAS, UTAH, WASHINGTON, OR WYOMING,

SEND APPLICATIONS TO:

NUCLEAR MATERIALS LICENSING BRANCH
U.S. NUCLEAR REGULATORY COMMISSION REGION V
1600 E LAMAR BOULEVARD
ARLINGTON TX 76011-4511

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTIONS.

1 THIS IS AN APPLICATION FOR (Check appropriate item)

- A NEW LICENSE
- B. AMENDMENT TO LICENSE NUMBER 54-28275-02MD
- C RENEWAL OF LICENSE NUMBER _____

2 NAME AND MAILING ADDRESS OF APPLICANT (Include ZIP code)

Nordion (Canada) Inc.
447 March Rd.
Ottawa, Ontario, Canada
K2k 1X8

3 ADDRESS WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Anywhere in the United States where the NRC has jurisdiction.

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

Luc Desgagne

BUSINESS TELEPHONE NUMBER

(613) 592-3400

BUSINESS CELLULAR TELEPHONE NUMBER

BUSINESS EMAIL ADDRESS

luc.desgagne@nordion.com

SUBMIT ITEMS 5 THROUGH 11 ON 8-1/2 X 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5 RAD OACTIVE MATERIAL

a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7 INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS.

9 FACILITIES AND EQUIPMENT

10 RAD IATION SAFETY PROGRAM.

11 WASTE MANAGEMENT

12 LICENSE FEES (Fees required only for new applications, with few exceptions*) (See 10 CFR 170 and Section 170.31)

*Amendments/Renewals that increase the scope of the existing license to a new or higher fee category will require a fee.

FEE CATEGORY

none

AMOUNT ENCLOSED \$

13 CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2 CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, 36, 37, 39, AND 40, AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF
WARNING 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

CERTIFYING OFFICER - TYPED/PRINTED NAME AND TITLE

Richard Wassenaar, Senior Manager Transportation Licensing and Radiation Safety

SIGNATURE

DATE

Sept 12/17


FOR NRC USE ONLY

TYPE OF FEE	FEE LOG	FEE CATEGORY	AMOUNT RECEIVED	CHECK NUMBER	COMMENTS
			\$		
APPROVED BY				DATE	

SUPPLEMENTARY PAGES FOR ITEMS 5-11 FORM 313

Items 5 to 11 of Form 313:

There are no changes pertaining to Items 5 to 11 of Form 313.



Proof # 2
 Client: Nordion (Canada) Inc
 Item #: 10094908
 M.S.F.#: 347347
 Date: July 7, 2017
 Proof not for colour accuracy.

GRAPHICS

1st : Checked by:

2nd : Checked by:

PLEASE NOTE!
 CCL LABEL CAN NOT PRINTED WITH THIS
 BACKS WITHOUT FIRST PRINTING ON THE
 FRONT. CCL LABEL WILL NOT BE REPRINTED
 FOR ANY REASON IN ANY CASE OR IN THE
 FUTURE. AFTER THE PROOF HAS BEEN
 APPROVED ANY REQUESTS (CHANGES) IN
 THE ORIGINAL ORDER WILL BE REJECTED. CCL
 LABELS WILL BE PRINTED IN STANDARD COLORS
 (CMYK) UNLESS OTHERWISE SPECIFIED. THESE
 APPROVALS DO NOT MEAN THAT THE LABELS
 WILL BE PRINTED IN THE BEST QUALITY
 THAT CAN BE OBTAINED.

APPROVED NEW PROOF REQUIRED

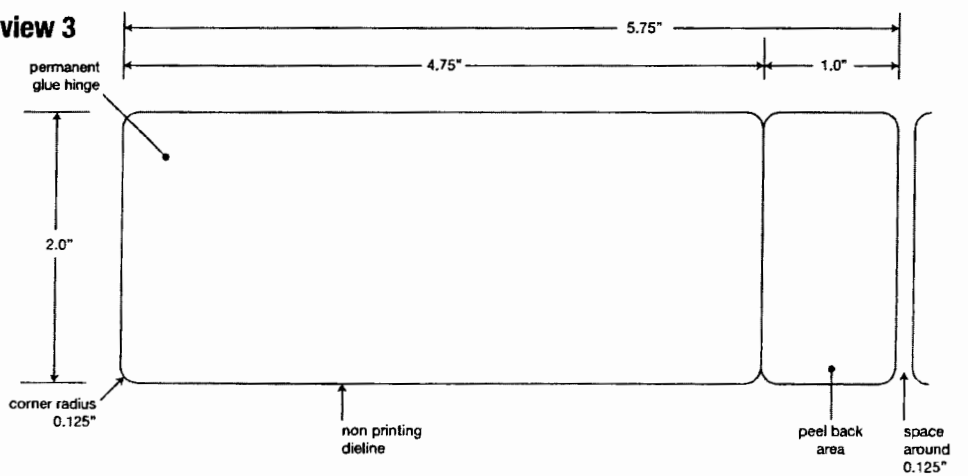
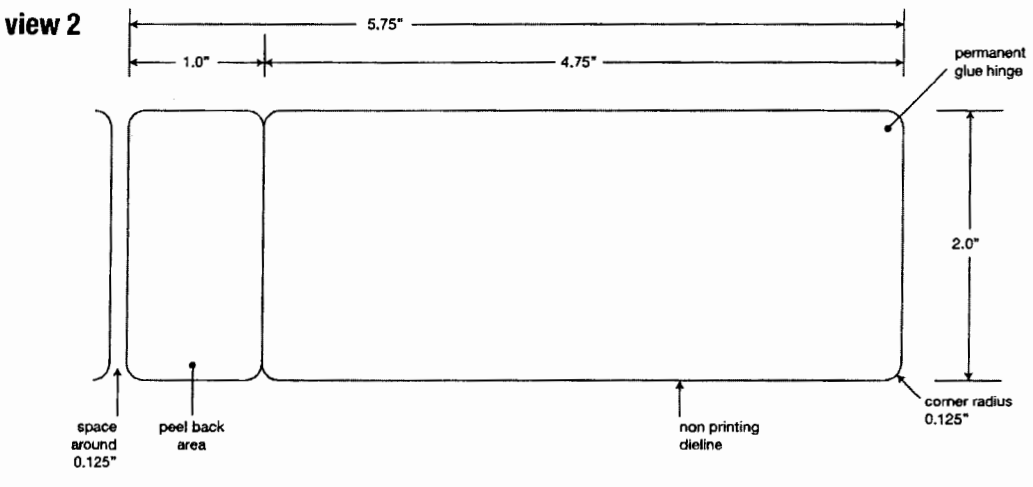
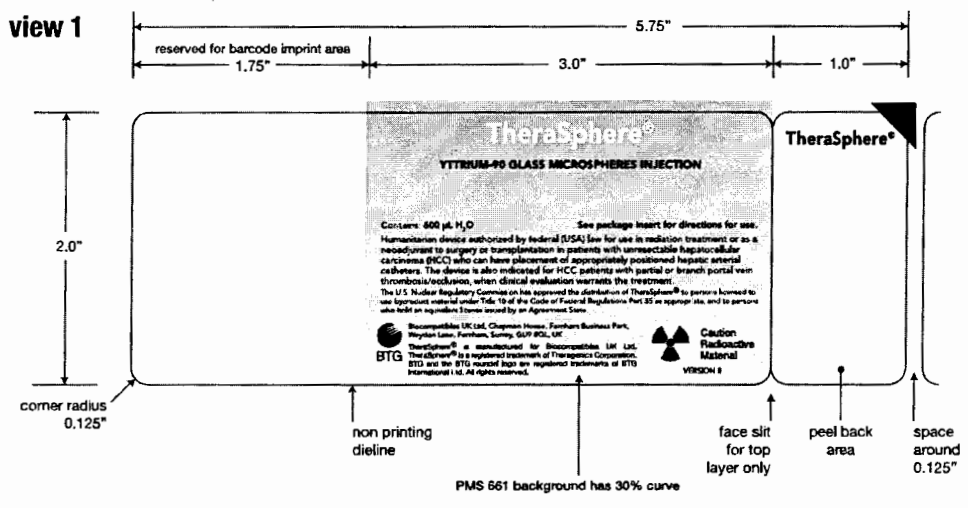
DATE	AUTHORIZED SIGNATURE
	<i>Janet Buller</i>


17 JUL 17

Esiko Xref:

To keep your order on schedule for delivery, please approve this PDF by: **July 12/17**

To keep your order on schedule for delivery, PLEASE RETURN THIS PROOF by:





Proof # 2
 Client: Nordion (Canada) Inc
 Item #: 10094907
 M.S.F.#: 347346
 Date: July 7, 2017
 Proof not for colour accuracy.

GRAPHICS

1st : Checked by:

2nd : Checked by:

APPROVED NEW PROOF REQUIRED

DATE	AUTHORIZED SIGNATURE
*	<i>Janet Bullock</i>

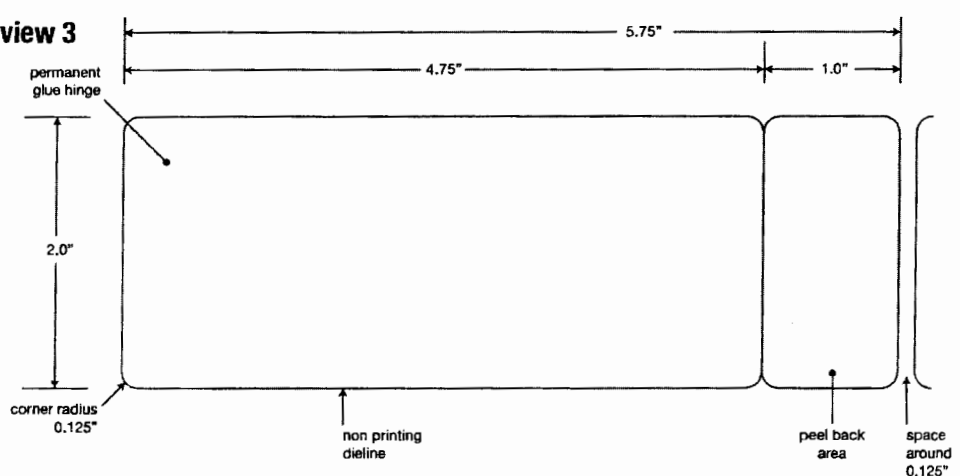
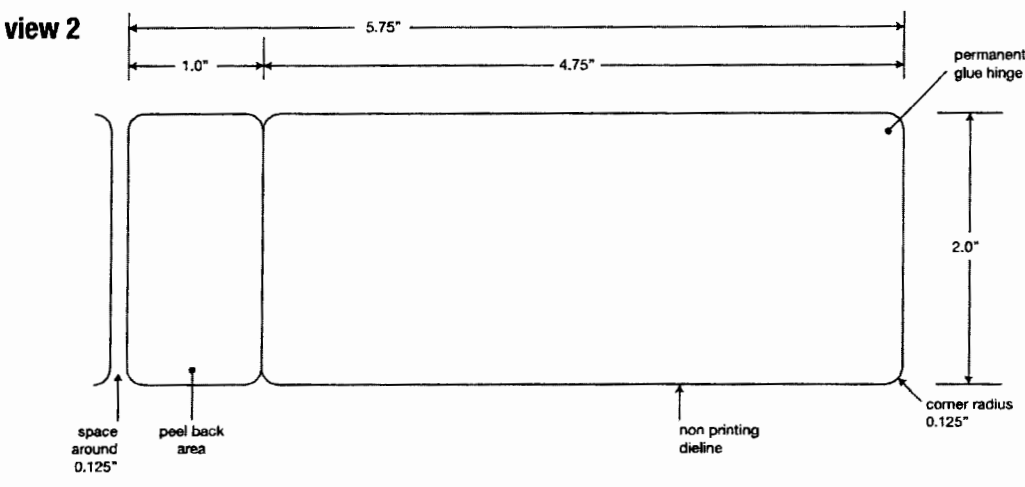
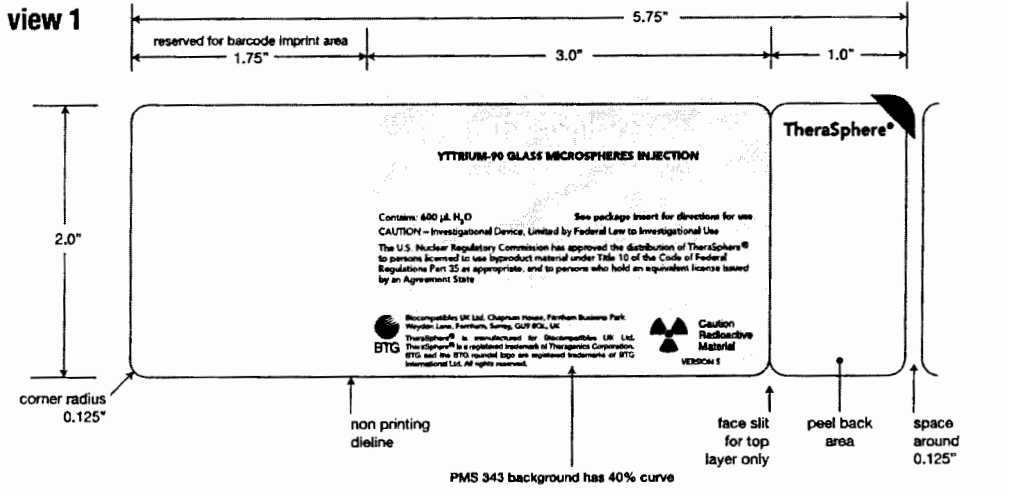
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PLEASE NOTE:
 ALL SALES FOR THE PROCEED WITH THIS MUST BE MADE WITHIN YOUR BUSINESS OR THE FIRST 30 DAYS. ALL SALES WILL BE THE RESPONSIBILITY OF THE SALES. IN RESPONSE TO THE PROOF AFTER THE PROOF HAS BEEN APPROVED AND REJECTED. CHANGES TO YOUR ORIGINAL APPROVALS WILL BE THE RESPONSIBILITY OF THE SALES. ALL CHANGES TO YOUR ORIGINAL APPROVALS WILL BE THE RESPONSIBILITY OF THE SALES. ALL CHANGES TO YOUR ORIGINAL APPROVALS WILL BE THE RESPONSIBILITY OF THE SALES. ALL CHANGES TO YOUR ORIGINAL APPROVALS WILL BE THE RESPONSIBILITY OF THE SALES.

To keep your order on schedule for delivery, please approve this PDF by: **July 12/17**

To keep your order on schedule for delivery, PLEASE RETURN THIS PROOF by:

Erko Xref



TO VIEW OVERPRINT PREVIEW, ACTIVATE WITHIN YOUR APPLICATION PREFERENCES Operator: cp

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, 37, 39, 40, 70 and 71, 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>In accordance with letter dated</p> <p>May 10, 2016</p>	<p>4. Expiration Date: March 31, 2025</p>
<p>2. 447 March Road Ottawa, Ontario, CN K2K 1X8</p>	<p>3. License number: 54-28275-02MD is amended in its entirety to read as follows:</p>	<p>5. Docket No.: 030-30793 Reference No.:</p>
<p>6. Byproduct, source, and/or special nuclear material</p> <p>A. Iodine-123</p> <p>B. Iodine-125</p>	<p>7. Chemical and/or physical form</p> <p>A. Any</p> <p>B. Any</p>	<p>8. Maximum amount that licensee may possess at any one time under this license</p> <p>A. No Possession Authorized</p> <p>B. No Possession Authorized</p> <p>9. Authorized use</p> <p>A. In accordance with 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 in accordance with 10 CFR 35.100, 35.200, 35.300, or under equivalent licenses of any Agreement State.</p> <p>B. In accordance with 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 in accordance with 10 CFR 35.100, 35.200, 35.300, or under equivalent licenses of any Agreement State.</p>

**MATERIALS LICENSE
SUPPLEMENTARY SHEET**

License Number
54-28275-02MD

Docket or Reference Number
030-30793

Amendment No. 13

6. Byproduct, source,
and/or special nuclear
material

C. Iodine-131

D. Yttrium-90

E. Cobalt-60

7. Chemical and/or physical form

C. Any

D. Microspheres (Nordion
(Canada), Inc., Model
Therasphere),

E. Sealed Sources
(Nordion(Canada), Inc., Model
C-375)

8. Maximum amount that licensee
may possess at any one time
under this license

C. No Possession
Authorized

D. No Possession
Authorized

E. No Possession
Authorized

9. Authorized use

C. In accordance with 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 in accordance with 10 CFR 35.100, 35.200, 35.300, or under equivalent licenses of any Agreement State.

D. In accordance with 10 CFR 32.74, the licensee is authorized to distribute the licensed material described in Items 6 and 7 of this license to persons licensed in accordance with 35.1000, or under equivalent licenses of any Agreement State.

E. In accordance with 10 CFR 32.74, the licensee is authorized to distribute the licensed material described in Items 6 and 7 of this license to persons licensed in accordance with 35.1000, or under equivalent licenses of any Agreement State.

CONDITIONS

10. The licensee may distribute material from 447 March Road, Ottawa, Ontario, Canada and 4004 Wesbrook Mall, Vancouver, British Columbia, Canada.

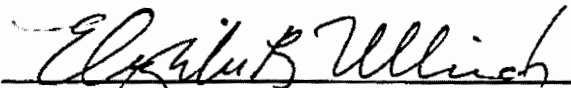
**MATERIALS LICENSE
SUPPLEMENTARY SHEET**License Number
54-28275-02MDDocket or Reference Number
030-30793

Amendment No. 13

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- 31 monoclonal antibody product in accordance with their letter dated November 24, 2005.
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 September 23, 2014 [ML14279A523]
 - B. Letter dated February 25, 2015 [ML15071A409]
 - C. Letter dated March 18, 2015 [ML15086A153]
 - D. Letter dated March 30, 2015 [ML15090A161]
 - E. Letter dated May 19, 2015 [ML15159A919]

Date: August 11, 2016

FOR THE U.S. NUCLEAR REGULATORY COMMISSION

By: 
Elizabeth Ullrich
Region I



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Jackie Kavanagh
Senior Manager
Nordion (Canada) Inc.
447 March Road
Ottawa, ON K2K 1X8
Canada

Date

September 13, 2017

License Number(s)

54-28275-02MD

Mail Control Number(s)

600884

Licensing and/or Technical Reviewer or Branch

Medical Branch

This is to acknowledge receipt of your: Letter and/or Application Dated: 9/11/2017

The initial processing, which included an administrative review, has been performed.

Amendment Termination New License Renewal

There were no administrative omissions identified during our initial review.

This is to acknowledge receipt of your application for renewal of the material(s) license identified above. Your application is deemed timely filed, and accordingly, the license will not expire until final action has been taken by this office.

Your application for a new NRC license did not include your taxpayer identification number. Please complete and submit NRC Form 531, Request for Taxpayer Identification Number, located at the following link: <http://www.nrc.gov/reading-rm/doc-collections/forms/nrc531.pdf>
Follow the instructions on the form for submission.

The following administrative omissions have been identified:

[Empty box for administrative omissions]

Your application has been assigned the above listed MAIL CONTROL NUMBER. When calling to inquire about this action, please refer to this control number. Your application has been forwarded to a technical reviewer. Please note that the technical review, which is normally completed within 180 days for a renewal application (90 days for all other requests), may identify additional omissions or require additional information. If you have any questions concerning the processing of your application, our contact information is listed below:

Region I
U. S. Nuclear Regulatory Commission
Division of Nuclear Materials Safety
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, (610) 337-5239