NRC FORM 313 (03-2014) 10 CFR 30, 32, 33, 34 35, 36, 37, 39, and 40

U.S. NUCLEAR REGULATORY COMMISSION

APPLICATION FOR MATERIALS LICENSE

APPROVED BY OMB: NO. 3150-0120 EXPIRES: 05/31/2015

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 internet e-mail to Infocollects.Resource@nrc.gov, and to the Desk Officer, Office of Information and Regulatory Affairs, NEOB-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 APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW. *AMENDMENTS/RENEWALS THAT INCREASE THE SCOPE OF THE EXISTING LICENSE TO A NEW OR HIGHER FEE CATEGORY WILL REQUIRE A FEE.

APPLICATION FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

OFFICE OF FEDERAL & STATE MATERIALS AND
ENVIRONMENTAL MANAGEMENT PROGRAMS
DIVISION OF MATERIALS SAFETY AND STATE AGREEMENTS
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 III
2443 WARRENVILLE ROAD, SUITE 210
LISLE, IL 60532-4352

Br. 1
03030793

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 IV
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
- [x] B. AMENDMENT TO LICENSE NUMBER 54-28275-02MD
- [ ] C. RENEWAL OF LICENSE NUMBER

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

Nordion (Canad) Inc.
447 March Road
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. RADIOACTIVE 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 EXPERIENCE.

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

9. FACILITIES AND EQUIPMENT.

10. RADIATION 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)* FEE CATEGORY _____ 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 CONTANED 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 C RIMINAL 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	SIGNATURE	DATE
Jackie Kavanagh Senior Manager, EHS Compliance Facility and Transport Licensing	J. Kavanagh	15/06/01

FOR NRC USE ONLY

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

NRC FORM 313 (03-2014)

5-88169
NMSS/RGN1 MATERIALS-002

nordion
SCIENCE ADVANCING HEALTH

June 1, 2015

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: REQUEST TO AMEND MATERIALS LICENSE NO. 54-28275-02MD

To Whom This May Concern,

Please find enclosed a request to amend our NRC License 54-28275-02MD.

This amendment request is in regards to this one item only:

1- Please remove Condition 12 listed on license 54-28275-02MD.

To this effect and as per NRC's Ms. Robin Elliott's instructions attached (email dated June 1, 2015), please find the email correspondence (and its FDA attachment) between FDA and NRC regarding the FDA confirmation that Nordion (Canada) Inc. is registered with the FDA under 21 CFR 207.20(a).

Should you have additional 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.

CC Jackie Kavanagh, Greg Fulford, Nordion

Desgagne, Luc

From: Elliott, Robin [Robin.Elliott@nrc.gov]
Sent: Monday, June 01, 2015 7:59 AM
To: Fulford, Greg
Cc: Desgagne, Luc; Lanzisera, Penny
Subject: FW: Nordion Canada, Inc.
Attachments: Nordion Canada May 22 2015.xls

Good Morning Greg,

Thanks for following up on the license condition regarding your registration with the FDA. Unfortunately, just sending the web link is not adequate.
Please print off the email and attachment below which contains verification from FDA of your registration, and send it in with a cover letter signed by a management representative requesting License Condition 12 be removed. If you have any questions, feel free to direct them to me.

Regards,
Robin

From: CDER Electronic Drug Registration and Listing [mailto:EDRLS@fda.hhs.gov]
Sent: Friday, May 22, 2015 12:31 AM
To: Elliott, Robin
Subject: RE: Nordion Canada, Inc.

Robin Elliott:

This is verification of the status for Nordion (Canada) Inc. that is registered with FDA , in the eDRLs database, provided in the attachment above.

Please contact us, if we can be of further assistance
eDRLs team
LK

CDER Direct is the user-friendly alternative to x-form/Pragamatic for electronic portal for Structured Product Labeling (SPL) submissions to the U.S Food and Drug Administration (FDA). The portal supports the goal of the Center for Drug Evaluation and Research (CDER) to provide a user friendly, web-based system for creating, reviewing, editing and SPL submissions.

You can create an account here - https://direct.fda.gov

If you have questions concerning Drug Registration and Listing please send an email to edrls@fda.hhs.gov.

For questions relating to SPL errors please send an email to SPL@fda.hhs.gov.
For Electronic Submission Gateway questions or issues please send an email to esghelpdesk@fda.hhs.gov.

From: Elliott, Robin [mailto:Robin.Elliott@nrc.gov]
Sent: Thursday, May 21, 2015 7:13 AM
To: CDER Electronic Drug Registration and Listing

Cc: Lanzisera, Penny
Subject: RE: Nordion Canada, Inc.

Can you please tell me if you provide anything in writing to registrants as evidence of their registration?

Or is listing on your site the only evidence of their registration.

Thank you,
Robin

From: CDER Electronic Drug Registration and Listing [mailto:EDRLS@fda.hhs.gov]
Sent: Tuesday, May 19, 2015 11:05 AM
To: Elliott, Robin
Subject: RE: Nordion Canada, Inc.

Robin L. Elliott:

This is a verification for the status of Nordion (Canada) Inc. is registered with the FDA in the eDRLs database and does meet the requirement for registration for the following statement below:

"Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacturer, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a)."

Please contact us, if we can be of further assistance
eDRLs team
LK

CDER Direct is the user-friendly alternative to x-form/Pragamatic for electronic portal for Structured Product Labeling (SPL) submissions to the U.S Food and Drug Administration (FDA). The portal supports the goal of the Center for Drug Evaluation and Research (CDER) to provide a user friendly, web-based system for creating, reviewing, editing and SPL submissions.

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For questions relating to SPL errors please send an email to SPL@fda.hhs.gov.
For Electronic Submission Gateway questions or issues please send an email to esghelpdesk@fda.hhs.gov.

From: Elliott, Robin [mailto:Robin.Elliott@nrc.gov]
Sent: Tuesday, May 19, 2015 8:43 AM
To: CDER Electronic Drug Registration and Listing
Cc: Lanzisera, Penny; Howe, Donna-Beth
Subject: Nordion Canada, Inc.

Hello,

I am trying to verify the status of Nordion Canada, Inc.

with respect to their registration with the FDA.

We have asked them to verify that they have met the following requirement: "Registered with the U.S. Food and Drug Administration (FDA) as the owner or operator of a drug establishment that engages in the manufacturer, preparation, propagation, compounding, or processing of a drug under 21 CFR 207.20(a)."

They sent a screen shot of your site showing them as registered here. Does this registration meet the above stated requirement?

Thank you,

Robin L. Elliott
Health Physicist
U. S. Nuclear Regulatory Commission
Region I, Division of Nuclear Materials Safety
2100 Renaissance Blvd
King of Prussia, PA 19406-2713
(610) 337-5076 voice
(610) 337-5269 fax
Robin.Elliott@nrc.gov

This is to acknowledge the receipt of your letter/application dated 06/15/2015, and to inform you that the initial processing which includes an administrative review has been performed.

54-28275-02MD (amendment)

☒ There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

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A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 588169.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.

NRC FORM 532 (RI)
(6-96)

Sincerely,
Licensing Assistance Team Leader