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03030788

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03030793

October 17, 2018

Arthur Burritt, Chief
Commercial, Industrial, R&D, and Academic Branch
Division of Nuclear and Materials Safety
U.S. Nuclear Regulatory Commission, Region I
2100 Renaissance Boulevard, Suite 100
King of Prussia, PA 19406-2713

SUBJECT: RADIOACTIVE MATERIALS LICENSE
LICENSE NOS. 54-28275-01 & 54-28275-02MD
DOCKET NOS. 03030788 & 03030793

APPLICATION FOR CONSENT TO THE TRANSFER OF CONTROL OF
RADIOACTIVE MATERIAL LICENSES

Dear Mr. Burritt:

In accordance with Section 184 of the Atomic Energy Act of 1954, as amended, and 10 C.F.R. § 30.34(b), Nordion (Canada) Inc. ("Nordion"), on behalf of itself and the proposed future corporate entity of the same name, hereby submits the enclosed application ("Application") requesting that the U.S. Nuclear Regulatory Commission ("NRC") consent to the transfer of control of Materials Licenses 54-28275-01, Docket No. 03030788, and 54-28275-02MD, Docket No. 03030793 (the "Licenses"). Nordion respectfully requests that the NRC review and complete action expeditiously on the enclosed Application as promptly as possible and by no later than November 30, 2018.

The transfer of control would result from a planned internal corporate reorganization whereby Nordion will be merged with its parent company, 8921903 Canada, Inc. and several other non-licensee affiliated companies. The resulting merged entity will also be named Nordion (Canada) Inc., but the existing Nordion (Canada) Inc. will not be the surviving company. Thus, a new corporate entity will assume the Licenses. Importantly, the new entity will have the same name, same address, same personnel, and the same ultimate owners as the existing company. As such, there is no need for any amendment to the Licenses.

There will be no change to how the new Nordion corporate entity manages any of the activities involving the byproduct materials authorized under the Licenses. It will continue to have the same equipment, facilities, personnel, and procedures needed to comply with all of its obligations under its Licenses to protect public health and safety. Current Nordion employees

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responsible for licensed materials and activities will continue to be responsible for such materials and activities after the completion of the reorganization. Accordingly, the new Nordion corporate entity will remain technically qualified as the licensee and will continue to fulfill all responsibilities as the licensee.

The current pre-merger organization structure of Nordion is reflected in the attached Figure 1. Figure 2 depicts the post-merger organization structure.

Nordion is a Canadian company headquartered in Ottawa, Ontario and is a leading global provider of gamma technologies. Nordion's gamma technologies business focuses on the prevention of disease through sterilizing medical products and devices, as well as food and consumer products. Nordion produces and installs Cobalt-60 ("Co-60") radiation sources for gamma sterilization systems.

The Canadian Nuclear Safety Commission ("CNSC") regulates Nordion's licensed radioactive materials activities in Canada. For activities in the U.S., Nordion holds the two NRC-issued materials licenses listed above. Under NRC Materials License No. 54-28275-01, Nordion is authorized to distribute Co-60 in sealed sources to persons authorized to receive the licensed material for installation and/or removal from irradiators, radiation surveys of irradiators and facilities, leak testing of sealed sources, installing, relocating, removing, repairing or maintaining irradiator units, and for training personnel in the operation of irradiator units. Under NRC Materials License No. 54-28275-02MD, Nordion is authorized to distribute certain byproduct materials to specific licensees in the United States. The byproduct materials covered by License 54-28275-02MD are Iodine-123, Iodine-125, Iodine-131, Yttrium-90, and Cobalt-60.

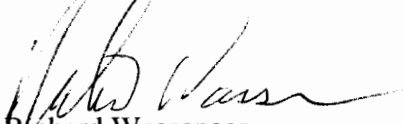
Nordion also holds Export License No. PXB3.10, which authorizes Nordion to export to Nordion's facility in Canada, Category 1 and Category 2 quantities of Co-60, contained in sealed sources used in the irradiators it services at customers' sites in the United States. Nordion is seeking NRC consent to the transfer of control of this license via a separate application filed with the NRC's Office of International Programs.

In summary, the proposed internal corporate reorganization and transfer of the Licenses will not be inimical to the common defense and security or result in any undue risk to public health and safety, and the transfer will be consistent with the requirements of the Atomic Energy Act and NRC regulations.

If the NRC has any questions about the proposed internal corporate reorganization described in this letter or the Application, or wishes to obtain any additional information about the transfer of the Licenses, please contact me at (613) 592-3400 ext. 2539.

I declare under penalty of perjury that the foregoing is true and correct. Executed on the 17th day of October 2018.

Respectfully,

A handwritten signature in black ink, appearing to read "Richard Wassenaar", written over a horizontal line.

Richard Wassenaar
Director, Regulatory and EHS
Nordion (Canada) Inc.

Figures 1&2: Pre- and Post-Reorganization Structures

Attachment 1: Application Requesting U.S. Nuclear Regulatory Commission Approval of
Transfer of Control of Licenses

FIGURE 1: PRE-MERGER ORGANIZATION CHART

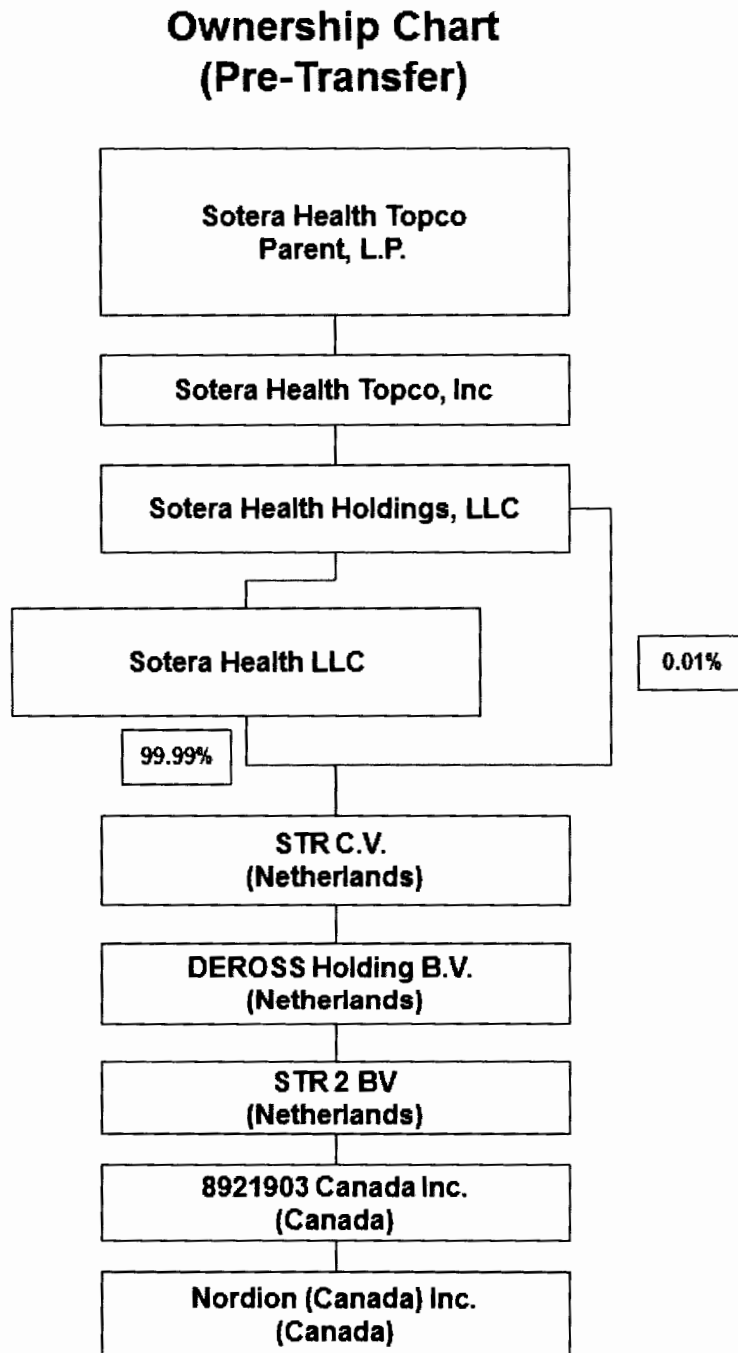
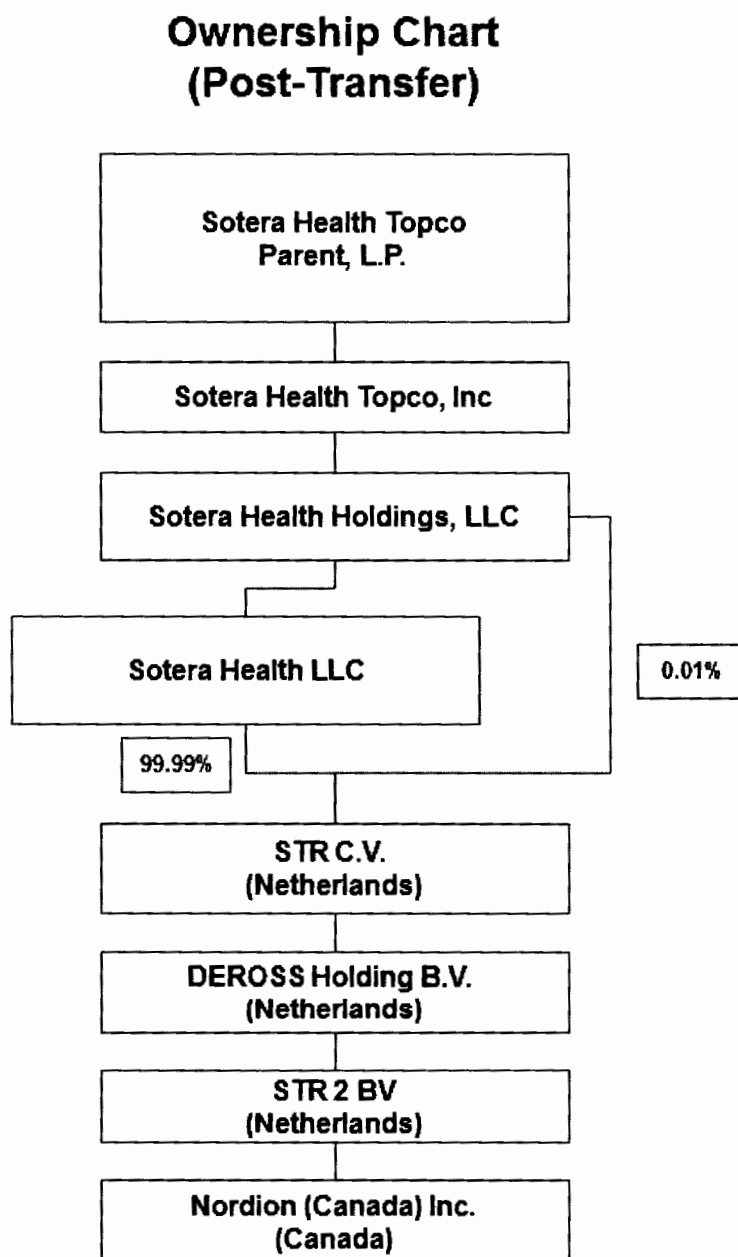


FIGURE 2: POST-MERGER ORGANIZATION CHART



ATTACHMENT 1

**Application Requesting U.S. Nuclear Regulatory Commission
Approval of Transfer of Control of Licenses**

**Material License No. 54-28275-01
Material License No. 54-28275-02MD**

This Application is submitted pursuant to Section 184 of the Atomic Energy Act of 1954, as amended, and the NRC's implementing regulations in 10 C.F.R. § 30.34(b). The Application follows NRC Guidance provided in NUREG-1556, Volume 15, Rev. 1, Consolidated Guidance About Materials Licenses: Guidance about Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses (June 2016) and Regulatory Issue Summary (RIS) 2014-08, Revision 1, "Regulatory Requirements for Transfer of Control (Change of Ownership) of Specific Materials Licenses," (May 5, 2016).

5.1 DESCRIPTION OF TRANSACTION

A complete, clear description of the transaction, including the identity and the technical and financial qualifications of the proposed transferee and financial assurance for decommissioning information. The required description includes, but is not limited to, any transfer of stocks or assets, or mergers.

In accordance with Section 184 of the Atomic Energy Act of 1954, as amended, and 10 C.F.R. § 30.34(b), Nordion (Canada) Inc. ("Nordion" or "Licensee") hereby submits the enclosed application ("Application") requesting that the U.S. Nuclear Regulatory Commission ("NRC") consent to the transfer of control of Materials License Nos. 54-28275-01, Docket No. 03030788, and 54-28275-02MD, Docket No. 03030793 (the "Licenses").

The transfer of control would result from a proposed internal corporate reorganization whereby Nordion will be merged with its parent company, 8921903 Canada, Inc., and several other non-licensee affiliated companies. The resulting merged entity will also be named Nordion (Canada) Inc., but the existing Nordion (Canada) Inc. will not be the surviving company. Thus, a new corporate entity will assume the Licenses. Importantly, the new entity will have the same name, same address, same personnel, and the same ultimate owners as the existing company. As such, there is no need for any amendment to the Licenses.

There will be no change to how the new Nordion corporate entity manages any of the activities involving the byproduct materials authorized under the Licenses. It will continue to have the same equipment, facilities, personnel, and procedures needed to comply with all of its obligations under its Licenses to protect public health and safety. Current Nordion employees responsible for licensed materials and activities will continue to be responsible for such materials and activities after the completion of the reorganization. Accordingly, the new Nordion corporate entity will remain technically qualified as the licensee and will continue to fulfill all responsibilities as the licensee.

The current pre-merger organization structure of Nordion is reflected in the attached Figure 1. Figure 2 depicts the post-merger organization structure.

- 1. The new name of the licensed organization. If there is no change, the licensee should so state.*

Nordion (Canada) Inc. will be a new corporate entity, but there will be no change in the name of the licensed organization as a result of the planned internal corporate reorganization.

2. *The new licensee contact and telephone number(s) to facilitate communications.*

The Licensee's contact and telephone information will remain the same.

5.2 CHANGES IN PERSONNEL

All changes in personnel must be documented, reviewed, and approved.

Changes in personnel that need to be documented include those involving individuals who have control over licensed activities. These may include, in some cases, officers of a corporation or other management individuals who are listed on the license or are referred to in the supporting documentation. The licensee should also document any changes in personnel that have responsibility for radiation safety or are authorized to use licensed material. As with any change in personnel listed on a license, pertinent information with regard to training, experience, and qualifications applicable to the type of use will be required. The licensee should include applicable information concerning the qualifications, training, and responsibilities of any new individuals not previously listed on the current license or who are referred to in the supporting documentation.

The internal corporate reorganization does not involve planned changes in any personnel directly responsible for radiation safety or use of licensed material. Any future changes in management personnel will be those that occur in the ordinary course of business.

5.3 CHANGES OF LOCATION, EQUIPMENT & PROCEDURES

A complete description of any planned changes in location, facilities, equipment, or procedures.

Provide a detailed description of any changes in the licensee's location(s) of use, facility description, equipment, or procedures (i.e., changes in operating or emergency procedures) that would normally require a license amendment.

There are no planned changes in the location, facility, equipment, or procedures relating to the Licenses as a result of the planned internal corporate reorganization.

5.4 SURVEILLANCE RECORDS

An indication of whether all surveillance items and records (e.g., calibrations, leak tests, surveys, inventories, and accountability requirements) will be current at the time of transfer. A description of the status of all surveillance requirements and records should also be provided.

To the extent such records are required to be maintained under the Licenses, the proposed internal corporate reorganization will have no effect on the surveillance records. All licensed activities and related records are current and will continue on an ongoing basis without interruption as required by the Licenses. Nordion will retain the Licenses after completion of the

internal corporate reorganization. Surveillance items and records required by the Licenses will be implemented and maintained as described therein.

5.5 DECOMMISSIONING AND RELATED RECORDS TRANSFER

- 1. Confirmation that all records concerning the safe and effective decommissioning of the facility have been transferred to the new licensee if licensed activities will continue at the same facilities.*

Nordion does not own or operate any facilities in the United States. Thus, Nordion is not subject to any NRC decommissioning-related recordkeeping requirements. Nordion's facilities are in Canada and regulated by the Canadian Nuclear Safety Commission. All of the records applicable to the safe and effective decommissioning and closure of Nordion's Canadian facilities will not change as a result of the corporate reorganization.

- 2. A description of the status of the facility. Specifically, the presence or absence of contamination should be documented. If contamination is present, will decontamination occur before transfer? If not, is the transferee knowledgeable of the extent and levels of contamination and applicable decommissioning requirements, and does the transferee agree to assume full liability for the decontamination of the facility or site?*

Nordion does not own or operate any facilities in the United States. The status of the Nordion's Canadian facilities will remain unchanged as a result of the internal corporate reorganization, and the liability for any decommissioning or decontamination activities for Nordion's facilities in Canada will remain with the new Nordion corporate entity.

- 3. A description of how the parties agree to assume the responsibility for decontamination and decommissioning.*

Nordion does not own or operate any facilities in the United States. Thus, Nordion is not subject to any NRC decommissioning funding financial assurance requirements. The proposed internal corporate reorganization will have no effect on the obligations of the new Nordion corporate entity or its ability to meet the requirements of its decommissioning responsibilities for the facilities in Canada.

5.6 TRANSFEREE'S COMMITMENT TO ABIDE BY THE TRANSFEROR'S COMMITMENTS

Confirmation that the transferee agrees to abide by all constraints, license conditions, requirements, representations, and commitments previously made to the NRC by the transferor. These include, but are not limited to: information submitted in support of license amendments; maintenance of decommissioning records and completion of corrective actions for open inspection items and enforcement actions.

With regard to open inspection items, etc., the transferee should confirm, in writing, that it is knowledgeable of and accepts full responsibility for open inspection items and/or any resulting enforcement actions; or the transferee may propose alternative measures for meeting the requirements; or the transferor may provide a commitment to close out all such actions with NRC before license transfer.

The new Nordion corporate entity agrees to abide by all commitments and representations previously made in connection with the License. These commitments and representations remain unaffected by the proposed internal corporate reorganization. To the extent changes to such commitments are proposed, they will be subject to review and approval consistent with applicable NRC requirements. The new Nordion corporate entity will be knowledgeable of and accept full responsibility for open inspection items and/or any resulting enforcement actions relating to the License, and prior commitments to do so are unaffected by the proposed internal corporate reorganization.



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee

Nordion (Canada) Inc.
ATTN: Richard Wassenaar, Senior Manager
447 March Road
Ottawa, Ontario, Canada K2K 1XB

Date

October 23, 2018

License Number(s)

54-28275-01

Mail Control Number(s)

610268

Licensing and/or Technical Reviewer or Branch

Commercial, Industrial, R&D, & Academic Branch
Notification

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: 10/17/2018

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:

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:

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King of Prussia, PA 19406-2713
(610) 337-5260, (610) 337-5313,
(610) 337-5398, or (610) 337-5239



ACKNOWLEDGEMENT - RECEIPT OF CORRESPONDENCE

Name and Address of Applicant and/or Licensee Nordion (Canada) Inc. ATTN: Jackie Kavanagh, Manager 447 March Road Ottawa, Ontario, Canada K2K 1XB	Date October 23, 2018
	License Number(s) 54-28275-02MD
	Mail Control Number(s) 610285
	Licensing and/or Technical Reviewer or Branch Medical Branch Notification

This is to acknowledge receipt of your: ☒ Letter and/or ☐ Application Dated: 10/17/2018

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

☐ Amendment ☐ Termination ☐ New License ☐ Renewal

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