



May 21, 2014

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

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**SUBJECT: License No. 54-28275-02MD (Docket No. 03030793) and License No. 54-28275-01 (Docket No. 03030788); Application for Approval of Indirect Transfer of Control of Licenses**

Dear Mr. Welling:

Nordion Inc. ("Nordion"), on behalf of its indirect wholly owned subsidiary, Nordion (Canada) Inc. ("Nordion (Canada) Inc." or "the Licensee"), and STHI Holding Corp. ("STHI"), hereby request written approval by the U.S. Nuclear Regulatory Commission ("NRC") of a planned transfer of control of the above-captioned licenses. Attachments (1) through (3) provide the basis for this request. As explained below, the planned indirect transfer of control would occur as a result of the acquisition of Nordion by STHI, the indirect parent company of Sterigenics U.S., LLC (together with STHI and other affiliates "Sterigenics"), a global leader in sterilization services headquartered in Oak Brook, Illinois.

The Licensee is a leading provider of medical isotopes and sterilization technologies and its products are used daily by pharmaceutical and biotechnology companies, medical-device manufacturers, hospitals, clinics, and research laboratories. Both the Licensee and Nordion are Canadian companies with offices in Canada, with the Licensee located in Ottawa, Ontario, Canada. The Licensee possesses certain NRC licenses to distribute medical isotopes and to distribute, install and/or remove Co-60 from irradiators, and to provide installation, removal, and servicing of irradiators in the United States.

The Licensee's medical isotopes business focuses on products used in the diagnosis and treatment of disease, including cardiac and neurological conditions, and several types of cancer. It sells a variety of isotopes, which its customers incorporate into products that are used in medical procedures. The Licensee's sterilization technologies business focuses on the prevention of disease through terminal sterilization of medical products and devices, as well as food and consumer products. The Licensee produces and installs Cobalt-60 (Co-60) radiation sources for gamma sterilization systems. It also designs, constructs, installs, and maintains commercial gamma sterilization systems, referred to as production irradiators.

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While the Licensee's radioactive materials licenses for its activities in Canada are regulated by the Canadian Nuclear Safety Commission (CNSC),<sup>1</sup> as part of its business, the Licensee also holds two NRC materials licenses: License No. 54-28275-02MD, Docket No. 03030793 and License No. 54-28275-01, Docket No. 03030788.<sup>2</sup> Under License No. 54-28275-02MD, the Licensee is authorized to distribute medical isotopes in the United States. Under License No. 54-28275-01, the Licensee is authorized to distribute Co-60 in a sealed source, to possess it at the Licensee's temporary job sites in the United States, to install and/or remove Co-60 from irradiators, to perform installation and servicing of irradiators, and to provide training in the operation of irradiators.

Like the Licensee, Sterigenics is a world leader in contract sterilization and ionization services for the medical devices, food safety, and high performance/specialty materials industries. Sterigenics is a provider of high-quality contract sterilization and radiation processing services, with more than 30 years of experience in the operation, design, and development of gamma irradiation ("gamma") systems and facilities. Sterigenics maintains a worldwide network of facilities comprised of a number of gamma facilities and electron beam radiation facilities operating in the United States. Sterigenics is also an Agreement State licensee with a number of licenses that are unaffected by the planned transaction. *See* Attachment (3), "Sterigenics U.S., LLC Radioactive Materials Licenses."

On March 28, 2014, Nordion announced that it has entered into a definitive arrangement agreement (the "Arrangement Agreement") to be acquired by Sterigenics, with Sterigenics acquiring all the issued and outstanding shares of Nordion as described below. As a result of the proposed transaction, STHI, a U.S. company, will indirectly acquire the Licensee.

As described more fully in Attachment (1), after the transaction is complete, Nordion (Canada) Inc. will be an indirect wholly owned subsidiary of STHI. *See* Attachment (2), "Pre- and Post-Transaction Simplified Organizations." The proposed indirect transfer does not involve any amendment to the existing licenses and would not result in any change to the Licensee's organization or personnel responsible for licensed activities.

The closing of the proposed transaction could occur as early as mid-July, but depends upon the receipt of certain government approvals. Accordingly, we respectfully request that this request for written consent be reviewed, and such consent provided, expeditiously, and, in any event, no

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<sup>1</sup> The Licensee is seeking approvals for the transaction from the CNSC, among other Canadian authorities. The acquisition of Nordion is also subject to shareholder approval and to Canadian court approval under Canadian securities law and the Canada Business Corporations Act.

<sup>2</sup> The Licensee also holds an NRC export license, four NRC Sealed Source and Device Registrations, and has an NRC-approved QA program under 10 C.F.R. Part 71: NRC Export License No. PXB3.07-R (Docket No. 110061113); SSDR Registration numbers NR-0220-S-103-S (sealed source containing C-60), NR-0220-S-120-S (sealed source containing C-60), NR-0220-S-126-S (sealed source containing C-60), and NR-0220-D-131-S (sealed source containing Y-90); and NRC Quality Assurance Program Approval for Radioactive Material Packages, Approval No. 0703, Rev. 10. The parties are also coordinating any necessary transfer approvals and notifications with the NRC offices that oversee these licenses, registrations, and approvals.

later than July 14, 2014, if possible, in order to permit the companies to take the necessary steps to close on schedule.

Nordion and Sterigenics look forward to continuing to provide these critical medical isotopes and sterilization services in the United States. If you have any questions or comments, please contact Jackie Kavanagh, Senior Manager of EHS Compliance, Facility & Transportation Licensing for Nordion (Canada) Inc., at (613) 592-3400 ext. 2730.

**Enclosures:**

Attachment (1), Application for Approval of Transfer of Control of Licenses

Attachment (2), Pre- and Post-Transaction Simplified Organizations

Attachment (3), Sterigenics U.S., LLC Radioactive Materials Licenses

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on May 21, 2014.

Sincerely,

A handwritten signature in black ink, appearing to read "J. Kavanagh". The signature is fluid and cursive, with a large initial "J" and a stylized "K".

Jackie Kavanagh  
Senior Manager  
EHS Compliance, Facility & Transportation Licensing  
Nordion Inc.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on May 21, 2014.

Sincerely,

A handwritten signature in cursive script, appearing to read "J. Kavanagh".

Jackie Kavanagh  
Senior Manager  
EHS Compliance, Facility & Transportation Licensing  
Nordion (Canada) Inc.

I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on May 21, 2014.

Sincerely,

A handwritten signature in black ink, appearing to read 'G.H. Grauer', with a long horizontal stroke extending to the right.

Corey H. Grauer  
Vice President, General Counsel & Corporate Secretary  
STHI Holding Corp.

A handwritten signature in black ink, appearing to read 'Kathy Hoffman', with a long horizontal stroke extending to the right.

Kathy Hoffman  
Senior Vice President  
Global Environmental, Health & Safety  
STHI Holding Corp.

## **Attachment 1**

### **Application for Approval of Transfer of Control of Licenses**

This information is submitted consistent with NUREG-1556, Vol. 15, *Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses* (November 2000), at Section 5.1 through 5.6.

## **Section 5.1 DESCRIPTION OF TRANSACTION**

1. *A complete clear description of the transaction, including any transfer of stocks or assets, mergers, etc., so that legal counsel is able, when necessary, to differentiate between name changes and changes of ownership.*

Nordion (Canada) Inc. (“Nordion (Canada) Inc.” or “the Licensee”) is a Canadian company and a leading provider of medical isotopes and sterilization technologies. While the Licensee’s radioactive materials licenses for its activities in Canada are regulated by the Canadian Nuclear Safety Commission (CNSC), as part of its business, the Licensee also holds two NRC materials licenses: License No. 54-28275-02MD, Docket No. 03030793 and License No. 54-28275-01, Docket No. 03030788 (collectively, the “Licenses”). Under License No. 54-28275-02MD, the Licensee is authorized to distribute medical isotopes in the United States. Under License No. 54-28275-01, the Licensee is authorized to distribute Co-60 in a sealed source and to possess it at the Licensee’s temporary job sites in the United States, to install and/or remove Co-60 from irradiators, to perform installation and servicing of irradiators, and to provide training in the operation of irradiators.

The planned indirect transfer of control of the Licenses would occur as a result of the acquisition of Nordion by STHI Holding Corp. (“STHI”), the indirect parent company of Sterigenics U.S., LLC<sup>1</sup> (together with STHI and other affiliates “Sterigenics”), a global leader in sterilization services headquartered in Oak Brook, Illinois. Sterigenics is a privately held portfolio company of GTCR LLC, a leading private equity firm based in Chicago, Illinois.

On March 28, 2014, Nordion announced that it has entered into a definitive arrangement agreement (the “Arrangement Agreement”) to be acquired by Sterigenics, with Sterigenics acquiring all the issued and outstanding shares of Nordion as described below. As a result of the proposed transaction, STHI, a U.S. company, will indirectly acquire the Licensee. The proposed transaction, as relevant for NRC purposes, will occur in the following steps that will all occur substantially simultaneously (i.e., they will occur pursuant to a court-approved plan of arrangement in a specified order on the same day):

- First, to facilitate the transaction, Nordion, its intermediate subsidiary company Laboratories Nordion Inc. (a holding company that is the direct parent company of the Licensee), and the Licensee will amalgamate (i.e., combine) into one company, with Nordion (Canada) Inc. being the name of the amalgamated company.<sup>2</sup>

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<sup>1</sup> There are two companies in the corporate chain between Sterigenics U.S., LLC and STHI: Sterigenics Holdings LLC and Sterigenics International LLC.

<sup>2</sup> For tax purposes, as part of the planned transaction, the Licensee will also create a subsidiary company and a Limited Partnership, with the Licensee as the General Partner (i.e., the controlling partner), and the subsidiary



- Next, STHI's direct wholly owned subsidiary, 8832528 Canada Inc., will create a new subsidiary, referred to herein as "CanAcquisitionCo.," to facilitate the transaction. CanAcquisitionCo. will pay cash to acquire all of the issued and outstanding common shares of Nordion (Canada) Inc., making Nordion (Canada) Inc. a CanAcquisitionCo. subsidiary.
- Finally, CanAcquisitionCo. will be amalgamated with Nordion (Canada) Inc., with Nordion (Canada) Inc. being the name of the amalgamated company.<sup>3</sup>

Thus, the planned transaction will change ownership above Nordion (Canada) Inc. See Attachment (2), "Pre- and Post-Transaction Simplified Organizations." The proposed indirect transfer does not involve any amendment to the Licenses or changes to the Licensee's name, organization, or personnel responsible for licensed activities. Thus, the Licenses do not need to be amended as a result of the proposed transaction.

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

There will be no change in the name of the Licensee in connection with the proposed transaction.

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

The Licensee contact and telephone information will remain the same. The contact information is as follows:

Luc Desgagne, Senior Licensing Coordinator  
 Nordion (Canada) Inc.  
 447 March Road  
 Ottawa, Ontario, Canada K2K 1X8  
 Phone: (613) 592-3400 ext. 2108  
 E-mail: [luc.desgagne@nordion.com](mailto:luc.desgagne@nordion.com)

## **Section 5.2 CHANGES OF PERSONNEL**

1. *Any changes in personnel having control over licensed activities (e.g., officers of a corporation and any changes in personnel named in the license such as radiation safety officer, authorized users, or any other persons identified in previous license*

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as the Limited Partner (i.e., the passive partner). The Limited Partnership will be assigned economic benefits from the Licensee's sterilization business, but it will have no employees and no control or impact on licensed activities conducted by the Licensee.

<sup>3</sup> While the parties intend for this step to occur the same day as the previous steps, depending on timing it may occur one business day after the transaction closes, but no later.

*applications as responsible for radiation safety or use of licensed material). The licensee should include information concerning the qualifications, training and responsibilities of new individuals.*

Following the proposed transaction, there are no planned changes in personnel having control over licensed activities.

2. *An indication of whether the transferor will remain in non-licensed business without the license.*

After the transaction, the Licensee will remain in business as an indirect wholly owned subsidiary of STHI.

### **Section 5.3 CHANGES OF LOCATION, EQUIPMENT & PROCEDURES**

1. *A complete description of any planned changes in organization, location, facility, equipment, or procedures (i.e., changes in operating or emergency procedures).*

There are no planned changes in the organization, location, facility, equipment, or procedures in connection with the transaction.

2. *A detailed description of any changes in the use, possession, location or storage of the licensed materials.*

There are no planned changes in the use, possession, location or storage of the radioactive materials to occur in connection with the transaction.

3. *Any changes in organization, location, facilities, equipment, procedures, or personnel that would require a license amendment even without the change of ownership.*

There are no planned changes in the organization, facilities, equipment, procedures, or personnel that would require a license amendment even without the change of ownership.

### **Section 5.4 SURVEILLANCE RECORDS**

1. *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 transaction 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 under the Licenses. Such

records will continue to be maintained in their existing state and in accordance with applicable requirements.

## **Section 5.5 DECOMMISSIONING AND RELATED RECORDS TRANSFERS**

1. *Confirmation that all records concerning the safe and effective decommissioning/closure of the facility: public dose and waste disposal by release to sewers, incineration, radioactive material spills, and on-site burials, have been transferred to the new licensee if licensed activities will continue at the same location.*

All of the records concerning the safe and effective decommissioning and closure of the facility in Canada will remain in the same physical location. The Licensee's facility is in Canada and is regulated by the CNSC.

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?*

The status of the facility will remain unchanged after the transaction closes, and the liability for any decommissioning or decontamination activities for the Licensee's facility in Canada will remain with the Licensee.

3. *A description of any decontamination plans, including financial surety arrangements of the transferee. This should include information about how the transferee and transferor propose to divide the transferor's assets and responsibility for any cleanup needed at the time of transfer.*

The transaction would have no effect on the Licensee's obligations to meet the requirements of its decommissioning responsibilities for its facility in Canada.

## **Section 5.6 TRANSFEREE'S COMMITMENT TO ABIDE BY THE TRANSFEROR'S COMMITMENTS**

1. *Confirmation that the transferee agrees to abide by all commitments and representations previously made by the transferor. These include, but are not limited to: maintaining decommissioning records; implementing decontamination activities and decommissioning of the site; and completing corrective actions for open inspection items and enforcement actions.*

*With regard to contamination of facilities and equipment, the transferee should confirm, in writing, that it accepts full liability for the site, and should provide evidence of adequate resources to fund decommissioning; or the transferor should provide a commitment to decontaminate the facility before the change of control or ownership.*

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

The indirect change in control resulting from the transaction would not create a new licensee and would not change the Licensee's existing commitments under the Licenses.

Following the proposed transaction, the Licensee agrees to continue to abide by all constraints, license conditions, requirements, representations and commitments identified in and attributed to the existing Licenses, including any decommissioning and decommissioning funding obligations. The Licensee agrees to continue to accept full responsibility for open inspection items and any resulting enforcement action. The proposed change in the Licensee's parent company will not affect these commitments and representations.

2. *Documentation that the transferor and transferee agree to the change in ownership or control of the licensed material and activity, and the conditions of the transfer; and the transferee is made aware of all open inspection items and its responsibility for possible resulting enforcement actions.*

The proposed transaction would not create a new licensee and would not change the Licensee's existing commitments under the license. The Licensee is aware of and will continue to be responsible for all open inspection items and the Licensee will remain responsible for any possible resulting enforcement actions.

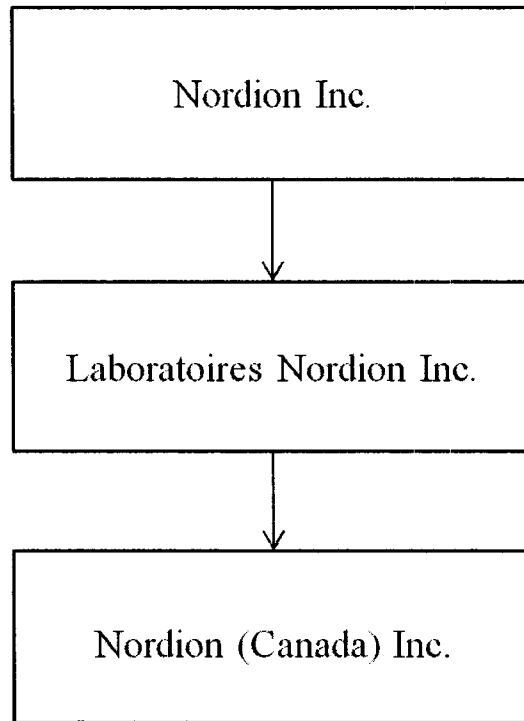
3. *A commitment by the transferee to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing licenses. If not, the transferee must provide a description of its program to ensure compliance with the license and regulations.*

The indirect change in control resulting from the transaction would not create a new licensee and would not change the Licensee's existing commitments under the Licenses. Following the transaction, the Licensee agrees to continue to abide by all constraints, conditions, requirements, representations, and commitments identified in the existing licenses.

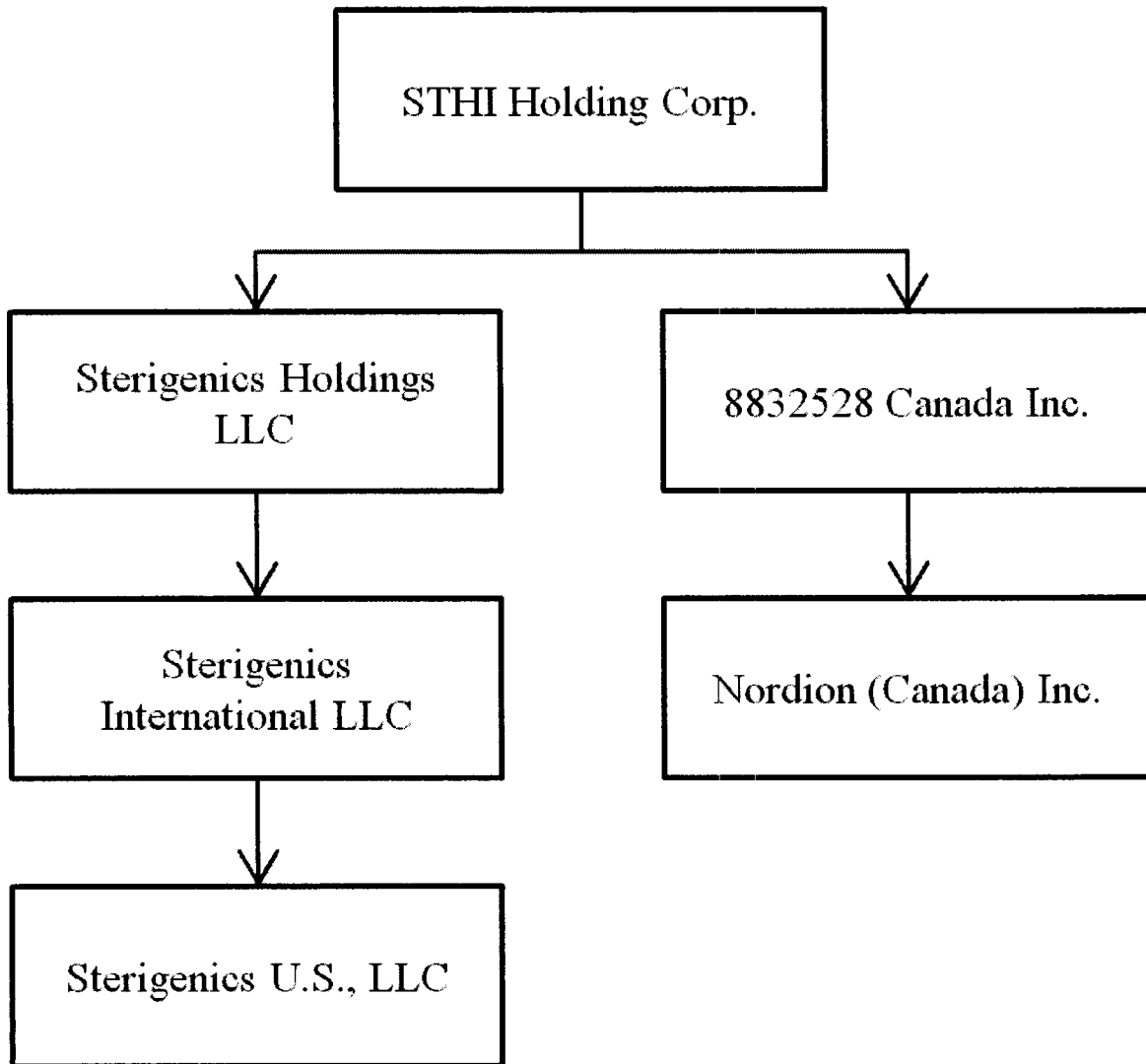
## **Attachment 2**

### **PRE- AND POST-TRANSACTION SIMPLIFIED ORGANIZATIONS**

# **PRE-TRANSACTION SIMPLIFIED ORGANIZATION**



**POST-TRANSACTION SIMPLIFIED ORGANIZATION**



## **Attachment 3**

### **STERIGENICS U.S., LLC RADIOACTIVE MATERIALS LICENSES**



**Agreement State Radioactive Materials Licenses Held by Sterigenics U.S., LLC**

State	License Number	Docket Number
NJ	RAD11001-507153	030-22307
NJ	RAD11001-507156	030-34162
CA	CA 5956	030-36690
CA	CA 3390	030-36691
AR	ARK-903-03521	030-36696
CA	CA 6579	030-36697
CA	CA 6268	030-36698
TX	L03851	030-36699
IL	IL 860122001	030-36741
IL	IL 860122001	030-36739
NC	NC 0974-1	030-36847
NC	NC 0701-1	030-36848
FL	FL 2244-1	