



May 21, 2014

Margie Kotzalas, Chief
Licensing Branch
Division of Materials Safety and State Agreements
Office of Federal and State Materials and
Environmental Management Programs
U.S. Nuclear Regulatory Commission
Washington, D.C. 20555-0001

**SUBJECT: Sealed Source and Device Registration Certificate Nos. NR-0220-S-103-S,
NR-0220-S-120-S, NR-0220-S-126-S, and NR-0220-D-131-S
Notice of Indirect Transfer of Control of SSDR Certificates**

Dear Ms. Kotzalas:

Nordion Inc. (“Nordion”), on behalf of its indirect wholly owned subsidiary, Nordion (Canada) Inc., and STHI Holding Corp. (“STHI”), hereby notify the U.S. Nuclear Regulatory Commission (“NRC”) of a planned indirect transfer of control of the above-captioned Sealed Source and Device Registration (“SSDR”) certificates resulting from the planned acquisition of Nordion (Canada) Inc. 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. Nordion (Canada) Inc. possesses the above-captioned SSDR certificates.

Nordion 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 Nordion and Nordion (Canada) Inc. are Canadian companies with offices in Canada, with the Nordion (Canada) Inc. located in Ottawa, Ontario, Canada. Nordion (Canada) Inc. 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.

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 (2), “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 Nordion (Canada) Inc. 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 Nordion (Canada) Inc.), and Nordion (Canada) Inc. will amalgamate (i.e., combine) into one company, with Nordion (Canada) Inc. being the name of the amalgamated company.
- Next, STHI’s direct wholly owned subsidiary, 8832528 Canada Inc., will create a new subsidiary, referred to herein as “CanAcquisitionCo.,” to facilitate the transaction.¹ 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.²

Thus, the planned transaction will change ownership above Nordion (Canada) Inc. The proposed indirect transfer of control does not involve any amendment to the SSDR certificates or changes to Nordion (Canada) Inc.’s name, organization, or personnel responsible for licensed activities.

No information on the face of the SSDR certificates will change as a result of the proposed transaction, nor will there be any new information or changes to any products, records, service arrangements, labeling, prior commitments, or quality assurance program, associated with the SSDR certificates. Thus, the SSDR certificates do not need to be amended as a result of the proposed transaction. For informational purposes, Attachment 1 contains the information requested by Section 13.6 of NUREG-1556, Vol. 3, Rev. 1, *Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration* (Apr. 2004).

Nordion (Canada) Inc. also holds two NRC materials licenses, an NRC export license, and an NRC Approved Quality Assurance Program.³ The proposed transaction will not result in an amendment to any of these licenses or approvals. The parties are also coordinating any necessary transfer approvals and notifications with the NRC offices that oversee these licenses and approvals.

¹ 8832528 Canada Inc. is a new holding company and a direct subsidiary of STHI Holding Corp.

² 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.

³ NRC Materials License Nos. 54-28275-02MD and 54-28275-01; NRC Export License No. PXB3.07-R; and NRC Quality Assurance Program Approval for Radioactive Material Packages, Approval No. 0703, Rev. 10.

The closing of the transaction is scheduled as early as mid-July 2014, but depends upon the receipt of certain government approvals. We will notify you when the transaction has closed. If you have questions or comments, please me at (613) 592-3400 ext. 2730.

Sincerely,



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

Enclosure:

Attachment (1), Information Requested in NUREG-1556, Vol. 3 (Rev. 1), Section 13.6
Attachment (2), Sterigenics U.S., LLC Radioactive Materials Licenses

Attachment 1

Information Requested in Section 13.6 of NUREG-1556, Vol. 3, Rev. 1, *Consolidated Guidance About Materials Licenses: Applications for Sealed Source and Device Evaluation and Registration* (Apr. 2004).

1. Delineate the facility's name and location where the products are manufactured.

The products will continue to be manufactured by Nordion (Canada) Inc. at 447 March Road, Ottawa, Ontario, Canada, K2K 1X8.

2. Specify the serial number of the last unit that was distributed by the old company prior to the name/address change, and the number of completed units that were transferred to be distributed by the old company to the new company.

There is no new company created by the transaction, and all distributions will continue to be made by Nordion (Canada) Inc.

3. Change of ownership information discussing transfer of products, records custody, and servicing arrangements for products previously distributed.

Ownership of all products, records custody, and servicing arrangements remain with Nordion (Canada) Inc.

4. Provide a new label for the devices indicating the new company name and the effective date of the label change.

There is no new company name and labeling will continue to be the same.

5. Confirm that no changes were made to the product since its initial registration or last amendment.

No changes have been made to the products covered by the SDDR since their last amendments.

6. Verify that there are no changes to previous commitments that have been made by the old company.

There are no changes to previous commitments made by Nordion (Canada) Inc.

7. Provide details regarding the quality assurance program at the new location.

There is no change of location and no change to Nordion (Canada) Inc.'s quality assurance program.

Attachment 2

Sterigenics U.S., LLC Radioactive Materials Licenses

| 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 | |