

SAFETY EVALUATION REPORT
PROPOSED TRANSFER OF CONTROL OF BYPRODUCT MATERIALS LICENSE
NUMBERS 54-28275-01 and 54-28275-02MD, NORDION (CANADA) INC.

DATE: December 6, 2018

DOCKET NOS.: 030-30788 and 030-30793

LICENSE NOS.: 54-28275-01 and 54-28275-02MD

LICENSEE: Nordion (Canada) Inc.
447 March Road, Ottawa, Ontario, Canada K2K 1X8

TECHNICAL REVIEWER: Janice Nguyen, Senior Health Physicist, Region I

SUMMARY AND CONCLUSIONS

Nordion (Canada) Inc. holds two byproduct materials licenses issued by the U.S. Nuclear Regulatory Commission (NRC). Under NRC Materials License 54-28275-01, Nordion (Canada) Inc. is authorized to possess and use byproduct material for purposes of distribution of sources to authorized persons and servicing of irradiators at temporary job sites in NRC's areas of regulatory jurisdiction. They are authorized by NRC Materials License 54-28275-02MD to distribute byproduct material from 447 March Road, Ottawa, Ontario, Canada and 4004 Wesbrook Mall, Vancouver, British Columbia, Canada to authorized licensees in the United States.

The U.S. Nuclear Regulatory Commission (NRC) staff reviewed a request for consent to a direct license transfer submitted by Nordion (Canada) Inc. (Nordion). Nordion's ultimate parent company, Sotera Health Topco, Inc. (Topco) is not changing as a result of the proposed corporate reorganization. Currently, Nordion (Canada) Inc. is a wholly-owned subsidiary of 8921903 Canada, Inc. Nordion will be merged with its parent company, 8921903 Canada, Inc. and Lakeshore Health Centre Inc., a non-operating wholly owned subsidiary of Nordion that has no assets and no operations. The emerging company will merge with Nordion Sterilization, an affiliated sister company. The resulting merged entity will also be named Nordion (Canada) Inc., but the existing Nordion (Canada) Inc. will not be the surviving entity. Nordion (Canada) Inc. will become a newly registered company, with a different registration number as a federal Canadian corporation, directly owned by its current indirect parent company, STR 2 BV, an intermediate parent holding company registered in the Netherlands. The new corporate entity will assume the licenses. The direct transfer of control is described in Agency Documents Access and Management System (ADAMS) package accession numbers ML18298A277 and ML18298A280. The ADAMS packages consist of the following agency documents: letter dated October 17, 2018 (ML18298A278), email requesting additional information dated November 19, 2018 (ML18332A139), and letter dated November 19, 2018 (ML18332A191).

The licensee's request for consent to a direct transfer of ownership was posted for public comment on the NRC website for 30 days in accordance with 10 CFR Part 2 and following the guidance provided in the NRC's Regulatory Issue Summary 2014-08. No comments were received from members of the public.

The request for consent was reviewed by NRC staff for a direct transfer of control of two 10 CFR Part 30 licenses using the guidance in NUREG-1556, Volume 15, Rev. 1, "Consolidated Guidance About Materials Licenses: Program-Specific Guidance About Changes of Control and About Bankruptcy Involving Byproduct, Source, or Special Nuclear Materials Licenses," dated June 2016. The NRC staff finds that the information submitted by Nordion sufficiently describes and documents the transaction and commitments made by Nordion.

As required by 10 CFR 30.34 and section 184 of the Atomic Energy Act of 1954, as amended (the Act), NRC staff has reviewed the application and finds that the proposed transfer of control is in accordance with the Act. The staff finds that, after the transfer of control, Nordion (Canada) Inc. will remain qualified to use byproduct material for the purpose requested and will continue to have the equipment, facilities, and procedures needed to protect public health and safety and to promote the common defense and security.

SAFETY AND SECURITY REVIEW

According to data obtained from the NRC's Web Based Licensing system, Nordion (Canada) Inc. has been an NRC licensee since March 6, 1989. The NRC conducted a main office inspection of Nordion (Canada) Inc. on September 15, 2015, NRC Materials License Nos. 54-28275-01 and 54-28275-02MD, and no violations were identified during this inspection. The NRC conducted a temporary job site inspection of NRC License No. 54-28275-01 on September 25, 2017, and no violations were identified. The commitments made by Nordion state that there will be:

- A. no change to the radiation safety officer listed in the NRC licenses;
- B. no change in personnel involved in licensed activities;
- C. no change in the locations, facilities, and equipment authorized in the NRC licenses;
- D. no change in the radiation safety program authorized in the NRC licenses;
and
- E. no change in the organization's name listed in the NRC licenses.

Further, Nordion will maintain required surveillance records and decommissioning records as required by NRC regulations.

Sotera Health Topco, Inc. (Topco), the ultimate parent company for Nordion, hold subsidiaries which possess material licenses issued by the following Agreement States: New Jersey, California, Arkansas, Texas, Illinois, Florida, and North Carolina. Therefore, for security purposes, Topco is considered a known entity following the guidance provided by the NRC's Office of Federal and State Materials and Environmental Management Programs (FSME) "Checklist to provide a basis for confidence that radioactive materials will be used as specified on the license," September 3, 2008 revision. The purpose of this checklist is for the NRC to obtain reasonable assurance from new license applicants or NRC licensees transferring control of licensed activities that the licensed material will be used for its intended purpose and not for malevolent use.

Nordion (Canada) Inc. is not required to have decommissioning financial assurance based on the types and amount of material authorized in License Nos. 54-28275-01 and 54-28275-02MD, as outlined by 10 CFR 30.35.

REGULATORY FRAMEWORK

Nordion (Canada) Inc.'s License Nos. 54-28275-01 and 54-28275-02MD were issued under 10 CFR Part 30, "Rules of General Applicability to Domestic Licensing of Byproduct Material." The Commission is required by 10 CFR 30.34 to determine if the transfer of control is in accordance with the provisions of the Act and give its consent in writing.

10 CFR 30.34(b) states: "No license issued or granted pursuant to the regulations in this part and parts 31 through 36, and 39 nor any right under a license shall be transferred, assigned or in any manner disposed of, either voluntarily or involuntarily, directly or indirectly, through transfer of control of any license to any person, unless the Commission shall, after securing full information, find that the transfer is in accordance with the provisions of the Act and shall give its consent in writing."

As previously indicated, the staff evaluation is based on guidance in NUREG-1556, Volume 15, Revision 1. Nordion (Canada) Inc.'s request for consent describes a direct transfer of control and, as such, the transfer requires NRC consent.

DESCRIPTION OF TRANSACTION

The direct transfer of control is described in Agency Documents Access and Management System (ADAMS) package accession numbers ML18298A277 and ML18298A280. The ADAMS packages consist of the following agency documents: letter dated October 17, 2018 (ML18298A278), email requesting additional information dated November 19, 2018 (ML18332A139), and letter dated November 19, 2018 (ML18332A191). After completion of the merger, Nordion (Canada) Inc. will continue as the licensee and remain in control of all licensed activities under Materials License Nos. 54-28275-01 and 54-28275-02MD. The NRC staff finds that the request for consent adequately provides a complete and clear description of the transaction and is consistent with the guidance provided in Appendix E of NUREG-1556, Volume 15, Revision 1.

TRANSFeree'S COMMITMENT TO ABIDE BY THE TRANSFEROR'S COMMITMENTS

The NRC staff finds that the information submitted by Nordion sufficiently describes and documents the commitments made by Nordion (Canada) Inc., and is consistent with the guidance in NUREG-1556, Volume 15, Revision 1.

ENVIRONMENTAL REVIEW

An environmental assessment for this action is not required since this action is categorically excluded under 10 CFR 51.22(c)(21).

CONCLUSION

The staff has reviewed the request for consent submitted by the Nordion with regard to a direct transfer of control of byproduct materials license Nos. 54-28275-01 and 54-28275-02MD; and consents to the transfer pursuant to 10 CFR 30.34(b).

Consistent with the guidance in NUREG-1556, Volume 15, Revision 1, the submitted information sufficiently describes the transaction; documents the understanding of the license and commitments of the transferee; demonstrates that personnel have the experience and training to properly implement and maintain the license and that they will maintain the existing records; and provides that, in the future, the transferee will abide by all existing commitments on the license.

Therefore, the staff concludes that the proposed transfer of control would not alter the previous findings, made under 10 CFR Part 30, that licensed operations will not be inimical to the common defense and security, or to the health and safety of the public.