



**UNITED STATES
NUCLEAR REGULATORY COMMISSION
REGION I
2100 RENAISSANCE BLVD.
KING OF PRUSSIA, PA 19406-2713**

June 8, 2017

Greg Fulford
Nuclear Transportation Specialist
Nordion (Canada) Inc.
447 March Road
Ottawa, ON K2K 1X8
Canada

**SUBJECT: VOIDANCE OF YOUR REQUEST FOR AMENDED LICENSE, MAIL CONTROL
NO. 594718**

Dear Mr Fulford:

This concerns your request for an amended license in a letter dated March 30, 2017. Because you informed us that you would like to withdraw your request at this time, we have voided your request. This action is taken without prejudice to the resubmission of your request. In your resubmission, please address the following as outlined in Appendix U of NUREG-1556, Volume 12 and in NUREG-1556, Volume 13:

1. Indicate the maximum activity in each source, and the anticipated use of the sources. If the sealed sources are usually used in a device, specify the manufacturer's name and the model number of the device.
2. Confirm that the activity per source will not exceed the maximum activity listed on the approved certificate of registration issued by NRC (when issued).
3. Submit copies or facsimiles of the labels that will accompany the sources and specify where each label will be placed (e.g., on the source shield).
4. Submit copies of all leaflets and brochures that will accompany the sources.
5. Provide a copy of correspondence to and from the FDA that clearly shows that the FDA finds the source to be safe for medical use (e.g., 510(K) approval).
6. For shipping containers used, describe the type of shipping container, container shielding, maximum radiation level expected for a fully loaded container, and maximum activity allowed per container.
7. If you do not plan to offer a source return program, so state; no additional information is necessary. However, if you offer a source return program, you must have developed, and must supply to your customers, sufficiently detailed instructions (including instructions on labeling and shipping documents) to ensure that the shipper can comply with 10 CFR 71.5 and with DOT regulations; and will return the sources to an appropriately licensed recipient. Please note that the sources may not be returned to

you under this license 54-28275-02MD. You must also submit to NRC copies of all forms, labels, and instructions that you will provide to customers for shipping sources back to a facility separately licensed for possession. As a minimum, the instructions must:

- a. Establish the user's responsibility and liability as the shipper;
- b. Provide step-by-step instructions for completing each item on each form and label that is involved in the shipping process; and
- c. Discuss all the customer's responsibilities as a shipper under 49 CFR Parts 170 to 189. This discussion of the customer's responsibilities should include (but is not limited to):
 - * The requirements to survey and wipe-test packages;
 - * The distance at which to survey packages;
 - * The action levels for the package wipe-test results;
 - * The dose rate limitations on the particular shipping label that you will provide;
 - * The need for sealing tape or another mechanism to fulfill the security seal requirement.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web Site at <http://www.nrc.gov/reading-rm/adams.html>.

Thank you for your cooperation.

Sincerely,



Penny Lanzisera, Senior Health Physicist
Medical Branch
Division of Nuclear Materials Safety
Region I

License No. 54-28275-02MD
Docket No. 03030793
Mail Control No. 594718

cc: Jackie Kavanagh, Senior Manager

you under this license 54-28275-02MD. You must also submit to NRC copies of all forms, labels, and instructions that you will provide to customers for shipping sources back to a facility separately licensed for possession. As a minimum, the instructions must:

- a. Establish the user's responsibility and liability as the shipper;
- b. Provide step-by-step instructions for completing each item on each form and label that is involved in the shipping process; and
- c. Discuss all the customer's responsibilities as a shipper under 49 CFR Parts 170 to 189. This discussion of the customer's responsibilities should include (but is not limited to):
 - * The requirements to survey and wipe-test packages;
 - * The distance at which to survey packages;
 - * The action levels for the package wipe-test results;
 - * The dose rate limitations on the particular shipping label that you will provide;
 - * The need for sealing tape or another mechanism to fulfill the security seal requirement.

In accordance with 10 CFR 2.390 of the NRC's "Agency Rules of Practice and Procedure," a copy of this letter will be available electronically for public inspection in the NRC Public Document Room or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible from the NRC Web Site at <http://www.nrc.gov/reading-rm/adams.html>.

Thank you for your cooperation.

Sincerely,

Penny Lanzisera, Senior Health Physicist
 Medical Branch
 Division of Nuclear Materials Safety
 Region I

License No. 54-28275-02MD
 Docket No. 03030793
 Mail Control No. 594718

cc: Jackie Kavanagh, Senior Manager
 DOCUMENT NAME: G:\WBL Documents\WBL License Cover Letter\L54-28275-02MD.594718.docx

SUNSI Review Complete: PLanzisera

After declaring this document "An Official Agency Record" it **will** be released to the Public.
 To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

| | | | | | | | |
|--------|----------------------|---|--|--|--|--|--|
| OFFICE | RI:DNMS | N | | | | | |
| NAME | PLanzisera <i>PL</i> | | | | | | |
| DATE | 6-8-17 | | | | | | |

OFFICIAL RECORD COPY