



**UNITED STATES
NUCLEAR REGULATORY COMMISSION**
REGION I
2100 RENAISSANCE BOULEVARD, SUITE 100
KING OF PRUSSIA, PA 19406-2713

June 11, 2014

Docket No. 03030788
Control No. 583923

License No. 54-28275-01

Luc Desgagne
Senior Licensing Coordinator
Nordion (Canada) Inc.
447 March Road
Ottawa, ON K2X 1X8
Canada

**SUBJECT: NORDION (CANADA) INC., REQUEST FOR ADDITIONAL INFORMATION
CONCERNING APPLICATION FOR RENEWAL OF LICENSE, CONTROL NO.
583923**

Dear Mr. Desgagne:

This is in reference to your application dated May 14, 2014, requesting to renew Nuclear Regulatory Commission License No. 54-28275-01. In order to continue our review, we need the following additional information:

1. NUREG 1556, Volume 12, Consolidated Guidance About Materials Licenses Program-Specific Guidance About Possession Licenses for Manufacturing and Distribution section 8.8 states, to submit a description of the radiation safety training program, including groups of workers, assessment of training, qualifications of instructors, and the method and frequency of training. Your submittal only discussed the "Installation and Service Technicians" and did not discuss any other group of workers, assessment of training, qualifications of instructors, and the method and frequency of training and appears to not train about regulatory requirements. Since you only have temporary job sites you might only have one standard of training to all personnel at temporary job sites. Please provide the training program for different groups of workers with the associated topics covered, if applicable, the assessment of training, qualifications of instructors, the method and frequency of training and that regulatory requirements besides transportation are also covered. If there are different groups of workers, please specify which group would be authorized to use or supervise the licensed material. You may wish to refer to NUREG-1556, Volume 18, Appendix H before submitting your response.
2. NUREG-1556, Volume 12, section 8.9 states to describe the equipment made available at each location where radioactive material will be possessed or possessed and used. NUREG-1556, Volume 18, Consolidated Guidance About Materials Licenses Program-Specific Guidance About Service Provider Licenses, section 8.9 states for service providers requesting the use of licensed sealed radioactive material that requires the use of specialized equipment or handling tools should provide a description, photograph, sketch, or drawing. Please provide a description, photograph, sketch, or drawing of the

specialized equipment or handling tools that are used at your temporary job sites. Please highlight the methods employed to ensure ALARA is achieved.

3. NUREG-1556, Volume 12, section 8.10.2, states to provide a description of your instrumentation, calibration, and to reserve the right to upgrade our survey instruments as necessary. You provided a list of instrumentation and the method of calibration. It is recommended that you provide a statement, "We reserve the right to upgrade our survey instruments as necessary," so that you can change instrumentation models without a license amendment in the future.
4. NUREG-1556, Volume 12, section 8.10.6 states the applicant should submit the following statement about operating and emergency procedures: "Procedures will be revised only if: (1) the changes are reviewed and approved by the licensee management and the RSO in writing; (2) the licensee staff is provided training in the revised procedures prior to implementation; (3) the changes are in compliance with NRC regulations and the license; and (4) the changes do not degrade the effectiveness of the program." Please state, "Procedures will be revised only if: (1) the changes are reviewed and approved by the licensee management and the RSO in writing; (2) the licensee staff is provided training in the revised procedures prior to implementation; (3) the changes are in compliance with NRC regulations and the license; and (4) the changes do not degrade the effectiveness of the program."
5. NUREG-1556, Volume 18, section 8.10.6 states, service providers who perform specific operations involving sealed sources such as inspection and maintenance of devices, and removal and replacement of sealed sources, should include appropriate procedures and instructions for these operations in the applicant's operating and emergency procedures. Please provide the procedures, portions of procedures, or outline of the procedures used to remove or change sealed sources at temporary job sites. Based on the list of procedures you provided, it would appear the following procedures should be outlined or submitted:
 - a. Emergency Procedure for Handling Co-60 leaking Capsule
 - b. Emergency Guidance to Free a Stuck Source Rack
 - c. Emergency Guidance to Recover Source in Maze
 - d. Emergency Procedures for Underwater Cobalt-60 loading
 - e. Underwater Transport Package Unload Procedure
 - f. Underwater Transport Package Load Procedure
 - g. Source Holder Load Procedure for Wet Storage irradiator
6. Current License Condition 15 requires after installation of the irradiator and/or Cobalt 60 and prior to initiation of the irradiation program, a radiation survey shall be conducted to determine the maximum radiation levels in each area adjoining the irradiation room. Please confirm that you will perform this survey and please provide the portion of the procedure that supports this survey.
7. NUREG-1556, Volume 12, section 8.10.7 states that you should provide leak test procedures and the following statement: "We will perform contamination checks on all

fabricated sealed sources prior to distribution. Leak tests will be performed at the intervals approved by NRC or an Agreement State and specified in the SSD Registration Certificate.” Please submit a description of equipment and/or procedures to evaluate whether there is radioactive leakage from sealed sources or plated foil along with the above statement.

8. You have requested decontamination of irradiators and facilities as an authorized use. Please submit a summary of the procedure describing that addresses the important radiation safety aspect of each procedure or the procedure(s) for performing decontamination of irradiators and facilities.
9. You have requested to perform operational testing of irradiator units. NUREG-1556, Volume 6, Consolidated Guidance About Materials Licenses Program-Specific Guidance About Material Licenses, Program-specific Guidance About 10 CFR Part 36 Irradiator Licenses, section 8.8.1, that licensee’s should provide the statement, “Before using licensed materials, irradiator operators will have successfully completed one of the training courses described in Criteria in the section entitled ‘Initial Training and Experience for Irradiator Operators’ in NUREG-1556, Vol. 6, dated January 1999”, or provide a description of the initial training program for irradiator operators that demonstrates compliance with the requirements of 10 CFR 36.51(a), (b), and (c).
10. You have requested to perform the instruction of personnel in the operation of irradiator units. NUREG-1556, Volume 6, Appendix G, “Training for Radiation Safety Officers and Irradiator Operators” provides proposed irradiator course instructor qualifications. Please state that 10 CFR Part 36 irradiator operator instructors will be qualified as stated in NUREG-1556, Volume 6, Appendix G,” or provide a description of the minimum qualification of instructors for performance of this training.

Current NRC regulations and guidance are included on the NRC's website at www.nrc.gov; select **Nuclear Materials; Med, Ind, & Academic Uses**; then **Licensee Toolkits**, see our **toolkit index page**. You may also obtain these documents by contacting the Government Printing Office (GPO) toll-free at 1-866-512-1800. The GPO is open from 8:00 a.m. to 5:30 p.m. EST, Monday through Friday (except Federal holidays).

We will continue our review upon receipt of this information. Please reply to my attention at the Region I Office and refer to Mail Control No. 583923. If you have any technical questions regarding this deficiency letter, please call me at (610) 337-5366.

The NRC’s Safety Culture Policy Statement became effective in June 2011. While a policy statement and not a regulation, it sets forth the agency’s *expectations* for individuals and organizations to establish and maintain a positive safety culture. You can access the policy statement and supporting material that may benefit your organization on NRC’s safety culture Web site at <http://www.nrc.gov/about-nrc/safety-culture.html>. We strongly encourage you to review this material and adapt it to your particular needs in order to develop and maintain a positive safety culture as you engage in NRC-regulated activities.

L. Desgagne

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In order to continue prompt review of your application, we request that you submit your response to this letter within 30 calendar days from the date of this letter.

Sincerely,

Original signed by Dennis R. Lawyer

Dennis R. Lawyer
Health Physicist
Commercial, Industrial, R&D and Academic
Branch
Division of Nuclear Materials Safety

cc:
Philip Danks, Radiation Safety Officer

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