



UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 30, 2018

Mr. Richard W. Boyle
Radioactive Materials Branch
U.S. Department of Transportation
400 Seventh Street, S.W.
Washington, D.C. 20590

SUBJECT: REVIEW OF DEPARTMENT OF TRANSPORTATION'S SUBMITTAL FOR
REVALIDATION OF THE CANADIAN COMPETENT AUTHORITY
CERTIFICATE OF APPROVAL NO. CDN/2094/B(U)-96, REVISION 1, MODEL
NO. F-522 -WITHHOLDING OF INFORMATION FROM PUBLIC DISCLOSURE

Dear Mr. Boyle:

By letter dated March 15, 2017 [Agencywide Documents Access and Management System (ADAMS) Package Accession No. ML18137A496], and as supplemented on September 20, 2017 (ADAMS Accession No. ML18151A700), November 16, 2017 (ADAMS Package Accession No. ML18143B680), January 16, 2018 (ADAMS Package Accession No. ML18151A695), April 4, 2018 (ADAMS Accession Nos. ML18143B343 and ML18151A701), and May 30, 2018 (ADAMS Package Accession No. ML18151A695), you requested our assistance in evaluating the Model No. F-522 transport package, authorized by Canadian Certificate of Approval No. CDN/2094/B(U)-96, Revision 1. These requests included the following affidavits from Nordion Canada Inc. (the applicant) seeking to withhold information in the items below from public disclosure pursuant to Title 10 of the *Code of Federal Regulations* (10 CFR) Part 2, Section 2.390:

1. Affidavit dated September 20, 2017 (ADAMS Accession No. ML18142A796) [transmittal letter dated September 20, 2017 (ADAMS Accession No. ML18151A700)] and affidavit dated September 20, 2017 (ADAMS Accession No. ML18137A504) [transmittal letter dated October 12, 2017 (ADAMS Accession No. ML18137A504)].
 - a. Procedures No. IS/DS 2651 F522 and IS/TR 2650 F522,
 - b. Drawing No. F652201-001, and
 - c. Responses to requests for additional information (RAIs).
2. Affidavit Dated November 15, 2017, (ADAMS Accession No. ML18143B672) [transmittal letter dated November 16, 2017 (ADAMS Accession No. ML18143B674)]
Responses to RAIs.
3. Affidavit Dated January 16, 2018, (ADAMS Accession No. ML18143B732) [transmittal letter dated January 16, 2018 (ADAMS Accession No. ML18151A697)]
Responses to RAIs.

4. Affidavit dated May 29, 2018, (ADAMS Accession No. ML18151A696) [transmittal letter dated May 30, 2018 (ADAMS Accession No. ML18151A703)]
 - a. Microshield analysis provided by letter dated September 20, 2017, and
 - b. Procedure No. R119.017.SUR[1], Shielding Analysis Report for F-522 Mo-99 Impurities.”

The affidavits state that the information submitted should be considered exempt from mandatory public disclosure for the following reasons:

- The information provided in Nordion's submission to the United States (U.S.) Department of Transportation (DOT) for the Model No. F-522 transport package endorsement contains privileged and confidential information related to the design processes, technical information, and procedures of Nordion;
- Nordion has expended extensive funds and manpower in developing the aforementioned documents and these documents represent a Nordion's transport package design that include a detailed description of the package, testing, and regulatory justifications implemented by Nordion;
- The information includes items that are provided in “confidence” for business purposes, developmental purposes, or otherwise has been protected as proprietary information; and
- The information, if used by a competitor, would cause “substantial” harm to Nordion by reducing its competitors’ expenditure of resources or improve their competitive position in the design, manufacture, shipment, installation, assurance of quality, or licensing of a similar product.

We reviewed your application and the material in accordance with the requirements of 10 CFR 2.390 and, on the basis of Nordion's statements, have determined that the submitted information sought to be withheld contains proprietary commercial information and should be withheld from public disclosure. Therefore, the version(s) of the submitted information marked as proprietary will be withheld from public disclosure pursuant to 10 CFR 2.390(b)(5) and Section 103(b) of the Atomic Energy Act of 1954, as amended.

If the basis for withholding this information from public inspection should change in the future such that the information could then be made available for public inspection, you should promptly notify the NRC. You also should understand that the NRC may have cause to review this determination in the future, for example, if the scope of a Freedom of Information Act request includes your information. In all review situations, if the NRC makes a determination adverse to the above, you will be notified of the date of public disclosure, in advance, which will be a reasonable time thereafter.

R. Boyle

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If you have any questions regarding this matter, you may contact me at 301-415-6999.

Sincerely,

/RA/

Norma Garcia Santos, Project Manager
Spent Fuel Licensing Branch
Division of Spent Fuel Management
Office of Nuclear Material Safety
and Safeguards

Docket No. 71-3091
CAC No. L25212
EPID L-2017-LLA-0022

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DOCUMENT DATE: July 30, 2018

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ADAMS Accession No.: ML18213A018

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|------------|----------------|------------|-----------------------------|
| NAME | NGarcía Santos | SFiguerroa | CJacobs for JMcKirgan |
| DATE | 7/26/18 | 7/27/18 | 7/30/18 |

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