

August 5, 2004

MEMORANDUM TO: Jack Strosnider, Director  
Office of Nuclear Material Safety  
and Safeguards

THROUGH E. William Brach, Director /RA/  
Spent Fuel Project Office, NMSS

FROM: Robert R. Temps /RA/  
Transportation and Storage Safety Section  
Spent Fuel Project Office, NMSS

SUBJECT: FOREIGN TRIP REPORT FOR INSPECTION AT MDS NORDION AND  
MEETING WITH CANADIAN GOVERNMENT COUNTERPARTS

Attached is a trip report for the 10 CFR Part 71 team inspection conducted the week of July 12, 2004, at the MDS Nordion facility in Ottawa, Canada. Nordion is the holder of a full-scope NRC-approved Part 71 Quality Assurance (QA) Program Approval and also holds NRC certificates of compliance (CoCs) for four different package designs. The focus of the inspection by the Spent Fuel Project Office (SFPO) was to determine whether Nordion's design, fabrication, testing, and maintenance activities were in accordance with their NRC-approved QA program and the applicable package design CoCs. An inspector in the Packaging and Transport Licensing Division of the Canadian Nuclear Safety Commission (CNSC), accompanied the NRC inspection team as an observer.

Separate from the inspection, on July 13, 2004, an SFPO representative, Robert Lewis, met with Messrs. Sylvain Faille of CNSC and Ray Clark of Transports Canada (TC) to discuss topics of mutual interest.

I believe the content of this report is not likely to be of interest to the Commission.

Attachment: NRC Foreign Trip Report  
w/ Attachment 1

cc: W. Dean, EDO  
J. Dunn-Lee, OIPM  
M. Federline, NMSS  
R. Zimmerman, NSIR  
T. Rothschild, OGC  
L. Silvious, NSIR  
T. Sherr, NMSS  
SFPO Management Team

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## NRC FOREIGN TRIP REPORT

**Subject** TRIP REPORT FOR INSPECTION AT MDS NORDION AND MEETING WITH CANADIAN GOVERNMENT COUNTERPARTS

**Dates of Travel and Countries/Organizations Visited:**

Travel from July 11-16, 2004, to Ottawa, Ontario, Canada. Inspection at MDS Nordion and separate meeting with Canadian Nuclear Safety Commission (CNSC) and Transports Canada(TC) officials.

**Author, Title, and Agency Affiliation:**

Robert Temps, Senior Transportation and Storage Safety Inspector  
Spent Fuel Project Office  
Office of Nuclear Material Safety and Safeguards

**Sensitivity:** Non-sensitive.

**Background/Purpose:**

The Spent Fuel Project Office (SFPO) conducted a team inspection during the week of July 12, 2004, at the MDS Nordion facility in Ottawa, Canada. Nordion is the holder of a full-scope NRC-approved Part 71 Quality Assurance (QA) Program Approval and also holds NRC certificates of compliance (CoCs) for four different package designs. The purpose of the inspection was to determine whether Nordion's design, fabrication, testing, and maintenance activities were in accordance with their NRC-approved QA program and the applicable package design CoCs.

Separate from the inspection, on July 13, 2004, Robert Lewis met with Messrs. Sylvain Faille of CNSC and Ray Clark of Transports Canada. The meeting consisted of (1) presentations outlining the activities and responsibilities of SFPO, CNSC's Transport Licensing Division, and the TC Office of the Director General; (2) a discussion of planned U.S. and Canadian change proposals for the 2007 IAEA Transport Regulations; (3) plans for papers and participation at the PATRAM 2004 conference; (4) the interface of security and safety requirements and border crossing issues; and (5) IAEA's programs to investigate denials of shipments of radioactive material.

**Abstract/Summary of pertinent Points/Issues:**

With respect to the inspection, the SFPO inspection team identified weaknesses in Nordion's design control and fabrication control processes that allowed changes to be made to packages that were not consistent with the approved design in the CoCs.

With respect to the meeting with the CNSC and TC, the TC and CNSC staff were very like-minded with NRC and U.S. DOT staff views on the topics of discussion. CNSC was also interested in SFPO's spent fuel dry storage activities as several Canadian plants are considering that option.

**Discussion:**

From July 12 through 16, 2004, the SFPO conducted an inspection of MDS Nordion and met

with the Canadian government in Ottawa, Ontario. The SFPO inspectors were Robert Temps (team leader), Frank Jacobs and James Pearson. The team was accompanied by Robert Lewis, Section Chief for the Transportation and Storage Safety and Inspection Section in SFPO. Robert Irvine, an inspector in the Packaging and Transport Licensing Division of the CNSC, accompanied the NRC inspection team as an observer. Nordion is the holder of a full-scope NRC-approved Part 71 Quality Assurance Program Approval and also holds NRC CoCs for four different packaging designs. The focus of the inspection was to determine whether Nordion's design, fabrication, testing, and maintenance activities were in accordance with their NRC-approved QA program and the applicable packaging design CoCs.

During the inspection, a number of concerns were identified by the team in various program areas. One major concern was a weakness identified in Nordion's design control and fabrication control processes that allowed changes to be made to packagings that were not consistent with the approved design in the CoCs. Other concerns involved inadequacies in the documentation of quality-related work activities, the maintenance of quality records, and invoking 10 CFR Part 21 requirements on certain purchase orders. An inspection report that documented these, and other, inspection findings was issued on July 28, 2004 (reference ML042100486).

Inspection of a non-U.S. based licensee did introduce some unique aspects to the conduct of the inspection, particularly in the area of 10 CFR Part 21 requirements that apply to all U.S.-based licensees. In accordance with legal clarification provided after the previous inspection at Nordion, the inspection team was mindful, when reviewing purchase order records, that the requirement in 10 CFR 21.31 for invoking Part 21 provisions applies only to materials and services procured by Nordion from U.S.-based suppliers and not from Canadian suppliers. Also, the postings required by Part 21 apply only on premises within the U.S. where activities subject to Part 21 are conducted.

The team also noted that while Nordion's transport package quality plan (submitted to and used by the NRC for issuance of Nordion's Part 71 Quality Assurance Program Approval) was written to satisfy the 10 CFR Part 71, Subpart H, requirements, Nordion's actual implementation of package design, fabrication, and maintenance activities (as directed through the quality plan) is through two separate Nordion divisional QA Programs and their associated implementing procedures. These programs were noted to be ISO-9001 based, and in general, provided controls comparable to those in 10 CFR Part 71, Subpart H, as well as to IAEA QA program requirements.

Separate from the inspection, on July 13, 2004, Robert Lewis met with Messrs. Sylvain Faille of CNSC and Ray Clark of TC. The CNSC transport group consists of a staff of nine individuals, with package review responsibilities, transport licensing, and transport operational inspection responsibilities. CNSC acts as the competent authority for radioactive material transportation issues. TC has a single individual who coordinates radioactive material transport activities, and is the overall competent authority for transportation of dangerous goods. Regional/provincial offices also have a role. The TC-CNSC relationship is similar to the DOT-NRC relationship in the U.S. Like the U.S., the Canadians just recently passed regulations for IAEA 1996 transport regulation compatibility, and are in the implementation phase.

Current higher resource activities for CNSC and TC include security issues and implementing radiation protection plans (RPPs) for transport carriers. On the RPPs, guidance was recently issued by CNSC, a copy of which was provided. Mr. Lewis described that the U.S. DOT had not adopted the carrier RPP provisions, and provided the related history. Regarding security,

CNSC and TC brought up two specific issues which Mr. Lewis relayed to NSIR staff upon return from the inspection. On July 22, 2004, NSIR staff made separate contact to TC in follow-up to these issues.

Mr. Lewis presented the U.S. proposals to be submitted to the IAEA for the 2007 Edition of TS-R-1 transport regulations. Specifically, proposals and justifications were described related to the fissile exemptions system, the factor of 10 exemption based on intended use, and an identified problem for contamination limits. Mr. Lewis requested CNSC's and TC's views, and expressed that their possible support on these issues would be very welcome. The CNSC and TC described Canadian proposals for TS-R-1 (2007), including requiring labels for overpacks, shipping by post (TS-R-1 para 591), redefining low-dispersable material, expansion of shipment prior notification (para 558) to include domestic transport, and an identified problem for the uranium hexafluoride thermal test. The Canadian proposals, like the U.S. proposals, are relatively few and are minor changes that appear to have justification and support. The Canadians, like the U.S., solicit change proposals from stakeholders, but screen them before passing on to IAEA. This avoids competing, alternative, or questionable proposals from the same member state. We agreed to continue to encourage this practice by other member states.

The Canadians are very interested in a standard review process for transport package applications. CNSC and NRC management had met in early 2004, at NRC, to discuss this effort. It was agreed that both NRC and CNSC staff continue to be very interested in pursuing North American 'standard' applicant's and possibly reviewer's guides. The goals would be to add a degree of assurance that could reduce efforts needed in revalidation reviews, and to share review information and acceptance criteria at the reviewer's level. NRC and CNSC are co-authoring a paper for the PATRAM 2004 conference. CNSC was interested in being copied on some work related to their activities (e.g., Nordion package design docket materials).

Overall, the on-site interface between CNSC and NRC inspection staff was very valuable in terms of learning how different regulatory agencies apply and audit the same IAEA requirements in practice. Mr. Irvine, the CNSC observer, expressed appreciation for being invited to observe the NRC inspection and commented that the extent and depth of the NRC inspection was considerably greater than comparable inspections performed by the CNSC.

The meeting with CNSC and TC officials was also worthwhile. Due to increasing international commerce, and the need for unified North American approaches, SFPO recommends continued, close cooperation with CNSC and TC staff on a wide range of transportation issues, including transport package design certification, inspections and enforcement, regulatory development, and coordination on IAEA transport and storage meetings.

Business cards from the Nordion and CNSC personnel are included in Attachment 1.

**Pending Actions/Planned Next Steps for NRC:**

No specific actions for NRC resulting from the inspection or from the meeting with the CNSC and TC.

**Points for Commission Consideration/Items of Interest:**

None

**“On the Margins”:**

None

**ATTACHMENT 1**

**BUSINESS CARDS**