

447 March Road  
Kanata, Ontario  
Canada K2K 1X8  
Tel: 613 592-2790



June 8, 2001

Mr. Frederick Sturz  
Section Chief  
Mail Stop: 6F18  
United States Nuclear Regulatory Commission  
One White Flint North  
11555 Rockville Pike  
Rockville, MD  
20852-2738

Dear Mr. Sturz:

**RE: Sealed Source Registration for MDS Nordion C-168**

Please find attached the Safety Analysis Report to re-activate and update the Sealed Source Registration number NR-169-S-803-U for the C-168 Sealed Source. The Safety Analysis Report provides a detail description of the C-168 sealed source, drawings and prototype testing done to the classified level of E64435 as prescribed in the American National Standard N43.6. It should be noted however, that the C-168 Sealed Source design has not been changed.

An application and review checklist has been completed and is attached. A copy of the checklist can be provided electronically upon request.

If you have any questions or require further information please feel free to contact me by telephone at (613) 592-3400 extension 2421 or by email at [mcharette@mds.nordion.com](mailto:mcharette@mds.nordion.com).

Yours sincerely

A handwritten signature in black ink, appearing to read 'Marc-André Charette', written in a cursive style.

Marc-André Charette  
Regulatory Affairs Senior Associate  
MDS Nordion

Attached: IN/TR 1740 C168 (1), Application and Review Checklist

Copy to: Mike Krzaniak, Fred Taylor, MDS Nordion

<b>SUMMARY DATA</b>	
<b>Name and Complete Mailing Address of the Applicant:</b> MDS Nordion Inc. (formerly Nordion International Inc. and Atomic Energy of Canada Ltd.) 447 March Road Kanata, Ontario Canada, K2K 1X8	<b>Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC:</b>  Mr. Marc Andre Charette Regulatory Affairs 592-3400 ext. 2421
<b>The Applicant is (check one):</b>  <input type="checkbox"/> Custom User <input type="checkbox"/> Manufacturer <input type="checkbox"/> Distributor <input checked="" type="checkbox"/> Manufacturer and Distributor	<b>If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:</b>
<b>If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor:</b> N.A.	<b>Provide the Name, Complete Mailing Address, and Function of Other Companies Involved:</b> N.A.
<b>Model Number:</b> C-168	<b>Principal Use Code (see Appendix F):</b> (D) Gamma Gauges
<b>Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.):</b> Sealed Source	<b>For Use by:</b>  <input type="checkbox"/> Specific Licensees Only <input type="checkbox"/> General Licensees Only <input checked="" type="checkbox"/> Both Specific and General Licensees <input type="checkbox"/> Persons Exempt from Licensing
<b>Leak-Test Frequency:</b>  <input type="checkbox"/> Periodic Leak-Testing is Not Required <input checked="" type="checkbox"/> 6 Months Attached is justification for a leak test frequency of greater than 6 months	<b>Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5):</b> 10 CFR 36  <b>Radionuclides and Maximum Activities (including loading tolerance):</b> C-168 Cobalt-60 Pellet Material: 5 curies (0.185 TBq)
<b>CERTIFICATION:</b> THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT. THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30 AND 32 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF. WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.	
<b>Certifying Officer — Typed Name and Title</b>	
<b>Signature:</b>	<b>Date:</b>

**CHECKLIST****Registration Certificate Holder:** MDS Nordion Inc.**Model:** C-168

DESCRIPTION	OK/DEF	COMMENTS
DESCRIPTION/CONSTRUCTION		
If registration certificate holder is requesting to register more than one source/device on a certificate, are designs similar enough to do so?	NA	
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	OK	
Assembly methods (screw, welds, etc.); verify integrity	OK	
Source mounting (size and integrity) and security	NA	
Is source ANSI classification sufficient (from ANSI N542-1977): Radiography - Unprotected 43515 Radiography - In Device 43313 Medical - Radiography 32312 Medical - $\gamma$ Teletherapy 53524 $\gamma$ Gauges - Unprotected 43333 $\gamma$ Gauges - In Device 43232 $\beta$ Gauges, Low Energy $\gamma$ Gauges, or X-ray fluorescence 33222 Oil Well Logging 56522 Portable Moist/Density 43333 Neutron Applications 43323 $\gamma$ Irradiators (II, III, IV) 43424 $\gamma$ Irradiators (I) 43323 Static Eliminators 22222 Smoke Detectors 32222	OK	$\gamma$ Gauges - Unprotected require 43333 and $\gamma$ Gauges - In Device require 43232. MDS Nordion classifies to 64435.
Definition of shutter operation (locked in Off position, not locked in On position), Fail safe, spacing and tolerances	NA	
On-Off indicators (description, qty., location)	NA	
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels	NA	
Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.)	NA	
Shielding efficiency and integrity	NA	
For medical devices: Was a 510(k) provided? (provide written notification to FDA)	NA	
Well logging sources must be nondispersible and nonsoluble. (see Appendix B for a list of approved well logging sources as of November 1991)	NA	
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)	OK	
LABELING		
Copy of label	OK	
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)	OK	
Permanent attachment and location(s) - visible to users?	OK	Engraved
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be	OK	

**CHECKLIST**

Registration Certificate Holder: MDS Nordion Inc.

Model: C-168

DESCRIPTION	OK/DEF	COMMENTS
included)		
CONDITIONS OF USE		
Expected working life of the source/device (years, operations)	OK	
Actions to be taken when product reaches end of its working life.	OK	Disposal
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)	OK	Do not exceed the values in Performance Classification Tests
How the device will be used	NA	
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing	NA	
PROTOTYPE TESTING/HISTORICAL USE		
Tests methods and conditions (for source and device)	OK	
Tests results	OK	
Years of use (incidents, failures, etc.)	OK	
Similarities to other sources/devices if they are used as basis.	OK	
RADIATION PROFILES		
Survey instrument used (type, window thickness, sensitivity, etc.)	NA	
Conditions: including environments, scatter (product in beam), and use of guards and shields	NA	
Distance from source/surface (per ANSI 538-1979)	NA	
Shutter Open and Closed/Source Shielded	NA	
Verify radiation surveys for $\gamma$ radiation meet $inv^2$ law.	NA	
Verify radiation surveys for non- $\gamma$ radiation have not been calculated using $inv^2$ law.	NA	
QUALITY ASSURANCE		
Materials, subassemblies, services	OK	
Assembly methods (screws, welding, etc.)	OK	
Dimensions and tolerances	OK	
Activity, radiation levels, leak tests	OK	
QA Manual and comparison of manual to Regulatory Guide 6.9	OK	MDS Nordion has an NRC approved quality assurance and control program

**CHECKLIST**

Registration Certificate Holder: MDS Nordion Inc.

Model: C-168

DESCRIPTION				OK/DEF	COMMENTS
INSTALLATION					
Fixed, portable, movable, fixed installation but portable source housing				NA	
Inherent shielding, inaccessibility				NA	
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers				NA	
Mounting integrity				NA	
SAFETY INSTRUCTIONS					
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys				OK	
ACCOMPANYING DOCUMENTATION					
Leak tests results and radiation surveys				OK	
Transportation documents				NA	
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable				OK	
For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations				NA	
SERVICING					
The following activities may be performed by the persons indicated:				OK	
Activity	by a General Licensee	Only by a Specific Licensee	Will be Offered by the Applicant		
Installation	√				
Relocation	√				
Maintenance	√				
Repair	√				
Source Exchange	√				
Calibration	√				
Leak Testing	√				
Radiation Survey	√				
Training	√				
FOREIGN VENDORS					
Drop ship				NA	MDS Nordion does not drop ship

**CHECKLIST****Registration Certificate Holder:** MDS Nordion Inc.**Model:** C-168

DESCRIPTION	OK/DEF	COMMENTS
Who and where is source installed	OK	Sources may be installed in various gauge devices.
Leak test and radiation surveys	OK	
QA in the U.S.	OK	MDS Nordion has an NRC approved quality assurance and control program