

Application and Review Checklist
 new source: NR-0220-S-126-S

SSD 01-31

M.Burgess/J.Jankovich

The Application and Review Checklist are shown on the following pages.

SUMMARY DATA									
Name and Complete Mailing Address of the Applicant: MDS Nordion Inc. 447 March Road Kanata ON Canada K2K 1X8	Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: Marc-Andre Charette Regulatory Affairs Senior Associate 613-592-3400 x2421 mcharette@mds.nordion.com								
The Applicant is (check one): <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;"></td> <td>Custom User</td> </tr> <tr> <td></td> <td>Manufacturer</td> </tr> <tr> <td></td> <td>Distributor</td> </tr> <tr> <td style="text-align: center;">x</td> <td>Manufacturer and Distributor</td> </tr> </table>		Custom User		Manufacturer		Distributor	x	Manufacturer and Distributor	If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer: NA
	Custom User								
	Manufacturer								
	Distributor								
x	Manufacturer and Distributor								
If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor: NA	Provide the Name, Complete Mailing Address, and Function of Other Companies Involved: NA								
Model Number: C-442	Principal Use Code (see Appendix F): M								
Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.): Gamma Irradiator Source (Category IV)	For Use by: <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%; text-align: center;">x</td> <td>Specific Licensees Only</td> </tr> <tr> <td></td> <td>General Licensees Only</td> </tr> <tr> <td></td> <td>Both Specific and General Licensees</td> </tr> <tr> <td></td> <td>Persons Exempt from Licensing</td> </tr> </table>	x	Specific Licensees Only		General Licensees Only		Both Specific and General Licensees		Persons Exempt from Licensing
x	Specific Licensees Only								
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Leak-Test Frequency: <table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%;"></td> <td>Periodic Leak-Testing is Not Required</td> </tr> <tr> <td style="text-align: center;">x</td> <td>6 Months</td> </tr> <tr> <td></td> <td>Attached is justification for a leak test frequency of greater than 6 months</td> </tr> </table>		Periodic Leak-Testing is Not Required	x	6 Months		Attached is justification for a leak test frequency of greater than 6 months	Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5): 10 CFR 36 Radionuclides and Maximum Activities (including loading tolerance): Co-60 Slug Material: 17000 Ci (629 TBq) Co-60 Pellet and Wafer Material: 14000 Ci (518 TBq)		
	Periodic Leak-Testing is Not Required								
x	6 Months								
	Attached is justification for a leak test frequency of greater than 6 months								

CERTIFICATION:
 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.

Certifying Officer — Typed Name and Title

Signature: _____ **Date:** _____

CHECKLIST

Registration Certificate Holder: MDS Nordion

Model: C-442

DESCRIPTION	OK/DEF	COMMENTS
DESCRIPTION/CONSTRUCTION	DEF	
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) DEF Q: The wall thickness as calculated by the dimensions on both the outer tube and inner tube drawing is 0.042-0.0394 inch. The wall thickness listed on the drawings is 0.025 inch. Please explain the discrepancy. DEF Q: The maximum gap between the tube and cap (for both the outer tube and inner tube) as calculated from the drawing dimensions is 0.0012 inch. Please verify that this does not exceed the maximum allowable gap for the welding process used. DEF Q: Specify the material for the end cap of the inner body (p. 3/8, Drawing Nos. 144202-006 and 144202-014.	DEF	
Assembly methods (screw, welds, etc.); verify integrity	OK	welded
Source mounting (size and integrity) and security	NA	

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DESCRIPTION	OK/DEF	COMMENTS
Is source ANSI classification sufficient (from ANSI N542-1977):	OK	
Radiography - Unprotected 43515		
Radiography - In Device 43313		
Medical - Radiography..... 32312		
Medical - γ Teletherapy 53524		
γ Gauges - Unprotected 43333		
γ Gauges - In Device 43232		
β Gauges, Low Energy γ Gauges, or X-ray fluorescence ... 33222		
Oil Well Logging.... 56522		
Portable Moist/Density..... 43333		
Neutron Applications 43323		
γ Irradiators (II, III, IV) 43424		
γ Irradiators (I) 43323		
Static Eliminators ... 22222		
Smoke Detectors ... 32222		
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.)	OK	
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 -done	DEF	
Copy of label		
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)		
Permanent attachment and location(s) - visible to users?		engraved on source

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DESCRIPTION	OK/DEF	COMMENTS
<p>Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)</p> <p>DEF Q: Your application does not address how the activity level and date of assay is communicated to the user. Please describe the accompanying paperwork that is transferred with the source. Verify that Nordion will maintain, and make available to the NRC, records containing activity and date of assay information for each serial number.</p>		<p>no date of assay or activity anywhere (has trefoil, SN, model#, isotope)</p>
<p>CONDITIONS OF USE - done</p>	<p>DEF</p>	
<p>Expected working life of the source/device (years, operations)</p> <p>DEF Q: Please indicate the estimated working life of the sources, with respect to structural integrity of the source containment and design integrity. Please indicate the estimated maximum useful life of the source loaded to maximum activity and used as described in your application.</p>		<p>need them to state estimated working life</p>
<p>Actions to be taken when product reaches end of its working life.</p>		<p>expect that working life based on integrity will far outlast useful life based on activity so disposal will occur first NIMA: disposal</p>
<p>Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)</p>		<p>NIMA: need info on sensitization during transportation</p>
<p>How the device/source will be used</p>	<p>OK</p>	
<p>Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing</p>	<p>NA</p>	
<p>PROTOTYPE TESTING/HISTORICAL USE</p>	<p>????</p>	

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DESCRIPTION	OK/DEF	COMMENTS
<p>Tests methods and conditions (for source and device)</p> <p>DEF Q: Provide the internal void volume of the sources used in the prototype tests.</p> <p>(NOTE: ANSI section A1. General requires 0.01 ml since they used the helium pressure test)</p> <p>DEF Q: Provide the dimensions of the C-442 outer capsule that was used in the prototype tests.</p> <p>DEF Q: Describe how the prototype tests, that were conducted with solid stainless steel and hollow aluminum slugs, apply as worst-case scenario for sources that will be filled with wafers. Please also address what the ANSI 43.6 classification would be if the prototype test series were conducted with wafers. Please also describe the relevancy of the bending tests, conducted in accordance with 10 CFR 36.26(g), to sources which will be filled with wafers.</p>		<p>need to verify that they used the worst case. JPJ - dimensions OK, should ask about wafer filling</p>
Tests results		
Years of use (incidents, failures, etc.)		NIMA: C-188 in use since 1964
Similarities to other sources/devices if they are used as basis.		NIMA: compared to C-188
RADIATION PROFILES - done	DEF	
<p>Survey instrument used (type, window thickness, sensitivity, etc.)</p> <p>DEF Q: The radiation levels provided in your application are calculated using a method acceptable for a point source, however this method is not acceptable to a line source like the C-442. Please provide corrected radiation levels at the source surface, and 5, 30, and 100 cm from the source.</p>	DEF	
Conditions: including environments, scatter (product in beam), and use of guards and shields	NA	
Distance from source/surface (per ANSI 538-1979)	OK	
Shutter Open and Closed/Source Shielded	NA	

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DESCRIPTION	OK/DEF	COMMENTS
Verify radiation surveys for γ radiation meet inv^2 law.	NA	is a gamma source, however line source will not meet inv square law close to the source surface
Verify radiation surveys for non- γ radiation have not been calculated using inv^2 law.	NA	
QUALITY ASSURANCE - done DEF Q: Verify that all Nordion sources are manufactured and distributed under the existing NRC-approved QA program. Please provide the date that that QA program was last reviewed and approved by the NRC. (NOTE: if yes, then no additional review) DEF Q: Please confirm that the acceptance limit of the wipe tests, that you intend to use in the fabrication process, is 0.5 nanocuries (18.5 Becquerels), see Appendix G.	DEF	
Materials, subassemblies, services		
Assembly methods (screws, welding, etc.)		
Dimensions and tolerances		
Activity, radiation levels, leak tests		
QA Manual and comparison of manual to Regulatory Guide 6.9		NIMA: approved QA/QC program 0703, ISO 9001
INSTALLATION - done	NA	
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 - done	DEF	

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DESCRIPTION				OK/DEF	COMMENTS
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys DEF Q: Please describe all documentation sent to the user with the source, including specific warnings, leak test and radiation survey documentation, and activity level statement.					NIMA: DEF, no instruction provided on installation, servicing, instructions.
ACCOMPANYING DOCUMENTATION - done				DEF - SEE ABOVE	
Leak tests results and radiation surveys					see above
Transportation documents				NA	
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable					see above NIMA: DEF, no instruction provided on installation, servicing, instructions
For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations				NA	
SERVICING- done				OK	
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		X	X		
Relocation		X	X		
Maintenance		X	X		
Repair		X	X		
Source Exchange		X	X		
Calibration		NA	NA		
Leak Testing		X	X		
Radiation Survey		X	X		

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DESCRIPTION				OK/DEF	COMMENTS
Training		X	X		
FOREIGN VENDORS - Nordion is both distrib and manufacturer and is handled as a US company per historical practice.				NA	
Drop ship				NA	
Who and where is source installed				NA	
Leak test and radiation surveys				NA	
QA in the U.S.				NA	

OTHER:

**SSD Requirements Checklist for Category IV Irradiators
from 10 CFR 36 - Licenses and Radiation Safety Requirements for Irradiators
36.21 Performance criteria for sealed sources.**

OK/DEF	Requirement
OK	(a) Requirements. Sealed sources installed after July 1, 1993:
	OK (1) Must have a certificate of registration issued under 10 CFR 32.210;
	OK (2) Must be doubly encapsulated;
	OK (3) Must use radioactive material that is as nondispersible as practical and that is as insoluble as practical if the source is used in a wet-source-storage or wet-source-change irradiator;
	OK (4) Must be encapsulated in a material resistant to general corrosion and to localized corrosion, such as 316L stainless steel or other material with equivalent resistance if the sources are for use in irradiator pools; and
OK (5) In prototype testing of the sealed source, must have been leak tested and found leak-free after each of the tests described in paragraphs (b) through (g) of this section.	
OK	(b) Temperature. The test source must be held at -40 deg C for 20 minutes, 600 deg C for 1 hour, and then be subjected to a thermal shock test with a temperature drop from 600 deg C to 20 deg C within 15 seconds.
OK	(c) Pressure. The test source must be twice subjected for at least 5 minutes to an external pressure (absolute) of 2 million newtons per square meter.
OK	(d) Impact. A 2-kilogram steel weight, 2.5 centimeters in diameter, must be dropped from a height of 1 meter onto the test source.
DEF	<p>(e) Vibration. The test source must be subjected 3 times for 10 minutes each to vibrations sweeping from 25 hertz to 500 hertz with a peak amplitude of 5 times the acceleration of gravity. In addition, each test source must be vibrated for 30 minutes at each resonant frequency found.</p> <p>DEF Q: Demonstrate that the 0.635 mm amplitude peak to peak used in the vibration tests meets or exceeds the 5 g requirement in 10 CFR 36.21(e) for the range of 50-90 Hz.</p> <p>(NOTE: if no, then not meet regs)</p>

OK	(f) Puncture. A 50-gram weight and pin, 0.3-centimeter pin diameter, must be dropped from a height of 1 meter onto the test source.
OK	(g) Bend. If the length of the source is more than 15 times larger than the minimum cross-sectional dimension, the test source must be subjected to a force of 2000 newtons at its center equidistant from two support cylinders, the distance between which is 10 times the minimum cross-sectional dimension of the source.

OK/DEF	Other Items
OK	need to verify which version of the ANSI standard was used. 1977 and 1997 versions match reg requirements. - THEY USED 1997
OK	need to verify that worst case(s) configuration tested
OK	1977 ANSI requires 43424, 1997 ANSI requires 53424. - model tested to 64435

DEF Q: You submitted two copies of your application (a proprietary version and a non-proprietary version), along with an affidavit. There is a 8.5x11” drawing in Appendix A (drawing number “C-442”, title “C-442 Sealed Source”) that is marked proprietary in the lower left corner, however it is in the non-proprietary version and is not listed on the affidavit. Please confirm that this drawing can be released to the public, or provide an affidavit for the drawing.

DEF Q: Verify that the source will not be subjected to temperatures that could result in sensitization, including during both wet-storage and dry-storage use, and during transport. Please refer to NRC’s Information Notice IN 96-54, “Vulnerability of Stainless Steel to Corrosion when Sensitized”, for additional information.

Reviewers:

Michele Burgess /RA/ 11/12/01
John Jankovich