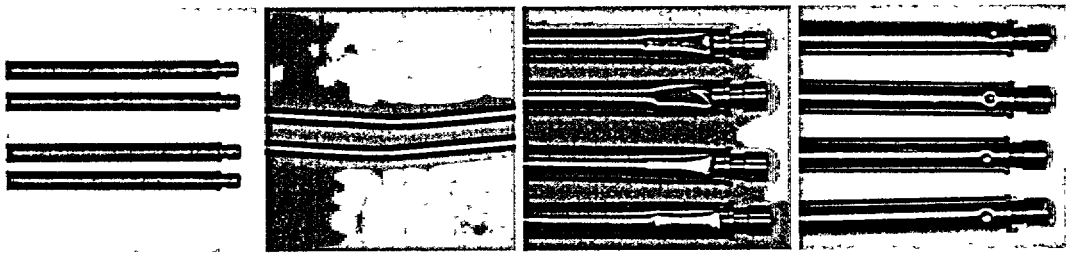
Registry of Radioactive Sealed Sources and Devices

Safety Evaluation of Sealed Source for the C-442



IN/TR 1515 C442 (1)

Non-proprietary version – proprietary information removed

MDS Nordion

Science Advancing Health

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

MDS Nordion
Science Advancing Health

June 15, 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-442

Please find attached the Safety Analysis Report IN/TR 1515 C442 (1) in support of MDS Nordion request to obtain a Sealed Source Registration for the C-442 Sealed Source. The C-442 is similar in design to the C-188 sealed source previously registered by the U.S. Nuclear Regulatory Commission under number NR-220-S-103-S. Both sources are double encapsulated sources consisting of inner capsules in an outer capsule of stainless steel. The C-442 sealed source is designed for use in wet source storage, pool type irradiators.

The Safety Analysis Report provides a detail description of the C-442 sealed source, drawings and prototype testing done to the classified level of E64435 as prescribed in the American National Standard N43.6. To facilitate the review process an application and review checklist has been completed and is attached. A copy of the checklist can be provided electronically upon request.

Attached is a proprietary copy of MDS Nordion's Report "IN/TR 1515 C442 (1), Registry of Radioactive Sealed Source and Devices Safety Evaluation of Sealed Source for the C-442" and a non-proprietary copy for the Public Document Room. Attached is a copy of the affidavit to support MDS Nordion's request to withhold parts of the Safety Analysis Report IN/TR 1515 C442 (1) from public disclosure. Parts of these sections have been deleted from the Safety Analysis Report, as they are specific to the design and fabrication of the C-442 and would enable a third party to manufacture a similar sealed source.

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.

Yours sincerely

Marc-André Charette
Regulatory Affairs Senior Associate
MDS Nordion

Attached: IN/TR 1515 C442 (1), Application and Review Checklist, Affidavit

Copy to: Mike Krzaniak, Jeff Ramsay, Ann Warbick Cerone, MDS Nordion

AFFIDAVIT

I, E. S. Martell, in my capacity as Vice President, Quality & Regulatory Affairs, having been duly authorized to apply for withholding from disclosure of proprietary information by and on behalf of MDS Nordion Inc., do depose and say:

1. I, E.S. Martell, am the Vice President, Quality & Regulatory Affairs, of MDS Nordion Inc.

   The information contained in MDS Nordion Inc.'s Report "IN/TR 1515 C442 (1), Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Sealed Source for the C-442" is the property of MDS Nordion Inc.
   This report contains proprietary information related to the design and qualification of the C-442 Sealed Source.

2. MDS Nordion Inc. has expended extensive funds and manpower in developing the aforementioned drawings and any release for disclosure of such information to third parties would enable and assist third parties to use the information to fabricate and register a similar sealed source without incurring any development costs. This could compromise MDS Nordion Inc.'s ability to compete in the marketplace. Therefore, MDS Nordion Inc. submits that the drawings listed below as well as the Capsule Work Sheets attached to the Certificate of Sealed Source Classification Designation No. 97 and the Capsule Work Sheets attached to the Special Form Radioactive Material Test Summary No. 43 of IN/TR 1515 C442 (1), should be withheld from public disclosure.

   G144202-001 (A) C-442 Capsule Active Welding Assembly
   G144202-002 (B) Outer Tube
   G144202-003 (A) End Cap, Outer Body
   G144202-004 (B) Tube, Inner
   G144202-005 (A) "MDSN X" Engraved End Cap
   G144202-006 (A) End Cap, Inner Body Engraved
   G144202-007 (A) Cobalt 60 Slug, Aluminum Clad
   G144202-010 (A) Inactive Welding Assembly Outer Body
   G144202-011 (B) C133 Active Welding Assembly
   G144202-012 (A) C133 Inactive Welding Assy Inner Body
   G144202-013 (A) "C-442" Engraved End Cap
   G144202-014 (B) End Cap, Inner Body Plain
   G110101-A01980 (F) Nickel Plated Cobalt 59 Slug

3. The information has been held in confidence by MDS Nordion Inc. and any disclosure thereof for developmental purposes, has been accompanied by a confidentiality agreement protecting the trade secrets contained herein.

4. The information has been transmitted to and received by the Nuclear Regulatory Commission in the United States in confidence.

5. This information is not available in public sources.

6. The information contained in this affidavit is to the best of my knowledge true and correct.

Sworn before me this 15 day of June, 2001 in the City of Kanata, Ontario, Canada.

Neil J. Gotfrit
Notary Public in and
for the Province of Ontario, Canada

per: E. S. Martell
V.P., Quality and Regulatory Affairs
MDS Nordion Inc.

Appendix C

SUMMARY DATA

Name and Complete Mailing Address of the Applicant: MDS Nordion Inc. 447 March Road Kanata, Ontario Canada, K2K 1X8	**Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC:** Mr. Marc Andre Charette Regulatory Affairs 592-3400 ext. 2421
The Applicant is (check one): Custom User Manufacturer Distributor √ Manufacturer and Distributor	**If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:**
If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor: N.A.	**Provide the Name, Complete Mailing Address, and Function of Other Companies Involved:** N.A.
Model Number: C-442	**Principal Use Code (see Appendix F):** (M) Gamma Irradiator Category IV
Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.): Gamma Irradiator Source	**For Use by:** √ Specific Licensees Only General Licensees Only Both Specific and General Licensees Persons Exempt from Licensing
Leak-Test Frequency: Periodic Leak-Testing is Not Required √ 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):** C-442 Cobalt-60 Slug Material: 17,000 curies (629 TBq) C-442 Cobalt-60 Pellet and Wafer Material: 14,000 curies (518 TBq)

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: Mr. E.S. Martell, Vice-President, Quality & Regulatory Affairs

Signature: [signature] **Date:** 15 June 2001

CHECKLIST

Registration Certificate Holder: MDS Nordion Inc.

Model: C-442

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 - 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	OK	Class IV irradiators require 53424. 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 included)	OK	
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 γ radiation meet inv^2 law.	NA	
Verify radiation surveys for non-γ 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
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			NA		
Leak Testing			√		
Radiation Survey			√		
Training			√		
FOREIGN VENDORS					
Drop ship				NA	MDS Nordion does not drop ship
Who and where is source installed				OK	Sources are installed in licensed Class IV irradiators
Leak test and radiation surveys				OK	
QA in the U.S.				OK	MDS Nordion has an NRC approved quality assurance and control program

Registry of Radioactive Sealed Sources and Devices
Safety Evaluation of Sealed Source for the C-442

Prepared by: M.-A. Charette, Regulatory Affairs Date: June 14, 2001

Reviewed by: J. Ramsay, Package Engineering Date: 01.06.14

Reviewed by: A. Warbick-Cerone, Regulatory Affairs Date: 01.06.14

Approved by: M. Krzaniak, Manager, Package Engineering Date: 01 June 14

Document History

Date	Version	Comments	Prepared by	Reviewed by	Approved by
Jun 01	1	DCN A1881-D-04	M. Charette	J. Ramsay A. Warbick Cerone	M. Krzaniak

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE FOR THE C-442

SUMMARY DATA:

SOURCE TYPE:	Gamma Irradiator Source
MODEL:	C-442 Series
MANUFACTURER/DISTRIBUTOR:	MDS Nordion Inc. 447 March Road Kanata ON Canada K2K 1X8

ISOTOPE:	MAXIMUM ACTIVITY:
Cobalt-60	C-442, Slug Material 17,000 curies (629 TBq) C-442, Pellet and Wafer Material 14,000 curies (518 TBq)

LEAK TEST FREQUENCY:	6 months
PRINCIPAL USE:	(M) Gamma Irradiator, Category IV
CUSTOM SOURCE:	__ YES X NO

INTRODUCTION

The C-442 sealed source is designed primarily for use in wet source storage, pool type irradiators (Category IV). Typical environments associated with these irradiators include high temperatures, thermal shock due to sources being cycled out of and into the pool water, and long-term contact with water.

This report demonstrates that the C-442 sealed source meets the requirements for a Category IV Irradiator sealed source as prescribed in ANSI N43.6 [1] and 10 CFR 36 SS 36.21(g) [2].

DESCRIPTION

Description of Model C-442

The C-442 sealed source specification sheet is attached as Appendix A.

The Model C-442 is a doubly encapsulated source consisting of one inner capsule contained in an outer capsule of 316L stainless steel. The C-442 outer capsule consists of a tubular body with solid caps fusion welded into either end.

The C-442 is produced by inserting the active inner capsule into the C-442 body with one end cap already welded into place. The final end cap is then inserted into the C-442 body and fusion welded to achieve closure.

The C-442 outer capsule has a maximum length of 17.8" (452 mm), a maximum diameter of 0.57" (14.5 mm) at the end caps, and an outside tube diameter of 0.49-0.53" (12.4-13.5 mm) with a 0.023-0.027" (0.58-0.69 mm) wall thickness.

The C-442 has been tested and classified to ANSI 77 E64435 as prescribed in ANSI N43.6, "Sealed Radioactive Sources, Classification". They have also passed the Class 5 bend test as prescribed in 10 CFR 36 SS 36.21(g) [2]. Bounding tests have been completed as discussed in Assessment section.

The C-442 also meets the test requirements for Special Form Radioactive Material as prescribed in the IAEA regulations [4].

Description of Inner Capsules and Cobalt

The inner C-133 source is produced by loading a quantity of cobalt-60 into tubular capsule bodies and fusion welding caps onto the ends to achieve closure. The properties of the C-133 inner capsule are summarised in the following table.

Model Number of Inner Capsule	Cobalt-60 Form	Inner Capsule Material	Maximum Length
C-133	Nickel-plated or aluminum-clad slugs, pellets or wafers	Zircaloy 2/4 or SS316L	16.1" (409 mm)
C-133	Slugs, pellets or wafers within a Zircaloy or stainless steel encapsulation	Zircaloy 2/4 or SS316L	16.1" (409 mm)

The active volume of all inner capsules contains Cobalt-60 in the form of slugs, pellets or wafers which may be nickel-plated or aluminum-clad. The inner capsules may be loaded with any combination of nickel-plated and/or aluminum-clad slugs, pellets or wafers. The C-133 may also contain cobalt-60 in the form of slugs, pellets and wafers within a Zircaloy or stainless steel encapsulation. The capsules contain up to 17,000 curies (629 TBq) in slug form and up to 14,000 curies (518 TBq) in pellet or wafer form. Stainless steel spacers may also be used inside the inner capsules to distribute the cobalt activity.

Drawings

The USNRC specification drawing for the C-442 sealed source is attached as Appendix A. This drawing includes a design envelope that is greater than the current manufacturing practice. The USNRC specification drawing for the MDS Nordion C-133 inner capsule assembly is attached as Appendix B.

The sources are manufactured in accordance with controlled engineering drawings. The C-442 sealed source engineering drawings attached in Appendix C are within the design envelope for the C-442. The dimensions listed on the controlled engineering drawings may change in the future but will remain within the design envelope specified on the USNRC specification drawing for the C-442 attached in Appendix A.

CONDITIONS OF USE

The C-442 is designed primarily for use in wet source storage, pool type irradiators. Typical environments associated with these irradiators include high temperatures, thermal shock due to sources being cycled out of and into the pool water, and long-term contact with water.

This source may also be used in dry source storage irradiators where the environment would typically be less harsh and they would be subjected to ambient temperatures and pressures.

LABELLING

The C-442 source is engraved in the following manner:

- A unique Serial Number on the upper end cap face.
- "C-442" and "Co 60" on the upper end cap diameter.
- The radiation trefoil symbol and "MDSN X" (where X is the material heat number) on the lower end cap diameter.

ASSESSMENT

The following assessment justifies that the C-442 sealed source meets the requirements prescribed in ANSI N43.6 [1] and 10 CFR 36 SS 36.21(g) [2]. Justification is provided via comparison with the C-188 and full scale testing of the worst case prototype source assemblies.

Comparison of the C-442 to the C-188

The C-442 is very similar in design to the C-188. Both the C-442 and the C-188 are doubly encapsulated sources consisting of inner capsules contained in an outer capsule of 316L stainless steel. The outer capsule for both sources consists of a tubular body with solid caps fusion welded into either end. The table below compares the C-442 and the C-188.

	C-188	C-442
Maximum length	17.8" (452 mm)	17.8" (452 mm)
Maximum diameter (end caps)	0.44" (11.2 mm)	0.57" (14.5 mm)
Capsule tube outside diameter	0.37–0.44" (9.4-11.2 mm)	0.49–0.53" (12.4-13.5 mm)
Capsule tube wall thickness	0.023–0.027" (0.58-0.69 mm)	0.023–0.027" (0.58-0.69 mm)

The C-188 was originally tested and classified to ANSI 77 E65646 as prescribed in ANSI N43.6 [1]. The C-188 has also passed the Class 5 bend test as prescribed in 10 CFR 36 SS 36.21(g) [2]. This exceeds the ANSI minimum classification of E53424 required for category IV irradiators.

Copies of the Classification Certificate and all testing work sheets describing the rationale for choice of inner capsules as worst-case scenarios for various tests can be found in the MDS Nordion report IN/TR 1382 C188/C306 (3), Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Sealed Source [3]. As well, the results of the Class 5 bend tests as required by 10 CFR 36 SS 36.21(g) [2] for Category IV irradiators can also be found in the MDS Nordion report IN/TR 1382 C188/C306 (3).

Worst-case testing was also performed on the C-188 sealed source to show its robustness over a bounding stiffness range for the inner capsules. ANSI N43.6 tests were performed on C-188 capsules loaded with two equal-length solid bars and with two equal-length inner capsule tubes. The maximum outer diameter was 0.323" (8.2 mm) and the maximum length

was 8.241" (209.32 mm) for both the bar and tubing. The tubing wall thickness was 0.023-0.027"(0.58-0.69 mm). The material for both bars and tubes was 316L stainless steel, since stainless steel has a higher stiffness than Zircaloy.

Two equal length bars and tubes were used to provide the maximum damage at the mid-span of the C-188 capsule and at the end caps for the ANSI N43.6 tests. The solid bars are representative of the stiffest inner capsule that could be expected. The empty tubes are representative of the least stiff inner capsule that would still exert shearing forces during deformation.

These worst-case prototypes were tested and classified to ANSI 77 E64424 as prescribed in ANSI N43.6, "Sealed Radioactive Sources, Classification" [1]. They have also passed the Class 5 Bend Test as prescribed in 10 CFR 36 SS 36.21(g) [2]. Appendix D contains a copy of the test summary.

These worst-case tests indicate that the C-188 sealed source is robust and maintains its integrity regardless of the geometry or stiffness of the inner capsule(s). These results are directly applicable to the C-442, as the designs are similar as seen in the table above. It can therefore be concluded that the C-442 sealed source will maintain its integrity regardless of the geometry or stiffness of the inner capsule(s).

The C-188 source types 1 though 13 has been registered by the US Nuclear Regulatory Commission and issued the Sealed Source Registration Certificate Number NR-220-S-103-S (Appendix E). As well the C-188 source types 1 through 13 are certified as Special Form Radioactive Material by the Canadian Nuclear Safety Commission under certificate number CDN/00 10/S-85 (Appendix E).

Testing of Worst-Case Prototype C-442 Sealed Sources

Worst-case testing was performed on the C-442 sealed source to show its robustness over a bounding stiffness range for the inner capsules. ANSI N43.6 tests were performed on C-442 capsules loaded with a C-133 inner capsule loaded with either solid stainless steel slugs or with aluminum tube slugs. The maximum outer diameter of the C-133 inner capsule was 0.450" (11.43 mm) and the maximum length was 16.036" (407.31 mm). The tubing wall thickness was 0.023-0.027" (0.58-0.69 mm).

The material for the solid stainless slugs was 316L stainless steel, which represents the stiffest inner slugs that could be expected. The material for the aluminum tubing slugs was aluminum, since aluminum represents the least stiff inner slugs that would still exert shearing forces during deformation.

These worst-case prototypes were tested and classified to ANSI 77 E64435 as prescribed in ANSI N43.6 [1]. They have also passed the Class 5 Bend Test as prescribed in 10 CFR 36 SS 36.21(g) [2]. Appendix F contains a copy of the test summary and all test work sheets.

These worst-case tests indicate that the C-442 sealed source is robust and maintains its integrity regardless of the geometry or stiffness of the inner capsule. These tests completely bound all C-442 inner configurations. Any inner capsule that meets the requirements specified herein may be used within the C-442.

It is therefore concluded that the C-442 capsule meets the Category IV Irradiators test prescribed in the ANSI N43.6 [1] and the class 5 bend test as prescribed in 10 CFR 36 SS 36.21(g) [2].

Operational Experience

MDS Nordion has manufactured over 60,000 C-188 sealed sources since 1964. Routine surveillance, including metallurgical examination is completed on returned sources. Operational experience has shown no evidence of leakage when the sources have been used in accordance with MDS Nordion specifications.

As the design of the C-442 is similar to that of the C-188 the same operational performance is expected from the C-442.

RADIATION LEVELS

A calculation of dose rates was carried out using the gamma radiation constant for Cobalt-60 of 1.32 R/hr (13.2 mSv/hr) at one meter, per curie (39.4", per 37 GBq).

The following table shows the dose rates a C-442 source containing 17,000 curies would be expected to yield.

Distance from Source	Radiation Level	
	R/hr	Sv/hr
100 cm/39.4 in	22,000	220
30 cm/11.8 in	250,000	2,500
5 cm/1.97 in	9,000,000	90,000

The following table shows the dose rates a C-442 source containing 14,000 curies would be expected to yield.

Distance from Source	Radiation Level	
	R/hr	Sv/hr
100 cm/39.4 in	18,500	185
30 cm/11.8 in	205,000	2,050
5 cm/1.97 in	7,400,000	74,000

QUALITY ASSURANCE

MDS Nordion maintains a quality assurance and control program, which has been deemed acceptable for licensing purposes by the USNRC under Quality Assurance Program No. 0703.

All MDS Nordion Cobalt-60 source quality requirements for design, manufacturing, inspection and testing are carried out under an ISO 9001 Quality System. To assure these requirements, Technical Specifications have been prepared and are available for inspection purposes.

IN/TS 1694 C350/C442, Technical Specification for the C-350/C-442 Type Sealed Sources Part I — Components

IN/TS 1695 C350/C442, Technical Specification for the C-350/C-442 Type Sealed Sources Part II — Inactive and Active Weld Assemblies

IN/TS 1487 Co60, Technical Specification for Industrial End-Welded Cobalt-60 Sealed Sources Part I — Components

IN/TS 0474 Co60, Technical Specification for Industrial End-Welded Cobalt-60 Sealed Sources Part II — Inactive and Active Weld Assemblies

Critical elements of these specifications are summarised in Appendix G.

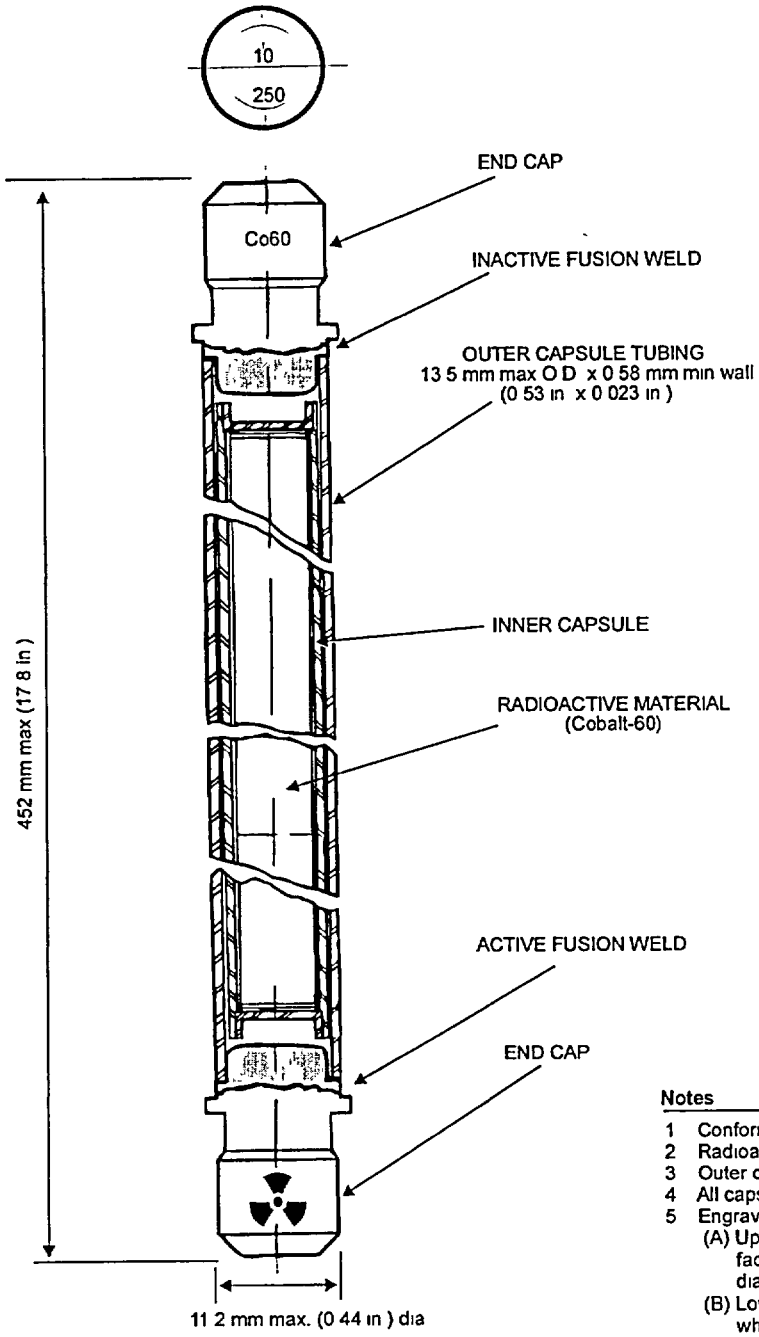
Any inner capsules MDS Nordion acquires from other manufacturers are subject to MDS Nordion quality requirements and the requirements specified herein. MDS Nordion is responsible for ensuring manufacturer's conformance to these requirements.

REFERENCES

1. ANSI/HPS N43.6-1997, American National Standard, Sealed Radioactive Sources – Classification.
2. Code of Federal Regulations 10 CFR Ch.I (1-1,01 Edition) Part 36.
3. MDS Nordion IN/TR 1382 C188/C306 (3), Registry of Radioactive Sealed Sources and Devices Safety Evaluation of Sealed Source.
4. International Atomic Energy Agency, Safety Series No. 6, Regulations for the Safe Transport of Radioactive Material 1985 Edition, (As Amended 1990).

APPENDIX A

C-442 SEALED SOURCE SPECIFICATION DRAWING



Notes

1. Conforms to IAEA Special Form requirements
2. Radioactive Material Cobalt-60 in solid form
3. Outer capsule material Type 316L stainless steel
4. All capsules are sealed by fusion welds
5. Engraved on capsule:
   (A) Upper end cap
   face serial number
   diameter. C442 Co60
   (B) Lower end cap diameter MDSN X and Trefoil
   where X is material heat number

MDS Nordion
447 March Road, P.O Box 13500
Kanata, Ontario, Canada, K2K 1X8
Tel. (613) 592-2790 · Fax. (613) 592-6937

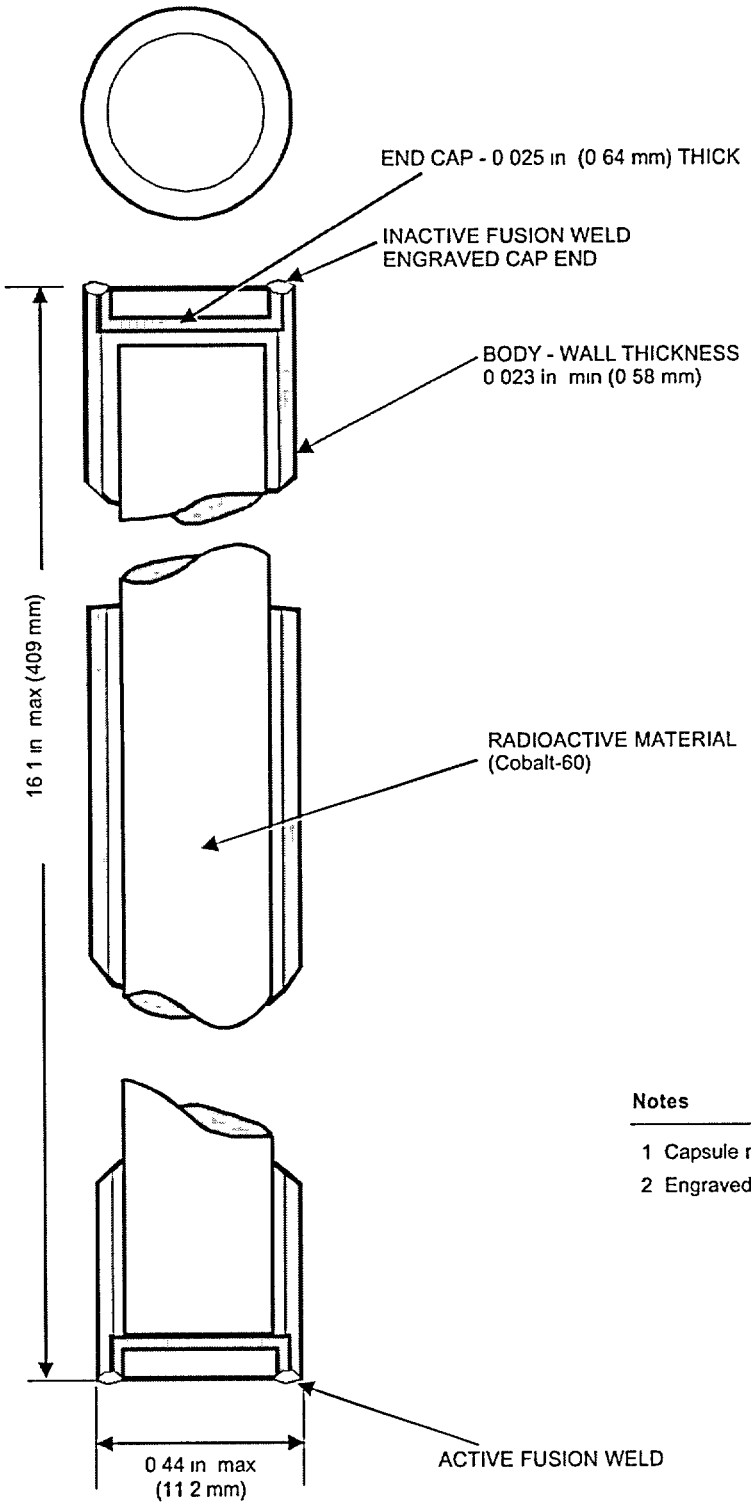
TITLE

C-442 Sealed Source

REF IN/SS 1729 C442 G144202-001		REVISED JUN 01	DCN A-1881-D-05A
DATE FEB 01		No C-442	ISSUE 2
DRAWN BW	CHECKED R	APPROVED MK	SHEET 1 OF 1

APPENDIX B

C-133 INNER CAPSULE SPECIFICATION DRAWING



Notes

1 Capsule material Type 316L Stainless Steel
2 Engraved on end cap - MDSN Serial No

Figure B-1
C-133 Inner Source for use in C-442 Outer Sealed Source

APPENDIX C

C-442 SEALED SOURCE DRAWINGS

(G144202-001 to -007, G144202-010 to -014, A01980)

APPENDIX D

C-188 SEALED SOURCE CLASSIFICATION AND SPECIAL FORM TEST SUMMARY

MDS Nordion

CERTIFICATE

SEALED SOURCE
CLASSIFICATION DESIGNATION AND PERFORMANCE

Sealed sources are classified in accord with standards established by
THE AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI) and
THE INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)

CERTIFICATE NO: 95 DATE: 99-12-12

CAPSULE MODEL:. C-188 (Bounding Conditions) CONTENTS: Cobalt -60

TEST REFERENCE REPORT: IN/TR1382 C188

CAPSULE MATERIAL: 316L Stainless steel OVERALL DIAMETER: 0.380"

ENCAPSULATION: Double OVERALL LENGTH: 17.777"

ANSI CLASSIFICATION AND PERFORMANCE STANDARD[1] ANSI 96:E64424

CLASSIFIED PERFORMANCE STANDARD[2]

TEST	CLASS	METHOD	REMARKS
TEMPERATURE	6	Test	Pass
EXTERNAL PRESSURE	4	Test	Pass
IMPACT	4	Test	Pass
VIBRATION	2	Test	Pass
PUNCTURE	4	Test	Pass

(1) See definition on reverse side
(2) See Table 1. Performance Standards on reverse side
(3) American National Standard N43.6-1997 is a revision of ANSI N542-1977

(4) Exceptions: Category II, III Gamma irradiation sources- Temperature class 5.

COMMENTS: Capsule integrity assured by Helium leak tests (ANS /HPS N43.6-1997, paragraphs A2.2.6 to A2.2.6.3.)

It is hereby certified that the described sealed source meets the specified standard as prescribed in [3] American National Standard N43.6-1997 "Sealed Radioactive sources, Classification". This standard complies with the classification and performance requirements of ISO 2919-1999(E), (see Note 4 above for exceptions).

Tested by [signature]
Title Materials Specialist
Date 99-12-14

Approved [signature]
Title Manager, Package Engineering
Date 99/12/15

REFERENCES

[1] DEFINITION - CLASSIFICATION DESIGNATION:

The classification of a sealed source shall be designated by the code ANSI followed by two digits to indicate the year of approval of the American National Standard used to determine the classification followed by a letter and five digits.

The letter shall be either a C or an E. The letter C designates that the contained activity does not exceed the maximum levels established by ANSI. The letter E designates that the contained activity exceeds the maximum levels established by ANSI.

The first digit shall be the class number which describes the performance standards for temperature.

The second digit shall be the class number which describes the performance standards for external pressure.

The third digit shall be the class number which describes the performance standards for impact.

The fourth digit shall be the class number which describes the performance standards for vibration.

The fifth digit shall be the class number which describes the performance standards for puncture.

[2] TABLE 1 - PERFORMANCE STANDARDS:

TEST	CLASS						
	1	2	3	4	5	6	X
Temperature	No Test	-40°C (20 min) +80°C (1h)	-40°C (20 min) +180°C (1h)	-40°C (20 min) +400°C (1h) and thermal shock 400°C to 20°C	-40°C (20 min) +600°C (1h) and thermal shock 600°C to 20°C	-40°C (20 min) +800°C (1h) and thermal shock 800°C to 20°C	Special Test
External Pressure	No Test	25 kN/m² abs. (3.6 lbf/in²) to atmosphere	25 kN/m² abs. to 2 MN/m² (290 lbf/in²) abs.	25 kN/m² abs. to 7 MN/m² (1015 lbf/in²) abs.	25 kN/m² abs. to 70 MN/m² (10153 lbf/in²) abs.	25 kN/m² abs. to 170 MN/m² (24 656 lbf/in²) abs.	Special Test
Impact	No Test	50 g(1.8oz) from 1 m (3.28 ft) and free drop ten times to a steel surface from 1.5 m (4.92 ft)	200 g (7 oz) from 1 m	2 kg (4.4 lb) from 1 m	5 kg (11 lb) from 1 m	20 kg (44 lb) from 1 m	Special Test
Vibration	No Test	30 min 25 to 500 Hz at 5 g peak amp.	30 min 25 to 50 Hz at 5 g peak amp. and 50 to 90 Hz at 0.635 mm amp. peak to peak and 90 to 500 Hz at 10 g	90 min 25 to 80 Hz at 1.5 mm amp. peak to peak and 80 to 2000 Hz at 20g	Not Used	Not Used	Special Test
Puncture	No Test	1 g (15.4 gr) from 1 m (3.28 ft)	10 g (154 gr) from 1 m	50 g (1.76 oz) from 1 m	300 g (10.6 oz) from 1 m	1 kg (2.2 lb) from 1 m	Special Test

MDS Nordion

SPECIAL FORM RADIOACTIVE MATERIAL TEST SUMMARY

The capsule model specified herein has been evaluated in accord with the International Atomic Energy Agency (I.A.E.A.) Safety Series No. 6, Regulations for the Safe Transport of Radioactive Material, 1985 Edition, (as amended 1990) Section VI, paragraphs 604-613 and 618.

TEST SUMMARY: 41 DATE: 99-12-12

CAPSULE MODEL: C-188 (Bounding Conditions) CONTENTS: Cobalt-60

TEST REFERENCE REPORT: IN/TR 1596 C188

CAPSULE MATERIAL: 316L Stainless Steel OVERALL DIAMETER: 0.380"

ENCAPSULATION: Double OVERALL LENGTH: 17.777"

SPECIAL FORM REQUIREMENTS(1)

TEST	PASS	FAIL	METHOD	REMARKS
IMPACT (607)(618)	X		Comparison	See Comments 3, 4, 5
PERCUSSION (608)	X		Comparison	See Comments 3, 4, 5
BENDING (609)	X		Test	Pass
HEAT (610)	X		Comparison	See Comments 2, 4, 5
LEACHING (612)(613)	---		---	See Comment 1

(1) See Special Form requirements on reverse side

COMMENTS: 1) Capsule integrity following bend test was verified by helium leak testing.

2) Paragraph 611(b), Safety series no. 6 specifies that the requirements of the Heat Test can be satisfied with the completion of a Class 6 Temperature Test per ISO 2919-1980 (E).

3) Paragraph 611(a), Safety series no. 6 specifies that the Impact and Percussion performance tests can be satisfied with the completion of a Class 4 Impact test per ISO 2919-1980 (E).

4) ISO 2919-1980 (E) Heat and Impact Tests are identical to ANS N43.6-1997.

5) The test reports for the Class 6 Temperature Test and the Class 4 Impact Tests are attached to ANSI certificate #95.

This summary verifies that the described capsule model meets the requirements of Special Form in accordance with the I.A.E.A. Safety Series No. 6, Regulations for the Safe Transport of Radioactive Material, 1985 Edition, (as amended 1990) Section VI, paragraphs 604-613 and 618.

Tested by J. Culbertson
Title Materials Specialist
Date 99-12-15

Approved M. Lyamcil
Title Manager, Package and Facility Engineering
Date 99/12/16

I.A.E.A. TESTS FOR SPECIAL FORM RADIOACTIVE MATERIAL

General

604. The tests which shall be performed on specimens that comprise or simulate **special form radioactive material** are: the impact test, the percussion test, the bending test, and the heat test.

605. A different specimen may be used for each of the tests.

606. After each test specified in paras 607-611, a leaching assessment or volumetric leakage test shall be performed on the specimen by a method no less sensitive than the methods given in para 612 for indispersible solid material and para. 613 for encapsulated material.

Test Methods

607. **Impact test.** The specimen shall drop onto the target from a height of 9 m. The target shall be as defined in para. 618.

618. The target for the drop test specified in para 607 shall be a flat, horizontal surface of such a character that any increase in its resistance to displacement or deformation upon impact by the specimen would not significantly increase the damage to the specimen.

608 **Percussion test.** The specimen shall be placed on a sheet of lead which is supported by a smooth solid surface and struck by the flat face of a steel billet so as to produce an impact equivalent to that resulting from a free drop of 1.4 kg through 1 m. The flat face of the billet shall be 25 mm in diameter with the edges rounded off to a radius of (3.0 ± 0.3)mm. The lead, of hardness number 3.5 to 4.5 on the Vickers scale and not more than 25 mm thick, shall cover an area greater than that covered by the specimen. A fresh surface of lead shall be used for each impact. The billet shall strike the specimen so as to cause maximum damage.

609. **Bending test.** The test shall apply only to long, slender sources with both a minimum length of 10 cm and a length to minimum width ratio of not less than 10. The specimen shall be rigidly clamped in a horizontal position so that one half of its length protrudes from the face of the clamp. The orientation of the specimen shall be such that the specimen will suffer maximum damage when its free end is struck by the flat face of a steel billet. The billet shall strike the specimen so as to produce an impact equivalent to that resulting from a free vertical drop of 1.4 kg through 1 m. The flat face of the billet shall be 25 mm in diameter with the edges rounded off to a radius of (3.0 ± 0.3)mm.

6.10 **Heat test.** The specimen shall be heated in air to a temperature of 800°C and held at that temperature for a period of 10 minutes and shall then be allowed to cool.

6.11 Specimens that comprise or simulate radioactive material enclosed in a sealed capsule may be excepted from:

(a) The tests prescribed in paras 607 and 608 provided they are alternatively subjected to the Class 4 impact test prescribed in the International Organization for Standardization document ISO 2919-1980(E), "Sealed radioactive sources - Classification", and

(b) The test prescribed in para 610 provided they are alternatively subjected to the Class 6 temperature test specified in the International Organization for Standardization document ISO 2919-1980(E), "Sealed radioactive sources - Classification".

Leaching and volumetric leakage assessment methods

612. For specimens which comprise or simulate indispersible solid material, a leaching assessment shall be performed as follows:

(a) The specimen shall be immersed for 7 days in water at ambient temperature. The volume of water to be used in the test shall be sufficient to ensure that at the end of the 7 day test period the free volume of the unabsorbed and unreacted water remaining shall be at least 10% of the volume of the solid test sample itself. The water shall have an initial pH of 6-8 and a maximum conductivity of 1 mS/m(10 μmho/cm) at 20°C.

(b) The water with specimen shall then be heated to a temperature of (50 ± 5)°C and maintained at this temperature for 4 hours.

(c) The activity of the water shall then be determined.

(d) The specimen shall then be stored for a least 7 days in still air of relative humidity not less than 90% at 30°C

(e) The specimen shall then be immersed in water of the same specification as in (a) above and the water with the specimen heated to (50 ± 5)°C and maintained at this temperature for 4 hours.

(f) The activity of the water shall then be determined.

613. For specimens which comprise or simulate radioactive material enclosed in a sealed capsule, either a leaching assessment or a volumetric leakage assessment shall be performed as follows:

(a) The leaching assessment shall consist of the following steps:

(i) The specimen shall be immersed in water at ambient temperature. The water shall have an initial pH of 6-8 with a maximum conductivity of 1 mS/m(10μmho/cm) at 20°C.

(ii) The water and specimen shall be heated to a temperature of (50 ± 5)°C and maintained at this temperature for 4 hours.

(iii) the activity of the water shall then be determined

(iv) The specimen shall then be stored for at least 7 days in still air at a temperature of not less than 30°C.

(v) The process in (i),(ii) and (iii) shall be repeated

(b) The alternative volumetric leakage assessment shall comprise any of the tests prescribed in the International Organization for standardization document ISO 9978:1992(E) "Radiation Protection - Sealed Radioactive Sources - Leakage Test Methods." which are acceptable to the competent authority

APPENDIX E

C-188 USNRC SEALED SOURCE REGISTRATION CERTIFICATE AND C-188 CNSC SPECIAL FORM RADIOACTIVE MATERIAL CERTIFICATE

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

March 30, 2000

Mr. Mark-Andre' Charette
Regulatory Affairs Senior Associate
MDS Nordion Inc.
447 March Road
Kanata, Ontario
Canada K2K 1X8

Subject: NR-220-S-103-S SSD Registration Certificate Amended To Include Type 13 Configuration to Source Model C-188.

Dear Mr. Charette:

Based on the information submitted in your letters dated December 21, 1999, and March 6, 2000, we have amended in its entirety the Sealed Source Registration Certificate Number NR-220-S-103-S. This amendment includes your new Type 13 configuration to Source Model C-188. Also, the certificate has been amended to reflect the requested new minimum tolerances and the minimum shell thickness of an inner capsule from 0.025 inches to 0.015 inches.

Please be advised that you must manufacture and distribute the product in accordance with the statements and representations contained in the application submitted by MDS Nordion Inc. with enclosures thereto, and the information set out in the attached registration certificate. As a general rule, you must request and obtain an amendment to the certificate before you make changes or modifications to the information submitted to obtain the registration certificate. You are obligated to notify us promptly in writing should you decide to no longer manufacture or offer service support for the product.

Please be aware that, as a holder of an NRC registration, you may be subject to the NRC's licensing fees in accordance with 10 CFR Part 170, and annual fees in accordance with 10 CFR Part 171. If you have any questions concerning the fee requirements, please contact the License Fee and Debt Collection Branch at (301) 415-6096.

Please read over the registration certificate in its entirety and notify us immediately of any errors or omissions. If you have any questions, please contact me at (301) 415-7894 or Seung Lee on (301) 415-5787.

Sincerely,

Ujagar S. Bhachu, Mechanical Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

cc w/encl: SKimberley, LFDCB

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-220-S-103-S DATE: March 30, 2000 PAGE: 1 of 10

SOURCE TYPE: Gamma Irradiator Source

MODEL: C-188 (Series) Types **1 through 13**
C-306 (Series) Types **1 and 2**

MANUFACTURER/DISTRIBUTOR: MDS Nordion, Inc.
(formerly Nordion International, Inc. and Atomic Energy of Canada, Ltd.)
447 March Road
Kanata, Ontario, Canada K2K 1X8

ISOTOPE:	MAXIMUM ACTIVITY:
Cobalt-60	(C-188, slug material) 17,000 curies(629 TBq) (C-188, **wafer** and pellet material) 14,000 curies(518 TBq) (C-306) 8,500 curies(314.5 TBq)

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (M) Gamma Irradiator, Category IV

CUSTOM-SOURCE: _____ YES __X__ NO

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-220-S-103-S DATE: March 30, 2000

SOURCE TYPE: Gamma Irradiator Source

DESCRIPTION:

The Models C-188 and C-306 are doubly encapsulated fusion welded sources consisting of one or two inner capsules and an outer capsule. The outer capsule is the same for each source model except for the length. The inner capsules vary according to the type and activity required.

The Model C-188 contains one or two inner capsules in various combinations according to type as shown in the table below:

C-188 Type Number	Model Number Of Inner(s)	C-188 Type Number	Model Number Of Inner(s)
1	C-177/C-177	7	C-177/AC-191
2	AC-191/AC-191	8	C-177/AC-195
3	AC-195/AC-195	9	C-177/AC-339
4	C-246	10	AC-191/AC-195
5	AC-339/AC-339	11	AC-191/AC-339
6	AC-345/C-348	12	AC-195/AC-339
		13	**Two inners maximum.**

The inner capsules vary according to the user requirements. The Model C-188 outer encapsulation is constructed of 316L stainless steel having dimensions as shown:

	Max.		Nominal		Min.	
	(inch)	(mm)	(inch)	(mm)	(inch)	(mm)
Overall length	17.9	454.7	17.8	452.1	17.7	449.6
Outside dia. at end caps	0.50	12.7	0.44	11.2	0.40	10.2
Outside dia. of body	0.40	10.2	0.38	9.7	0.37	9.4
Wall thickness of body	0.027	0.69	0.026	0.63	0.023	0.58

The end cap is attached to the main body using a fusion weld. Selection of the inner capsule/s varies according to user requirements in a configuration as shown above for **Type Number 1 through 13. Source Models C-188 and C-306 have a consistent fit of minimum overall diameter and length dimensions between the inner and outer capsules to be within the range of a minimum diametrical clearance 0.001 inches (0.025 mm) and a minimum length clearance of 0.06 inches (1.5 mm) respectively.**

SOURCE TYPE: Gamma Irradiator Source

DESCRIPTION (contd.):

This does not mean the diametrical gap will be 0.001 inches (0.025 mm) in all sources of Models C-188 and C-306. Previously distributed C-188 Types 1 to 12 and C-306 Types 1 and 2 have the same diametrical and longitudinal gap as they always had, as the designs of these sources have not changed.

The Model C-306 outer capsule is the same for all types. The inner capsule varies according to the user requirements. The Model C-306, Type 1 source contains one Model C-339 inner capsule; the Type 2 contains one C-177 inner capsule. Prior to **December 21, 1998,** the Model C-306, Type 1 source contained one Model AC-195 inner capsule, Type 2 contained one AC-191, and Type 3 contained one C-177 inner capsule.

The Model C-306 outer encapsulation is constructed of 316L stainless steel having dimensions as shown:

	Max.		Nominal		Min.	
	(inch)	(mm)	(inch)	(mm)	(inch)	(mm)
Overall length	9.6	243.9	9.5	241.3	9.4	238.8
Outside dia. at end caps	0.50	12.7	0.44	11.2	0.40	10.2
Outside dia. of body	0.40	10.2	0.38	9.7	0.37	9.4
Wall thickness of body	0.027	0.69	0.026	0.63	0.023	0.58

The end cap is attached to the main body using a fusion weld. Selection of the inner capsule varies according to user requirements; i.e., either Type 1 or Type 2 configuration. The fit of overall diameter and length dimensions between the inner and outer capsules is within the range of a minimum diametrical clearance **0.001** inches (**0.025** mm) and a minimum length clearance of 0.06 inches (1.5 mm) respectively.

The inner capsules of source Models C-188 and C-306 have a maximum diameter of 0.32 inches (8.13 mm) and a minimum wall thickness of 0.015 inches (0.38 mm). The length of the inner capsules, the capsule material, and the radioactive source contents vary for each model as shown here in:

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-220-S-103-S DATE: March 30, 2000 PAGE: 4 of 10

SOURCE TYPE: Gamma Irradiator Source

DESCRIPTION (contd.):

Model No. of Inner	Radioactive Contents	Capsule Material	Max.length (inch)	(mm)
C-246	pellets or slugs	SS316L	16.6	422
AC-339	pellets or slugs	Zircaloy 2/4	8.3	211
C-177	pellets or slugs	SS316L	8.3	211
AC-191	pellets or slugs	SS316L	8.3	211
AC-195	pellets or slugs	Zircaloy 2	8.3	211
AC-345	slugs	Zircaloy 2/4	11.3	287
C-348	slugs	SS316L	5.3	134
C-188 Type 13	**slugs, pallets, or, wafers**	**Zircaloy 2/4 SS316L**	**16.6**	**422**

The source material in the inner capsules is either 0.03-0.25 inches (0.76-6.35 mm) long and 0.03-0.25 inches (0.76-6.35 mm) diameter nickel plated cobalt pellets, or approximately 0.25 inches (6.35 mm) diameter and 0.03-0.5 inches (0.76-12.7mm) long nickel plated cobalt wafers, or approximately 0.25 inches (6.35mm) diameter and 0.5-3.0 inches (12.7-76.2 mm) long nickel plated slugs.

The majority of sources contain slug material as active contents. Occasionally, for low activity or sources requiring close tolerance dose outputs, material in pellet/**wafer** form is used as the active contents. The use of pellets/**wafers** makes it possible to mix pellets/**wafers** of various activities along with inactive pellets/**wafers** to accurately obtain required dose outputs. The pellets/**wafers** are of metallic form and nickel plated and, thus, indispersable in water.

LABELING:

Each model of the inner capsule assemblies is engraved on the end capsule with a serial number except the Model C-246 which is engraved on the body. **All batches of inner capsules used in Model C-188 shall be traceable to the C-188 serial numbers. The Quality Assurance records for the inner capsules of all sources are maintained by MDS Nordion, Inc. The serial numbers for all sources shall be issued and controlled by MDS Nordion, Inc.**

SOURCE TYPE: Gamma Irradiator Source

Labeling(Contd.):

The Model C-188 and C-306 sources are engraved in the following manner:

- a unique serial number on the upper end cap face;
- either "C-188" or "C-306" and "Co 60" on the upper end cap diameter;
- the radiation trefoil and "MDSN X" (where MDSN designation of manufacturer, MDS Nordion, Inc., and X is the material heat number) on the lower end cap diameter. Sources manufactured under the earlier names of the company had been engraved correspondingly as "AECL" or "NII X."

DIAGRAM:

See Attachments 1 and 2.

CONDITIONS OF NORMAL USE:

The source Models C-188 and C-306 sources are designed primarily for use in wet source storage, pool type irradiators. Typical environments associated with the use of these irradiators include high temperatures, thermal shock due to sources being brought out of and into the water, and long term contact with water.

The sources may be used in dry source storage irradiators and environments for these devices would typically be less harsh. These uses would typically be medical facilities and laboratories fit for human occupancy. Therefore, the sources would be expected to be subjected to ambient temperatures and pressures. However, high activity sources may be exposed to elevated temperatures and temperature cycling due to internally generated heat.

SOURCE TYPE: Gamma Irradiator Source

PROTOTYPE TESTING:

The manufacturer conducted ANSI classification tests in order to classify the Model C-188 source. Category IV iradiators must have a minimum classification of E53424 to meet the requirements of 10 CFR 36.21 and ANSI N43.6. The Model C-188 source was successfully tested to E65646 in accordance with ANSI N542-1977, "Sealed Radioactive Sources, Classification." The tests were conducted by using dummy slug material rather than pellet material, because the slug configuration represented the more severe conditions. The manufacturer conducted an additional bend test, as specified in ANSI N43.10, "Safe design and Use of Panoramic Wet Source Storage gamma Irradiators." In the bend test, the Model C-188 source performed to Class 5.

The manufacturer stated that the Model C-306, Types 1 and 2, capsule met the standards of ANSI classification E54434 based on comparison with the Model C-188 capsule.

The manufacturer tested Model C-188 Type 13 for a worst-case scenario. Prototype models tested had a minimum 0.001 inches (0.025 mm) diametrical tolerance between the inner and the outer encapsulation. The inner length was represented by two equal solid rods of Type 316L stainless steel (stainless steel has a higher stiffness than Zircaloy). These solid bars exerted worst-case forces on the outer capsule during the ANSI testing. The solid bars were used to simulate the maximum resistance offered by the inner during testing. Tubing, without end caps, was used to simulate the least resistance by the inner during testing.

The outer source encapsulation retained its integrity over bounding stiffness range for the inner capsules. These worst-case prototypes were tested to E64424 classification and an additional class 5 bend test was done. The manufacturer test reports indicated that the outer encapsulation retained its integrity under these worst-case test conditions.

EXTERNAL RADIATION LEVELS:

A calculation of dose rates was done using the gamma radiation constant for cobalt-60 of 1.32 R/hr (13.2 mSv/hr) at one meter, per curie (39.4 in., per 37 GBq). A source containing **maximum** 17,000 curies **(629 TBq)** would be expected to yield the following dose rates:

SOURCE TYPE: Gamma Irradiator Source

EXTERNAL RADIATION LEVELS (Contd.):

Distance from source	Radiation Level R/hr	Sv/hr
100 cm/39.4 in	22,000	220
30 cm/11.8 in	250,000	2,500
5 cm/1.97 in	9,000,000	90,000

A source containing 14,000 curies **(518 TBq)** would be expected to yield the following dose rates:

Distance from source	Radiation Level R/hr	Sv/hr
100 cm/39.4 in	18,500	185
30 cm/11.8 in	205,000	2,050
5 cm/1.97 in	7,400,000	74,000

A source containing 8,500 curies **(314.5 TBq)** would be expected to yield the following dose rates:

Distance from source	Radiation Level R/hr	Sv/hr
100 cm/39.4 in	11,000	110
30 cm/11.8 in	125,000	1,250
5 cm/1.97 in	4,500,000	45,000

QUALITY ASSURANCE AND CONTROL:

MDS Nordion, Inc. (formerly AECL and Nordion International, Inc.) maintains a quality assurance and control program which has been deemed acceptable for licensing purposes by NRC. A copy of the program is on file with the NRC.

As a sole manufacturer and distributor of source Model C-188, Type 13, MDS Nordion, Inc. is committed to ensure that inners of Model C-188, Type 13 sources manufactured and supplied to MDS Nordion, Inc. by other manufacturers, who maintain a NRC license, shall meet the requirements outlined in this registration certificate.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

SOURCE TYPE: Gamma Irradiator Source

QUALITY ASSURANCE AND CONTROL (Contd.):

MDS Nordion, Inc. has committed to periodically conduct audits of subcontractors and source suppliers to ensure consistency and sustained production of quality products. Subcontractor and suppliers shall be audited as needed in accordance with the provisions of ISO 9000 registered Quality Program. The results of such audits, follow-ups and corrective actions shall be recorded, retained, maintained and made available for inspections and audits.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The sources shall be distributed only to persons specifically licensed by the NRC or an Agreement State.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority. In view that the sealed sources exhibit high surface dose rates when unshielded, they should be handled only by experienced licensed personnel using adequate remote handling equipment and procedures.
- These sources shall not be subjected to an environmental or other condition of use which would exceed an ANSI N542-1977 Classification of **77E54434.**
- **All C-188 Type 13 source will be tested to ANSI N542 classification 77E64424. It must also pass the additional Class 5 bend test prescribed in ISO 2919-1999(E). A Type 13 configuration shall not be used until these tests have been successfully completed and the simulated sources have been found leak tight.**
- **Any inner capsules acquired from other manufacturers are subject to MDS Nordion, Inc. approved quality requirements. MDS Nordion, Inc. is responsible for ensuring manufacturer's conformance to these requirements and requirements of other USA regulatory authorities.**
- This registration sheet and the information contained within

SOURCE TYPE: Gamma Irradiator Source

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE (Contd.):

the references shall not be changed without the written consent of the NRC.

REVIEWER NOTE: Sources used in wet source storage irradiators shall be tested for contamination according to Section 36.59, 10 CFR Part 36.

REVIEWER NOTE: These sources may be used in dry source storage irradiators. Sources used in these devices shall be leak tested at intervals not to exceed six months using techniques capable of detecting 0.005 micro curie (185 Bq) of removable contamination.

SAFETY ANALYSIS SUMMARY:

Based on our review of the information and test data cited below, including the claimed ANSI classification, we continue to conclude that the Model C-188 and C-306 source designs are acceptable for licensing purposes.

Furthermore, we continue to conclude that the Model C-188 and C-306 sources would be expected to maintain their containment integrity for normal conditions of use and accidental conditions which might occur during the uses specified in this certificate.

REFERENCES:

The following supporting documents for the Models C-188 and C-306 sources are hereby incorporated by reference and are made a part of this registry document.

- Atomic Energy of Canada, Ltd. letters dated October 29, 1973, June 14, 1974, September 20, 1984, and July 18, 1985 with enclosures thereto.
- Nordion International, Inc. letters dated June 25, 1993, March 16, 1992, December 5, 1991, and October 3, 1988, with enclosures thereto, and letter received November 18, 1991, with enclosures thereto.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-220-S-103-S DATE: March 30, 2000

SOURCE TYPE: Gamma Irradiator Source

REFERENCES (Contd.):

- MDS Nordion, Inc. letters dated January 13, 1998, February 16, 1998, April 3, 1998, **December 21, 1999, and March 6, 2000, with enclosures thereto.**

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

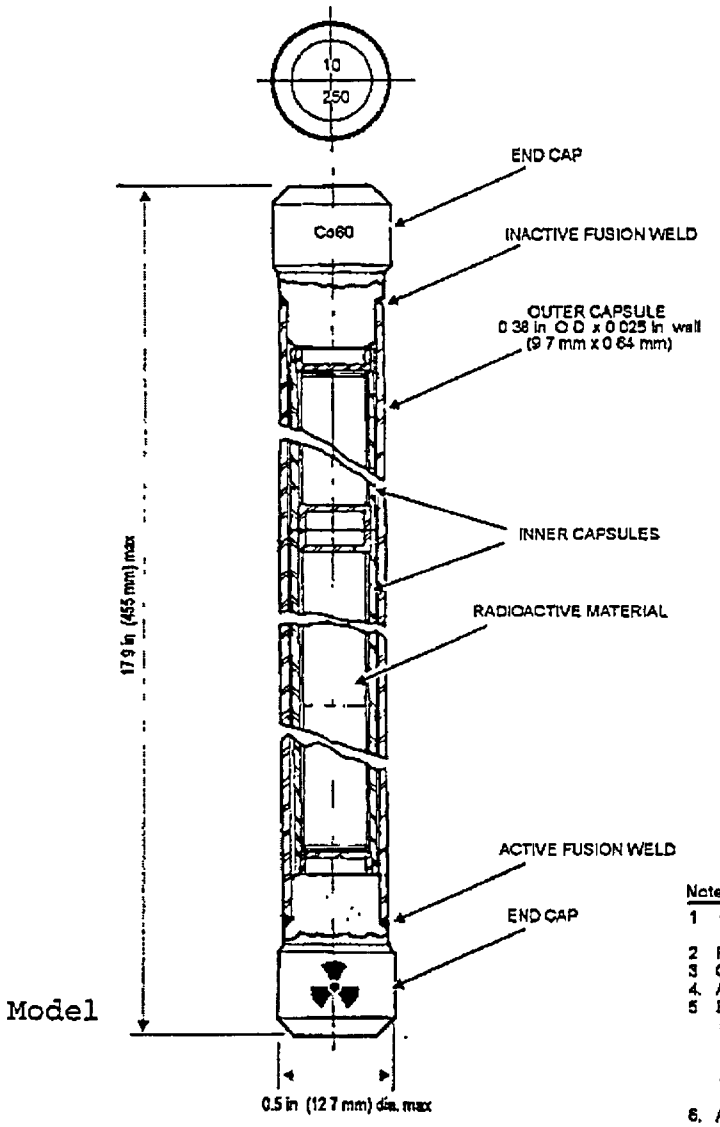
Date: March 30, 2000 Reviewer: Ujagar S. Bhachu

Date: March 30, 2000 Concurrence: Seung Lee

Date: March 30, 2000 Concurrence: John Jankovich

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-220-S-103-S DATE: March 30, 20000 ATTACHMENT 1



C-188 Type Number	Model Number of Inners
1	C-177/C-177
2	AC-191/AC-191
3	AC-195/AC195
4	C-246
5	AC-339/AC-339
6	AC-345/AC-348
7.	C-177/AC-191
8.	C-177/AC-195
9	C-177/AC-339
10.	AC-191/AC-195
11	AC-191/AC-339
12	AC-195/AC-339
13	See Note 6

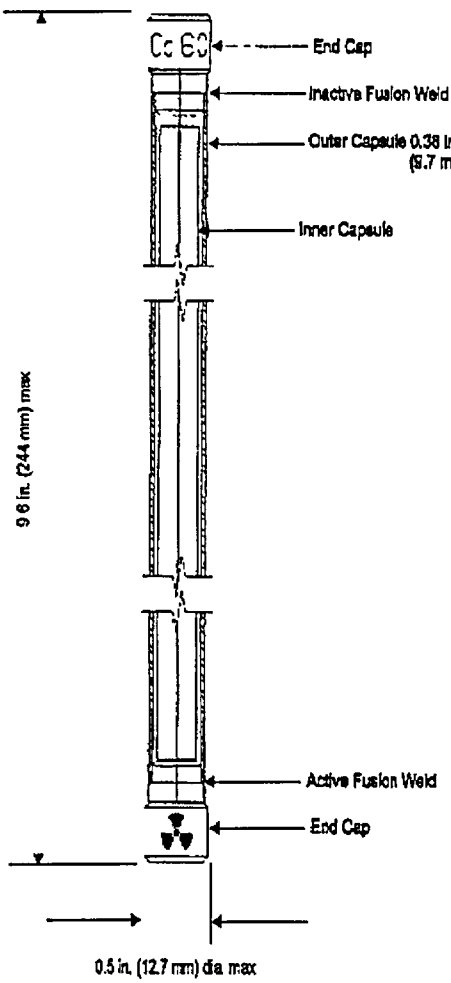
Notes

1 Conforms to IAEA Special Form requirements AECB Certificate No. CDN/0010/S-85
2 Radioactive Material Cobalt-60 in solid form
3 Outer capsule material, Type 316L stainless steel
4. All capsules are sealed by fusion welds.
5 Engraved on capsule
(A) Upper end cap
face: serial number
diameter C188 Co60
(B) Lower end cap diameter MDSN X and Trefoil where X is material heat number.
6. Any inner design constructed from stainless steel or zircaloy consisting of one or more capsules containing Cobalt-60 pellets slugs or wafers and of a design similar, but not identical to one or more of those contained in types 1 to 12.

C-188 Sealed Source Assembly

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE
(AMENDED IN ITS ENTIRETY)

NO.: NR-220-S-103-S DATE: March 30, 20000 ATTACHMENT 2



Type No.	Inner Capsule	Qty
1.	C-339	1
2.	C-177	1

Notes

1. Radioactive Material: Cobalt-60 in solid form.
2. Outer capsule material: Type 316L stainless steel.
3. All capsules are sealed by fusion welds.
4. Engraved on capsule:
   (A) Upper end cap (face: serial number
   (diameter): C306 Co60
   (B) Lower end cap (diameter): MDSN X and Trefoil
   where X is material heat number.

C-306 Sealed Source Assembly

Certification

Atomic Energy Control Board | Commission de contrôle de l'énergie atomique

SPECIAL FORM RADIOACTIVE MATERIAL CERTIFICATE NO. CDN/0010/S-85, (REV. 4)

30-A2-187-0

March 7, 2000

The Atomic Energy Control Board hereby certifies that the capsule, as described below, has been demonstrated to meet the regulatory requirements prescribed for special form radioactive material as defined in the Canadian *Transport Packaging of Radioactive Materials Regulations* and in the IAEA Regulations*, subject to the following limitations, terms and conditions.

CAPSULE IDENTIFICATION

MDS Nordion Inc. C-188 Capsule, Types 1 to 13 inclusive.

CAPSULE DESCRIPTION

The C-188 capsule, Types 1 to 13 inclusive, as shown on MDS Nordion Drawing No. G130102-177 , (Issue B) consists of an outer welded stainless steel body with solid end caps containing a variety of welded inner capsules. The overall length is 452 mm. The end cap diameters are 11.2 mm and the body diameter is 9.7 mm. The inner configurations consist of either one or two welded stainless steel or zircaloy capsules containing Cobalt-60 metal in slug, wafer or pellet form.

An illustration of the capsule is shown on attached specification Drawing No. C-188 (Issue 17).

AUTHORIZED RADIOACTIVE CONTENTS

This capsule is authorized to contain not more than 630 TBq (17,000 Ci) of Cobalt-60 in slug form or not more than 520 TBq (14,000 Ci) of Cobalt-60 in wafer or pellet form.

QUALITY ASSURANCE

All sources described by this certificate meet the MDS Nordion Inc. Quality Assurance Program IN/QA 0148 Z000, or equivalent, which meets the applicable requirements of Paragraph 209 of the IAEA Regulations*. Users and consignors of these sources shall satisfy the requirements of Paragraph 209 of the IAEA Regulations*.

EXPIRY DATE

This certificate expires October 31, 2002.

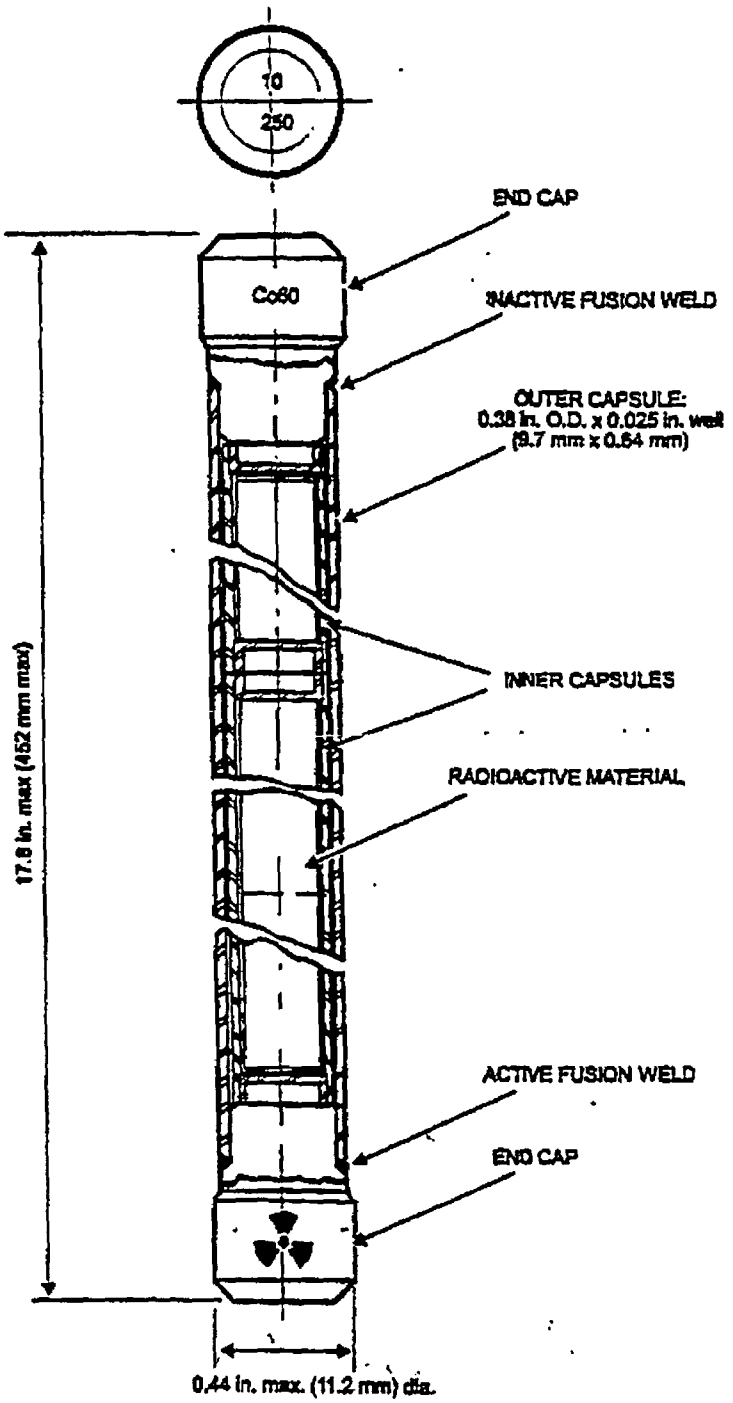
R. Thomas
Director
Materials Regulation Division

REFERENCE

* International Atomic Energy Agency Safety Series No. 6, Regulations for the Safe Transport of Radioactive Materials, 1985 Revised Edition (As Amended 1990).

NOTES

1. Revision 0: November 9, 1989. Original certificate.
2. Revision 1: November 16, 1993. Issued to the IAEA 1985 Regulations.
3. Revision 2: October 4, 1994. Revised to include the "-85" suffix.
4. Revision 3: January 15, 1999. Certificate renewed.
5. Revision 4: March 7, 2000. Certificate revised.



C-188 Type Number	Model Number of Inners
1.	C-177/C-177
2.	AC-191/AC-191
3.	AC-195/AC195
4.	C-248
5.	AC-339/AC-339
6.	AC-345/AC-345
7.	C-177/AC-191
8.	C-177/AC-195
9.	C-177/AC-339
10.	AC-191/AC-195
11.	AC-191/AC-339
12.	AC-195/AC-339
13.	See Note 6

Notes

1. Conforms to IAEA Special Form requirements AECB Certificate No. CDN/0010/S-85.
2. Radioactive Material: Cobalt-60 in solid form.
3. Outer capsule material: Type 316L stainless steel.
4. All capsules are sealed by fusion welds.
5. Engraved on capsule:
   (A) Upper end cap
   face: serial number
   diameter: C188 Co60
   (B) Lower end cap diameter: MDSN X and Trefoil where X is material heat number.
6. Any inner design constructed from stainless steel or zircaloy consisting of one or more capsules containing Cobalt-60 pellets, slugs or wafers and of a design similar, but not identical to one or more of those contained in types 1 to 12.

MDS Nordion
447 March Road, P.O. Box 13500
Kanata, Ontario, Canada, K2K 1X8
Tel: (613) 592-2790 · Fax. (613) 592-6937

TITLE

C-188 Cobalt-60 Sealed Source

REF. G130102-177 IN/SS 1383 C188	REVISED FEB 00	DCN A-1688-D-01A
DATE FEB 67	No. C-188	ISSUE 17
DRAWN	CHECKED	APPROVED
		SHEET 1 OF 1

APPENDIX F

C-442 BOUNDING SEALED SOURCE CLASSIFICATION TESTS AND CLASS 5 BEND TEST

MDS Nordion

CERTIFICATE

SEALED SOURCE
CLASSIFICATION DESIGNATION AND PERFORMANCE

Sealed sources are classified in accord with standards established by
THE AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI) and
THE INTERNATIONAL ORGANIZATION FOR STANDARDIZATION (ISO)

CERTIFICATE NO: 97
DATE: 01-02-22
CAPSULE MODEL: C-442
CONTENTS: Cobalt -60 Slugs/Pellets/ Wafers
DRAWING NO: G144202-001
CAPSULE MATERIAL: 316L Stainless Steel
OVERALL TUBE DIAMETER: 0.515"
ENCAPSULATION: Double
OVERALL LENGTH: 17.77"
CLASSIFICATION DESIGNATION ANSI: 96: E64435 ISO/ 98 /E64435(5)

CLASSIFIED PERFORMANCE STANDARD[2]

TEST	CLASS	METHOD	REMARKS
TEMPERATURE	6	TEST	PASS
EXTERNAL PRESSURE	4	TEST	PASS
IMPACT	4	TEST	PASS
VIBRATION	3	TEST	PASS
PUNCTURE	5	TEST	PASS
BENDING TEST	5	TEST	PASS

(1) See definition on reverse side
(2) See Table 1. Performance Standards on reverse side

COMMENTS: Capsule integrity assured by Helium leak tests (ANS /HPS N43.6-1997, Annex A paragraphs A2.2.6)

It is hereby certified that the described sealed source meets the requirements and classification specified in American National Standard ANSI/HPS N43.6-1997 "Sealed Radioactive Sources, Classification" and in International Standard, ISO 2919-1999(E), " Radiation Protection – Sealed Radioisotope sources – General Requirements and Classification".

Tested by Kolan Sheehan
Title Materials Technologist
Date 26 Feb 2001

Approved M Lyancel
Title Manager, Package Engineering
Date 26 FEB 2001

REFERENCES

[1]DEFINITION - CLASSIFICATION DESIGNATION:

The classification of a sealed source shall be designated by the code ANSI followed by two digits to indicate the year of approval of the American National Standard used to determine the classification followed by a letter and five digits.

The letter shall be either a C or an E. The letter C designates that the contained activity does not exceed the maximum levels established by ANSI. The letter E designates that the contained activity exceeds the maximum levels established by ANSI.

The first digit shall be the class number which describes the performance standards for temperature.

The second digit shall be the class number which describes the performance standards for external pressure.

The third digit shall be the class number which describes the performance standards for impact.

The fourth digit shall be the class number which describes the performance standards for vibration

The fifth digit shall be the class number which describes the performance standards for puncture.

[2] TABLE 1 - PERFORMANCE STANDARDS:

TEST	CLASS						
	1	2	3	4	5	6	X
Temperature	No Test	-40°C (20 min) +80°C (1h)	-40°C (20 min) +180°C (1h)	-40°C (20 min) +400°C (1h) and thermal shock 400°C to 20°C	-40°C (20 min) +600°C (1h) and thermal shock 600°C to 20°C	-40°C (20 min) +800°C (1h) and thermal shock 800°C to 20°C	Special Test
External Pressure	No Test	25 kN/m² abs. (3 6 lbf/in²) to atmosphere	25 kN/m²abs to 2 MN/m² (290 lbf/in²) abs	25 kN/m²abs to 7 MN/m² (1015 lbf/in²) abs	25 kN/m² abs to 70 MN/m² (10153 lbf/in²) abs	25 kN/m² abs. to 170 MN/m² (24 656 lbf/in²) abs	Special Test
Impact	No Test	50 g(1.8oz) from 1 m (3 28 ft) and free drop ten times to a steel surface from 1.5 m (4 92 ft)	200 g (7 oz) from 1 m	2 kg (4.4 lb) from 1 m	5 kg (11 lb) from 1 m	20 kg (44 lb) from 1 m	Special Test
Vibration	No Test	30 min 25 to 500 Hz at 5 g peak amp	30 min 25 to 50 Hz at 5 g peak amp and 50 to 90 Hz at 0 635 mm amp peak to peak and 90 to 500 Hz at 10 g	90 min 25 to 80 Hz at 1 5 mm amp peak to peak and 80 to 2000 Hz at 20g	Not Used	Not Used	Special Test
Puncture	No Test	1 g (15.4 gr) from 1 m (3 28 ft)	10 g (154 gr) from 1 m	50 g (1 76 oz) from 1 m	300 g (10 6 oz) from 1 m	1 kg (2 2 lb) from 1 m	Special Test

MDS Nordion

SPECIAL FORM RADIOACTIVE MATERIAL TEST SUMMARY

The capsule model specified herein has been evaluated in accord with the International Atomic Energy Agency (I.A.E.A.) Safety Series No. 6, Regulations for the Safe Transport of Radioactive Material, 1985 Edition, (as amended 1990) Section VI, paragraphs 604-613 and 618.

TEST SUMMARY: 43
DATE: 01-02-22
CAPSULE MODEL: C-442
CONTENTS: Cobalt-60 Slugs/Pellets/Wafers
TEST REFERENCE REPORT: IN/TR 1728 C442
CAPSULE MATERIAL: 316L Stainless Steel
OVERALL TUBE DIAMETER: 0.515"
ENCAPSULATION: Double
OVERALL LENGTH: 17.77"

SPECIAL FORM REQUIREMENTS[1]

TEST	PASS	FAIL	METHOD	REMARKS
IMPACT (607)(618)	X		Comparison	See Comment 3
PERCUSSION (608)	X		Comparison	See Comment 3
BENDING (609)	X		Test	Pass
HEAT (610)	X		Comparison	See Comment 2
LEACHING (612)(613)	---		---	See Comment 1

(1) See Special Form requirements on reverse side

COMMENTS: 1) Capsule integrity following bend test was verified by helium leak testing.

2) Paragraph 611(b), Safety series no. 6 specifies that the heat test requirements have been satisfied by the completion of the Class 6 Temperature test, ANS N43.6-1997 as referenced in ANSI certificate # 97.

3) Paragraph 611(b), Safety series no. 6 specifies that impact and percussion requirements have been satisfied by the completion of the Class 4 Impact test, ANS N43.6-1997 as referenced in ANSI certificate # 97.

This summary verifies that the described capsule model meets the requirements of Special Form in accordance with the I.A.E.A. Safety Series No. 6, Regulations for the Safe Transport of Radioactive Material, 1985 Edition, (as amended 1990) Section VI, paragraphs 604-613 and 618.

Tested by Helen Leeder
Title Materials Technologist
Date 26 Feb 2001

Approved M Lyons
Title Manager, Package Engineering
Date 01 FEB 26

I.A.E.A. TESTS FOR SPECIAL FORM RADIOACTIVE MATERIAL

General

604. The tests which shall be performed on specimens that comprise or simulate **special form radioactive material** are the impact test, the percussion test, the bending test, and the heat test

605. A different specimen may be used for each of the tests

606. After each test specified in paras 607-611, a leaching assessment or volumetric leakage test shall be performed on the specimen by a method no less sensitive than the methods given in para 612 for indispersible solid material and para. 613 for encapsulated material

Test Methods

607. **Impact test,** The specimen shall drop onto the target from a height of 9 m. The target shall be as defined in para 618.

618 The target for the drop test specified in para 607 shall be a flat, horizontal surface of such a character that any increase in its resistance to displacement or deformation upon impact by the specimen would not significantly increase the damage to the specimen.

608 **Percussion test.** The specimen shall be placed on a sheet of lead which is supported by a smooth solid surface and struck by the flat face of a steel billet so as to produce an impact equivalent to that resulting from a free drop of 1 4 kg through 1 m The flat face of the billet shall be 25 mm in diameter with the edges rounded off to a radius of (3 0 ± 0 3)mm The lead, of hardness number 3 5 to 4.5 on the Vickers scale and not more than 25 mm thick, shall cover an area greater than that covered by the specimen. A fresh surface of lead shall be used for each impact The billet shall strike the specimen so as to cause maximum damage

609 **Bending test** The test shall apply only to long, slender sources with both a minimum length of 10 cm and a length to minimum width ratio of not less than 10 The specimen shall be rigidly clamped in a horizontal position so that one half of its length protrudes from the face of the clamp The orientation of the specimen shall be such that the specimen will suffer maximum damage when its free end is struck by the flat face of a steel billet The billet shall strike the specimen so as to produce an impact equivalent to that resulting from a free vertical drop of 1 4 kg through 1 m The flat face of the billet shall be 25 mm in diameter with the edges rounded off to a radius of (3 0 ± 0 3)mm

6 10 **Heat test** The specimen shall be heated in air to a temperature of 800°C and held at that temperature for a period of 10 minutes and shall then be allowed to cool

6 11 Specimens that comprise or simulate radioactive material enclosed in a sealed capsule may be excepted from

(a) The tests prescribed in paras 607 and 608 provided they are alternatively subjected to the Class 4 impact test prescribed in the International Organization for Standardization document ISO 2919-1980(E), "Sealed radioactive sources - Classification", and

(b) The test prescribed in para 610 provided they are alternatively subjected to the Class 6 temperature test specified in the International Organization for Standardization document ISO 2919-1980(E), "Sealed radioactive sources - Classification".

Leaching and volumetric leakage assessment methods

612 For specimens which comprise or simulate indispersible solid material, a leaching assessment shall be performed as follows

(a) The specimen shall be immersed for 7 days in water at ambient temperature. The volume of water to be used in the test shall be sufficient to ensure that at the end of the 7 day test period the free volume of the unabsorbed and unreacted water remaining shall be at least 10% of the volume of the solid test sample itself The water shall have an initial pH of 6-8 and a maximum conductivity of 1 mS/m(10 µmho/cm) at 20°C

(b) The water with specimen shall then be heated to a temperature of (50 ± 5)°C and maintained at this temperature for 4 hours

(c) The activity of the water shall then be determined.

(d) The specimen shall then be stored for a least 7 days in still air of relative humidity not less than 90% at 30°C.

(e) The specimen shall then be immersed in water of the same specification as in (a) above and the water with the specimen heated to (50 ± 5)°C and maintained at this temperature for 4 hours

(f) The activity of the water shall then be determined

613 For specimens which comprise or simulate radioactive material enclosed in a sealed capsule, either a leaching assessment or a volumetric leakage assessment shall be performed as follows:

(a) The leaching assessment shall consist of the following steps

(i) The specimen shall be immersed in water at ambient temperature The water shall have an initial pH of 6-8 with a maximum conductivity of 1 mS/m(10µmho/cm) at 20°C

(ii) The water and specimen shall be heated to a temperature of (50 ± 5)°C and maintained at this temperature for 4 hours

(iii) the activity of the water shall then be determined

(iv) The specimen shall then be stored for at least 7 days in still air at a temperature of not less than 30°C

(v) The process in (i),(ii) and (iii) shall be repeated

(b) The alternative volumetric leakage assessment shall comprise any of the tests prescribed in the International Organization for standardization document ISO 9978 1992(E) "Radiation Protection - Sealed Radioactive Sources - Leakage Test Methods " which are acceptable to the competent authority

APPENDIX G

CRITICAL ELEMENTS OF THE TECHNICAL SPECIFICATIONS

CRITICAL ELEMENTS OF THE TECHNICAL SPECIFICATIONS

Manufacture of Inactive Components

All stainless steel components of the C-442 are fabricated in accordance with a manufacturing, inspection and test plan. Handling of all materials and components is such that scratching, denting or marking of any kind is minimized. Parts are cleaned and passivated. Completed components are stored in a manner that ensures that they will not become damaged or distorted during transit and storage. Incoming inspection is completed on capsule components in accordance with written procedures.

Inactive Welding

Inactive welding is completed in accordance with written welding procedures. All changes to weld processes are validated. In-process controls are designed to determine if the weld penetration requirements are satisfied. Periodic test welds are used to confirm process control. In the absence of process control, 100% inspection of critical dimensions is completed.

Visual examination and dimensional inspection are carried out on sub-assembled components. They are stored in a manner that ensures that they will not become damaged or distorted.

Active Welding

Active assembly and welding is completed in accordance with written manufacturing procedures. Cleaning, assembly and decontamination requirements are specified.

Assembled C-442 sources are inspected for overall integrity and are helium leak tested. Dry wipe tests are also carried out to ensure that the level of contamination on the assembled source is less than 0.5 nanocuries (18.5 Becquerel).

In-process controls are designed to determine if C-442 penetration requirements are satisfied. A test weld on a dummy capsule is carried out by each individual welder at the start of each production run, batch, shift or day and at the end of the production run, batch, shift or day. A test weld is also performed prior to and immediately following a change in the weld configuration (i.e. new electrode, gap set-up etc.)

Notes:

1. If the test weld at the end of the production run fails to meet the welding penetration criteria, the preceding welded capsules must be examined in proper reverse manufactured order until 3 successive acceptable capsules are found.
2. Visual defects such as, but not limited to, voids, pinholes and blowholes are regarded as anomalies and do not require the destructive testing of the previously manufactured capsules. However, if two or more visual defects appear in any batch, that batch is considered non-conforming and the capsules are to be dispositioned. The cause of the defects must be resolved.
3. A batch of sources is deemed to be those sources produced between weld test capsules.

Traceability

Individual subassemblies are uniquely identified and both body and end cap are traceable back to the material supplier's material certifications. This serial number is then traceable to the active welded end cap material batch number.