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MDS Nordion
Science Advancing Health

December 14, 2001

Mr. William R. Ward
Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
Mail Stop: T-8F5
United States Nuclear Regulatory Commission
Two White Flint North
11545 Rockville Pike
Rockville, MD
20852-2738

Dear Mr. Ward:

RE: Sealed Source Registration for MDS Nordion C-168

Thank you for your e-mail of November 20, 2001, in which you requested additional information. Please find below the response to your questions.

1. Based on an analysis of the dimensions provided in your DESCRIPTION section, there appears to be slack space inside the capsule. Specifically, the cavity depth is .350 inch; the plug length is .27 inch leaving .08 inches for the source. The source is 1mm, or .04 inches, leaving .04 inches of cavity length unaccounted for. Your prototype test extended length capsules used a spring inside, however you stated no springs are used in the standard capsule. Are the pellets allowed to move freely within the standard capsule?

   Normally two cobalt-60 pellets are installed. The plug, when installed, rests on top of the pellets. Therefore, the pellets are not free to move within the standard capsule.

2. In the CONDITIONS OF USE section, page 3, you stated that the physical life of the C-168 source could be infinite. However, you didn't state the working life, which is dependent on other factors such as radioisotope half-life. Please provide a working life for the source as discussed in NUREG 1556, Volume 3, section 10.2.

The estimated working life of the C-168 is theoretically infinite, with respect to structural integrity of the source containment and design integrity, provided the recommended conditions of use have been maintained. The source will have a warranted life of 1 year. The maximum useful life of the source loaded to maximum activity is approximately 25 years

3. In the LABELLING section, page 3, you stated that the source is engraved with either "NII" or "MDSN". What do these abbreviations stand for?

NII is an abbreviation for Nordion International Incorporated, the previous name of the Company.

MDSN is an abbreviation for the current name of the Company, consisting of MDS, the name of our parent Corporation MDS Inc., and N for Nordion, which is a division of MDS Inc.

4. The drawing provided in Appendix A agrees with the LABELLING section on page 3 in that it states that either "NII" or "MDSN" is engraved on the capsule. However, the drawing provided in Appendix B only states that "NII" is engraved. Please explain the difference. Note that the Appendix B drawing is also used for the Canadian Special Form Radioactive Material Certificate shown in Appendix D.

Please see attached revised drawings G530102-141, Issue D and C-168, Issue 1, showing current engraving instructions, i.e. MDSN.

5. It is not clear from your description or pictures of the prototype testing whether the prototype sources were engraved prior to testing. Since engraving labeling information on a source may have a detrimental effect on the source integrity, we need to know if the tested units were engraved. If they were not engraved, please explain how the prototype tests would be a valid test of actual, engraved sources.

The specimens used for testing were engraved in the same manner as production sources.

6. In the TESTING OF PROTOTYPES section, page 3, you state that the prototypes tested contained inactive pellets. Please describe inactive pellets. How are they different from active pellets? Describe the construction and material(s) of active pellets.

Inactive material is Cobalt-59 in form of pellets. The inactive pellets are placed into a neutron flux and become activeCo-60 pellets.

7. Paragraph A.2.2.7 of ANSI/HPS 43.6-1997 states that the liquid nitrogen-alcohol bubble test is only for sources having high decay heat. Since you used inactive pellets, why did you use this test to check for leakage?

Due to the small size of the evaluated sources, the results of helium leak tests were not conclusive. Therefore, in addition to helium leak tests, we did the nitrogen-alcohol bubble test to confirm that requirements were met.

8. In the TESTING OF PROTOTYPES section, page 3, you state that one test capsule, number 0007, "had a degraded surface condition that resulted in an inconclusive helium leak test." Additionally, in the CAPSULE TESTING WORK SHEET for the temperature test, you stated that the helium leak test "results were inconclusive see appendix B." Please provide additional information on the degraded surface condition, specifically, what it was and why it prevented a successful helium leak test. Also, please provide a copy of the appendix B referenced by the work sheet.

Please find enclosed a copy of appendix B which explains the degraded surface condition.

9. In your CAPSULE TESTING WORK SHEET for the temperature test, you state that the capsules were placed in dry ice for a minimum of 40 minutes, then removed inserted into a furnace at 800□C and held for 1 hour. ISO 2919 and ANSI/HPS N43.6 both require that the prototypes be cooled in less than 45 minutes and held at the lower temperature for at least 20 minutes. It is not clear how much of your 40 minutes in dry ice was cooling time and how much was time at minimum temperature. Also, both standards require heating to 800□C in less than 70 minutes and holding at 800□C for an hour. It is not clear that your prototypes were allowed time to heat to 800□C.

Cooling:
The ISO and/or ANSI requirement is to cool the test specimen to temperature of -40°C in less than 45 minutes and hold it at that temperature for 20 minutes. The actual process of cooling was done in a dry ice, with a temperature of about -75°C. The total volume of the test pieces was 0.311 cm^3 and the volume of the 'dry ice' was 400 cm^3. Considering the very small size of the test specimens we submit that cooling time of these specimens was quite short, positively less than 20 minutes, therefore allowing them to be held at this temperature for a time equal or longer than 20 minutes.

Heating:
The actual heating process consisted of preheat of the furnace to 800°C and subsequent placing the test specimens into the furnace. Due to opening of the furnace when handling the test pieces, it took about 10

minutes for the furnace to reach again equilibrium at 800°C. The one-hour time period was measured from this point. Once again, the low thermal mass of the specimen ensures that it reaches temperature quickly.

10. The Capsule Testing Work Sheet for the Vibration test, you reference an Appendix A concerning an extended length capsule which bubbled in leak testing. Please provide a copy of the Appendix A referenced by the work sheet.

    Please find enclosed a copy of Appendix A.

11. The SPECIAL FORM RADIOACTIVE MATERIAL TEST SUMMARY has remarks for four of the five tests, such as "See Comment 3". However, there are only two comments. Comment 1 seems to be consistent with the remark, 'See Comment 2', and Comment 2 seems to be consistent with the remark, 'See Comment 3'. The original Comment 1 concerning leaching seems to have been deleted. Please provide this comment or state that there should only be the 2 comments.

    Please find enclosed a copy of the updated Special Form Radioactive Material Test Summary No. 46A/ Dec 12, 01.

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

Enclosed: Special Form Radioactive Material Test Summary, Appendix A, Appendix B, drawing No. C-168 Issue 1, drawing No. G530102-141 Issue D

Copy to: Mike Krzaniak, Viktor Eichler, MDS Nordion

MDS Nordion

SPECIAL FORM RADIOACTIVE MATERIAL TEST SUMMARY

The capsule model specified herein has been evaluated in accordance with the International Atomic Energy Agency (I.A.E.A.) Safety Standard TS-R-1, Regulations for the Safe Transport of Radioactive Material, 1996 Edition, (Revised) Section VII, paragraphs 705 -> 708 and 711.

TEST SUMMARY. 46A
CAPSULE MODEL. C-168
DRAWING. NO: A04141
CAPSULE MATERIAL: 316L Stainless Steel
ENCAPSULATION: Single

DATE: 01-12-12
CONTENTS: Cobalt-60 Pellets
OVERALL DIAMETER. 0.127"
OVERALL LENGTH: 0.5"

SPECIAL FORM REQUIREMENTS(1)

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

(1) See Special Form requirements on reverse side

COMMENTS:

1) Paragraph 709(a), The tests prescribed in para. 705 and 706 provided the mass of the *special form radioactive material* is less than 200g and they are alternatively subjected to Class 4 impact test prescribed in the International Organization for Standardization document ISO 2919: "Sealed Radioactive Sources – Classification" . as referenced in ANSI certificate # 100.

2) Paragraph 709(b), The tests prescribed in para. 708 provided they are alternatively subjected to the Class 6 temperature test specified in the International Organization for Standardization document ISO 2919: "Sealed Radioactive Sources – Classification" , as referenced in ANSI certificate # 100.

3) The capsule integrity was assured by Liquid Nitrogen Bubble Test and Helium Pressurization Test (ISO 9978 section 6.2.4 and 6.1.2).

This summary verifies that the described capsule model meets the requirements of Special Form in accordance with the I.A.E.A. Safety Standard TS-R-1, Regulations for the Safe Transport of Radioactive Material, 1996 Edition (revised) Section VII, paragraphs 705 ->708 and 711.

Tested by Helen Shaban
Title Materials Technologist
Date 12 Dec 2001

Approved Mlyanek
Title Manager, Package Engineering
Date 13 Dec 2001

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

General

704 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.

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

After each test specified in paras 704-711, 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. 710 for indispersible solid material and para. 711 for encapsulated material

Test Methods

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

The target for the drop test specified in para. 705 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.

706 **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.

707. **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.

708. **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.

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

(a) The tests prescribed in paras 705 and 706 provided the mass of the special form radioactive material is less than 200g and they are alternatively subjected to the Class 4 impact test prescribed in the International Organization for Standardization document ISO 2919 "Sealed radioactive sources - Classification" [11], and

(b) The test prescribed in para . 708 provided they are alternatively subjected to the Class 6 temperature test specified in the International Organization for Standardization document ISO 2919 "Sealed radioactive sources - Classification"[11]

Leaching and volumetric leakage assessment methods

710. 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

711 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(10umho/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.

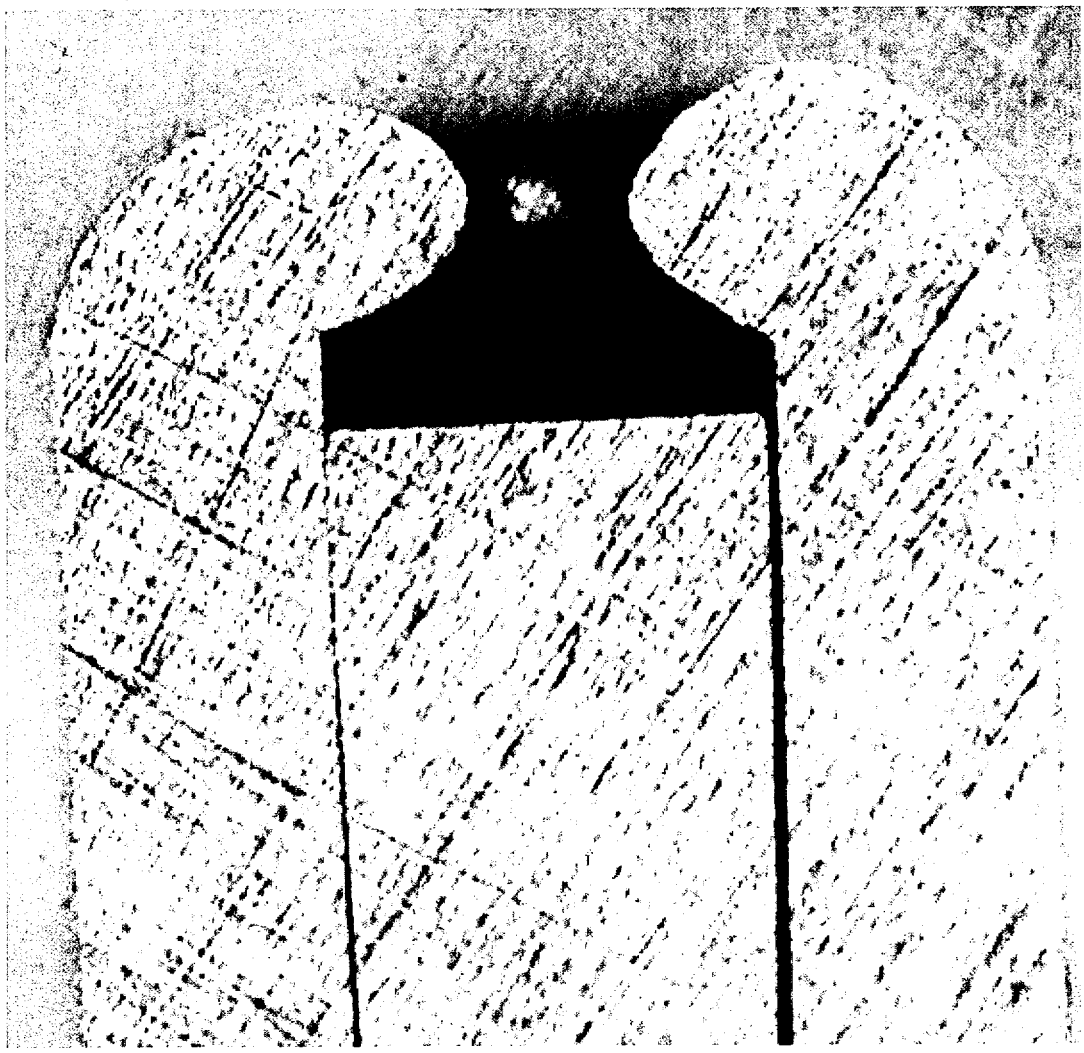
(b) The alternative volumetric leakage assessment shall comprise any of the tests prescribed in the International Organization for standardization document ISO 9978 "Radiation Protection - Sealed Radioactive Sources - Leakage Test Methods." which are acceptable to the competent authority.

APPENDIX A

An extended length capsule was used to ensure adequate free air space for the validity of the Helium Leak Test. The extended length capsule contains a pellet and a spring between the pellet and the plug. The spring has a diameter of 0.016". In one case, serial number 0001, the spring came off the pellet during handling and lodged beside the pellet allowing the plug to drop down. As a result, the welding was done without fusing the plug as seen in the polished section in Figure A below. This made it impossible to complete a vibration test on a second unit.

The spring is used to support the plug only for the longer capsule. During planning of the tests using an extended capsule length, it was proposed to use a spring to ensure sufficient free air space for helium leak testing, but a deficiency resulted from using the spring. The longer capsule with a spring is not used in production, but only for validation of the helium leak test. This fault could not happen in C168 production because a spring is not used.

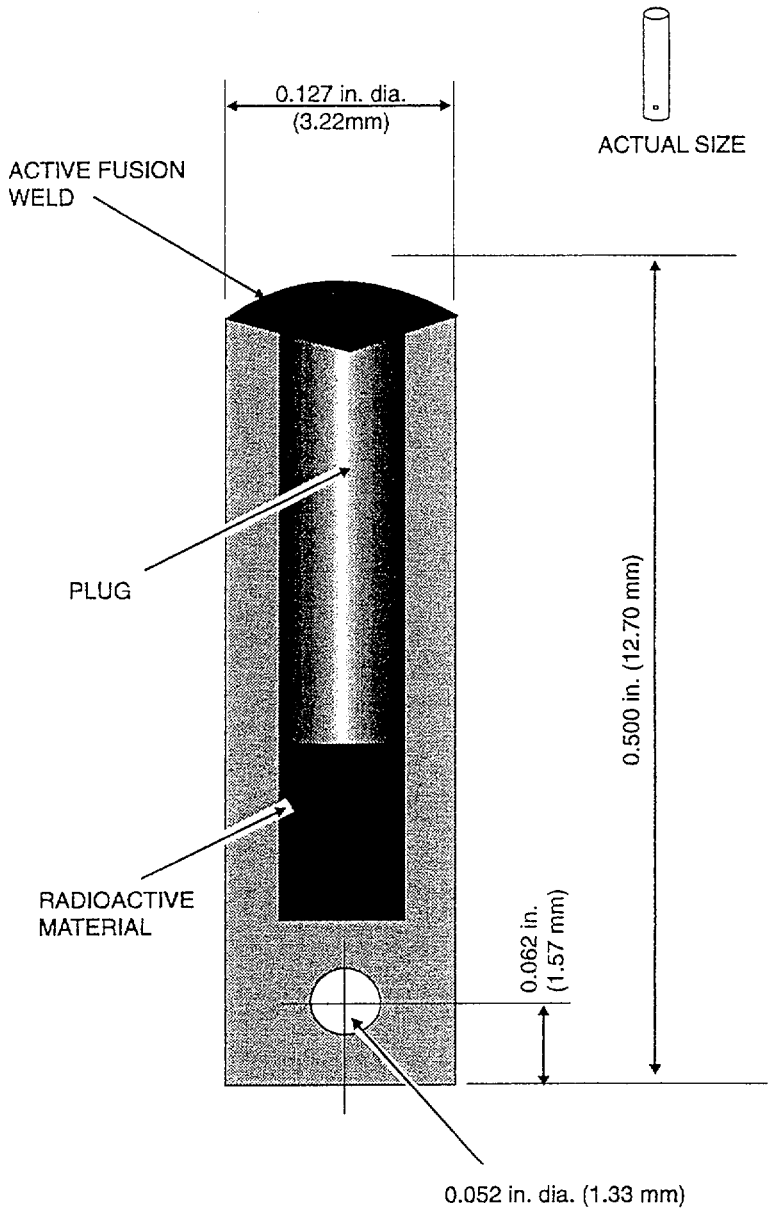
Figure A Serial Number 0001 Section, Polished (43x Magnification)



APPENDIX B

During the temperature test the surface of the extended length capsule greatly degraded. As seen in Figure 1 below, the weld of serial number 0007 has a lot of scale and loose surface material. The rough surface condition resulted in helium becoming absorbed and trapped in the surface of the capsule. This surface condition resulted in inconclusive helium leak test results. The solid bar dummy also did not pass the leak test. As a result the Liquid Nitrogen-Alcohol Bubble test was used to qualify these capsules.

Figure 1 Serial Number 0007 Weld (76x Magnification)



Notes

1. Conforms to IAEA Special Form requirements
   CNSC Certificate No. CDN/0015/S-85
2. Radioactive Material: Cobalt-60 in solid form
3. Material: Type 316L stainless steel
4. Engraved on capsule:
   RADIOACTIVE
   Co-60 C-168
   MDSN
   XXXX (Serial No. as specified)

MDS Nordion

447 March Road, P.O. Box 13500
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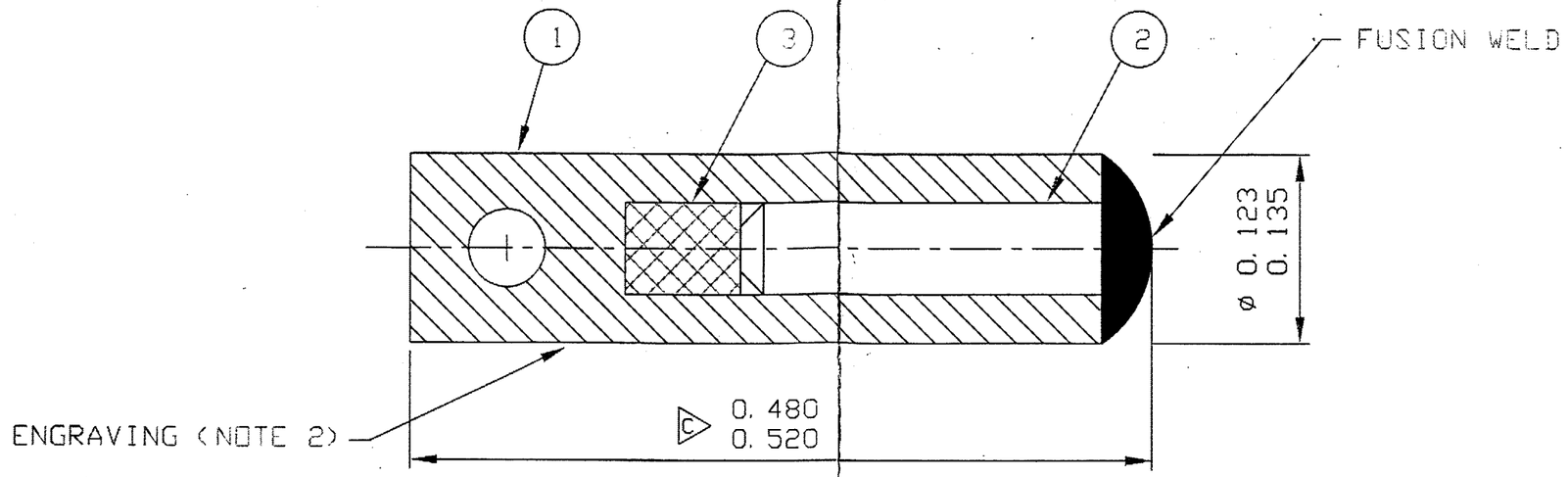
TITLE

C-168 Cobalt-60 Sealed Source

REF. IN/SS 1817 C168 DWG A04141		REVISED Dec 01	DCN A1362-D-07A
DATE December 2001		No. C-168	ISSUE 1
DRAWN	CHECKED APPROVED	SHEET 1 OF 1	



NOTES:
1. THIS INFORMATION DRAWING IS BASED ON MDS NORDION DWG A04141.
2. CAPSULE TO BE ENGRAVED - RADIOACTIVE
   Co60 C-168
   D MDSN
   XXXX (SERIAL # AS SPECIFIED)
3. ALL DIMENSIONS SHOWN AT 20°C.

ITEM NO.	QUANTITY	PART NO.	ASSY	DWG SIZE	DESCRIPTION
3					ACTIVE MATERIAL Co 60 PELLETS
2	1				STAINLESS STEEL ASTM A276 TYPE 316L
1	1				STAINLESS STEEL ASTM A276 TYPE 316L

BILL OF MATERIALS

ISSUE	DESCRIPTION	DATE	DRAWN	DFTG APPVL	ENGR
A	DCN# A1362-D-01A				
B	DCN# A1362-D-03A	01may01	RV	GF	FT
C	DCN# A1362-D-04A	01may28	RV	GF	FT
D	DCN# A1362-D-07A	01nov10	RV	MM	VE

DRAWN	DATE	DFTG APPVL
RV	01 APR 21	GF

FT				
MECH ENGR	ELEC ENGR	CIVIL ENGR	PHYSICS	ENGRG APPVL

FINISH

THIRD ANGLE PROJ

PRODUCT

MDS Nordion

TITLE
C-168 COBALT -60
SEALED SOURCE ASSY
INFORMATION DRAWING

USED ON

UNLESS OTHERWISE SPECIFIED, ALL DIMENSIONS ARE IN INCHES.
TOLERANCES: DECIMALS .x ± .xx ± .xxx ± ANGLES ± SURFACE 63

SIZE	DWG NO.	ISSUE
B	G530102-141	D

SCALE 10:1 SHEET 1 OF 1