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

MDS Nordion
Science Advancing Health

September 13, 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

RE: Sealed Source Registration for MDS Nordion Haan, GammaMed 212

Dear Mr. Ward:

Thank you for your email of September 7, 2001, in which you requested further clarifications.

1. In section 7.1, BAM Testing, you stated that BAM tested models in configurations per drawings GM212.03-004, GM212.13-002 and GM212.13-001. However, reading the test results in Appendix G, it appears that both source assemblies tested were only of the configuration per drawing GM212.03-004. Drawings of the GM212.13 series are not mentioned in the BAM testing. Please confirm that BAM tested only models constructed per drawing GM212.03-004 or provide additional information showing the results of testing on other designs. Also, please describe any effect to the design due to raising the maximum source capacity from 10 Ci as stated on GM212.03-004 (tested version) to the 15 Ci stated on GM212.13-010 (application version).

   The two source assemblies tested by BAM and described in the certificate D/0048/S were of the model GM212.03-004. The drawing GM212.03-004 is the general assembly drawing. The additional two drawings GM212.13-002 and GM212.13-001 are detail drawings of the source assembly and describe the source enclosure and source cover respectively. These drawings are listed as such in paragraph 5 titled, "Essential drawings," of the German Special Form certificate D/0048/S-85 (Rev.1).

   The source capsule assembly will not be affected by an activity of 555 GBq. The source is manufactured from either ANSI Type 316L or DIN 8556 Type 1.4404 stainless steel. The similarly designed CIS-US, Inc. model 724 source assembly, is also manufactured from ANSI Type 316 or 316L stainless steel and has been approved for 740 GBq (20 Ci).

2. In Appendix G, the certificate provided from BAM expired on June 6, 1991. Please provide a copy of the current certificate demonstrating compliance with Special Form requirements.

   The German Special Form certificate D/0048/S expired June 6, 1991. The renewal of the German Special Form certificate D/0048/S-85 (Rev.1) expired June 5, 2001. A copy of this certificate was provided with the application of April 19, 2001. The D/0048/S-85 (Rev.1) has been extended by the BAM to December 31, 2001. A copy of the extension letter has been enclosed with the English translation.

3. In Appendix G, the temperature test appears to have been to 800 degrees C for 10 minutes. ISO 2919 requires holding the maximum temperature for 1 hour, and a thermal shock test down to 20 degrees C. Additionally, if the 800 degree requirement were met, the source would have rated a '6' for the temperature requirement versus the '5' stated in the certificate. Please describe how the BAM testing demonstrates that the source can be classified as a '5' for the temperature test.

   The testing done by BAM was to qualify the source to the Special Form requirements set in the IAEA Safety Series No.6, "Regulations for the Safe Transport of Radioactive Material 1985 Edition (As Amended 1990)." The requirements prescribed in the IAEA regulations are compatible with 49 CFR 173.469. The 800°C for 10 minutes is the heat test prescribed for Special Form sources in 49 CFR 173.469 (4).

   MDS Nordion Haan has not been provided with any additional test information from BAM. As a government testing agency, BAM issues certificate but does not typically provide the actual test reports. As a result MDS Nordion Haan does not have copies of these test reports and therefore can not describe how BAM testing demonstrates that the source can be classified as a "5" for temperature test. Please refer to the ISO testing done by the French Laboratoire National D'Essais.

4. In Appendix G, there is no mention of any external pressure testing. However, BAM stated that the source satisfied the rating for a '3' for ISO 2919 classification purposes. Please describe how the BAM testing demonstrates that the source can be classified as a '3' for the external pressure test.

   As previous mentioned above, MDS Nordion Haan does not have copies of these test reports and therefore can not describe how BAM testing demonstrates that the source can be classified as a "3" for the external pressure test. Please refer to the ISO testing done by the French Laboratoire National D'Essais.

5. In the German version of Appendix G, it appears to state that the minimum detectability of the Helium testing equipment is 10E-4 mbar/sec. In the English translation, it says 10E-10 mbar/sec. Please clarify this apparent transcription error.

   There is an error in the English translation of the test criteria for the soluble contents standard for helium leak device. This should be 10^{-4} mbar/s. Please note that the measuring accuracy of the equipment is $5X10^{-10}$ mbars/s.

6. In section 7.2, you describe tests performed by the French Laboratoire National D'Essais to demonstrate the source assembly's compliance with the ISO 2919 classification of 53211. Copies of the documents provided to you by the French laboratory are provided in Appendix F. In Appendix F, test report file 2080231 - document DEMB/2 references file 2080231-document DEMB/1 as the test report for the ISO 2919 testing. However, you did not provide a copy of the test report DEMB/1. DEMB/2 appears to only be a certification that the source meets the ISO 2919 classification of 53211, whereas DEMB/1 is apparently the test descriptions and results. Please provide a copy of DEMB/1.

   A copy of DEMB/1 has been enclosed. A copy of this report should have been available with the application of April 19, 2001.

With the addition of MDS Nordion S.A. as a new subcontractor, MDS Nordion performed ISO testing on the GammaMed 212 source assembly manufactured by MDS Nordion S.A. The GammaMed 212 source assembly was tested to the requirements of ISO 2919:1999 (E) and meet the classification E63322. As indicated in the application of June 18, 2001, the GammaMed 212 source manufactured by MDS Nordion S.A. is identical to the one manufactured by Mallinckrodt. A copy of the ISO 2919 test report has been enclosed.

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

Enclosed: Extension of D/0048/S-85 (Rev.1) German and English translation, the French Laboratoire National D'Essais DEMB/1 French and English Translation, MDS Nordion ISO 2919 test report

Copy to: Ann Warbick Cerone, Scott McIntosh, David Gill, MDS Nordion
Dr. Wolfgang Nuding, Jurgen Handke MDS Nordion Haan

BAM
Bundesanstalt für Materialforschung und -prüfung
D-12200 Berlin
Telefon: 0 30/81 04-0
Telefax: 0 30/8 11 20 29

Verlängerung des

Zulassungsscheines für die Bauart eines „radioaktiven Stoffes in besonderer Form" („special form radioactive material") Nr. D/0048/S-85 (Rev. 1)

Entsprechend dem Antrag der Firma

MDS Nordion Haan GmbH
Bergische Straße 16
42781 Haan

vom 10. August 2001 (BAM-Antrags-Nr. III.3/20800) wird die Gültigkeit des am 31.01.1997 ausgestellten Zulassungsscheines Nr. D/0048/S-85 (Rev. 1) bis zum 31.12.2001 unter dem Vorbehalt des jederzeitigen Widerrufes verlängert.

Rechtsbehelfsbelehrung

Gegen diesen Bescheid kann innerhalb eines Monats nach Bekanntgabe Widerspruch erhoben werden. Der Widerspruch ist bei dem Präsidenten der Bundesanstalt für Materialforschung und -prüfung (BAM), 12205 Berlin, Unter den Eichen 87, schriftlich oder zur Niederschrift einzulegen.

Rechtsverbindlich ist der deutsche Text.

BUNDESANSTALT FÜR MATERIALFORSCHUNG UND -PRÜFUNG (BAM)
Berlin, den 21. August 2001

Referat III.32
Transportbehälter für radioaktive Stoffe

Im Auftrag

Dipl.-Ing. L. Buhlemann

BUNDESANSTALT FÜR MATERIALFORSCHUNG UND -PRÜFUNG (BAM) 10 01

ZULASSUNG

Sicherheit und Zuverlässigkeit in Chemie- und Materialtechnik

BAM
Bundesanstalt für Material-forschung und -prüfung
(Fed. Institute for Materials Research and Testing)
D-12200 Berlin
Telephone: 030/81 04-0
Fax: 030/8 11 20 29

Extension of the

License Certificate for the Construction Type of a "special form of radioactive material" No. D/0048/S-85 (Rev. 1)

According to the application by the company

MDS Nordion Haan GmbH
Bergische Straße 16
42781 Haan,

received on 10 August 2001 (BAM application no. III.3/20800) the validity of the license certificate no. D/0048/S-85 (Rev. 1) issued on 31-01-1997 is extended until 31-12-2001 subject to revocation at any time.

Instructions about the right to appeal

An objection may be filed against this notice within one month after notification. The objection is to be filed in writing with the President of the Federal Institute for Materials Research and Testing (BAM), 12205 Berlin, Unter den Eichen 87, or may be reported there for being recorded.

The German text is legally binding.

BUNDESANSTALT FÜR MATERIALFORSCHUNG UND -PRÜFUNG (BAM)
(Federal Institute for Materials Research and Testing)
Berlin, 21 August 2001

Section III.32
Transport containers for radioactive materials

By order
(signed)
Dipl.-Ing. L. Buhlemann

(Stamp:) Bundesanstalt für Materialforschung und -prüfung

LNE
LABORATOIRE
NATIONAL
D'ESSAIS

RAPPORT D'ESSAI

Demandeur : ISOTOPEN - TECHNIK
DR. SAUERWEIN GMBH
Postfach 1354
D - 5657 HAAN 1

Date de la demande : Lettre du 21 mai 1994

Objet : Contrôle de qualité de l'ensemble (source radioactive scellée-câble) du type 12i (plan n° GM212.03-004) correspondant aux spécifications"sous forme spéciale"

Documents de référence: Arrêté du 24 novembre 1977 relatif aux caractéristiques des matières radioactives sous forme spéciale (Ministère de l'Environnement)

Annexe A à l'arrêté du 15 septembre 1992 relative au règlement pour le transport des matières dangereuses par route - Prescriptions relatives aux matières et objets dangereux - Classe 7 : Matières radioactives - (Ministère de l'Equipement, du Logement et des Transports)

Norme NF ISO 9978 (1992) - Radioprotection - Sources radioactives scellées - Méthodes d'essais d'étanchéité

La reproduction du présent document n'est autorisée que sous sa forme intégrale.
Il comporte 4 pages.

1. IDENTIFICATION DU TYPE DE SOURCES RADIOACTIVES SCELLEES

Type : 12i (plan n° GM212.03-004)

Fabricant : ISOTOPEN - TECHNIK DR. SAUERWHEIN GMBH

Radioélément : ^{192}Ir

Radiotoxicité : groupe 3

Activité maximale : 370 GBq

Enveloppe : simple en acier inoxydable

L'ensemble (source scellée-câble), objet du présent rapport, est défini par le plan n° GM212.03-004 joint en annexe.

2. CONDITIONS DE REALISATION DES ESSAIS

Le contrôle qualité, correspondant aux spécifications des sources radioactives scellées "sous forme spéciale", comprend les épreuves suivantes :

- Choc : chute de 9 m de la source scellée sur une plaque d'acier de 5 cm d'épaisseur ;

- Percussion : équivalence d'une masse de 1,4 kg tombant en chute libre d'une hauteur de 1 m. La source est posée sur une feuille de plomb reposant sur une surface dure et lisse et est frappée avec la face plate d'une billette d'acier ;

- Température: la source est placée dans une atmosphère dont la température est maintenue à 800 °C pendant 10 min puis est soumise à un refroidissement libre.

Chacun de ces essais a été effectué sur deux ensembles (source scellée fictive-câble).

Un examen visuel ou macrographique a été effectué après chaque essai sur chaque source. L'étanchéité de chaque source a été vérifiée avant essai, après essai et 8 jours après, par bullage dans de l'eau à une température comprise entre 90 °C et 95 °C, la source étant immergée à une profondeur d'au moins 5 cm.

Quatre échantillons ont été déposés au LABORATOIRE NATIONAL D'ESSAIS par la Société VALKEY. Ils ont été référencés arbitrairement par le LNE de 1 à 4.

Les essais ont été réalisés du 30 mai au 10 juin 1994.

3. RESULTATS

L'essai de percussion a provoqué l'aplatissement des 2 sources testées, les autres essais n'ont pas endommagé les sources. Les examens visuels et macrographiques n'ont pas révélé la présence de fissures ou tout autre signe laissant prévoir une rupture de l'enveloppe des sources ou une détérioration de sa liaison au câble.

A l'issue de chaque essai de bullage, aucune émission de bulles n'a été observée pendant une période d'au moins 2 min.

4. CONCLUSION

Il résulte des essais réalisés au LNE que l'ensemble (source scellée - câble) du type 12i, défini au chapitre 1, a la qualité de matières radioactives en source scellée sous forme spéciale conformément aux spécifications des arrêtés cités en première page du présent rapport d'essai.

Trappes, le 13 juin 1994

Réalisation de l'essai
Nicolas BONNEFOND

L'Adjoint du Chef de Département
Emballage et Conditionnement

Hervé MARCEL

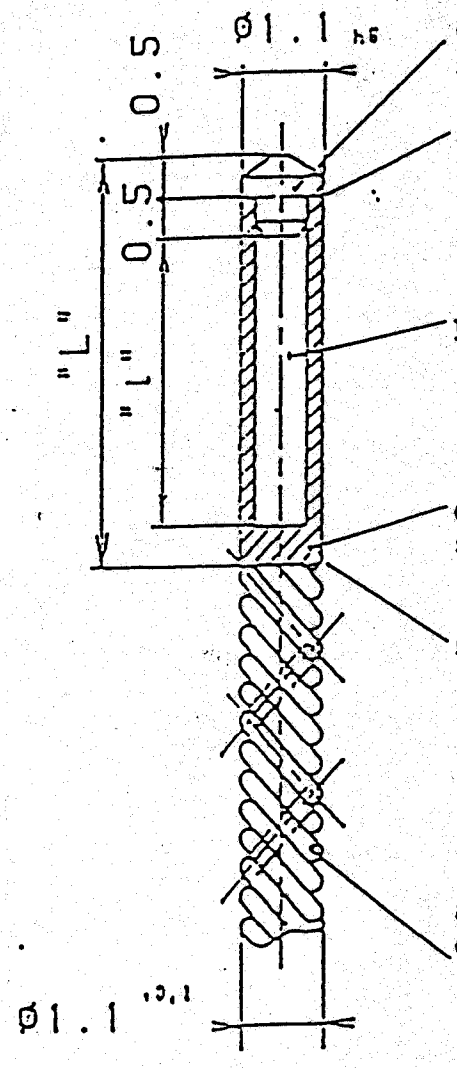
RÉPUBLIQUE FRANÇAISE
LABORATOIRE NATIONAL D'ESSAIS

Responsable de l'essai

Xuan-Dao PHAN

Les résultats mentionnés ne sont applicables qu'aux échantillons, aux produits ou aux matériels soumis au LNE et tels qu'ils sont définis dans le présent document.

ANNEXE



21

20

LABORATOIRE NATIONAL D'ESSAIS
Agréé par arrêté
Secrétariat d'État aux Transports
(Transport des matières radioactives)

Charge: max.	370GBq(10Ci)
"l" min.=2,0	"l" max.=3,6
"L" min.=3,5	"L" max.=5,1

Toll. gezeichn. nicht bemaßte Radien oder Fasen mm ~ ▽ ▽▽ ▽▽▽

	Datum	Name
gezeichn.		
Geprüft	10.10	
Norm.		

ISOTOPEN-TECHNIK
DR. SAUERWEIN GMBH
D-5657 HAAN (W.-GERMANY)

Freimaßtoleranzen nach DIN 7168 mittel

Maßstab 10:1

Désignation: Capuchon complet

Matériau GM 121

Schéma N° GM212.03-004

Ersatz für:

Ersatz f.:

TEST REPORT

Requested by :	ISOTOPEN-TECHNIK Dr. Sauerwein GMBH Postfach 1354 D – 5657 HAAN 1
Date of Request :	Letter of May 21, 1994
Purpose :	Quality Control of type 12i (plan # GM212.03-004) assembly (sealed radioactive source-cable) as per « special form » specifications.
Reference Documents:	Decree of November 24, 1977 relating to special form radioactive materials (Ministry of the Environment) Appendix A of the Decree of September 15, 1992 relating to regulations for transportation by road of dangerous goods – *Prescriptions relatives aux matières et objets dangereux* – Class 7 – Radioactive Materials (Ministry of Equipment, Housing and Transportation). NF ISO 9978 (1992) Standard – Radiation Protection – Sealed Radioactive Sources – Leakproof Test Methods

1 – IDENTIFICATION OF TYPE OF SEALED RADIOACTIVE SOURCE

Type :	12i (plan #GM212.03-004)
Manufacturer :	ISOTOPEN – TECHNIK DR. SAUERWEIN GMBH
Radioisotope :	^{192} Ir
Radiotoxicity :	Group 3
Max. Activity :	370 GBq
Encapsulation :	single – stainless steel

The assembly (sealed source-cable), referenced in the present report, is defined by plan #GM212.03-004 attached.

2 – CONDITIONS FOR CARRYING OUT TESTS

Quality Control, as per the specifications for « special form » sealed radioactive sources, includes the following tests :

Drop -	sealed source dropped 9 m onto a 5 cm thick steel plate.
Shock -	equivalent of a 1.4 kg mass in a free fall from a 1 m height. The source is placed on a lead sheet resting on a hard, flat surface and is struck with the flat face of a steel hammer.
Temperature -	the source is placed in an 800° environment for 10 min. then cooled.

Each of these tests were carried out on two assemblies (fictitious sealed source-cable).

A visual or macrographic examination was carried out after each test on each source. The leakproofness of each source was tested before the test, after the test and 8 days later, by airbubbles under water at a temperature between 90°C and 95°C, the source being immersed in at least 5 cm of water.

Four samples were taken to the LABORATOIRE NATIONAL D'ESSAIS by the VALKEY Company. They were arbitrarily referenced by the LNE from 1 to 4.

The tests were carried out on May 30 and June 10, 1994.

3. RESULTS

The shock test resulted in the flattening of both sources tested, the other tests did not damage the sources. The visual and macrographic examinations did not indicate the presence of any cracks or any other indication that the source covering or its link with the cable were damaged.

At the completion of each underwater test, no bubbles were observed during a period of at least 2 min.

4. CONCLUSION

From the tests carried out at the LNE, the type 12i assembly (sealed source-cable), defined in Chapter 1, is qualified as a special form sealed radioactive source in accordance with the specifications of the decrees listed on the front page of this test report.

Trappes, June 13, 1994

Parts List

1 – special steel lid
2 – Laser weld
3 – Ir-192 pellet
4 – Special steel covering
5 – Laser weld
6 – Special steel flexible torque shaft

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: 99 (Revision 1) DATE: 01-09-12

CAPSULE MODEL: GammaMed 12i/12it CONTENTS: Iridium pellets

DRAWING. NO: MDS/GM-M04-00 (Vibration test) and MDS/GM-M03-00 (All other tests)
With additional length for free air space to validate Helium Pressurization test.

CAPSULE MATERIAL: DIN 1.4541 or 1.4404 OVERALL DIAMETER: 1.1 mm

ENCAPSULATION: Single OVERALL LENGTH: 10.06 mm

ANSI CLASSIFICATION AND PERFORMANCE STANDARD(1) ANSI 97:C63322 ISO/99/C63322

CLASSIFIED PERFORMANCE STANDARD(2)

TEST	CLASS	METHOD	REMARKS
TEMPERATURE	6	TEST	PASS
EXTERNAL PRESSURE	3	TEST	PASS
IMPACT	3	TEST	PASS
VIBRATION	2	TEST	PASS
PUNCTURE	2	TEST	PASS

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

COMMENTS: Capsule integrity assured by Liquid Nitrogen bubble tests (ANS N43.6-1997 paragraph A.2.2.7) and Helium leak tests (ANS N43.6-1997, paragraph A.2.2.6.).

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

Tested by Helen Sheldon
Title Materials Technologist
Date 01 Sept 12

Approved Michael Kyanek
Title Manager, Package Engineering
Date 01 Sept 12

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^{0}C (20 min) +80^{0}C (1h)	-40^{0}C (20 min) +180^{0}C (1h)	-40^{0}C (20 min) +400^{0}C (1h) and thermal shock 400^{0}C to 20^{0}C	-40^{0}C (20 min) +600^{0}C (1h) and thermal shock 600^{0}C to 20^{0}C	-40^{0}C (20 min) +800^{0}C (1h) and thermal shock 800^{0}C to 20^{0}C	Special Test
External Pressure	No Test	25 kN/m^2 abs. (3.6 lbf/in^2) to atmosphere	25 kN/m^{2}abs. to 2 MN/m^2 (290 lbf/in^2) abs.	25 kN/m^{2}abs. to 7 MN/m^2 (1015 lbf/in^2) abs.	25 kN/m^2 abs. to 70 MN/m^2 (10153 lbf/in^2) abs.	25 kN/m^2 abs. to 170 MN/m^2 (24 656 lbf/in^2) 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

CAPSULE TESTING WORK SHEET

DATE: 01-09-12

TEST: Temperature **CLASS:** 6 ANSI / ISO

CAPSULE DESCRIPTION: Brachytherapy Source

MODEL: GammaMed 12i/12it **CONTENT:** Iridium Pellets

DRAWING REFERENCE: MDS/GM-M03-00 (with additional length for free air space)

CAPSULE MATERIAL: DIN 1.4541 or 1.4404 **ENCAPSULATION:** Single

OUTSIDE TUBE DIAMETER: 1.1 mm **OVERALL LENGTH:** 10.06 mm

LEAK TEST TYPE: Liquid Nitrogen Bubble and Helium leak tests. **RESULTS:** Pass

COMMENTS : Two Gammamed plus capsules serial numbers 6 and 7 were temperature tested.

Test: The two capsules were held at -40^0C for 40 minutes. The capsules were removed and immediately inserted into the furnace at 800^0C and held for 1 hour. The samples were removed from the furnace and cooled at ambient temperature.
Following this, the capsules were returned to the furnace for 15 minutes at 800^0C and then the capsules were immediately immersed in water at 20^0C. This test series is described in ANSI/HPS N43.6-1997, paragraphs 7.2.1, 7.2.2 and 7.2.3. and is more severe than ISO 2919:80 (Class 6). Following the test series the capsules were leak tested using the Liquid Nitrogen Bubble Test and Helium leak test ANS/HPS 43.6-1997 sections A.2.2.6 and A.2.2.7..
In addition to the above tests the source capsules were examined stereoscopically up to 50 magnifications and there was no visible damage.

Note: The Helium test requires that the source capsules be helium pressurized at 150 lb_f/in^2 for a period of 30 minutes. In order to increase test validity the source capsules were pressurized at $200lb_f/in^2$ for 16 hours. This pressurization was immediately followed by the specified leak test.

See Figure 1.

CONDUCTED BY: Helen Hooker
Materials Technologist

APPROVED BY: M Lyons
Manager, Package Eng.

GammaMed 12i/12it source Temperature test (cont'd)

Photograph

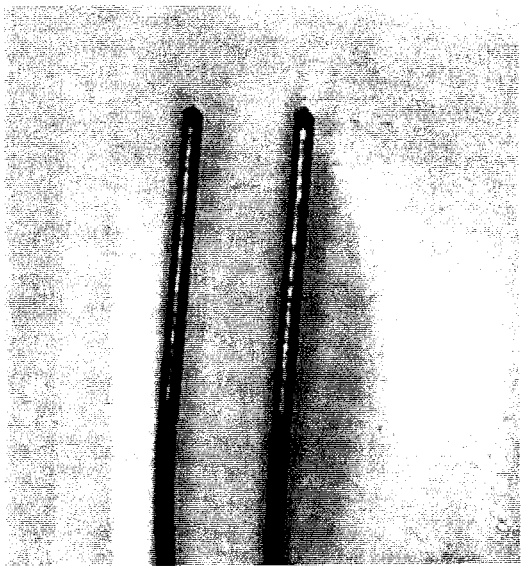


FIGURE 1: Discolouration from ANSI Class 6 temperature testing of two 1.1 mm GammaMed 12i/12it capsules.

MDS NORDION

CAPSULE TESTING WORK SHEET

DATE: 01-09-12

TEST: External Pressure **CLASS**: 3

CAPSULE DESCRIPTION: Brachytherapy Source

MODEL: GammaMed 12i/12it **CONTENT**: Iridium pellets

DRAWING REFERENCE: MDS/GM-M03-00 (With additional length for free air space)

CAPSULE MATERIAL: DIN 1.4541 or 1.4404 **ENCAPSULATION**: Single

OUTSIDE DIAMETER: 1.1 mm. **OVERALL LENGTH**: 10.06 mm

LEAK TEST TYPE: Liquid Nitrogen bubble and Helium leak tests. **RESULTS**: Pass

COMMENTS: ANSI level 3 external pressure test involves two separate five minute exposures to pressure lower than 25kN/m^2 abs. (3.6 lb_f/in^2). This is followed by pressurizing at 290 lb_f/in^2 and holding for 5 minutes (described in ANS N43.6-1997, section 7.3) This cycle is performed twice. This test is the same for ISO 2919. This test was performed on source numbers eight and nine.

Following the test series the capsules were leak tested using the Liquid Nitrogen Bubble Test and Helium leak test ANS/HPS 43.6-1997 sections A.2.2.6 and A.2.2.7..

In addition to the above leak tests following external pressure testing, the source capsules were examined stereoscopically to 50 magnifications and there was no visible damage.

Note that the Helium leak test requires that the source capsules be helium pressurized at 150 lb_f/in^2 for a period of 30 minutes. In order to increase test validity the source capsules were actually pressurized at 200 lb_f/in^2 for a period of 16 hours. This pressurization was immediately followed by the specified leak test.

CONDUCTED BY: Helen Heehan
Materials Technologist

APPROVED BY: M Ryan
Manager, Package Eng.

MDS NORDION

CAPSULE TESTING WORK SHEET

DATE: 01-09-12

TEST: Vibration **CLASS:** 2

CAPSULE DESCRIPTION: Brachytherapy Source

MODEL: GammaMed 12i/12it **CONTENT:** Iridium pellets

DRWG. REFERENCE: MDS/GM-M04-00 (With additional length for free air space)

CAPSULE MATERIAL: DIN 1.4541 or 1.4404 **ENCAPSULATION:** Single

OUTSIDE DIAMETER: 1.1 mm. **OVERALL LENGTH:** 10.06 mm

LEAK TEST TYPE: Liquid Nitrogen bubble and Helium leak tests. **RESULTS:** Pass

COMMENTS: ANSI level 2 vibration was performed as per ANS N43.6-1997 section 7.5. This test was performed on source numbers one and five.

See attached Ortech Report Number 01-03-M0103

Following the test series the capsules were leak tested using the Liquid Nitrogen Bubble Test and Helium leak test ANS/HPS 43.6-1997 sections A.2.2.6 and A.2.2.7..

In addition to the above leak tests following vibration testing, the source capsules were examined stereoscopically to 50 magnifications and there was no visible damage.

Note that the Helium leak test requires that the source capsules be helium pressurized at 150 lb_f/in^2 for a period of 30 minutes. In order to increase test validity the source capsules were actually pressurized at 200 lb_f/in^2 for a period of 16 hours. This pressurization was immediately followed by the specified leak test.

CONDUCTED BY: Helen Sadan
Materials Technologist

APPROVED BY: M Lyons
Manager, Package Eng.

Bodycote MATERIALS TESTING CANADA INC.

2395 SPEAKMAN DRIVE, MISSISSAUGA, ONTARIO CANADA L5K 1B3 • TEL: (905) 822-4111 • FAX: (905) 823-1446

Vibration Testing of Gammamed Simulated Source Capsules

A Report to:	MDS Nordion 447 March Road P.O. Box 13500 Kanata, Ontario Canada, K2K 1X8
Attention:	Ms. Helen Sheehan
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Report Number:	01-03-M0103 3 Pages, 2 Appendices
Date:	07 March 2001

1.0 INTRODUCTION

This report contains the procedures and results from the vibration test of the Gammamed simulated source capsules. The vibration test was carried out as specified on a document sent to Bodycote Ortech dated 06 March 2000 (section 7.5, Class 2). A quantity of four (4) capsules was tested, consisting of two samples of 0.9mm and two of 1.1-mm in diameter. The samples were attached to a spring extension, which was used to hold down the sample during the vibration tests.

The samples sent to Bodycote Ortech were identified as follows:

MDS Nordion Serial Number	Description	Bodycote Ortech Identification
#0	Gammamed – 1.1mm Dia.	01-03-M0103-1
#1	Gammamed – 1.1mm Dia.	01-03-M0103-2
#0	Gammamed – 0.9mm Dia.	01-03-M0103-3
#1	Gammamed – 0.9mm Dia.	01-03-M0103-4

2.0 TEST EQUIPMENT

- LDS Vibration Testing System – Asset No. 13756
- M&P VibPilot vibration controller MII No. A13871
- Kistler 4 channel coupler/signal conditioner – MII No. B04882
- Kistler Accelerometer – MII No. B02126 calibrated
- Toe clamps and associated hardware

3.0 PROCEDURES

All testing was performed at ambient conditions.

The four Gammamed simulated source capsules were secured to the LDS slip table using toe clamps and suitable hardware on the spring extension attached to the end of each sample. The samples were mounted such that the capsules would be free and the distance from the end of the capsule to the attaching point was measured as approximately 2 inches. Sample attachment to the slip table can be seen in the photographs in appendix A at the end of this report.

3.1 VIBRATION TEST

The four Gammamed capsules were subjected to a sinusoidal vibration with the following characteristics: Sweep from 25 to 500Hz at a constant peak acceleration of 5g's. The samples were subjected to 30 minutes of the sweeps in each of the two orthogonal directions employing a logarithmic sweep rate of 10 minutes per sweep.

All four samples were tested simultaneously.

A resonance search was conducted by visually observing the response of each type of capsule during the sweep.

The natural frequencies of the capsule assemblies that were found are listed in the table below.

Capsule ID (Sample dash #'s)	f_n longitudinal (Hz)	f_n radial (Hz)
Gammamed 1.1mm (-1 & -2)	27, 40	28, 36, 31, 55
Gammamed 0.9mm (-3 & -4)	27,40	27, 36, 41, 50, 65, 111

Note that the frequencies indicated above are obtained by observing the samples during a complete sweep, and visually comparing the displacement of the slip table to the response of the samples.

The samples were subjected to a fixed frequency dwell at each of the frequencies noted in the table above for a period of 30 minutes at each frequency in the two directions.

4.0 DISCUSSION

The four Gammamed capsules were subjected to Class 2 vibration levels outlined in a specification sent to Bodycote Ortech. The vibration sweep was repeated in the two axes, and a resonance search was also conducted. Each of the four samples were subjected to vibration levels at each of the resonance frequencies listed in the above table for a period of 30 minutes in each axis. During the entire duration of the tests, none of the four capsules suffered from any visual physical damage. A copy of the sine sweep waveform from the vibration controller is included in appendix B at the end of this report.

Leak testing of the simulated source capsules will be performed at MDS Nordion as required by the client. The samples were returned to the client following the completion of the vibration tests.

Reported by:

A. Adili

Tony Adili, P.Eng.
Mechanical and Product Testing

Reviewed by:

Brian O'Connor

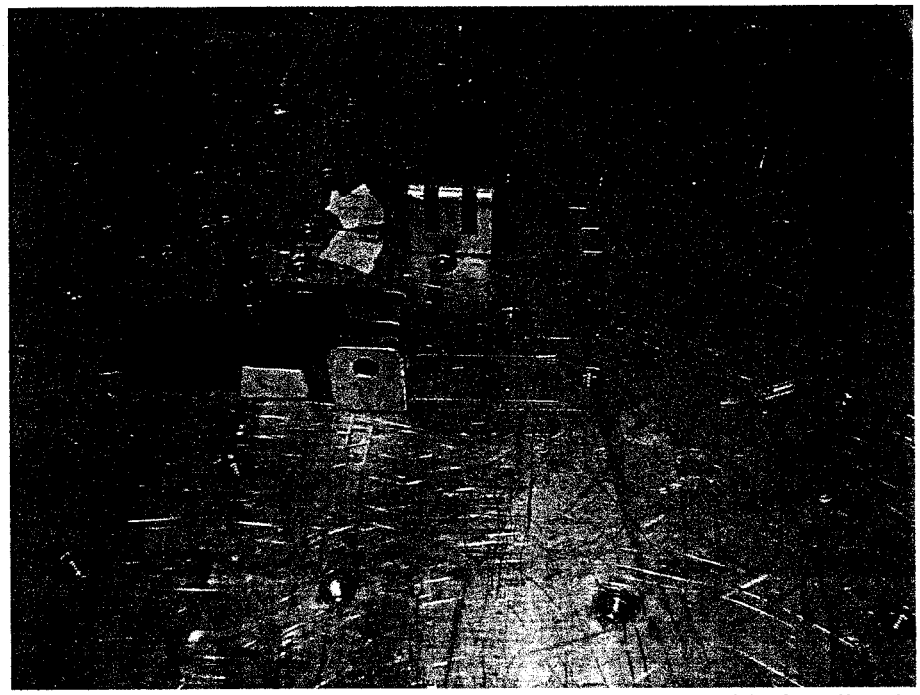
Brian O'Connor, P.Eng
Manager, Mechanical and Product Testing

This report refers only to the particular samples, units, material, instrument, or other subject used and referred to in it, and is limited by the tests and/or analyses performed. Similar articles may not be of like quality, and other testing and/or analysis programs might be desirable and might give different results.

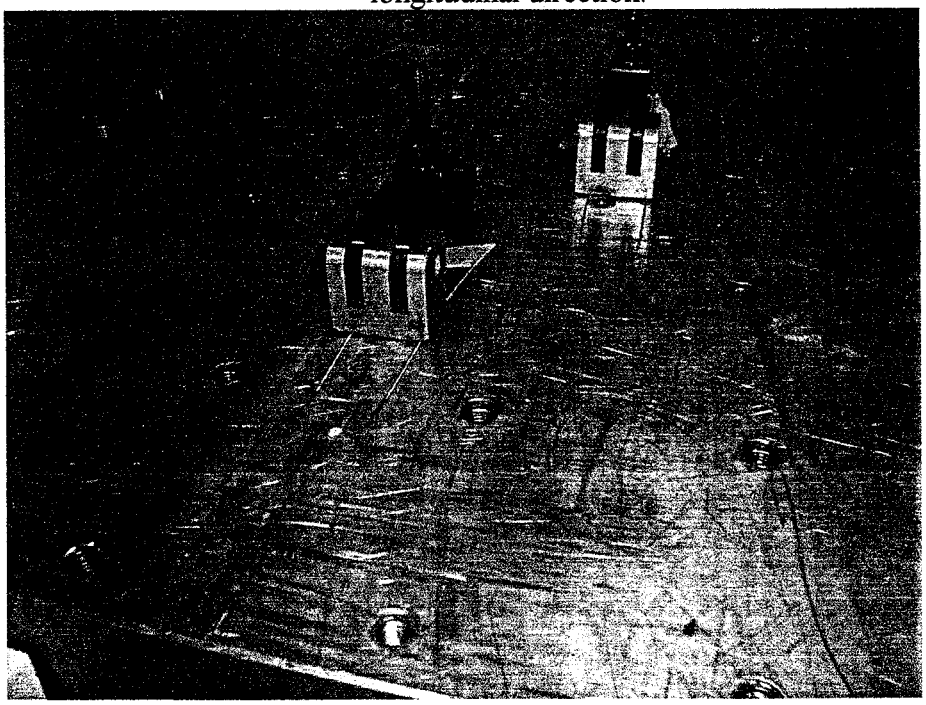
APPENDIX A

Photographs

(1 Page)



Photograph 1: Test set –up with capsules mounted on slip table for vibration testing in longitudinal direction.



Photograph 2: Test set –up with capsules mounted on slip table for vibration testing in radial direction.

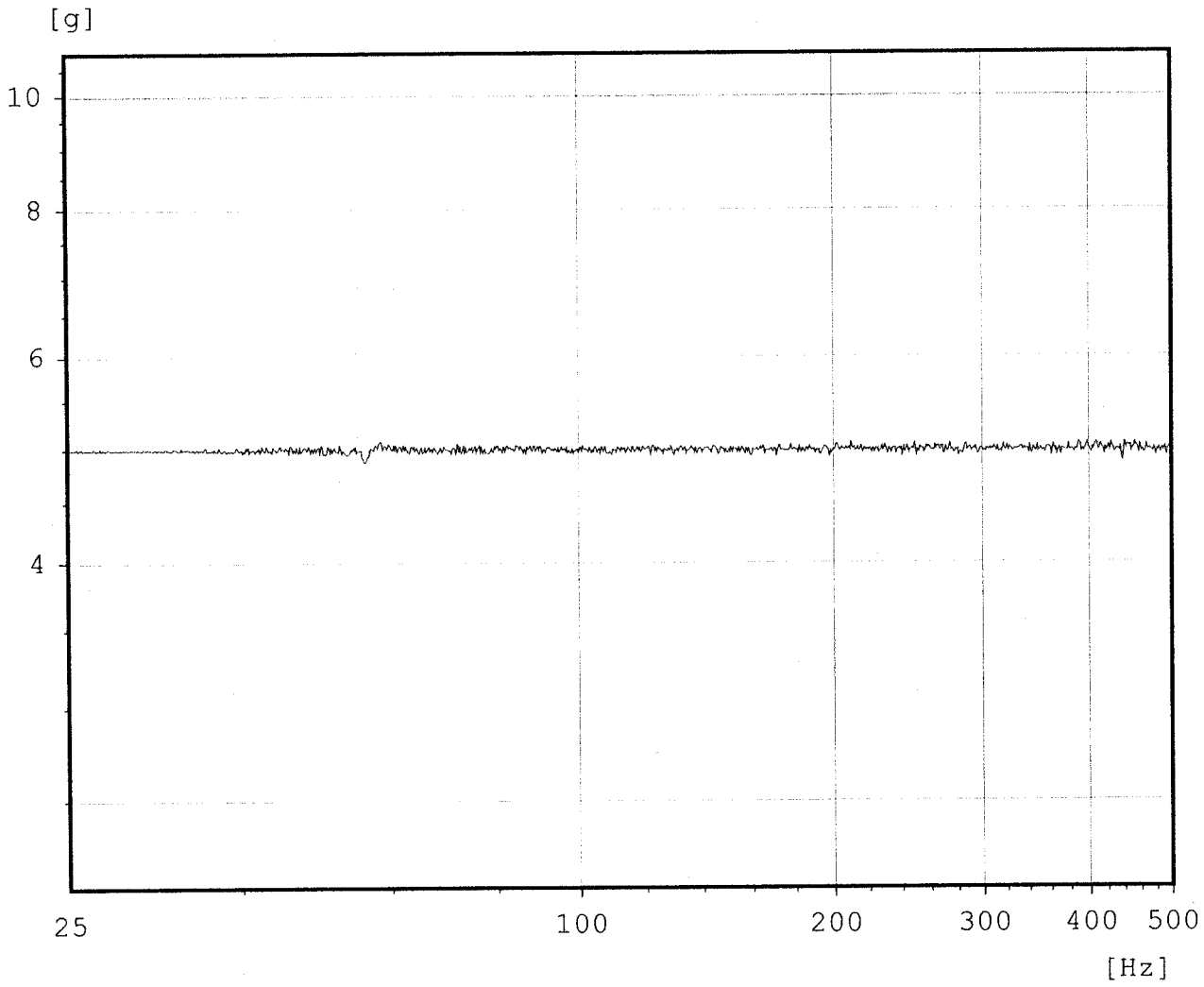
APPENDIX B

Test results

(2 pages)

Sine

control channel



Chan.no: 4
Chan.type: CW
Sweep type: logarithmic
Sweeps done: 3
Sweeps req.: 3
Sweep direct.:
Sweep rate: 0.40 Oct/min
Contr.strat.: Average
Unit: g
Contr.strat.: Closed loop

-- Testing time --
elapsed: 000:32:25
remaining: 000:00:00

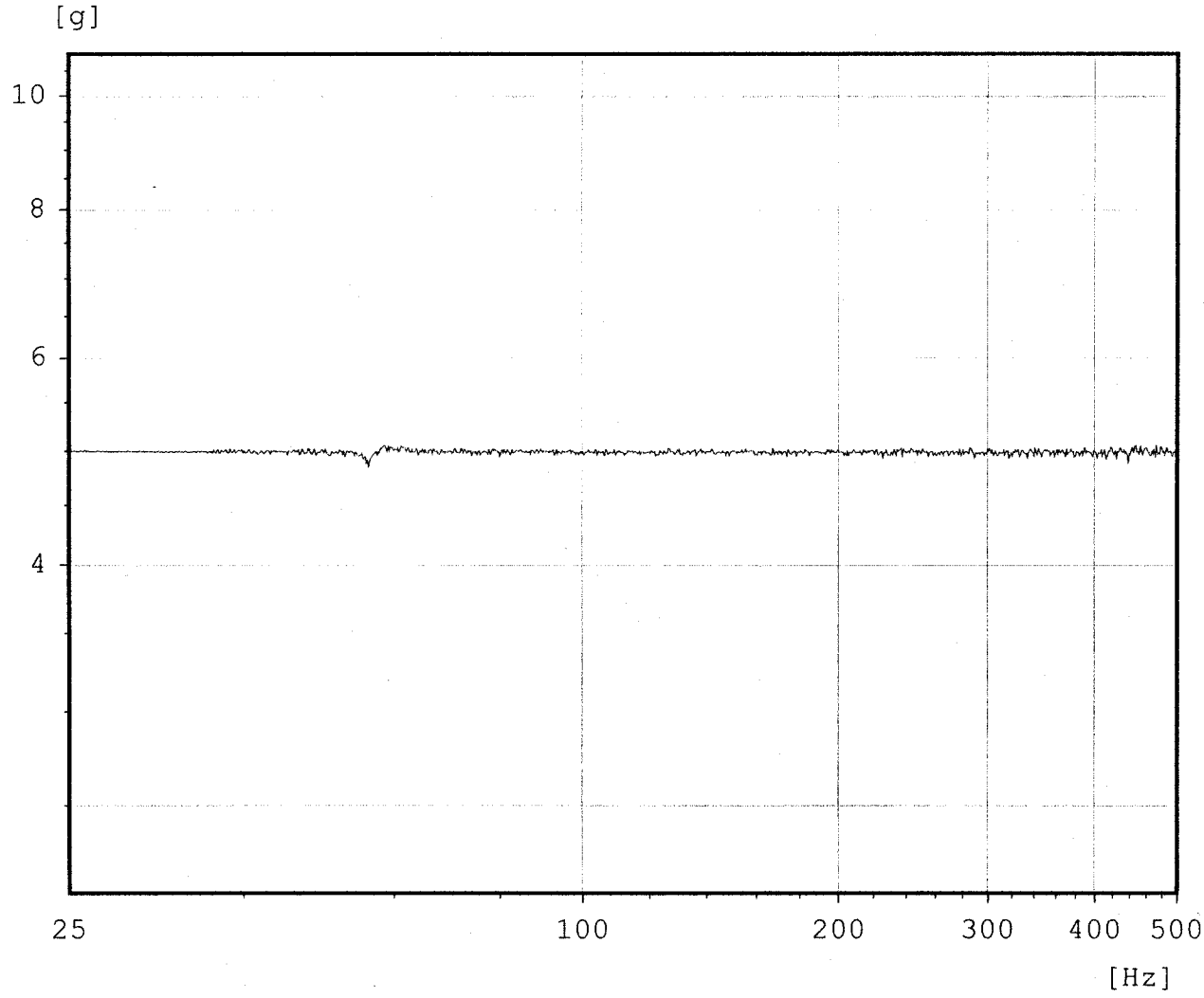
Date: 02-28-01
Time: 16:03:13

Bodycote Ortech
Sinusoidal vibration testing
MDS Nordion - 01-03-M0103
Gammamed samples (4)
Radial direction

C:\VcpNT\Daten\m+p\MDS Nordion Class 2_005.rsn

Sine

control channel



Chan.no: 4
Chan.type: CW
Sweep type: logarithmic
Sweeps done: 3
Sweeps req.: 3
Sweep direct.:
Sweep rate: 0.40 Oct/min
Contr.strat.: Average
Unit: g
Contr.strat.: Closed loop

-- Testing time --
elapsed: 000:32:24
remaining: 000:00:00

Date: 02-28-01
Time: 14:11:06

Bodycote Ortech
Sinusoidal vibration testing
MDS Nordion - 01-03-M0103
Gammamed samples (4)
Longitudinal direction

C:\VcpNT\Daten\m+p\MDS Nordion Class 2_002.rsn

MDS NORDION

CAPSULE TESTING WORK SHEET

DATE: 01-09-12

TEST: Impact **CLASS**: 3

CAPSULE DESCRIPTION: Brachytherapy Source

MODEL: GammaMed 12i/12it **CONTENT**: Iridium pellets

DRWG. REFERENCE: MDS/GM-M03-00 (With additional length for free air space)

CAPSULE MATERIAL: DIN 1.4541 or 1.4404 **ENCAPSULATION**: Single

OUTSIDE DIAMETER: 1.1 mm. **OVERALL LENGTH**: 10.06 mm

LEAK TEST TYPE: Liquid Nitrogen bubble and Helium leak tests. **RESULTS**: Pass

COMMENTS: ANSI level 3 impact test involves dropping 200 gram hammer onto the source from 1 meter (described in ANS N43.6-1997, section 7.4). This test is the same for ISO 2919. This test was performed on source numbers ten and thirteen where the weight was directed at the centre of the source. This test was performed on source numbers fourteen and fifteen where the weight was directed near the weld area of the source.

See Figure 2 and Figure 3.

Following the test series the capsule were leak tested using the Liquid Nitrogen Bubble Test and Helium leak test ANS/HPS 43.6-1997 sections A.2.2.6 and A.2.2.7.

In addition to the above leak tests following impact testing, the source capsules were examined stereoscopically to 50 magnifications and there was no visible evidence of any breakage.

Note that the Helium leak test requires that the source capsules be helium pressurized at 150 lb_f/in^2 for a period of 30 minutes. In order to increase test validity the source capsules were actually pressurized at 200 lb_f/in^2 for a period of 16 hours. This pressurization was immediately followed by the specified leak test.

CONDUCTED BY: Helen Hodson
Materials Specialist

APPROVED BY: M Kyanie
Manager, Package Eng.

GammaMed 12i/it source Impact test (cont'd)

Photograph

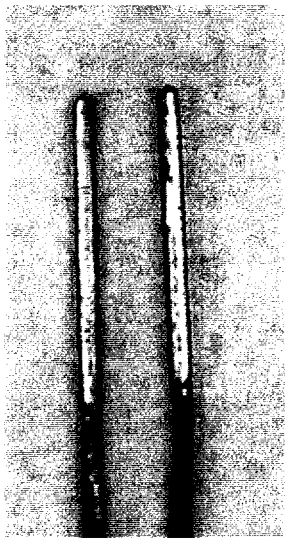


Figure 3 Photograph of source capsules 10 & 13 (impact tested in centre of capsule) Note: Some flattening of capsules but no breakage.

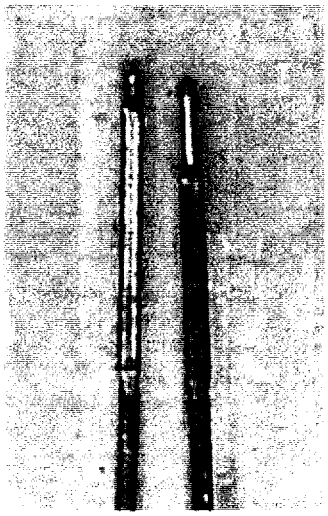


Figure 4 Photograph of source capsules 14 & 15 (impact tested near weld area of capsule) Note: Some flattening of capsules but no breakage.

MDS NORDION

CAPSULE TESTING WORK SHEET

DATE: 01-09-12

TEST: Puncture **CLASS:** 2

CAPSULE DESCRIPTION: Brachytherapy Source

MODEL: GammaMed 12i/12it **CONTENT:** Iridium pellets

DRWG. REFERENCE: MDS/GM-M03-00 (With additional length for free air space)

CAPSULE MATERIAL: DIN 1.4541 or 1.4404 **ENCAPSULATION:** Single

OUTSIDE DIAMETER: 1.1 mm. **OVERALL LENGTH:** 10.06 mm

LEAK TEST TYPE: Liquid Nitrogen bubble and Helium leak tests. **RESULTS:** Pass

COMMENTS: ANSI level 2 puncture test involves dropping of 1.0 gram hammer pin onto the sources from a distance of 1.0 meter (described in ANS N43.6-1997, section 7.6). This test is the same for ISO 2919. This test was performed on source numbers eight and nine. A photograph is attached.

See Figures 4 and 5.

Following the test series the capsules were leak tested using the Liquid Nitrogen Bubble Test and Helium leak test ANS/HPS 43.6-1997 sections A.2.2.6 and A.2.2.7.

In addition to the above leak tests following puncture testing, the source capsules were examined stereoscopically to 50 magnifications and there was no visible damage.

Note that the Helium leak test requires that the source capsules be helium pressurized at 150 lb_f/in^2 for a period of 30 minutes. In order to increase test validity the source capsules were actually pressurized at 200 lb_f/in^2 for a period of 16 hours. This pressurization was immediately followed by the specified leak test.

CONDUCTED BY: Helen Hedlan
Materials Specialist

APPROVED BY: M Lyons
Manager, Package Eng.

GammaMed 12i/12it source Puncture test (cont'd)

Photograph

Figure 4: Photograph of source capsules 8 & 9 (puncture tested)
Note: Some flattening but no breakage.

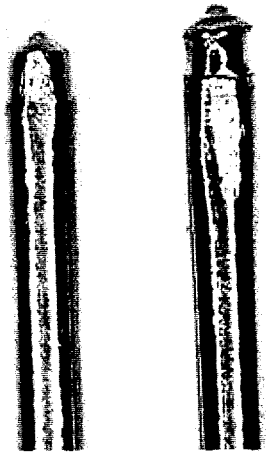


Figure 5: Photograph of source capsules 8 & 9 (puncture tested)
Note: Some flattening but no breakage.