STATE OF OHIO

Ohio Department of Health

Bureau of Radiation Protection

Nick Baird, Director

DATE: 5-24-05	FROM: KARL VON AHN
TO: M. Bachn	AGENCY/COMPANY:
COMPANY: NRC	PHONE NUMBER: 614-644-2724
FAX NUMBER: 301-415-5369	
PHONE NUMBER:	NO. OF PAGES (include cover sheet) 4

COMMENTS: COPY OF BRUSH WELLMAN LICENSE PER REQUEST

ADDRESS LICENSING QUESTIONS OR ISSUES TO STEVE JAMES AT 614-644-2727

35 EAST CHESTNUT ST. – 7TH FLOOR • COLUMBUS, OH IO 43216 • 614/644-2727 FAX 614/466-0381

Amendment No. 2

OHIO DEPARTMENT OF HEALTH
LICENSE FOR RADIOACTIVE MATERIAL

Pursuant to Chapter 3748 of the Ohio Revised Code, and in reliance on statements and representations made by the licensee, a license is hereby issued authorizing the licensee named herein to receive, acquire, possess, and transfer radioactive material as designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the applications of Chapter 3748 of the Ohio Revised Code and all rules promulgated thereunder. This license shall be deemed to contain the conditions specified *in Chapters 3701:1-38, 3701:1-39, 3701:1-50 and rule 3701-39-02.1 of the Ohio Administrative Code* and is subject to all applicable rules, regulations and orders of the Ohio Department of Health now or hereinafter in effect and to any conditions specified below.

LICENSEE	LICENSE NUMBER
1. Brush Wellman, Inc. 2. 14710 W. Portage River South Road Elmore, Ohio 43416-9582	3. 03122630000
	EXPIRATION DATE 4. September 30, 2005
	BUREAU DOCKET NUMBER 5. KK04-03-00

6. RADIOACTIVE MATERIAL	7. CHEMICAL AND/OR PHYSICAL FORM	8. MAXIMUM QUANTITY THAT LICENSEE MAY POSSESS AT ANY ONE TIME UNDER THIS LICENSE
A. Antimony-124	A. Sealed Source (U.S. Type 3130 or 3200, AECL Type RC-3, RC-5, RC-8, SRC-3 or C-129)	A. Two sources not to exceed 9.25 GBq (250 millicuries) each

9. Authorized Use

A. To be used in a Boulder Scientific Model 200 Beryllium Analyzer for sample analysis

CONDITIONS

10. Licensed material may only be used at the licensee's facilities located at:

14710 W. Portage River South Road,
Elmore, Ohio 43416

11. The Radiation Safety Officer for this license is:

Jason Thiel

12. *Licensed material shall be used by, or under the supervision and in the physical presence of, individuals who have received the training described in letter dated November 27, 2001, and have been approved in writing by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for inspection by the Director. Records retained for 3 years following the last use of licensed material by the individual may be disposed of after inspection by the Director.*

13. A Sealed sources and detector cells shall be tested for leakage and/or contamination at intervals not to exceed six (6) months or at such other intervals as specified by the certificate of registration referred to in 10 CFR 32.210, *as delineated in rule 3701-39-02.1 of the Administrative Code.*

B. Notwithstanding, Paragraph A of this Condition, sealed sources designed to emit alpha particles shall be tested for leakage and/or contamination at intervals not to exceed three (3) months.

C. In the absence of a certificate from a transferor indicating that a leak test has been made within 6 months prior to the transfer, a sealed source or detector cell received from another person shall not be put into service until tested.

I must help by

OHIO DEPARTMENT OF HEALTH	Page 2 of 3
LICENSE FOR RADIOACTIVE MATERIALS	License Number: 03122630000
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	Amendment No. 2

D. Sealed sources need not be tested if:

i) they contain only a radioactive gas; or

ii) the half-life of the isotope is 30 days or less; or

iii) they contain 3.7 MBq (100 μCi) or less of beta or gamma emitting material or 0.37 MBq (10 μCi) or less of alpha emitting material; or

iv) they are in storage and are not being used. However, when they are removed from storage for use or transfer to another person, and have not been tested within the required leak test interval, they shall be tested before use or transfer. No sealed source shall be stored for a period of more than 10 years without being tested for leakage and/or contamination.

v) *they contain only hydrogen-3.*

E. The leak test shall be capable of detecting the presence of 185 Bq *(0.005 μCi)* of radioactive material on the test sample. If the test reveals the presence of 185 Bq *(0.005 μCi)* or more of removable contamination, a report shall be filed with the Ohio Department of Health, and the source shall be removed immediately from service and decontaminated, repaired, or disposed of in accordance with Ohio Department of Health regulations. The report shall be filed within 5 days of the date the leak test result is known with the Bureau of Radiation Protection - Ohio Department of Health, 246 N. High St., P.O. Box 118, Columbus, Ohio 43266-0118. The report shall specify the source involved, the test results, and corrective action taken.

F. The licensee is authorized to collect leak test samples for analysis by Applied Health Physics. Alternatively, tests for leakage and/or contamination may be performed by persons specifically licensed by the Director, the NRC or an Agreement State to perform such services.

14. Sealed sources containing licensed material shall not be opened or sources removed from source holders by the licensee.

15. The licensee shall conduct a physical inventory every 6 months to account for all sources and/or devices received and possessed under the license.

16. Installation, initial radiation survey, relocation, removal from service, maintenance, and repair of devices containing sealed sources shall be performed by Boulder Scientific or by persons specifically licensed by the Director, USNRC, or an Agreement state to perform such services. Installation, replacement, and disposal of sealed sources shall be performed only by persons specifically licensed by the Director, USNRC, or an Agreement State to perform such services.

17. Notwithstanding License Condition No. 16 personnel authorized to exchange source holders will receive the training described in letter dated November 27, 2001, and have been approved in writing by the Radiation Safety Officer. The licensee shall maintain records of individuals designated as users for inspection by the Director. Records retained for 3 years following the last use of licensed material by the individual may be disposed of after inspection by the Director.

18. Prior to initial use and after installation, relocation, dismantling alignment, or any other activity involving the source or removal of the shielding, the licensee shall assure that a radiological survey is performed to determine radiation levels in accessible areas around, above and below the gauge with the shutter open. This survey shall be performed only by persons authorized to perform such services by the Director, USNRC, or an Agreement State.

19. *In addition to the possession limits in Item 8, the licensee shall further restrict the possession of sealed source licensed material to quantities below the minimum limit specified in rule 3701:1-40-17(C) of the Ohio Administrative Code for establishing decommissioning financial assurance.*

OHIO DEPARTMENT OF HEALTH	Page 3 of 3
LICENSE FOR RADIOACTIVE MATERIALS	License Number: 03122630000
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20. Except as specifically provided otherwise in this license, the license shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures. The Ohio Department of Health's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.

A. Correspondence on USNRC license number 34-08761-03, amendment number 5.

B. Letter dated March 9, 2000.

C. *Letters dated October 10, 2001 and November 27, 2001*

For the Ohio Department of Health

DATE: 12/18/01 BY: _____
Director, Ohio Department of Health

From: Ujagar Bhachu
To: John Kinneman
Date: 4/7/05 8:21AM
Subject: FYI : MODEL C-164 AND RELATED LICENSING ISSUES

Additional information.

CC: John Jankovich; Judith Joustra; Thomas Thompson; Tim Harris

From: "James Jarvis" <james.jarvis@state.co.us>
To: <USB@nrc.gov>
Date: 4/1/05 11:37AM
Subject: MODEL C-164 AND RELATED LICENSING ISSUES

Ujagar,
Per my recent conversation with you, I have had a conversation with the folks at MDS Nordion regarding our licensee and Nordion's distribution of source C-164 in accordance with the NRC Nordion SSD Evaluation NR-0220-S-127-S. Two things essentially came about during that conversation:

1. Nordion indicated that they would be submitting a request to the NRC to amend their SSD Evaluation for Source C-164 to increase the activity to ~1 Ci. (It appeared that our licensee in Colorado is the ONLY one in the U.S. receiving this model of source that contains Sb-124. Other licensees outside of Colorado may be using other isotopes contained in this source.?).

2. Nordion tended to indicate that the Antimony-124 C-164 source is not specifically identified on their NRC license (and possibly other versions of the C-164 containing other isotopes). They did however indicate that they sell and ship this and other radioactive materials that may not be specifically identified on their license and that the NRC was aware of this process. (An example of this was some form of Mo-99) The two licenses described are for service/repair/installation of irradiation sources and systems, while the other license is for distribution of FDA approved pharmaceuticals (and implantable seeds). (The aforementioned isotopes do not appear to fall under either of these licenses. Nordion did not provide a copy of their license to me.) The indication was something to the affect that the licensees in the U.S. are "importing" the RAM rather than Nordion "exporting" the RAM and that some agreement had been reached between the NRC and Nordion on this approach.

Could it be possible that the NRC allowed this approach under the assumption that these materials were addressed by the Canadian licensing authority/documentation.?

The person I spoke with at Nordion was Marc Andreas-Shret (not sure if the spelling is correct on that). His number is 613/592-3400 Extension 2421.

As we also discussed, we will work with our licensee to resolve the licensing and associated SSD evaluation issues, assuming the Nordion SSD is revised.

Please contact me should you have questions.

James S. Jarvis, M.S.
Health Physicist
Radiation Management Unit - HMWMD-B2
Colorado Dept. of Public Health and Environment
4300 Cherry Creeek Drive South
Denver, CO 80246-1530

(303) 692-3454
(303) 759-5355 FAX

james.jarvis@state.co.us

CC: "Steve Tarlton" <steve.tarlton@state.co.us>

From: Ujagar Bhachu
To: John Kinneman
Date: 3/30/05 2:09PM
Subject: For Review and Action: Unauthorized Use Of Licensed Material and Sealed Sources by MDS Nordian

Following the yesterday's telcon with Judith Joustra the contents of this e-mail are presented to you for your review and action.

Background:

On February 17, 2005, Charlie Gorday NRC-HQ Librarian had a telephone call from Todd Bingham of Brush Wellman, OH. Charlie Gorday was of the opinion that Brush Wellman is a NRC licensee and that Mr. Bringham uses a sealed source of Antimony 124 in his work. Subsequently, we eastablished that Mr. Bingham is a licensee of State of OH and is an end user of Model 200 beryllium detector and he was on a fishing exercise and wanted to find substitute sources to replace the sources indicated in his license. The detector device was manufactured by, Boulder Scientific Company, a licensee based in State of Colorado.

More specifically, Mr. Bingham was seeking NRC assistance to establish what the markings **U.S. Type 3130 and U.S. Type 3200 designate** meant. He also indicated that the sealed source of **Antimony 124** is additionally marked with these letters: AECL **Type RC-3 , and AECL Types RC-5, RC-8, and SR-3 .**

NRC Librarian searched the NRC library sources in an attempt to determine the meaning of these designations. When his search did not produce any tangible results, the librarian sent an e-mail asking for SS&D Section assistance and provided **Mr. Bingham's telephone number as 419-862-4269.**

The Model 200 beryllium detection device was originally reviewed by NRC-HQ. A maximum source of Antimony-124 (AECL source models of 100 mCi) was stated on the registration certificate. The original license was issued by NRC Region III. MDS Nordion, a Division of MDS (Canada) Inc. (formerly Nordion International Inc. and Atomic Energy of Canada Ltd.), 447 March Road, Ottawa, ON, Canada K2K 1X8, applied for registration of Model C-164 sealed source in 2002. A sealed source registration certificate number **NR-0220-S-127-S**, was issued to **MDS Nordion with a maximum source activity of 80 mCi -antimony-124.**

In summary the C-164 Model description is as follows:

The sealed source model C-164 is a single encapsulated fusion welded source that is used in self-contained, **portable detectors** such as a **Beryllium Analyzer.** The C-164 source may also be used for industrial radiography where the source remains in the device. **The C-164 source may contain up to 80 mCi (2.96 GBq) of antimony-124, or up to 50 Ci (1.85 TBq) of cobalt-60, or up to 500 Ci (18.5 TBq) of iridium-192, in pellet form.**

A quick search indicated that the sealed source model numbers stated on the current license issued by OH State were obsolete. The OH State and STP were made aware of the need to up-date the license.

Boulder Scientific Company the manufacturer of the Model 200 beryllium detector is located in Mead, CO. A copy of the Radioactive Material License issued to the manufacturer was obtained and reviewed. (Colo.011-01 Amendment 12, issued on JULY 04, see attachment 1).

Item 6 A. of the license reads:

This license is authorized to process and use not more than a total activity of 163 GBq (4.4 Ci) of Antimony-124 sealed source for use in Beryllium detection devices. **No individual source shall exceed 40.7 GBq (1.1 Ci). Sealed sources shall be MDS Nordion Inc. model SRC-3 or C-164 sources. (*this***

1200% increased activity authorization in the license above that was evaluated in the SS&D raised the flag).

It appears from this license condition and the admittance below by MDS Nordion that sealed sources were modified and or distributed by MDS Nordion to a USA licensee with out obtaining prior approval from NRC or an Agreement State.

Colorado State regulatory authority was approached and this issue was discussed over the telephone. On March 28, 2005, following response was transmitted by the State:

"This is in relation to our phone conversation a short time ago, and in relation to a phone conversation we had 1-2 weeks ago about one of our licensees (Boulder Scientific) and a licensee in Ohio that uses a Boulder Scientific device. I believe one of the issues with our licensee was that one of the sources listed on the Colorado license indicated a source no longer manufactured - I am in the process of taking care of that and deleting the model SRC-3 source. Another question has arisen, however.

Specifically:

1.) Is MDS Nordion (Canada) bound by the requirements of SSD Evaluation NR-0220-S-127-S for the model C-164 source? If so, it appears that they may be making and selling sources under this model number greater than 80 mCi. (Refer to the attached email from MDS Nordion).

https://www.hsrd.ornl.gov/nrc/sources/pdf/02200127.pdf

I have a call into our licensee regarding their devices and will work to resolve issues associated with them. Also note, that per MDS Nordion, Boulder Scientific is their ONLY customer for Sb-124 in the U.S.

Also, in the below link, it appears that MDS Nordion may have changed other sources/devices **without getting NRC approval several years ago:**

Attached is Boulder Scientific license. Note - we do not regularly convert licenses to PDF formats, so the attached has an electronic approval. The content is the same as what we have in our files.

http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/materials/ea97541.html

End of respone.

E-mail response from MDS Nordion:

Dear Mr. Jarvis,

You have contacted the correct supplier - MDS Nordion Inc.

We ship Antimony sources contained in C-164 capsules (typically 300 mCi Source Ordered) to our customer: Boulder Scientific.

The licensed maximum capacity of Antimony (SB-124) in a C-164 capsule is 37 GBq or 1 Ci.

Please do not hesitate to contact us if you require further information via e-mail or call toll free 1-800-267-6211.

Best regards,

Bruce Jones
Commercial Operations

Nuclear Medicine
MDS Nordion Inc.

State Of Colorado confirmed:

The two licensees using the Model 200 device are:

The following facility is using two of the model 200 devices:
Brush Wellman, Inc.
Utah Operations
P.O. Box 815
Delta, UT 84624

UTAH License: UT 140018, Amendment #8 (most recent copy we have)

The following facility is using one of the model 200 devices:
Brush Wellman, Inc.
14710 W. Portage River South Road
Elmore, OH 43416

We reviewed two MDS Nordion licenses issued by the NRC Region 1 and found that MDS Nordion has no authorization from NRC to distribute Antimony-124 sources. On March 28, 2005, this finding was confirmed in a telephone conversation with Judith Joustera of NRC Region 1.

Could you please review the historical data provided in the attachments below, links above and the information provided herein and advise the course of action to be taken or should be taken.

As always, with best regards.

Ujagar S. Bhachu
(301) 415-7894

CC: Charles Cox; Judith Joustra; Richard Correia; Tim Harris

State of Colorado
Department of Public Health and Environment

RADIOACTIVE MATERIALS LICENSE

Pursuant to the *Colorado Radiation Control Act*, Title 25, Article 11, *Colorado Revised Statutes*, and the State of Colorado *Rules and Regulations Pertaining to Radiation Control*(the Regulations), Part 3, and in reliance on statements and representations heretofore made by the licensee designated below; a license is hereby issued authorizing such licensee to transfer, receive, possess and use the radioactive material(s) designated below; and to use such radioactive material(s) for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders now or hereafter in effect of the Colorado Department of Public Health and Environment and to any conditions specified below.

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1. Licensee: Boulder Scientific Company

2. Address: P.O. Box 548, Mead, CO 80542

3. License Number: Colo. 011-01, Amendment No. 12

4. Expiration date: February 28, 2009

5. Reference Number: Fee Category: 3.B

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6. Authorized Radioactive Material and Uses:

   A. The licensee is authorized to possess and use not more than a total activity of 163 GBq (4.4 Ci) of ^{124}Sb (Antimony-124) sealed sources for use in Beryllium detection devices. No individual source shall exceed 40.7 GBq (1.1 Ci). The sealed sources shall be MDS Nordion Inc. model SRC-3 or C-164 sources.

   B. The licensee is authorized to possess and use not more than a total activity of 185 Bq (5 nCi) of ^{137}Cs (Cesium-137) contained in an Isotope Products sealed source.

CONDITIONS

7. Radioactive material shall be used and stored at 598 Third St., Mead, Colorado, and used at temporary job sites of the licensee anywhere in the State of Colorado where the State of Colorado maintains jurisdiction for regulating the use of radioactive materials.

8. Radioactive material authorized in Item 6.A to be used for the development, manufacture, demonstration, and use of the Boulder Scientific Company Model 310 beryllium detector.

9. The licensee may continue to provide source replacement of radioactive material authorized in Item 6.A in the following three (3) existing Model 200 beryllium detectors in use at:
   A. Brush Resources Inc., Delta Utah (mill laboratory, and mine laboratory)
   B. Brush Wellman Inc., Elmore, Ohio (laboratory only)

State of Colorado
Department of Public Health and Environment

RADIOACTIVE MATERIALS LICENSE

10. The licensee shall ensure that the users of the devices identified in License Condition 9 possess and maintain a current specific radioactive materials license specific to the model 200 Beryllium detectors.

11. Radioactive material authorized in Item 6.A to be used for the development, manufacture, demonstration, and use of new beryllium detectors. The licensee shall not distribute new devices without a proper device registry evaluation.

12. Radioactive material authorized by Item 6.A of this license shall be distributed only to persons with a valid radioactive materials license issued by the U.S. Nuclear Regulatory Commission or an Agreement State.

13. Radioactive material authorized by Item 6.B of this license shall be used as a reference source.

14. The licensee shall comply with the provisions of the State of Colorado *Rules and Regulations Pertaining to Radiation Control:* Part 3, "Licensing of Radioactive Material;" Part 4, "Standards for Protection Against Radiation;" Part 10, "Notices, Instructions and Reports to Workers; Inspections;" and Part 17, "Transportation of Radioactive Material."

15. Radioactive material shall be used by John M. Birmingham, Ph.D., Howard C. Hein, Alvin D. Nelson, or Richard Moore.

16. The designated Radiation Safety Officer is John M. Birmingham, Ph.D.,

17. All users of Radioactive Material must be equipped with personnel monitoring devices capable of detecting gamma radiation.

18. Radioactive material authorized by Item 6.A of this license shall be tested for leakage and/or contamination in accordance with RH 4.16 of the State of Colorado *Rules and Regulations Pertaining to Radiation Control.*

19. Sealed sources containing Radioactive Material shall not be opened by the licensee.

20. Radioactive material authorized by Item 6 of this license shall be stored and used in a manner that will preclude use by unauthorized personnel.

21. The licensee shall maintain a use log for licensee owned Beryllium detection devices used outside of 598 Third Street, Mead, Colorado. The use log shall indicate the serial number, user, date, and location of use.

22. The licensee shall list the emergency contact telephone number(s) of the Radiation Safety Officer in the procedures manual for emergency notification.

State of Colorado
Department of Public Health and Environment

RADIOACTIVE MATERIALS LICENSE

23. A. Each device distributed under this license shall bear a durable, clearly visible and legible label or labels containing the device model and serial number, the radiation symbol in colors magenta or purple on a yellow background, the words, "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL", and quantity, identity and date of measurement of the radioactive material, and the name of the distributor of the device.

    B. Each label required by this license condition shall bear the statement, "REMOVAL OF THIS LABEL IS PROHIBITED".

24. Prior to the use of licensed materials outside of the State of Colorado, or at any facility under exclusive Federal jurisdiction including a facility within the State of Colorado, the Licensee shall comply with the applicable provisions of 10 CFR 150.20 or if the use shall take place in an Agreement State the licensee shall comply with the applicable provisions of that State's reciprocity requirements.

25. The licensee shall not transfer possession and/or control of materials or products containing radioactive material as a contaminant except:

    A. by transfer of waste to an authorized recipient;

    B. by transfer to a specifically licensed recipient; or,

    C. as provided otherwise by specific condition of this license pursuant to the requirements of RH 3.22 of the Regulations.

26. The licensee shall maintain records of the sale, transfer, or disposal of radioactive sources. The records must include:

    A. the name and address of the recipient;

    B. the documents showing the recipient's authorization to receive the source;

    C. the radionuclide and activity of the source(s) transferred; and

    D. the date of the transfer.

27. The licensee may transport radioactive material or deliver radioactive material to a carrier for transport, in accordance with the provisions of RH 17.5 of the State of Colorado *Rules and Regulations Pertaining to Radiation Control*, "Transportation of Licensed Material".

28. The transportation of radioactive materials within the State of Colorado shall be subject to all applicable regulations of the Colorado Public Utilities Commission, Colorado Department of Transportation, Colorado Department of Public Safety, Colorado Department of Revenue (Port of Entry), U.S. Department of Transportation, and other agencies of the United States having jurisdiction. When the U.S. Department of Transportation Regulations (Title 49, Chapter I, *Code of Federal Regulations*) are not applicable to shipments by land

of radioactive material by reason of the fact that the transportation does not occur in interstate or foreign commerce, the licensee must be in compliance with the requirements relating to packaging of the radioactive material, marking and labeling of the package, placarding of the transport vehicle, and accident reporting set forth in the regulations of the U.S. Department of Transportation.

29. The State of Colorado *Rules and Regulations Pertaining to Radiation Control* shall govern unless the licensee's statements, representations, and procedures contained in the application and correspondence are more restrictive than the Regulations. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Item 6 of this license in accordance with the statements, representations, and procedures contained in:

    A. the REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES, SAFETY EVALUATION OF DEVICE, No: CO-175-D-101-S, issued March 12, 1991 (Model 310); and

    B. the application and attachments dated January 27, 2004; and

    C. the license correspondence and documents dated April 8, 2004; April 9, 2004 (facsimile); April 16, 2004 (facsimile); and May 7, 2004.

FOR THE COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Date:___ 7 July 04_____ By:_____/ Thomas Pentecost /_____

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FNWEBNAVIGATE=1.0
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STARTPAGE=1
LIBRARYNAME=ml_adams^hqntad01

From: "James Jarvis" <james.jarvis@state.co.us>
To: <USB@nrc.gov>
Date: 3/28/05 4:46PM
Subject: Fwd: RE: LOOKING FOR INFO ON MODEL C-164 SOURCE

Ujagar,
This is in relation to our phone conversation a short time ago, and in relation to a phone conversation we had 1-2 weeks ago about one of our licensees (Boulder Scientific) and a licensee in Ohio that uses a Boulder Scientific device. I believe one of the issues with our licensee was that one of the sources listed on the Colorado license indicated a source no longer manufactured - I am in the process of taking care of that and deleting the model SRC-3 source. Another question has arisen, however.

Specifically:
1.) Is MDS Nordion (Canada) bound by the requirements of SSD Evaluation NR-0220-S-127-S for the model C-164 source? If so, it appears that they may be making and selling sources under this model number greater than 80 mCi. (Refer to the attached email from MDS Nordion).

I have a call into our licensee regarding their devices and will work to resolve issues associated with them. Also note, that per MDS Nordion, Boulder Scientific is their ONLY customer for Sb-124 in the U.S..

Also, in the below link, it appears that MDS Nordion may have changed other sources/devices without getting NRC approval several years ago:
http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/materials/ea97541.html

James S. Jarvis, M.S.
Health Physicist
Radiation Management Unit - HMWMD-B2
Colorado Dept. of Public Health and Environment
4300 Cherry Creeek Drive South
Denver, CO 80246-1530

(303) 692-3454
(303) 759-5355 FAX

james.jarvis@state.co.us

CC: "Steve Tarlton" <steve.tarlton@state.co.us>

From: Isotope Orders <isotopeorders@MDS.Nordion.com>
To: "'James Jarvis'" <james.jarvis@state.co.us>
Date: 3/28/05 1:40PM
Subject: RE: LOOKING FOR INFO ON MODEL C-164 SOURCE

Dear Mr. Jarvis,

You have contacted the correct supplier - MDS Nordion Inc.

We ship Antimony sources contained in C-164 capsules (typically 300 mCi Source Ordered)to our customer: Boulder Scientific
The licensed maximum capacity of Antimony (SB-124) in a C-164 capsule is 37 GBq or 1 Ci.

Please do not hesitate to contact us if you require further information via e-mail or call tollfree 1-800-267-6211.

Best regards,
Bruce Jones
Commercial Operations
Nuclear Medicine
MDS Nordion Inc.

-----Original Message-----
From: James Jarvis [mailto:james.jarvis@state.co.us]
Sent: Monday, March 28, 2005 1:18 PM
To: Isotope Orders
Subject: LOOKING FOR INFO ON MODEL C-164 SOURCE

I am looking for information on the quantities and activites of the MDS Nordion Model C-164 sealed source. We have a radioactive material licensee here in Colorado (USA) who is using these sources in their devices used for non-destructive analysis. (I am not sure you are the correct recipient for my inquiry, but thought someone might be able to direct it appropriately).

Specifically, I am looking at what activity (or activities) the model C-164 is manufactured with when Antimony-124 (Sb-124) is used. That is, what is the maximum activity that can be incorporated into he model C-164 source?

Thank you for your assistance.

James S. Jarvis, M.S.
Health Physicist
Radiation Management Unit - HMWMD-B2
Colorado Dept. of Public Health and Environment
4300 Cherry Creeek Drive South
Denver, CO 80246-1530

(303) 692-3454
(303) 759-5355 FAX

james.jarvis@state.co.us

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO. NR-0220-S-127-S DATE: April3, 2002

SOURCE TYPE: Gamma Gauge or Industrial Radiography Source

MODEL: C-164

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

ISOTOPE:	MAXIMUM ACTIVITY:
Antimony-124	80 mCi (2.96 GBq)
Cobalt-60	50 ci (1.85 TBq)
Iridium-192	500 Ci (18.5 TBq)

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: (A) Industrial Radiography
Gamma Gauge

CUSTOM DEVICE: Y E S N X O

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

SOURCE TYPE: Gamma Gauge or Industrial Radiography Source

DESCRIPTION:

The sealed source model C-164 is a single encapsulated fusion welded source that is used in self-contained, portable detectors such as a Beryllium Analyzer. The C-164 source may also be used for industrial radiography where the source remains in the device. The C-164 source may contain up to 80 mCi (2.96 GBq) of antimony-124, or up to 50 Ci (1.85 TBq) of cobalt-60, or up to 500 Ci (18.5 TBq) of iridium-192, in pellet form.

The model C-164 capsule is constructed of stainless steel (Type 304L). It consists of two parts: a hexagonal shaped receptacle having a maximum outside dimension of 0.250" (6.35 mm) across the flats, a maximum overall length of 0.325" (8.25 mm) and a nominal wall thickness 0.015" (0.38 mm); and a plug having a maximum outside diameter of 0.238" (6.05 mm) and 0.270" (6.86 mm) in height. After the source is loaded, the two parts are threaded together via #8-36 UNF thread and fusion welded.

The isotope material is in pellet form, either 1 mm, 2 mm, or 3 mm (0.04", 0.08", or 0.12") in diameter. Nominal thickness may range between 1 and 2 mm. With 1 mm and 2 mm diameter pellets, a cylindrical spacer made of aluminum is used to hold the isotope in position.

LABELING:

The C-164 source is engraved on its outer surface in the following manner:

- MDSN (an abbreviation for MDS Nordion)
- DA (D is MDS Nordion's identification for antimony-124, and A is the identification for C-164 sources) or
- CA (C is MDS Nordion's identification for cobalt-60, and A is the identification for C-164 sources) or
- BL (B is MDS Nordion's identification for iridium-192, and L is the identification for C-164 sources)
- xxx (a unique serial number)
- Trefoil Symbol

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

SOURCE TYPE: Gamma Gauge or Industrial Radiography Source

DIAGRAMS:

See Attachment 1.

CONDITIONS OF NORMAL USE:

The C-164 source is designed primarily for use in portable detectors with the source secured in the device. The Detector is hand carried by trained technical personnel. Typical environmental conditions are:

Temperature:	-40°C to 80°C (-40°F to 176°F)
Pressure:	Atmospheric
Vibration:	None
Corrosion:	Range from none to mildly corrosive vapor

The manufacturer estimates that typical life of the source loaded to maximum activity is approximately 2 months, 6 months, and 25 years with antimony-124, iridium-192, and cobalt-60, respectively.

PROTOTYPE TESTING:

The C-164 prototypes have been tested and classified to E64334 as prescribed in ANSI/HPS N43.6-1997 and ISO 2919:1999(E). This classification exceeds the requirements for gamma gauge of E43232 and industrial radiography of E43313.

The C-164 sealed source is certified as Special Form Radioactive Material by the Canadian Nuclear Safety Commission (CNSC) under the certificate number CDN/0001/S.

MDS Nordion has manufactured well over 400 C-164 sealed sources since 1969. There have been no known written or verbal reports indicating leakage or other defects pertaining to the C-164 sources.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO.: NR-0220-S-127-S DATE: April 3, 2002

SOURCE TYPE: Gamma Gauge or Industrial Radiography Source

EXTERNAL RADIATION LEVELS:

The manufacturer provided the following dose rates for antimony-124 with 80 mCi (2.96 GBq), cobalt-60 with 50 Ci (1.85 TBq), and iridium-192 with 500 Ci (18.5 TBq).

Distance from Source	Isotope	Radiation Level	
		mR/hr	mSv/hr
100 cm (39.37")	antimony-124	78.40	0.78
	cobalt-60	66.00	0.66
	iridium-192	240.00	2.40
30 cm (11.81")	antimony-124	871.00	8.71
	cobalt-60	733.00	7.33
	iridium-192	2,667.00	26.67
10 cm (3.94")	antimony-124	7,840.00	78.40
	Cobalt-60	6,600.00	66.00
	Iridium-192	24,000.00	240.00

QUALITY ASSURANCE AND CONTROL:

MDS Nordion maintains an ISO 9001 compliant quality assurance and control program, which has been deemed acceptable for licensing purposes by the NRC under Quality Assurance Program No.0703 which expires July 31, 2005.

All MDS Nordion C-164 sealed source(s) quality requirements for design, manufacturing, inspection and testing are carried out in accordance with the ISO 9001 Quality System. To assure these requirements, Technical Specifications have been prepared and are available for inspection purposes. IN/TS 0010 C000 is used for Technical Specification for Radioisotopes and Sources and IS/OP 0040 C000 for Engraving Procedure.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

SOURCE TYPE: Gamma Gauge or Industrial Radiography Source

QUALITY ASSURANCE AND CONTROL (Cont'd):

Documented policies and procedures are maintained to ensure that all purchased components, materials, and services conform to specified requirements.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The source shall be distributed 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 these sources exhibit high dose rates, the sources should be handled by experienced licensed personnel using adequate handling equipment and procedures.
- The source shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 μCi (185 Bq) of removable contamination.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

Based on review of the Model C-164 sealed source, its ANSI and ISO classifications, and the information and test data cited below, we conclude that the source is acceptable for licensing purposes.

Furthermore, we conclude that the source would be expected to maintain its containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO.: NR-0220-S-127-S DATE: April 3, 2002

SOURCE TYPE: Gamma Gauge or Industrial Radiography Source

REFERENCES:

The following supporting documents for the Model C-164 sealed source are hereby incorporated by reference and are made part of this registry document.

- MDS Nordion, Inc. application dated February 12, 2002, with enclosures thereto.
- MDS Nordion, Inc. letter dated March 25, 2002, with enclosures thereto.

ISSUING AGENCY:

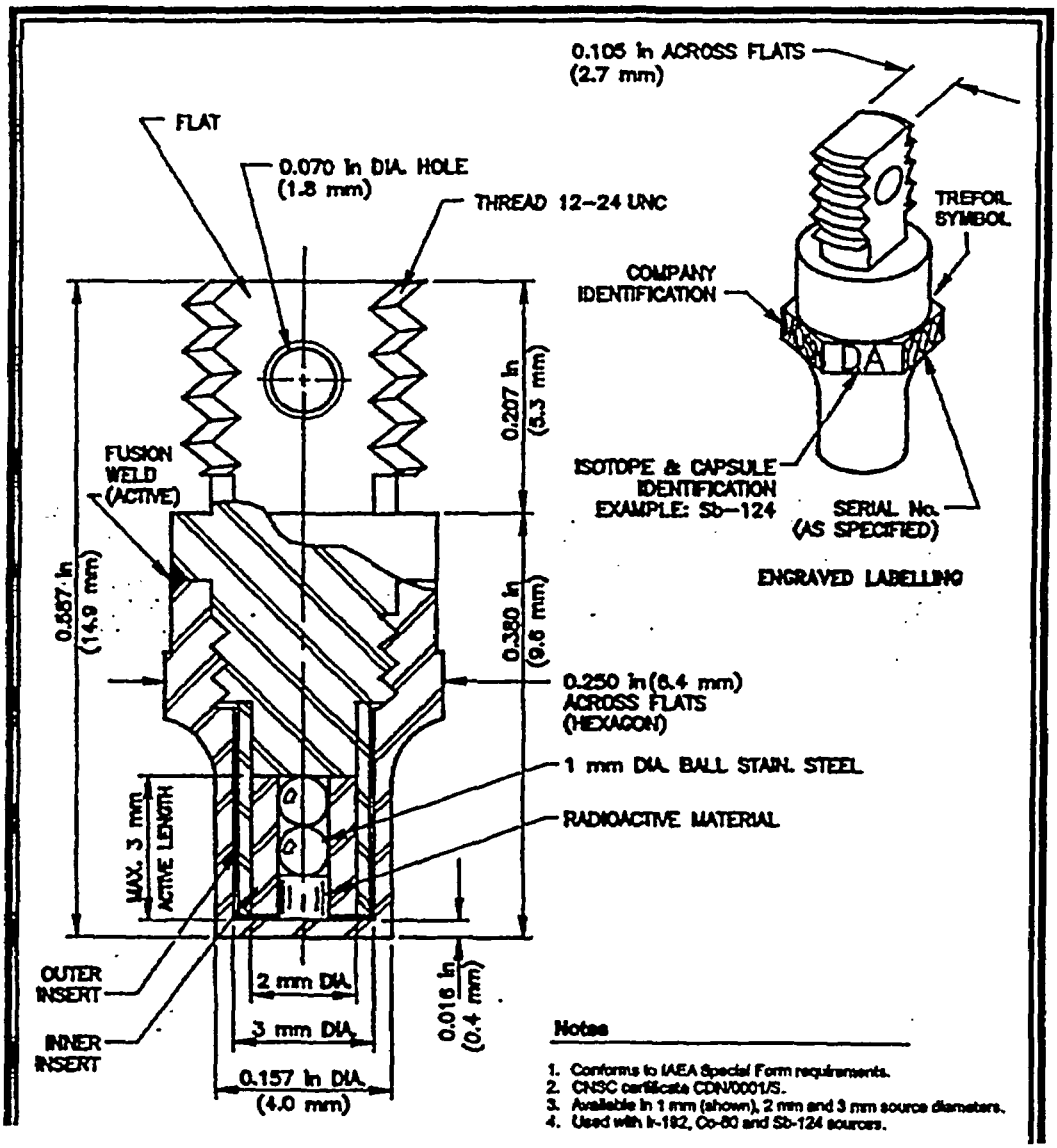
U.S. Nuclear Regulatory Commission

Date: April 3, 2002 Reviewer: _____
Seung J. Lee

Date: April 3, 2002 Concurrence: _____
John P. Jankovich

REGISTRATION OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF SEALED SOURCE

NO: NR-0220-S-127-S DATE: April 3, 2002 ATTACHMENT 1



Model C-164 Sealed Source

EA-97-541 - Nordion Internaltional, Inc.

January 23, 1998

EA No. 97-541

Mr. Ronald McGregor, Manager
Regulatory Affairs
MDS Nordion Incorporated
447 March Road
Kanata, Ontario, Canada K2K 1X8

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report No. 030-30788/97-001)

Dear Mr. McGregor:

This refers to the inspection conducted on September 17-19, 1997, at 447 March Road Kanata, Ontario, Canada. The inspection was limited to a review of your manufacturing process as it relates to conformance with your license, registration certificates and quality assurance program. The inspection was conducted to review your distribution of nuclear gauging devices to general licensees. During the inspection, violations of NRC requirements were identified, as described in the NRC inspection report transmitted with our letter dated December 9, 1997. In addition, in the December 9, 1997 letter, the NRC provided you an opportunity to either respond in writing to the apparent violations addressed in the inspection report or request a predecisional enforcement conference. You responded to the apparent violations in a January 13, 1998 letter to the NRC.

Based on the information developed during the inspection and the information you provided in your January 13,1998 response to the inspection report, the NRC has determined that four violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations involve modification to devices without obtaining NRC approval prior to the modifications. The NRC is concerned that the number of deviations between the devices being distributed and the registration certificates, is indicative of a lack of management oversight and understanding of regulatory requirements.

While the specific modifications to the sources, source holder or source drive mechanism do not appear to constitute a safety concern, making such changes without NRC approval constitutes a significant regulatory concern because the NRC was not give the opportunity, as required, to review the changes, and as such, the devices were distributed without an NRC approved registry certificate as required by 10 CFR 32.210. Therefore, the violations demonstrate a significant lack of oversight and control of licensed activities. As such, the violations have been classified in the aggregate as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III violation. Because your facility has not been the subject of an escalated enforcement action within the last two years, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit for corrective actions is warranted because your corrective actions were both prompt and comprehensive. These actions, which were described in your January 13, 1998 letter to the NRC, included, but were not limited to: submittal of current drawings of the C-188 source, C-3001 source and GC-3000 source holder to the NRC Sealed Source and Device Safety Section on September 25, 1997 in order to amend the

registration of these devices; and submitting further information on the changes to the GC-40 source movement to amend its registration by February 27, 1998. In addition, you met with the NRC on October 29, 1997 and have made changes in your practices to prevent recurrence of the violations, including training of personnel.

Therefore, to encourage prompt and comprehensive correction of violations, I have been authorized to not propose a civil penalty in this case. However, similar violations in the future could result in further escalated enforcement action.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket in your letter to the NRC dated January 13, 1998. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, and its enclosure, as well as your response if your choose to provide one, will be placed in the NRC Public Document Room (PDR).

Sincerely,

Hubert J. Miller
Regional Administrator

Docket No. 030-30788
License No. 54-28275-01

Enclosure: Notice of Violation

NOTICE OF VIOLATION

MDS Nordion Incorporated
Kanata, Ontario, Canada

Docket No. 030-30788
License No. 54-28275-01
EA 97-541

During an NRC inspection conducted on September 17-19, 1997, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the violations are listed below:

10 CFR 32.210(a) states that a manufacturer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license may submit a request to the NRC for evaluation of radiation safety information about its product and for its registration.

10 CFR 32.210(f)(1) and (2) states that the person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with (1) the statements and representations, including quality control program contained in the request and (2) the provisions of the registration certificate.

Contrary to the above, from February 11, 1992 to March 14, 1996, the licensee, after having submitted requests to the NRC for evaluation of radiation safety information about its product and for its registration, manufactured and distributed certain sealed sources and devices containing licensed material in a manner that was not in accordance with the provisions of the registration certificate, as evidenced by the following examples, each of which constitutes a separate violation.

1. In support of Registration Certificate NR-0220-D-102-S, Nordion specified, in a June 4, 1993, letter, the specific overall length of the source holder assembly for the Gammacell 3000; however, on May 31, 1993, the licensee had modified the overall length of the source holder assembly for the Gammacell 3000 such that the length was not consistent with the length specified in the June 4, 1993 letter. **(01013)**

2. In support of Registration Certificate NR-0220-S-103-S, Nordion specified, in its December 20, 1984 letter, the specific length of the outer body of the C-188 sealed source; however, on August 31, 1993, the licensee modified the overall length of the outer capsule of the C-188 sealed source. **(01023)**

3. Registration Certificate NR-0220-D-101-S specifies that "Irradiation is accomplished by moving two lead-filled cylindrical drawers, each containing a single radioactive source, simultaneously by pneumatic controls from the stored to the irradiate position;" however, in 1995, the licensee modified the source drive mechanism of the Gammacell 40 from a pneumatic system to a ball screw system. **(01033)**

4. In support of Registration Certificate NR-0220-D-101-S, Nordion specified, in its March 18, 1993, letter, the specific length and diameter for the inner capsule for the Model C-3001 source assembly; however, on March 15, 1996, the licensee modified the overall length and diameter of the inner capsule of the C-3001 source assembly. **(01043)**

These violations are categorized in the aggregate as a Severity Level III problem (Supplement VI).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket in a letter from the Licensee dated January 13, 1998. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

Dated at King of Prussia, Pennsylvania
this 23rd day of January 1998

Certificate Retrieval Page

NRC Certificates	DOE Certificates	DOT Certificates

NRC Certificates of Compliance			
Retrieval Number	Package ID Number	Rev	Model Number
1010361	USA/0361/B(U)F-96	8	PAT-1
1014888	USA/4888/B( )	12	SENTINEL-25A, LCG-25A; SENTINEL-25B, LCG-25B; SENTINEL-25C, LCG-25C; SENTINEL-25C3, -25D, -25E, -25F
1014986	USA/4986/AF	39	RA-3
1015059	USA/5059/AF	13	NFS URANYL NITRATE TANK TRAILER
1015086	USA/5086/B(U)F	12	UNC-2600
1015149	USA/5149/B( )F	10	814A
1015607	USA/5607/B( )F	12	T-2
1015740	USA/5740/B( )	6	ORNL TRU CALIFORNIUM SHIPPING CONTAINER
1015796	USA/5796/B(U)	15	181375 AND 181361
1015797	USA/5797/B(U)F	15	INNER HFIR UNIRRADIATED FUEL ELEMENT SHIPPING CONTAINER, AND OUTER HFIR UNIRRADIATED FUEL ELEMENT SHIPPING CONTAINER
1015805	USA/5805/B( )	23	CNS 3-55
1015830	USA/5830/B( )	9	SNAP-21
1015862	USA/5862/B( )	8	SENTINEL-100F
1015926	USA/5926/B( )F	18	GE-100
1015939	USA/5939/B( )F	32	1500
1015957	USA/5957/B( )F	27	BMI-1
1015979	USA/5979/B( )	11	5979
1015984	USA/5984/B( )	7	5984
1016058	USA/6058/B( )F	14	B-3
1016078	USA/6078/AF	30	927A1 AND 927C1
1016206	USA/6206/AF	29	MODEL B
1016280	USA/6280/B( )		A-0109 IRRADIATOR IN A-0117 OVERPACK (TERMINATION LETTER, JAN. 31, 2005)
1016294	USA/6294/AF		UNC-2901 (TERMINATION LETTER, MAR. 31, 2004)
1016346	USA/6346/B( )F	29	FSV-1
1016347	USA/6347/AF	10	FSV-3
1016357	USA/6357/AF	8	NNFD-10
1016400	USA/6400/B( )F	27	6400
1016553	USA/6553/AF	19	PADUCAH TIGER
1016574	USA/6574/B( )	29	3-82B
1016581	USA/6581/AF	33	51032-1
1016613	USA/6613/B(U)-85	10	702
1016642	USA/6642/B( )	7	4.5-TON CF

1016703	USA/6703/B( )	7	RG-1
1016786	USA/6786/B( )	8	URIPS-8A AND URIPS-8B
1019001	USA/9001/B( )F	39	IF-300
1019009	USA/9009/B( )F		FL 10-1 (TERMINATION LETTER, SEP. 10, 2004)
1019010	USA/9010/B( )F	40	NLI-1/2
1019015	USA/9015/B( )F	20	TN-8 AND TN-8L
1019016	USA/9016/B( )F	12	TN-9
1019023	USA/9023/B( )F	9	NLI-10/24
1019027	USA/9027/B(U)-85	17	741-OP
1019030	USA/9030/B( )	9	MW-3000 AND SENTINEL-8
1019034	USA/9034/AF	12	TRIGA-I
1019035	USA/9035/B(U)-85	18	680-OP
1019036	USA/9036/B(U)-85	10	C-1
1019037	USA/9037/AF	12	TRIGA-II
1019056	USA/9056/B(U)	12	SPEC 2-T
1019067	USA/9067/B( )F	7	BCL-3
1019068	USA/9068/B( )F		BCL-2 (TERMINATION LETTER, NOV. 16, 2004)
1019069	USA/9069/B( )F		MO-1 (TERMINATION LETTER, SEP. 9, 2004)
1019081	USA/9081/B( )	14	CNS 1-13C
1019098	USA/9098/B( )	10	CI-20WC-2 AND CI-20WC-2A
1019099	USA/9099/B(U)F-85	10	ATR
1019102	USA/9102/B( )	10	NPI-20WC-6
1019107	USA/9107/B(U)		771 (TERMINATION LETTER, NOV. 5, 2003)
1019132	USA/9132/B(M)F	14	T-3
1019148	USA/9148/B(U)-85	7	770
1019150	USA/9150/B(U)-85	6	PAT-2
1019152	USA/9152/B( )F	14	CNS 1-13C II
1019157	USA/9157/B(U)-85	11	IR-100
1019165	USA/9165/B(U)	5	855
1019168	USA/9168/B(U)	14	CNS 8-120B
1019183	USA/9183/B( )F		NAC-1 (TERMINATION LETTER, SEP. 10, 2004)
1019184	USA/9184/B(U)	6	PAS-1
1019185	USA/9185/B(U)-85	6	OP-100
1019187	USA/9187/B(U)-85	6	865
1019196	USA/9196/AF-85	21	UX-30
1019200	USA/9200/B(M)F	11	125-B
1019203	USA/9203/AF	13	DHTF
1019204	USA/9204/B(U)-85	9	CNS 10-160B
1019208	USA/9208/B( )	15	10-142
1019210	USA/9210/B( )		10-135B (TERMINATION LETTER, JAN. 18, 2005)
1019212	USA/9212/B(M)F-85	3	RH-TRU 72-B
1019215	USA/9215/B(U)	7	NPI-20WC-6 MKII
1019216	USA/9216/B( )F	9	CNS 1-13G

1019217	USA/9217/AF	12	ANF-250
1019218	USA/9218/B(U)F-85	17	TRUPACT-II
1019225	USA/9225/B(U)F-96	38	NAC-LWT
1019226	USA/9226/B(U)F-85	1	GA-4
1019228	USA/9228/B(U)F-85	20	2000
1019234	USA/9234/B(U)F	18	NCI-21PF-1
1019235	USA/9235/B(U)F-85	8	NAC-STC
1019239	USA/9239/AF	12	MCC-3, MCC-4, AND MCC-5
1019246	USA/9246/AF	3	ST
1019248	USA/9248/AF	18	SP-1, SP-2, AND SP-3
1019250	USA/9250/B(U)F-85	9	5X22
1019251	USA/9251/AF	12	BW-2901
1019252	USA/9252/AF	5	51032-2
1019253	USA/9253/B(U)F-85	10	TN-FSV
1019255	USA/9255/B(U)F-85	9	NUHOMS MP187 MULTI-PURPOSE CASK
1019258	USA/9258/B(U)-96	2	F-294
1019261	USA/9261/B(U)F-85	3	HI-STAR 100 SYSTEM
1019263	USA/9263/B(U)-85	3	SPEC-150
1019269	USA/9269/B(U)-85	3	650L
1019270	USA/9270/B(U)F-85	1	UMS UNIVERSAL TRANSPORT CASK PACKAGE
1019272	USA/9272/AF-85	6	CE-B1
1019274	USA/9274/AF	7	ABB-2901
1019276	USA/9276/B(U)F-85	2	FUELSOLUTIONS TS125 TRANSPORTATION PACKAGE
1019277	USA/9277/B(U)F	1	FSV-1 UNIT 3
1019279	USA/9279/B(U)F-85	2	HALFPACT WASTE SHIPPING CONTAINER
1019280	USA/9280/AF-85	2	UBE-1
1019281	USA/9281/AF-85	3	UBE-2
1019282	USA/9282/B(U)-85	0	SPEC-300
1019283	USA/9283/B(U)-85	1	OPL-660 AND OP-660
1019284	USA/9284/B(U)F-85	3	ESP-30X PROTECTIVE SHIPPING PACKAGE FOR 30-INCH UF6 CYLINDERS
1019285	USA/9285/AF-85	2	SRP-1
1019287	USA/9287/B(U)-85	1	STERIGENICS EAGLE
1019288	USA/9288/B(U)F-85	6	CHT-OP-TU
1019289	USA/9289/B(U)F-85	3	WE-1
1019290	USA/9290/B(U)-85	2	F-430/GC-40 TRANSPORT PACKAGE
1019291	USA/9291/B(U)F-85	4	ECO-PAK LIQUI-RAD (LR) TRANSPORT UNIT PACKAGE
1019293	USA/9293/B(U)-85	1	TN-68 TRANSPORT PACKAGE
1019294	USA/9294/AF-85	3	NPC
1019296	USA/9296/B(U)-85	3	880 SERIES PACKAGES
1019297	USA/9297/AF-96	0	TRAVELLER STD AND TRAVELLER XL
1019299	USA/9299/B(U)-85	0	F-423
1019300	USA/9300/B(U)-85		BRP RVP SAR-5339 (TERMINATION LETTER, AUG. 20, 2004)
1019301	USA/9301/AF-85	1	TNF-XI

1019309	USA/9309/B(U)F-96	1	RAJ-II
1019310	USA/9310/B(U)-96	2	F-431 TRANSPORT PACKAGE
1019511	USA/9511/B(U)	3	BUSS R-1

DOE Certificates of Compliance

Retrieval Number	Package ID Number	Rev	Model Number
1025320	USA/5320-3/B( )F (DOE)	21	5320 - For a copy of this CoC, contact Dirk Cairns-Gallimore, NE-50, at (301) 903-3332
1025467	USA/5467/AF-85 (DOE)	22	STEEL BANDED WOODEN SHIPPING CONTAINERS, MODELS G-4214, G-4255, G-4273 AND G-4292
1029132	USA/9132/B(M)F (DOE)	11	T-3
1029225	USA/9225/B(U)-85 (DOE)	2	NAC-LWT
1029511	USA/9511/B(U)-85 (DOE)	7	BENEFICIAL USES SHIPPING SYSTEM CASK (BUSS) MODEL R-1
1029516	USA/9516/B(U)F-85 (DOE)	9	MOUND 1KW - For a copy of this CoC, contact Dirk Cairns-Gallimore, NE-50, at (301) 903-3332
1029904	USA/9904/B(U)F-85 (DOE)	8	RTG PACKAGE - For a copy of this CoC, contact Dirk Cairns-Gallimore, NE-50, at (301) 903-3332
1029932	USA/9932/B(U) (DOE)	9	UC-609
1029975	USA/9975/B(M)F-85 (DOE)	11	9975

DOT Certificates of Competent Authority

Retrieval Number	Package ID Number	Rev	Model Number
1030018	USA/0018/S	7	SR-CF-100 SERIES NEUTRON SOURCE MANUFACTURED BY EITHER THE SAVANNAH RIVER LABORATORY OR THE OAK RIDGE NATIONAL LABORATORY (ORNL)
1030036	USA/0036/S	7	NRD MODEL A-001
1030043	USA/0043/S	10	MONSANTO RESEARCH CORPORATION MODEL 2720
1030046	USA/0046/S	5	MRC MODEL NO. 2404, RESTRICTED TO SOURCES MANUFACTURED PRIOR TO MARCH 31, 2002
1030061	USA/0061/B(U)	17	THERATRON 78, T780, T780-C, T780-E T780IEC, PHOENIX, THERATRON 1000 AND T1000E RADIOTHERAPY HEADS
1030065	USA/0065/S	7	MODEL SR CF-1000 SERIES NEUTRON SOURCE MANUFACTURED BY EITHER THE SAVANNAH RIVER LABORATORY OR THE OAK RIDGE NATIONAL LABORATORY (ORNL)
1030071	USA/0071/S	6	3M MODEL 4D6L CAPSULES MANUFACTURED PRIOR TO AUGUST 3, 1989
1030074	USA/0074/S	6	3M MODEL 4F6P
1030077	USA/0077/S	6	3M MODEL 4F6S
1030078	USA/0078/S	8	GULF NUCLEAR MODEL CSV
1030080	USA/0080/S	3	MONSANTO RESEARCH CORPORATION CAPSULE IDENTIFIED BY MRC DRAWING NO. SK19502A0 (A PROTOTYPE OF MODEL NO. 24132)
1030087	USA/0087/S	5	DRESSER ATLAS MODEL NO. DA-5
1030088	USA/0088/S	6	DRESSER ATLAS MODEL DA-20
1030095	USA/0095/S	8	SOURCE PRODUCTION AND EQUIPMENT CO. SERIES B, G, R AND T MODEL SOURCES
1030112	USA/0112/S	6	SCHLUMBERGER MODEL NSR-GB.
1030113	USA/0113/S	9	SCHLUMBERGER MODEL NOS. NSR-F, NSR-D AND NSR-R.
1030114	USA/0114/S	6	GULF NUCLEAR, INC. MODEL NO. AMBE 71-1
1030115	USA/0115/S	9	GULF NUCLEAR, INC. MODEL VL-1

1030116	USA/0116/S	4	HALLIBURTON SERVICES MODEL X-602-04-101 NEUTRON SOURCE
1030124	USA/0124/B(U)-96	16	MDS NORDION F-327/F-245 TRANSPORT PACKAGES, SERIAL NOS. 1 TO 5 INCLUSIVE, AND 7 AND SUBSEQUENT
1030125	USA/0125/B(U)-96	14	MDS NORDION F-327/F-247 TRANSPORT PACKAGES, SERIAL NOS. 1 TO 8, 10, 12 AND SUBSEQUENT
1030135	USA/0135/S	8	MODEL NOS. NSR-M AND NSR-L.
1030138	USA/0138/S	7	INDUSTRIAL NUCLEONICS SEALED SOURCE MODEL NO. 2-16 WHICH CONSISTS OF A MONSANTO RESEARCH CORPORATION MODEL NO. 2431, 2431-A, OR 2431-B
1030141	USA/0141/S	10	GENERAL ELECTRIC CO. NEUTRON SOURCE MODEL GEN-CF-1X OR 2765-AA00
1030149	USA/0149/S	5	GULF NUCLEAR MODEL AMBE 71-2A SOURCE CAPSULES MANUFACTURED PRIOR TO MARCH 8, 1988
1030154	USA/0154/S	8	AEA TECHNOLOGY QSA MODEL NOS. 60001, 60004, 60006, 60017, 60018, 60020, 60021, AND 68310
1030159	USA/0159/S	5	E. I. DUPONT/NEN MODEL NER-478C
1030161	USA/0161/S	2	NEW ENGLAND NUCLEAR MODEL NER-550
1030165	USA/0165/S	6	AEA TECHNOLOGY QSA, INC. MODEL NOS. A424-2 THROUGH A424-19 (EXCLUDING A424-6 THROUGH A424-9) AND A453-1 THROUGH A453-10 (EXCLUDING A453-3 AND A453-4)
1030174	USA/0174/S	5	GULF NUCLEAR, INC., MODEL NO. CS-2
1030179	USA/0179/S	8	AEA TECHNOLOGY QSA, INC. SERIES 900 IRIDIUM CAPSULE
1030185	USA/0185/S	5	NEW ENGLAND NUCLEAR MODEL NO. NER-476C
1030192	USA/0192/S	5	ISOMEDIX MODEL NO. ISO-1000, MANUFACTURED PRIOR TO JUNE 30, 1998
1030205	USA/0205/S	4	ORNL CAPSULE IR-192
1030214	USA/0214/B(U)	13	MDS NORDION MODEL F-168-X SHIPPING FLASK, SERIAL NOS. 22-X, 23-X, 24-X, 25-X, 26-X, 41-X
1030221	USA/0221/S	6	ISOTOPE PRODUCTS LABORATORIES LINE SOURCE
1030236	USA/0236/S	3	SR-CF-3000 AND OR-CF-3000 SERIES NEUTRON SOURCES
1030242	USA/0242/S	5	MONSANTO RESEARCH CORPORATION MODEL 24154-C SOURCE MANUFACTURED PRIOR TO DECEMBER 10, 2001
1030245	USA/0245/S	9	ELEKTA AB MODELS 43047 AND 43685
1030257	USA/0257/S	6	AEA TECHNOLOGY QSA, INC. MODEL 849
1030263	USA/0263/S	3	MONSANTO RESEARCH CORP. MODEL NO 24195
1030283	USA/0283/S	4	3M MODEL 3F1G CAPSULES MANUFACTURED PRIOR TO AUGUST 3, 1989
1030292	USA/0292/S	6	NEUTRON PRODUCT, INC. MODEL NOS. NPI-XX-XXXXW, NPI-XX-XXXX, NPI-XX-XXXXR, NPI-XX-XXXXCR, and NPI-XX-XXXXRC
1030297	USA/0297/S	4	INDUSTRIAL NUCLEAR COMPANY, INC. MODEL A SOURCE CAPSULE
1030331	USA/0331/S	6	GAMMATRON MODEL AN-HP SOURCE CAPSULE
1030335	USA/0335/S	6	AEA TECHNOLOGY QSA INC. MODEL 875 SERIES
1030336	USA/0336/S	8	ISOTOPE PRODUCTS LABORATORIES (IPL) MODEL NOS. XFB-3 AND XFB-4
1030337	USA/0337/B(U)-96	12	CROFT ASSOCIATES MODEL 2773A
1030348	USA/0348/B(U)	10	MDS NORDION INC. MODEL F-231, SERIAL NUMBERS 7, 8, AND 9
1030350	USA/0350/S	4	ISOTOPE PRODUCTS LABORATORIES (IPL) MODEL 343
1030351	USA/0351/S	5	ISOTOPE PRODUCTS LABORATORIES (IPL) MODEL N-252
1030352	USA/0352/S	4	ISOTOPE PRODUCTS LABORATORIES (IPL) MODEL 295
1030353	USA/0353/S	5	ISOTOPE PRODUCTS LABORATORIES (IPL) MODEL NO. 193

1030354	USA/0354/S	4	ISOTOPE PRODUCTS LABORATORIES (IPL) NO 274-1
1030356	USA/0356/S	9	ISOTOPE PRODUCTS LABORATORIES (IPL) MODEL NOS. A3000, A3015, A3023, A3024, AND A3030
1030357	USA/0357/S	7	ISOTOPE PRODUCTS LABORATORIES (IPL) MODEL NOS. A3214 AND A3203 SOURCE CAPSULES
1030363	USA/0363/S	5	AEA TECHNOLOGY MODEL NOS. X38/1, X38/3 AND X38/4
1030366	USA/0366/S	4	GAMMATRON MODEL GT-GHP
1030367	USA/0367/S	5	FRONTIER TECHNOLOGY CORPORATION MODEL 10 SERIES AND MODEL 100 SERIES
1030371	USA/0371/B(U)F-85	13	TN 7-2 TRANSPORT PACKAGE
1030376	USA/0376/S	3	SPECIFICATION SS-2050
1030377	USA/0377/S	6	AEA TECHNOLOGY QSA, INC., AMERSHAM CORPORATION, AND TECH/OPS RPD, INC. MODEL NOS. 60011, 60012, AND 60013
1030382	USA/0382/B(U)-96	15	CROFT ASSOCIATES MODEL 2835A
1030392	USA/0392/S	6	AEA TECHNOLOGY QSA, INC. SERIES 875 CAPSULE
1030393	USA/0393/S	3	CIS-US, INC. MODEL 791
1030401	USA/0401/B(U)F-96	10	JMS-87Y-18.5T
1030406	USA/0406/AF-96	11	21PF-1 OVERPACKS
1030411	USA/0411/H(U)-96	0	CYLINDER MODEL NOS. 5A, 5B, 8A, 12A, 12B, 30A, 30B, 48A, 48F, 48G, 48H, AND 48HX
1030411	USA/0411/AF	8	MODELS 5A, 5B, 8A, 12A, 12B, 30A, 30B, 48A, 48F, 48G 48H, 48X, 48HX AND 48Y
1030412	USA/0412/AF-96	11	MODEL BU-D
1030427	USA/0427/S	3	CIS-US, INC. MODELS 772 AND 774 SOURCE CAPSULES
1030444	USA/0444/B(U)-96	10	MDS NORDION INC. MODEL F-271 TRANSPORT PACKAGE, SERIAL NOS. 1 AND UP
1030452	USA/0452/B(U)F-96	10	JRF-90Y-950K
1030453	USA/0453/S	2	J. L. SHEPHERD & ASSOCIATES MODEL 6810/143-512 BNL STRIP
1030458	USA/0458/S	3	NEUTRON PRODUCTS, INC. MODEL NPRP 450-10-B
1030459	USA/0459/B(U)-96	6	MDS NORDION INC. F147(96) TRANSFER CASE, SERIAL NUMBERS 61 AND HIGHER
1030460	USA/0460/AF-96	12	MODEL RA-3D
1030462	USA/0462/S	4	ISOTOPE PRODUCTS LABORATORIES (IPL) MODELS 3021 AND 3027
1030463	USA/0463/S	1	J. L. SHEPHERD & ASSOCIATES MODEL 7810-109-BP
1030464	USA/0464/S	2	J. L. SHEPHERD & ASSOCIATES MODEL 6810-190
1030475	USA/0475/B(U)	2	MDS NORDION INC. GAMMACELL 1000 IRRADIATOR (SHIPPING MODEL IN THE 20WC-5 OVERPACK), SERIAL NOS. 1 TO 41, AND MDS NORDION INC. GAMMACELL 3000 IRRADIATOR (SHIPPING MODEL IN THE 20WC-5 OVERPACK), SERIAL NOS. 1 TO 41
1030480	USA/0480/AF	3	ATOMIC ENERGY OF CANADA LTD. (AECL) MAPLE 4 ENRICHED FUEL BUNDLE SHIPPING PACKAGE, SERIAL NOS. 1 TO 7
1030477	USA/0477/B(U)-85	5	MDS NORDION INC. GAMMACELL 1000 AND 3000, (SHIPPING MODELS IN THE 20WC-5 OVERPACK) SERIAL NUMBERS 42 AND UP
1030492	USA/0492/B(U)F-96	7	TN-BGC1
1030494	USA/0494/S	1	OMNITRON INTERNATIONAL, INC. SOURCE WIRE MODEL NOS. SL-777 AND SL-777V
1030495	USA/0495/AF-96	4	RAJ-II
1030497	USA/0497/S	2	AEA TECHNOLOGY QSA, INC. MODEL X.444

1030498	USA/0498/S	1	ISOTOPE PRODUCTS LABORATORIES (IPL) MODEL HEG-1
1030500	USA/0500/S	2	AEA TECHNOLOGY QSA, INC. MODEL X.1065
1030501	USA/0501/S	3	AEA TECHNOLOGY QSA, INC. MODEL X.44
1030502	USA/0502/S	4	AEA TECHNOLOGY QSA MODEL NOS. X54, X.540, AND X540/1
1030508	USA/0508/S	1	ISOTOPE PRODUCTS LABORATORIES (IPL) MODEL A3906
1030509	USA/0509/B(U)-96	5	MDS NORDION MODELS F-127, F-127-X AND RAI/F-127 TRANSPORT PACKAGES, SERIAL NUMBERS 59 AND UP
1030513	USA/0513/S	2	AEA TECHNOLOGY QSA MODEL NO. X.560
1030515	USA/0515/S	1	ISOTOPE PRODUCTS LABORATORIES (IPL) MODEL GFS-3 SOURCE CAPSULE
1030516	USA/0516/S	1	ISOTOPE PRODUCTS LABORATORIES (IPL) MODEL NOS. A3224-01, A3224-02, A3224-03, A3224-11, A3224-12, A3224-13 AND A3807 SOURCE CAPSULES
1030517	USA/0517/S	1	ISOTOPE PRODUCTS LABORATORIES (IPL) MODEL NOS. A3224-04, A3224-14, A3901-1 AND A3901-2 SOURCE CAPSULES
1030518	USA/0518/S	1	ISOTOPE PRODUCTS LABORATORIES (IPL) MODEL A3908 SOURCE CAPSULE
1030523	USA/0523/S	1	JLS&A MODEL NO. 7810-484-1
1030526	USA/0526/S	1	JLS&A MODEL NO. 7810-0109-R
1030530	USA/0530/S	1	J. L. SHEPHERD & ASSOCIATES MODEL 8810-AMBE-154
1030531	USA/0531/S	1	ORNL MODEL DSK 2384
1030540	USA/0540/S	1	J. L. SHEPARD MODEL NO. 7810-9
1030541	USA/0541/S	1	J. L. SHEPARD MODEL NO. 7810-8
1030542	USA/0542/AF-96	1	NFI-V
1030543	USA/0543/S	1	SPERRY SUN SOURCE PLUG ASSEMBLY NO. 009100
1030544	USA/0544/S	1	CIS-US MODEL 789
1030553	USA/0553/B(U)F-85	1	AECL-CRL IRRADIATED MATERIAL TRANSPORTATION PACKAGE
1030554	USA/0554/B(U)-85	4	MDS NORDION RADIOTHERAPY HEADS: THERATRON 780C (T780C), SERIAL NO. 274 AND UP; THERATRON 780E (T780E), SERIAL NO. 601 AND UP; THERATRON 1000E (T1000E), SERIAL NO. 44 AND UP; PHOENIX, SERIAL NO. 145 AND UP; THERATRON ELITE 80, SERIAL NO. 1 AND UP; THERATRON ELITE 100, SERIAL NO. 1 AND UP
1030558	USA/0558/B(U)F-96	2	JMS-87Y-18.5T
1030560	USA/0560/S	1	JLS & A MODEL NO. 7810-150
1030562	USA/0562/B(U)-96	6	ZA/NNR1005/B(U)-96 (BEATRICE)
1030563	USA/0563/AF-85	5	BNFL MODEL 3516 URANIUM TRANSPORT PACKAGE
1030565	USA/0565/B(U)F-96	1	TN-MTR
1030566	USA/0566/S	1	SOURCE PRODUCTION AND EQUIPMENT CO. MODEL NOS. G AND T
1030567	USA/0567/AF-85	1	DOT SPECIFICATION 21PF-1 AND 21PF-1B PROTECTIVE OVERPACKS
1030570	USA/0570/S	2	ALPHA-OMEGA SERVICES, INC. MODEL CSN0010-192 BRACHYTHERAPY SOURCE
1030571	USA/0571/S	1	VARIAN MODEL VS-2000
1030575	USA/0575/H(U)-96	1	2000 MED PACKAGE
1030577	USA/0577/B(U)F-96	1	COG-OP-30B OVERPACK
1030578	USA/0578/B(U)-96	1	MDS NORDION MODELS F-231 AND F-231-MK2; SERIAL NOS. 11 AND UP
1030585	USA/0585/AF-96	1	MODEL MST-30
1030587	USA/0587/B(U)-85	1	MDS NORDION GAMMACELL 40 MK3 IRRADIATOR, SERIAL NO. 11 AND SUBSEQUENT
1030589	USA/0589/B(U)-85	4	MDS NORDION F-327/F-448 TRANSPORT PACKAGE

1030591	USA/0591/B(U)-96	5	REVISS MODEL NO. 3750A
1030592	USA/0592/H(M)-96	0	MODEL 48X AND 48Y CYLINDERS
1030596	USA/0596/B(U)-96	0	U.K. DESIGN NO. 3605D
1030597	USA/0597/S	0	MODEL X.2050 SERIES SOURCE CAPSULES
1030603	USA/0603/S	1	AEA TECHNOLOGY QSA, INC. MODEL X.2163 SOURCE CAPSULE
1030606	USA/0606/S	0	AEA TECHNOLOGY MODEL VZ-64/1
1030608	USA/0608/S	0	SOURCE PRODUCTION AND EQUIPMENT CO. SERIES B, G, R AND T MODEL SOURCES MANUFACTURED AFTER NOV. 30, 2002
1030611	USA/0611/B(U)F-85	0	MTR-D TRANSPORT CASK
1030612	USA/0612/S	2	AEA TECHNOLOGY QSA, INC. MODEL NUMBERS X.1301 AND X.1302
1030614	USA/0614/S	1	AEA TECHNOLOGY QSA MODEL X.1218
1030615	USA/0615/S	1	AEA TECHNOLOGY MODEL X.2001
1030617	USA/0617/B(U)-96	2	MDS NORDION F-168(1996), SERIAL NOS. 53 TO 76 INCLUSIVE; 83 AND UP; AND F-168-X(1996), SERIAL NOS. 77-X, 78-X, 79-X, 80-X, 81-X, 82-X, AND UP
1030618	USA/0618/S	1	AEA TECHNOLOGY QSA, INC. MODEL NUMBER X.2109
1030619	USA/0619/S	3	AEA TECHNOLOGY QSA, INC. MODEL NUMBERS XN146 AND AXN146
1030620	USA/0620/S	1	AEA TECHNOLOGY QSA, INC. MODEL NUMBER X.1188
1030622	USA/0622/S	0	ISOTOPE PRODUCTS LABORATORIES MODEL NOS. CS7.50P/O, CS7.50P/P AND CS7.50P/S
1030623	USA/0623/S	1	AEA TECHNOLOGY QSA, INC. MODEL X.4
1030624	USA/0624/S	1	AEA TECHNOLOGY QSA, INC. MODEL NUMBER X.2
1030625	USA/0625/S	1	AEA TECHNOLOGY QSA, INC. MODEL X.25
1030627	USA/0627/S	1	AEA TECHNOLOGY QSA, INC. MODEL NUMBER X.2084
1030628	USA/0628/S	1	AEA TECHNOLOGY QSA, INC. MODEL NUMBER X.2055
1030629	USA/0629/S	1	AEA TECHNOLOGY QSA, INC. MODELS X.14 AND X.14/1
1030631	USA/0631/S	1	AEA TECHNOLOGY QSA, INC. MODEL NUMBER X.3
1030632	USA/0632/S	3	AEA TECHNOLOGY QSA, INC. MODEL NUMBERS AX1, X.1, AND X.1/2
1030634	USA/0634/S	2	AEA TECHNOLOGY QSA, INC. MODEL X.8
1030635	USA/0635/S	1	AEA TECHNOLOGY QSA, INC. MODEL X.1276
1030636	USA/0636/B(U)-96	2	CC 33 TRANSPORT CONTAINER LOADED AN IBL 437C IRRADIATOR
1030638	USA/0638/S	0	AEA TECHNOLOGY QSA, INC. MODEL VZ-260
1030639	USA/0639/S	2	AEA TECHNOLOGY QSA, INC. MODELS X.1191 AND X.1191/1
1030640	USA/0640/S	2	AEA TECHNOLOGY QSA, INC. MODEL X.9
1030643	USA/0643/S	2	AEA TECHNOLOGY QSA, INC. MODELS XN177 AND AXN177
1030645	USA/0645/S	2	AEA TECHNOLOGY QSA, INC. MODEL XN159/XN160
1030646	USA/0646/S	2	AEA TECHNOLOGY QSA, INC. MODELS X1094 AND AX1094
1030647	USA/0647/S	2	AEA TECHNOLOGY QSA, INC. MODELS X224 AND AX224
1030649	USA/0649/S	2	AEA TECHNOLOGY QSA, INC. MODEL X.1272
1030650	USA/0650/S	2	AEA TECHNOLOGY QSA, INC. MODEL X.1187
1030651	USA/0651/S	1	AEA TECHNOLOGY QSA, INC. MODEL X.1018
1030652	USA/0652/S	2	AEA TECHNOLOGY QSA, INC. MODEL XN.214
1030653	USA/0653/AF-96	3	TNF-XI
1030654	USA/0654/S-96	0	ISOTOPE PRODUCTS LABORATORIES MODELS 67-65XX
1030656	USA/0656/B(U)-96	0	GANUK MODEL GA-01 TRANSPORT CONTAINER

1030657	USA/0657/S	2	AEA TECHNOLOGY QSA, INC. MODEL X.103
1030659	USA/0659/S	2	AEA TECHNOLOGY QSA, INC. MODEL X.20
1030662	USA/0662/S	2	AEA TECHNOLOGY QSA, INC. MODEL X.1275
1030663	USA/0663/S	2	AEA TECHNOLOGY QSA, INC. MODEL X.1186
1030665	USA/0665/B(U)-96	1	MDS NORDION F-431/GC-1000 OR F-431/GC-3000
1030667	USA/0667/H(U)-96	0	48Y-JDTC
1030668	USA/0668/B(U)F-96	1	FS65
1030670	USA/0670/S	1	AEA TECHNOLOGY QSA, INC. MODEL X.220
1030670B	USA/0670/B(U)-96	0	AEA TECHNOLOGY MODEL 3746B
1030671	USA/0671/B(U)F-96	0	TN-MTR
1030672	USA/0672/S	1	AEA TECHNOLOGY QSA, INC. MODEL X21
1030673	USA/0673/S	1	AEA TECHNOLOGY QSA, INC. MODELS XN30/0, XN30/1, AND XN30/2
1030674	USA/0674/B(U)-96	0	MDS NORDION F-430/GC-40 OR F-430/CIS MODEL IBL 437C
1030675	USA/0675/S	0	AEA TECHNOLOGY QSA, INC. MODEL X2035
1030675B	USA/0675/B(U)F-96	0	FS47
1030676	USA/0676/S	0	AEA TECHNOLOGY QSA, INC. MODEL X451
1030677	USA/0677/S	0	AEA TECHNOLOGY QSA, INC. MODEL X9032/1
1030678	USA/0678/S	0	AEA TECHNOLOGY QSA, INC. MODEL X93
1030679	USA/0679/H(U)-96	1	48X OR 48Y CYLINDERS WITH BLANKET-TYPE THERMAL PROTECTION (BTP)
1030680	USA/0680/H(U)-96	2	48X OR 48Y CYLINDERS WITH COMPOSITE-TYPE THERMAL PROTECTION (CTP)
1030681	USA/0681/H(U)-96	1	48X OR 48Y CYLINDERS WITH RESIDUAL (HEEL) QUANTITY OF URANIUM HEXAFLUORIDE
1030682	USA/0682/S	0	AEA TECHNOLOGY QSA, INC. MODEL XN294/XN295
1030683	USA/0683/S	0	AEA TECHNOLOGY QSA, INC. MODEL X1290
1030684	USA/0684/S	0	AEA TECHNOLOGY QSA, INC. MODEL X2087
1030685	USA/0685/S	0	AEA TECHNOLOGY QSA, INC. MODEL X.117
1030686	USA/0686/S	0	AEA TECHNOLOGY QSA, INC. MODEL X.97
1030687	USA/0687/S	0	AEA TECHNOLOGY QSA, INC. MODEL X.94
1030688	USA/0688/S	0	AEA TECHNOLOGY QSA, INC. MODELS X.92 AND X.92/2
1030689	USA/0689/S	0	AEA TECHNOLOGY QSA, INC. MODEL X56
1030690	USA/0690/S	0	AEA TECHNOLOGY QSA, INC. MODEL X2110 INNER CAPSULE
1030691	USA/0691/S	0	AEA TECHNOLOGY QSA, INC. MODEL X1274
1030692	USA/0692/S	0	AEA TECHNOLOGY QSA, INC. MODELS X2162/1 THROUGH X2162/7
1030694	USA/0694/S	0	AEA TECHNOLOGY QSA, INC. MODEL XN46 CAPSULE IN A MODEL X0876 HOLDER
1030697	USA/0697/B(U)-96	0	MDS NORDION F-458/F-448 TRANSPORT PACKAGE
1030698	USA/0698/S	0	AEA TECHNOLOGY QSA, INC. MODEL X2083
1030699	USA/0699/S	0	AEA TECHNOLOGY QSA, INC. MODEL X2043
1030701	USA/0701/S	0	AEA TECHNOLOGY QSA, INC. MODEL X1237
1030702	USA/0702/S	0	AEA TECHNOLOGY QSA, INC. MODEL X108
1030703	USA/0703/S	0	AEA TECHNOLOGY QSA, INC. MODEL X7
1030704	USA/0704/S	0	AEA TECHNOLOGY QSA, INC. MODEL XN162/3
1030705	USA/0705/S	0	AEA TECHNOLOGY QSA, INC. MODEL XN28
1034909	USA/4909/AF	16	DOT SPECIFICATION 21PF-1A AND 21PF-1B OVERPACKS

1034986	USA/4986/AF	29	MODEL NO. RA-3
1035979	USA/5979/B( )	7	ALPHA OMEGA SERVICES, INC. 5979
1036050	USA/6050/B(U)	13	MDS NORDION INC. MODEL F-144 SHIPPING CONTAINER, SERIAL NUMBERS 1, 5, AND 9, AND MODEL F-144-AC, SERIAL NUMBER 3
1036078	USA/6078/AF	2	MODEL NOS. 927A1 AND 927C1
1036125	USA/6125/B(U)	13	MDS NORDION GAMMACELL 220 IRRADIATOR, SERIAL NOS. 1 TO 256 INCLUSIVE
1036162	USA/6162/B(U)	17	MDS NORDION INC. F-127 J-ROD SHIPPING CONTAINER, SERIAL NUMBERS 50, 52, AND 54
1036214	USA/6214/B(U)	17	MDS NORDION F-327/F-112 AND F-327/F-113 SHIPPING CONTAINERS IDENTIFIED BY SERIAL NO.
1036217	USA/6217/B(U)	16	MDS NORDION F-143 TRANSFER CASE, SERIAL NOS. 20, 50, 53, 54, 59, 62, AND 64; F-158 TRANSFER CASE, SERIAL NOS. 3, 4, 5, 6, 8, 9, 10 AND 14
1036306	USA/6306/B(U)	15	MDS NORDION F-168 SHIPPING FLASK, SERIAL NOS. 20, 21, 28, 31, 32, 33, 36, 38, 39, 42 TO 52 INCLUSIVE
1036355	USA/6355/B(U)	13	MDS NORDION F-147 TRANSFER CASE, SERIAL NUMBERS 3, 6, 7, 8, 10 TO 27, 29 TO 48, AND 50 TO 60
1036581	USA/6581/AF-85	26	SIEMENS POWER CORPORATION NO. 51032-1
1036613	USA/6613/B(U)-96	12	MODEL NO. 702
1036788	USA/6788/B(U)-96	4	SAFEKEG
1039027	USA/9027/B(U)-96	16	741-OP
1039034	USA/9034/AF-85	12	TRIGA-1
1039035	USA/9035/B(U)-96	12	680-OP
1039036	USA/9036/B(U)-96	13	MODEL SPEC C-1
1039037	USA/9037/AF-85	12	MODEL NO TRIGA-2
1039056	USA/9056/B(U)-85	11	SOURCE PRODUCTION & EQUIPMENT COMPANY, INC. MODEL SPEC 2-T
1039148	USA/9148/B(U)-96	8	770
1039150	USA/9150/B(U)-85	6	PAT-2
1039157	USA/9157/B(U)-85	6	IR-100
1039165	USA/9165/B(U)	6	AEA TECHNOLOGY MODEL NO. 855
1039185	USA/9185/B(U)-96	6	OP-100
1039187	USA/9187/B(U)-96	7	865
1039196	USA/9196/AF-85	23	UX-30
1039204	USA/9204/B(U)-85	1	CNS 10-160B
1039215	USA/9215/B(U)	8	NPI-20WC-6 MKII
1039217	USA/9217/AF	12	AMERICAN NUCLEAR FUELS CORPORATION MODEL ANF-250
1039225	USA/9225/B(U)F-96	31	NAC-LWT
1039228	USA/9228/B(U)F-85	11	GENERAL ELECTRIC MODEL 2000
1039234	USA/9234/B(U)F	12	NCI-21PF-1
1039239	USA/9239/AF	13	MODEL NOS. MCC-3, MCC-4, AND MCC-5 PACKAGINGS
1039248	USA/9248/AF	18	FRAMATOME ANP MODEL NOS. SP-1, SP-2, SP-3
1039250	USA/9250/B(U)F-85	6	5X22
1039258	USA/9258/B(U)-8596	2	MDS NORDION INC. MODEL NO. F-294 TRANSPORT PACKAGE
1039263	USA/9263/B(U)-96	6	SPEC-150
1039269	USA/9269/B(U)-96	4	MODEL NO. 650L

1039272	USA/9272/AF-85	1	CE-B1
1039282	USA/9282/B(U)-96	1	SPEC-300
1039283	USA/9283/B(U)-96	1	AEA TECHNOLOGY MODEL NOS. OPL-660 AND OP-660
1039284	USA/9284/B(U)F-85	0	ESP-30X PROTECTIVE SHIPPING PACKAGE
1039285	USA/9285/AF-85	2	SRP-1
1039288	USA/9288/AF-85	2	ECO-PAK OP URANIUM OXIDE TRANSPORT UNIT (OP-TU)
1039290	USA/9290/B(U)-96	3	MDS NORDION INC. MODEL NO. F-430/GC-40 TRANSPORT PACKAGE
1039294	USA/9294/AF-85	4	GLOBAL NUCLEAR FUEL MODEL NO. NPC
1039296	USA/9296/B(U)-96	3	AEA TECHNOLOGY 880 SERIES PACKAGES
1039297	USA/9297/AF-96	0	TRAVELLER STD AND TRAVELLER XL
1039299	USA/9299/B(U)-96	1	MDS NORDION INC. MODEL NO. F-423 PACKAGING/OVERPACK
1039309	USA/9309/B(U)F-96	0	RAJ-II
1039310	USA/9310/B(U)-96	0	MDS NORDION INC. MODEL NO. F-431/GC-1000 OR F-431/GC-3000
1039516	USA/9516/B(U)F-85	4	MOUND 1KW - For a copy of this CoCA, contact Dirk Cairns-Gallimore, NE-50, at (301) 903-3332

Marc-André Charette
Regulatory Affairs Senior Associate
MDS Nordion
447 March Road
Kanata, Ontario
Canada, K2K 1X8

SUBJECT: ISSUANCE OF NR-0220-S-127-S FOR MODEL C-164 SOURCE

Dear Mr. Charette:

Based on the information submitted in your application dated February 12, 2002, and subsequent communication, we conclude that the Model C-164 is acceptable for licensing purposes in accordance with the conditions of the enclosed registration certificate (NR-0220-S-127-S).

Please be advised that you must manufacture and distribute the product in accordance with the statements and representations contained in your application, with enclosures thereto, and the information set out in your 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 certificate.

Please read over the registration certificate in its entirety and notify us immediately of any errors or omissions.

Please be aware that, as a holder of an NRC registration, you may be subject to the NRC's licensing and inspection 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 Accounts Receivable Branch at (301) 415-7544.

If you have any questions, please contact me at (301) 415-5787 or Dr. John Jankovich at (301) 415-7904.

Sincerely,

Seung J. Lee, Mechanical Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated

cc w/encl: RJones, LFARB

Marc-André Charette
Regulatory Affairs Senior Associate
MDS Nordion
447 March Road
Kanata, Ontario
Canada, K2K 1X8

SUBJECT: ISSUANCE OF NR-0220-S-127-S FOR MODEL C-164 SOURCE

Dear Mr. Charette:

Based on the information submitted in your application dated February 12, 2002, and subsequent communication, we conclude that the Model C-164 is acceptable for licensing purposes in accordance with the conditions of the enclosed registration certificate (NR-0220-S-127-S).

Please be advised that you must manufacture and distribute the product in accordance with the statements and representations contained in your application, with enclosures thereto, and the information set out in your 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 certificate.

Please read over the registration certificate in its entirety and notify us immediately of any errors or omissions.

Please be aware that, as a holder of an NRC registration, you may be subject to the NRC's licensing and inspection 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 Accounts Receivable Branch at (301) 415-7544.

If you have any questions, please contact me at (301) 415-5787 or Dr. John Jankovich at (301) 415-7904.

Sincerely,

Seung J. Lee, Mechanical Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated
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NAME	SLee		JJankovich						
DATE	04/03/02		04/ /02						

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Application and Review Checklist for 1st and 2nd Review for SSD 02-007

SUMMARY DATA	
Name and Complete Mailing Address of the Applicant: MDS Nordion, a Division of MDS (Canada) Inc. 447 March Road Ottawa, Ontario Canada, 2K2 1X8	**Name, Title, and Telephone Number of the Individual to Be Contacted If Additional Information or Clarification Is Needed by the NRC: Mr. Marc-André Charette Regulatory Affairs 613-592-3400, ext 2421**
The Applicant is (check one): ( ) Custom User ( ) Manufacturer ( ) Distributor (X) Manufacturer and Distributor	**If the Applicant Is Not the Manufacturer, Provide the Name and Complete Mailing Address of the Manufacturer:**
If the Applicant Is a Custom User, Provide the Name and Complete Mailing Address of the Distributor:	**Provide the Name, Complete Mailing Address, and Function of Other Companies Involved:**
Model Number: C-164	***Principal Use Code* (see Appendix E): (D) and (A)**
Name Used by the Industry to Identify the Product (e.g., Radiography Exposure Device, Teletherapy Source, Calibration Source, etc.): Gamma gauges source, Industrial Radiography sources (source to be used in device)	**For Use by:** (X) Specific Licensees Only ( ) General Licensees Only ( ) Both Specific and General Licensees ( ) Persons Exempt from Licensing
Leak-Test Frequency: ( ) Periodic Leak-Testing is Not Required (X) 6 Months ( ) *Attached is justification for a leak test* frequency of greater than 6 months	**Principal Section of the 10 CFR that Applies to the User (e.g., General Licensees under 10 CFR 31.5): 10 CFR 34, 32.210** **Radionuclides and Maximum Activities (including loading tolerance): Antimony-124 pellets, 80 mCi (2.96 GBq) Cobalt-60 pellets, 50 Ci (1.85 TBq) Iridium-192 pellets, 500 Ci (18.55 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	
Signature:	**Date:**

CHECKLIST

Registration Certificate Holder: MDS Nordion

Model: C-164

DESCRIPTION	OK/DEF		COMMENTS
	1st Reviewer	2nd Reviewer	
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?	N/A		
Device/source design with complete engineering drawings (dimensions, tolerances, list of materials)	x		
Assembly methods (screw, welds, etc.); verify integrity	x		
Source mounting (size and integrity) and security	N/A		
Is source ANSI classification sufficient (from ANSI N43.6 and ISO 2919): Radiography - Unprotected ..... 43515 Radiography - In Device ..... 43313 Medical - Radiography ..... 32312 Medical - γ Teletherapy ..... 53524 Medical - Brachytherapy ..... 53211 Medical - Source Applicators ..... 43312 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 Calibration source activity > 30μCi (1 MBq) ..... 22212 γ Irradiators (I) ..... 43323 γ Irradiators (II, III) ..... 43424 γ Irradiators (II, III, IV) ..... 53424 Chromatography ..... 32211 Static Eliminators ..... 22222 Smoke Detectors 32222	x		Radiography in device - 43313 Gamma gauge in device - 43232 C-164: 64334
Definition of shutter operation (locked in Off position, not locked in On position), Fail safe, spacing and tolerances	N/A		
On-Off indicators (description, qty., location)	N/A		
Safety interlocks, guards, etc. to prevent access to beam or high radiation levels	N/A		
Corrosion between unlike materials (e.g., aluminum & steel, depleted uranium & steel, etc.)	X		Aluminum (spacer), SS
Shielding efficiency and integrity	N/A		
For medical devices: Was a 510(k) provided? (provide written notification to FDA)	N/A		
Well logging sources must be nondispersible and nonsoluble. (see Appendix B for a list of approved well logging sources as of November 1991)	N/A		
See "ANSI and Other Standards" list for references for particular source/device designs (e.g. radiography, Brachytherapy, etc.)	X		ANSI 43.6, ISO 2919

CHECKLIST

Registration Certificate Holder: MDS Nordion

Model: C-164

DESCRIPTION	OK/DEF		COMMENTS
	1st Reviewer	2nd Reviewer	
LABELING			
Copy of label	X		
Materials, dimensions, colors (note on registration certificate if labeling is exempt from the color requirements of 10 CFR Part 20)	X		
Permanent attachment and location(s) - visible to users?	X		Engraved
Contents: Model#, Serial#, Isotope, Activity, Manufacturer, Date of Assay, Trefoil, "CAUTION - RADIOACTIVE MATERIAL" (Depleted Uranium information must be included)	Def		RAI #3
CONDITIONS OF USE			
Expected working life of the source/device (years, operations)	X		Depends on isotope
Actions to be taken when product reaches end of its working life.	X		Disposal
Maximum allowable temperature, vibration, shock, corrosion, etc. (during use, handling, storage, and transport)	X		
How the device will be used	N/A		
Meets dose limits of Part 32 for distribution general licensees or persons exempt from licensing	N/A		
PROTOTYPE TESTING/HISTORICAL USE			
Tests methods and conditions (for source and device)	Def		RAI #4
Tests results	X		
Years of use (incidents, failures, etc.)	X		Over 400 units since 1969
Similarities to other sources/devices if they are used as basis.	X		
RADIATION PROFILES			
Survey instrument used (type, window thickness, sensitivity, etc.)	N/A		Estimation: Γ for antimony -124, Co-60, Ir-192 are 9.8, 13.2, 4.8 (R-cm^2/hr-mCi) Check antimony-124: 2100 vs 7840
Conditions: including environments, scatter (product in beam), and use of guards and shields	N/A		
Distance from source/surface (per ANSI 538-1979)	Def		RAI #5
Shutter Open and Closed/Source Shielded	N/A		
Verify radiation surveys for γ radiation meet inv^2 law.	N/A		
Verify radiation surveys for non-γ radiation have not been calculated using inv^2 law.	N/A		

CHECKLIST

Registration Certificate Holder: MDS Nordion

Model: C-164

DESCRIPTION	OK/DEF		COMMENTS
	1st Reviewer	2nd Reviewer	
QUALITY ASSURANCE			NRC QA Program No. 0703
Materials, subassemblies, services	X		
Assembly methods (screws, welding, etc.)	X		
Dimensions and tolerances	X		
Activity, radiation levels, leak tests	X		
QA Manual and comparison of manual to Regulatory Guide 6.9	X		
INSTALLATION			
Fixed, portable, movable, fixed installation but portable source housing	N/A		
Inherent shielding, inaccessibility	N/A		
Beam access: size of air gap/opening to beam and use of interlocks, locks, additional shielding or barriers	N/A		
Mounting integrity	N/A		
SAFETY INSTRUCTIONS			
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation surveys	X		
ACCOMPANYING DOCUMENTATION			
Leak tests results and radiation surveys	X		
Transportation documents	N/A		
Operation, maintenance, calibration, damage/failure, specific warnings, leak test, and radiation survey instructions if applicable	X		
For Distribution to General Licensees: Verify NRC Regions and Agreement State listing is up-to-date and copies of all pertinent regulations	N/A		

CHECKLIST

Registration Certificate Holder: MDS Nordion

Model: C-164

DESCRIPTION				OK/DEF		COMMENTS
				1st Reviewer	2nd Reviewer	
SERVICING						
The following activities may be performed by the persons indicated:						
Activity	by a General Licensee	Only by a Specific Licensee	Will be Offered by the Applicant			
Installation			X			
Relocation			X			
Maintenance			X			
Repair			X			
Source Exchange			X			
Calibration			N/A			
Leak Testing			X			
Radiation Survey			X			
Training			X			
FOREIGN VENDORS						
Drop ship				N/A		
Who and where is source installed				X		Gamma gauges or industrial radiography
Leak test and radiation surveys				X		6 months
QA in the U.S.				X		

1st Reviewer Signature: */RA/* **Date:** 02/19/02

2nd Reviewer Signature: **Date:**

State of Colorado
Department of Public Health and Environment

RADIOACTIVE MATERIALS LICENSE

Pursuant to the *Colorado Radiation Control Act*, Title 25, Article 11, *Colorado Revised Statutes*, and the State of Colorado *Rules and Regulations Pertaining to Radiation Control*(the Regulations), Part 3, and in reliance on statements and representations heretofore made by the licensee designated below; a license is hereby issued authorizing such licensee to transfer, receive, possess and use the radioactive material(s) designated below; and to use such radioactive material(s) for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders now or hereafter in effect of the Colorado Department of Public Health and Environment and to any conditions specified below.

---

1. Licensee: Boulder Scientific Company

2. Address: P.O. Box 548, Mead, CO 80542

3. License Number: Colo. 011-01, Amendment No. 12

4. Expiration date: February 28, 2009

5. Reference Number: Fee Category: 3.B

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6. Authorized Radioactive Material and Uses:

   A. The licensee is authorized to possess and use not more than a total activity of 163 GBq (4.4 Ci) of ^{124}Sb (Antimony-124) sealed sources for use in Beryllium detection devices. No individual source shall exceed 40.7 GBq (1.1 Ci). The sealed sources shall be MDS Nordion Inc. model SRC-3 or C-164 sources.

   B. The licensee is authorized to possess and use not more than a total activity of 185 Bq (5 nCi) of ^{137}Cs (Cesium-137) contained in an Isotope Products sealed source.

CONDITIONS

7. Radioactive material shall be used and stored at 598 Third St., Mead, Colorado, and used at temporary job sites of the licensee anywhere in the State of Colorado where the State of Colorado maintains jurisdiction for regulating the use of radioactive materials.

8. Radioactive material authorized in Item 6.A to be used for the development, manufacture, demonstration, and use of the Boulder Scientific Company Model 310 beryllium detector.

9. The licensee may continue to provide source replacement of radioactive material authorized in Item 6.A in the following three (3) existing Model 200 beryllium detectors in use at:
   A. Brush Resources Inc., Delta Utah (mill laboratory, and mine laboratory)
   B. Brush Wellman Inc., Elmore, Ohio (laboratory only)

RADIOACTIVE MATERIALS LICENSE

10. The licensee shall ensure that the users of the devices identified in License Condition 9 possess and maintain a current specific radioactive materials license specific to the model 200 Beryllium detectors.

11. Radioactive material authorized in Item 6.A to be used for the development, manufacture, demonstration, and use of new beryllium detectors. The licensee shall not distribute new devices without a proper device registry evaluation.

12. Radioactive material authorized by Item 6.A of this license shall be distributed only to persons with a valid radioactive materials license issued by the U.S. Nuclear Regulatory Commission or an Agreement State.

13. Radioactive material authorized by Item 6.B of this license shall be used as a reference source.

14. The licensee shall comply with the provisions of the State of Colorado *Rules and Regulations Pertaining to Radiation Control:* Part 3, "Licensing of Radioactive Material;" Part 4, "Standards for Protection Against Radiation;" Part 10, "Notices, Instructions and Reports to Workers; Inspections;" and Part 17, "Transportation of Radioactive Material."

15. Radioactive material shall be used by John M. Birmingham, Ph.D., Howard C. Hein, Alvin D. Nelson, or Richard Moore.

16. The designated Radiation Safety Officer is John M. Birmingham, Ph.D.,

17. All users of Radioactive Material must be equipped with personnel monitoring devices capable of detecting gamma radiation.

18. Radioactive material authorized by Item 6.A of this license shall be tested for leakage and/or contamination in accordance with RH 4.16 of the State of Colorado *Rules and Regulations Pertaining to Radiation Control.*

19. Sealed sources containing Radioactive Material shall not be opened by the licensee.

20. Radioactive material authorized by Item 6 of this license shall be stored and used in a manner that will preclude use by unauthorized personnel.

21. The licensee shall maintain a use log for licensee owned Beryllium detection devices used outside of 598 Third Street, Mead, Colorado. The use log shall indicate the serial number, user, date, and location of use.

22. The licensee shall list the emergency contact telephone number(s) of the Radiation Safety Officer in the procedures manual for emergency notification.

RADIOACTIVE MATERIALS LICENSE

23. A. Each device distributed under this license shall bear a durable, clearly visible and legible label or labels containing the device model and serial number, the radiation symbol in colors magenta or purple on a yellow background, the words, "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL", and quantity, identity and date of measurement of the radioactive material, and the name of the distributor of the device.

    B. Each label required by this license condition shall bear the statement, "REMOVAL OF THIS LABEL IS PROHIBITED".

24. Prior to the use of licensed materials outside of the State of Colorado, or at any facility under exclusive Federal jurisdiction including a facility within the State of Colorado, the Licensee shall comply with the applicable provisions of 10 CFR 150.20 or if the use shall take place in an Agreement State the licensee shall comply with the applicable provisions of that State's reciprocity requirements.

25. The licensee shall not transfer possession and/or control of materials or products containing radioactive material as a contaminant except:

    A. by transfer of waste to an authorized recipient;

    B. by transfer to a specifically licensed recipient; or,

    C. as provided otherwise by specific condition of this license pursuant to the requirements of RH 3.22 of the Regulations.

26. The licensee shall maintain records of the sale, transfer, or disposal of radioactive sources. The records must include:

    A. the name and address of the recipient;

    B. the documents showing the recipient's authorization to receive the source;

    C. the radionuclide and activity of the source(s) transferred; and

    D. the date of the transfer.

27. The licensee may transport radioactive material or deliver radioactive material to a carrier for transport, in accordance with the provisions of RH 17.5 of the State of Colorado *Rules and Regulations Pertaining to Radiation Control*, "Transportation of Licensed Material".

28. The transportation of radioactive materials within the State of Colorado shall be subject to all applicable regulations of the Colorado Public Utilities Commission, Colorado Department of Transportation, Colorado Department of Public Safety, Colorado Department of Revenue (Port of Entry), U.S. Department of Transportation, and other agencies of the United States having jurisdiction. When the U.S. Department of Transportation Regulations (Title 49, Chapter I, *Code of Federal Regulations*) are not applicable to shipments by land

of radioactive material by reason of the fact that the transportation does not occur in interstate or foreign commerce, the licensee must be in compliance with the requirements relating to packaging of the radioactive material, marking and labeling of the package, placarding of the transport vehicle, and accident reporting set forth in the regulations of the U.S. Department of Transportation.

29. The State of Colorado *Rules and Regulations Pertaining to Radiation Control* shall govern unless the licensee's statements, representations, and procedures contained in the application and correspondence are more restrictive than the Regulations. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Item 6 of this license in accordance with the statements, representations, and procedures contained in:

A. the REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES, SAFETY EVALUATION OF DEVICE, No: CO-175-D-101-S, issued March 12, 1991 (Model 310); and

B. the application and attachments dated January 27, 2004; and

C. the license correspondence and documents dated April 8, 2004; April 9, 2004 (facsimile); April 16, 2004 (facsimile); and May 7, 2004.

FOR THE COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Date:____ 7 July 04_____ By:_____/ Thomas Pentecost /_____

EA-97-541 - Nordion Internaltional, Inc.

January 23, 1998

EA No. 97-541

Mr. Ronald McGregor, Manager
Regulatory Affairs
MDS Nordion Incorporated
447 March Road
Kanata, Ontario, Canada K2K 1X8

SUBJECT: NOTICE OF VIOLATION
(NRC Inspection Report No. 030-30788/97-001)

Dear Mr. McGregor:

This refers to the inspection conducted on September 17-19, 1997, at 447 March Road Kanata, Ontario, Canada. The inspection was limited to a review of your manufacturing process as it relates to conformance with your license, registration certificates and quality assurance program. The inspection was conducted to review your distribution of nuclear gauging devices to general licensees. During the inspection, violations of NRC requirements were identified, as described in the NRC inspection report transmitted with our letter dated December 9, 1997. In addition, in the December 9, 1997 letter, the NRC provided you an opportunity to either respond in writing to the apparent violations addressed in the inspection report or request a predecisional enforcement conference. You responded to the apparent violations in a January 13, 1998 letter to the NRC.

Based on the information developed during the inspection and the information you provided in your January 13,1998 response to the inspection report, the NRC has determined that four violations of NRC requirements occurred. The violations are cited in the enclosed Notice of Violation (Notice) and the circumstances surrounding them are described in detail in the subject inspection report. The violations involve modification to devices without obtaining NRC approval prior to the modifications. The NRC is concerned that the number of deviations between the devices being distributed and the registration certificates, is indicative of a lack of management oversight and understanding of regulatory requirements.

While the specific modifications to the sources, source holder or source drive mechanism do not appear to constitute a safety concern, making such changes without NRC approval constitutes a significant regulatory concern because the NRC was not give the opportunity, as required, to review the changes, and as such, the devices were distributed without an NRC approved registry certificate as required by 10 CFR 32.210. Therefore, the violations demonstrate a significant lack of oversight and control of licensed activities. As such, the violations have been classified in the aggregate as a Severity Level III problem in accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions" (Enforcement Policy), NUREG-1600.

In accordance with the Enforcement Policy, a base civil penalty in the amount of $2,750 is considered for a Severity Level III violation. Because your facility has not been the subject of an escalated enforcement action within the last two years, the NRC considered whether credit was warranted for *Corrective Action* in accordance with the civil penalty assessment process in Section VI.B.2 of the Enforcement Policy. Credit for corrective actions is warranted because your corrective actions were both prompt and comprehensive. These actions, which were described in your January 13, 1998 letter to the NRC, included, but were not limited to: submittal of current drawings of the C-188 source, C-3001 source and GC-3000 source holder to the NRC Sealed Source and Device Safety Section on September 25, 1997 in order to amend the

registration of these devices; and submitting further information on the changes to the GC-40 source movement to amend its registration by February 27, 1998. In addition, you met with the NRC on October 29, 1997 and have made changes in your practices to prevent recurrence of the violations, including training of personnel.

Therefore, to encourage prompt and comprehensive correction of violations, I have been authorized to not propose a civil penalty in this case. However, similar violations in the future could result in further escalated enforcement action.

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket in your letter to the NRC dated January 13, 1998. Therefore, you are not required to respond to this letter unless the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to provide additional information, you should follow the instructions specified in the enclosed Notice.

In accordance with 10 CFR 2.790 of the NRC's "Rules of Practice," a copy of this letter, and its enclosure, as well as your response if your choose to provide one, will be placed in the NRC Public Document Room (PDR).

Sincerely,

Hubert J. Miller
Regional Administrator

Docket No. 030-30788
License No. 54-28275-01

Enclosure: Notice of Violation

NOTICE OF VIOLATION

MDS Nordion Incorporated
Kanata, Ontario, Canada

Docket No. 030-30788
License No. 54-28275-01
EA 97-541

During an NRC inspection conducted on September 17-19, 1997, violations of NRC requirements were identified. In accordance with the "General Statement of Policy and Procedure for NRC Enforcement Actions," (Enforcement Policy), NUREG-1600, the violations are listed below:

10 CFR 32.210(a) states that a manufacturer or initial distributor of a sealed source or device containing a sealed source whose product is intended for use under a specific license may submit a request to the NRC for evaluation of radiation safety information about its product and for its registration.

10 CFR 32.210(f)(1) and (2) states that the person submitting the request for evaluation and registration of safety information about the product shall manufacture and distribute the product in accordance with (1) the statements and representations, including quality control program contained in the request and (2) the provisions of the registration certificate.

Contrary to the above, from February 11, 1992 to March 14, 1996, the licensee, after having submitted requests to the NRC for evaluation of radiation safety information about its product and for its registration, manufactured and distributed certain sealed sources and devices containing licensed material in a manner that was not in accordance with the provisions of the registration certificate, as evidenced by the following examples, each of which constitutes a separate violation.

1. In support of Registration Certificate NR-0220-D-102-S, Nordion specified, in a June 4, 1993, letter, the specific overall length of the source holder assembly for the Gammacell 3000; however, on May 31, 1993, the licensee had modified the overall length of the source holder assembly for the Gammacell 3000 such that the length was not consistent with the length specified in the June 4, 1993 letter. **(01013)**

2. In support of Registration Certificate NR-0220-S-103-S, Nordion specified, in its December 20, 1984 letter, the specific length of the outer body of the C-188 sealed source; however, on August 31, 1993, the licensee modified the overall length of the outer capsule of the C-188 sealed source. **(01023)**

3. Registration Certificate NR-0220-D-101-S specifies that "Irradiation is accomplished by moving two lead-filled cylindrical drawers, each containing a single radioactive source, simultaneously by pneumatic controls from the stored to the irradiate position;" however, in 1995, the licensee modified the source drive mechanism of the Gammacell 40 from a pneumatic system to a ball screw system. **(01033)**

4. In support of Registration Certificate NR-0220-D-101-S, Nordion specified, in its March 18, 1993, letter, the specific length and diameter for the inner capsule for the Model C-3001 source assembly; however, on March 15, 1996, the licensee modified the overall length and diameter of the inner capsule of the C-3001 source assembly. **(01043)**

These violations are categorized in the aggregate as a Severity Level III problem (Supplement VI).

The NRC has concluded that information regarding the reason for the violations, the corrective actions taken and planned to correct the violations and prevent recurrence and the date when full compliance was achieved is already adequately addressed on the docket in a letter from the Licensee dated January 13, 1998. However, you are required to submit a written statement or explanation pursuant to 10 CFR 2.201 if the description therein does not accurately reflect your corrective actions or your position. In that case, or if you choose to respond, clearly mark your response as a "Reply to a Notice of Violation," and send it to the U.S. Nuclear Regulatory Commission, ATTN: Document Control Desk, Washington, D.C. 20555 with a copy to the Regional Administrator, Region I, within 30 days of the date of the letter transmitting this Notice of Violation (Notice).

Dated at King of Prussia, Pennsylvania
this 23rd day of January 1998

State of Colorado
Department of Public Health and Environment

RADIOACTIVE MATERIALS LICENSE

Pursuant to the *Colorado Radiation Control Act*, Title 25, Article 11, *Colorado Revised Statutes*, and the State of Colorado *Rules and Regulations Pertaining to Radiation Control*(the Regulations), Part 3, and in reliance on statements and representations heretofore made by the licensee designated below; a license is hereby issued authorizing such licensee to transfer, receive, possess and use the radioactive material(s) designated below; and to use such radioactive material(s) for the purpose(s) and at the place(s) designated below. This license is subject to all applicable rules, regulations, and orders now or hereafter in effect of the Colorado Department of Public Health and Environment and to any conditions specified below.

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1. Licensee: Boulder Scientific Company

2. Address: P.O. Box 548, Mead, CO 80542

3. License Number: Colo. 011-01, Amendment No. 12

4. Expiration date: February 28, 2009

5. Reference Number: Fee Category: 3.B

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6. Authorized Radioactive Material and Uses:

   A. The licensee is authorized to possess and use not more than a total activity of 163 GBq (4.4 Ci) of ^{124}Sb (Antimony-124) sealed sources for use in Beryllium detection devices. No individual source shall exceed 40.7 GBq (1.1 Ci). The sealed sources shall be MDS Nordion Inc. model SRC-3 or C-164 sources.

   B. The licensee is authorized to possess and use not more than a total activity of 185 Bq (5 nCi) of ^{137}Cs (Cesium-137) contained in an Isotope Products sealed source.

CONDITIONS

7. Radioactive material shall be used and stored at 598 Third St., Mead, Colorado, and used at temporary job sites of the licensee anywhere in the State of Colorado where the State of Colorado maintains jurisdiction for regulating the use of radioactive materials.

8. Radioactive material authorized in Item 6.A to be used for the development, manufacture, demonstration, and use of the Boulder Scientific Company Model 310 beryllium detector.

9. The licensee may continue to provide source replacement of radioactive material authorized in Item 6.A in the following three (3) existing Model 200 beryllium detectors in use at:
   A. Brush Resources Inc., Delta Utah (mill laboratory, and mine laboratory)
   B. Brush Wellman Inc., Elmore, Ohio (laboratory only)

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10. The licensee shall ensure that the users of the devices identified in License Condition 9 possess and maintain a current specific radioactive materials license specific to the model 200 Beryllium detectors.

11. Radioactive material authorized in Item 6.A to be used for the development, manufacture, demonstration, and use of new beryllium detectors. The licensee shall not distribute new devices without a proper device registry evaluation.

12. Radioactive material authorized by Item 6.A of this license shall be distributed only to persons with a valid radioactive materials license issued by the U.S. Nuclear Regulatory Commission or an Agreement State.

13. Radioactive material authorized by Item 6.B of this license shall be used as a reference source.

14. The licensee shall comply with the provisions of the State of Colorado *Rules and Regulations Pertaining to Radiation Control:* Part 3, "Licensing of Radioactive Material;" Part 4, "Standards for Protection Against Radiation;" Part 10, "Notices, Instructions and Reports to Workers; Inspections;" and Part 17, "Transportation of Radioactive Material."

15. Radioactive material shall be used by John M. Birmingham, Ph.D., Howard C. Hein, Alvin D. Nelson, or Richard Moore.

16. The designated Radiation Safety Officer is John M. Birmingham, Ph.D.,

17. All users of Radioactive Material must be equipped with personnel monitoring devices capable of detecting gamma radiation.

18. Radioactive material authorized by Item 6.A of this license shall be tested for leakage and/or contamination in accordance with RH 4.16 of the State of Colorado *Rules and Regulations Pertaining to Radiation Control.*

19. Sealed sources containing Radioactive Material shall not be opened by the licensee.

20. Radioactive material authorized by Item 6 of this license shall be stored and used in a manner that will preclude use by unauthorized personnel.

21. The licensee shall maintain a use log for licensee owned Beryllium detection devices used outside of 598 Third Street, Mead, Colorado. The use log shall indicate the serial number, user, date, and location of use.

22. The licensee shall list the emergency contact telephone number(s) of the Radiation Safety Officer in the procedures manual for emergency notification.

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23. A. Each device distributed under this license shall bear a durable, clearly visible and legible label or labels containing the device model and serial number, the radiation symbol in colors magenta or purple on a yellow background, the words, "CAUTION, RADIOACTIVE MATERIAL" or "DANGER, RADIOACTIVE MATERIAL", and quantity, identity and date of measurement of the radioactive material, and the name of the distributor of the device.

    B. Each label required by this license condition shall bear the statement, "REMOVAL OF THIS LABEL IS PROHIBITED".

24. Prior to the use of licensed materials outside of the State of Colorado, or at any facility under exclusive Federal jurisdiction including a facility within the State of Colorado, the Licensee shall comply with the applicable provisions of 10 CFR 150.20 or if the use shall take place in an Agreement State the licensee shall comply with the applicable provisions of that State's reciprocity requirements.

25. The licensee shall not transfer possession and/or control of materials or products containing radioactive material as a contaminant except:

    A. by transfer of waste to an authorized recipient;

    B. by transfer to a specifically licensed recipient; or,

    C. as provided otherwise by specific condition of this license pursuant to the requirements of RH 3.22 of the Regulations.

26. The licensee shall maintain records of the sale, transfer, or disposal of radioactive sources. The records must include:

    A. the name and address of the recipient;

    B. the documents showing the recipient's authorization to receive the source;

    C. the radionuclide and activity of the source(s) transferred; and

    D. the date of the transfer.

27. The licensee may transport radioactive material or deliver radioactive material to a carrier for transport, in accordance with the provisions of RH 17.5 of the State of Colorado *Rules and Regulations Pertaining to Radiation Control*, "Transportation of Licensed Material".

28. The transportation of radioactive materials within the State of Colorado shall be subject to all applicable regulations of the Colorado Public Utilities Commission, Colorado Department of Transportation, Colorado Department of Public Safety, Colorado Department of Revenue (Port of Entry), U.S. Department of Transportation, and other agencies of the United States having jurisdiction. When the U.S. Department of Transportation Regulations (Title 49, Chapter I, *Code of Federal Regulations*) are not applicable to shipments by land

of radioactive material by reason of the fact that the transportation does not occur in interstate or foreign commerce, the licensee must be in compliance with the requirements relating to packaging of the radioactive material, marking and labeling of the package, placarding of the transport vehicle, and accident reporting set forth in the regulations of the U.S. Department of Transportation.

29. The State of Colorado *Rules and Regulations Pertaining to Radiation Control* shall govern unless the licensee's statements, representations, and procedures contained in the application and correspondence are more restrictive than the Regulations. Except as specifically provided otherwise by this license, the licensee shall possess and use radioactive material described in Item 6 of this license in accordance with the statements, representations, and procedures contained in:

    A. the REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES, SAFETY EVALUATION OF DEVICE, No: CO-175-D-101-S, issued March 12, 1991 (Model 310); and

    B. the application and attachments dated January 27, 2004; and

    C. the license correspondence and documents dated April 8, 2004; April 9, 2004 (facsimile); April 16, 2004 (facsimile); and May 7, 2004.

FOR THE COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Date:___7 July 04_____ By:____/ Thomas Pentecost /_____

From: Isotope Orders <isotopeorders@MDS.Nordion.com>
To: "James Jarvis" <james.jarvis@state.co.us>
Date: 3/28/05 1:40PM
Subject: RE: LOOKING FOR INFO ON MODEL C-164 SOURCE

Dear Mr. Jarvis,

You have contacted the correct supplier - MDS Nordion Inc.

We ship Antimony sources contained in C-164 capsules (typically 300 mCi Source Ordered)to our customer: Boulder Scientific
The licensed maximum capacity of Antimony (SB-124) in a C-164 capsule is 37 GBq or 1 Ci.

Please do not hesitate to contact us if you require further information via e-mail or call tollfree 1-800-267-6211.

Best regards,
Bruce Jones
Commercial Operations
Nuclear Medicine
MDS Nordion Inc.

-----Original Message-----
From: James Jarvis [mailto:james.jarvis@state.co.us]
Sent: Monday, March 28, 2005 1:18 PM
To: Isotope Orders
Subject: LOOKING FOR INFO ON MODEL C-164 SOURCE

I am looking for information on the quantities and activites of the MDS Nordion Model C-164 sealed source. We have a radioactive material licensee here in Colorado (USA) who is using these sources in their devices used for non-destructive analysis. (I am not sure you are the correct recipient for my inquiry, but thought someone might be able to direct it appropriately).

Specifically, I am looking at what activity (or activities) the model C-164 is manufactured with when Antimony-124 (Sb-124) is used. That is, what is the maximum activity that can be incorporated into he model C-164 source?

Thank you for your assistance.

James S. Jarvis, M.S.
Health Physicist
Radiation Management Unit - HMWMD-B2
Colorado Dept. of Public Health and Environment
4300 Cherry Creeek Drive South
Denver, CO 80246-1530

(303) 692-3454
(303) 759-5355 FAX

james.jarvis@state.co.us

From: Ujagar Bhachu
To: John Kinneman
Date: 3/30/05 2:09PM
Subject: For Review and Action: Unauthorized Use Of Licensed Material and Sealed Sources by MDS Nordian

Following the yesterday's telcon with Judith Joustra the contents of this e-mail are presented to you for your review and action.

Background:

On February 17, 2005, Charlie Gorday NRC-HQ Librarian had a telephone call from Todd Bingham of Brush Wellman, OH. Charlie Gorday was of the opinion that Brush Wellman is a NRC licensee and that Mr. Bringham uses a sealed source of Antimony 124 in his work. Subsequently, we eastablished that Mr. Bingham is a licensee of State of OH and is an end user of Model 200 beryllium detector and he was on a fishing exercise and wanted to find substitute sources to replace the sources indicated in his license. The detector device was manufactured by, Boulder Scientific Company, a licensee based in State of Colorado.

More specifically, Mr. Bingham was seeking NRC assistance to establish what the markings **U.S. Type 3130 and U.S. Type 3200 designate** meant. He also indicated that the sealed source of **Antimony 124** is additionally marked with these letters: AECL **Type RC-3 , and AECL Types RC-5, RC-8, and SR-3 .**

NRC Librarian searched the NRC library sources in an attempt to determine the meaning of these designations. When his search did not produce any tangible results, the librarian sent an e-mail asking for SS&D Section assistance and provided **Mr. Bingham's telephone number as 419-862-4269.**

The Model 200 beryllium detection device was originally reviewed by NRC-HQ. A maximum source of Antimony-124 (AECL source models of 100 mCi) was stated on the registration certificate. The original license was issued by NRC Region III. MDS Nordion, a Division of MDS (Canada) Inc. (formerly Nordion International Inc. and Atomic Energy of Canada Ltd.), 447 March Road, Ottawa, ON, Canada K2K 1X8, applied for registration of Model C-164 sealed source in 2002. A sealed source registration certificate number **NR-0220-S-127-S**, was issued to **MDS Nordion with a maximum source activity of 80 mCi -antimony-124.**

In summary the C-164 Model description is as follows:

The sealed source model C-164 is a single encapsulated fusion welded source that is used in self-contained, **portable detectors** such as a **Beryllium Analyzer**. The C-164 source may also be used for industrial radiography where the source remains in the device. **The C-164 source may contain up to 80 mCi (2.96 GBq) of antimony-124, or up to 50 Ci (1.85 TBq) of cobalt-60, or up to 500 Ci (18.5 TBq) of iridium-192, in pellet form.**

A quick search indicated that the sealed source model numbers stated on the current license issued by OH State were obsolete. The OH State and STP were made aware of the need to up-date the license.

Boulder Scientific Company the manufacturer of the Model 200 beryllium detector is located in Mead, CO. A copy of the Radioactive Material License issued to the manufacturer was obtained and reviewed. (Colo.011-01 Amendment 12, issued on JULY 04, see attachment 1).

Item 6 A. of the license reads:

This license is authorized to process and use not more than a total activity of 163 GBq (4.4 Ci) of Antimony-124 sealed source for use in Beryllium detection devices. **No individual source shall exceed 40.7 GBq (1.1 Ci). Sealed sources shall be MDS Nordion Inc. model SRC-3 or C-164 sources. (*this***

1200% increased activity authorization in the license above that was evaluated in the SS&D raised the flag).

It appears from this license condition and the admittance below by MDS Nordion that sealed sources were modified and or distributed by MDS Nordion to a USA licensee with out obtaining prior approval from NRC or an Agreement State.

Colorado State regulatory authority was approached and this issue was discussed over the telephone. On March 28, 2005, following response was transmitted by the State:

"This is in relation to our phone conversation a short time ago, and in relation to a phone conversation we had 1-2 weeks ago about one of our licensees (Boulder Scientific) and a licensee in Ohio that uses a Boulder Scientific device. I believe one of the issues with our licensee was that one of the sources listed on the Colorado license indicated a source no longer manufactured - I am in the process of taking care of that and deleting the model SRC-3 source. Another question has arisen, however.

Specifically:

1.) Is MDS Nordion (Canada) bound by the requirements of SSD Evaluation NR-0220-S-127-S for the model C-164 source? If so, it appears that they may be making and selling sources under this model number greater than 80 mCi. (Refer to the attached email from MDS Nordion).

https://www.hsrd.ornl.gov/nrc/sources/pdf/02200127.pdf

I have a call into our licensee regarding their devices and will work to resolve issues associated with them. Also note, that per MDS Nordion, Boulder Scientific is their ONLY customer for Sb-124 in the U.S.

Also, in the below link, it appears that MDS Nordion may have changed other sources/devices **without getting NRC approval several years ago:**

Attached is Boulder Scientific license. Note - we do not regularly convert licenses to PDF formats, so the attached has an electronic approval. The content is the same as what we have in our files.

http://www.nrc.gov/reading-rm/doc-collections/enforcement/actions/materials/ea97541.html

End of respone.

E-mail response from MDS Nordion:

Dear Mr. Jarvis,

You have contacted the correct supplier - MDS Nordion Inc.

We ship Antimony sources contained in C-164 capsules (typically 300 mCi Source Ordered) to our customer: Boulder Scientific.

The licensed maximum capacity of Antimony (SB-124) in a C-164 capsule is 37 GBq or 1 Ci.

Please do not hesitate to contact us if you require further information via e-mail or call toll free 1-800-267-6211.

Best regards,

Bruce Jones
Commercial Operations

Nuclear Medicine
MDS Nordion Inc.

State Of Colorado confirmed:

The two licensees using the Model 200 device are:

The following facility is using two of the model 200 devices:
Brush Wellman, Inc.
Utah Operations
P.O. Box 815
Delta, UT 84624

UTAH License: UT 140018, Amendment #8 (most recent copy we have)

The following facility is using one of the model 200 devices:
Brush Wellman, Inc.
14710 W. Portage River South Road
Elmore, OH 43416

We reviewed two MDS Nordion licenses issued by the NRC Region 1 and found that MDS Nordion has no authorization from NRC to distribute Antimony-124 sources. On March 28, 2005, this finding was confirmed in a telephone conversation with Judith Joustera of NRC Region 1.

Could you please review the historical data provided in the attachments below, links above and the information provided herein and advise the course of action to be taken or should be taken.

As always, with best regards.

Ujagar S. Bhachu
(301) 415-7894

CC: Charles Cox; Judith Joustra; Richard Correia; Tim Harris