

RI - DNMS Licensee Event Report Disposition

Licensee:

Agilent Technologies

Event Description:

Loss of Material

License No:

07-28722-01

Docket No:

0332792

MLER-RI:

2016-013

Event Date:

09/21/16

Report Date:

10/21/16

HQ Ops Event #:

52312

1. REPORTING REQUIREMENT

- ☐ 10 CFR 20.1906 Package Contamination
- ☒ 10 CFR 20.2201 Theft or Loss
- ☐ 10 CFR 20.2203 30 Day Report
- ☐ Other

- ☐ 10 CFR 30.50 Report
- ☐ 10 CFR 35.3045 Medical Event
- ☐ License Condition

2. REGION I RESPONSE

- ☐ Immediate Site Inspection
- ☐ Special Inspection
- ☐ Telephone Inquiry
- ☐ Preliminary Notification/Report
- ☒ Information Entered in RI Log
- ☐ Report Referred To:

Inspector/Date

Inspector/Date

Inspector/Date

Daily Report

Review at Next Inspection

3. REPORT EVALUATION

- ☒ Description of Event
- ☒ Levels of RAM Involved
- ☒ Cause of Event

- ☒ Corrective Actions
- ☒ Calculations Adequate
- ☐ Additional Information Requested from Licensee

4. MANAGEMENT DIRECTIVE 8.3 EVALUATION

- ☐ Release w/Exposure > Limits
- ☐ Repeated Inadequate Control
- ☐ Exposure 5x Limits
- ☐ Potential Fatality

- ☐ Deliberate Misuse w/Exposure > Limits
- ☐ Pkging Failure > 10 rads/hr or Contamination > 1000x Limits
- ☐ Large# Indivs w/Exp > Limits or Medical Deterministic Effects
- ☐ Unique Circumstances or Safeguards Concerns

If any of the above are involved:

☐ Considered Need for IIT

☐ Considered Need for AIT

Decision/Made By/Date:

5. MANAGEMENT DIRECTIVE 8.10 EVALUATION (additional evaluation for medical events only)

- ☐ Timeliness - Inspection Meets Requirements (5 days for overdose / 10 days for underdose)
- ☐ Medical Consultant Used-Name of Consultant/Date of Report:
- ☐ Medical Consultant Determined Event Directly Contributed to Fatality
- ☐ Device Failure with Possible Adverse Generic Implications
- ☐ HQ or Contractor Support Required to Evaluate Consequences

6. SPECIAL INSTRUCTIONS OR COMMENTS

☐ Non-Public

Inspector Signature:

Date:

☒ Public-SUNSI REVIEW COMPLETE

Branch Chief Initials:

Date:

Location of File: G:\REFERENCE\BLANK FORMS\LER FORM.DOCX

Rev. 08/03/16



2850 Centerville Road
Wilmington, DE 19808

November 18, 2016

USNRC, Region I,
2100 Renaissance Boulevard, Suite 100,
King of Prussia, PA 19406-2713

Subject: Notification of loss of licensed material

To Whom It May Concern,

In accordance with 10 CFR 20.2201, Agilent Technologies, Inc., wishes to report the loss of an Electron Capture Detector (ECD) containing a 15 millicurie Nickel 63 (Ni-63) source.

Agilent Technologies, Inc. (Agilent) manufactures ECDs in its Shanghai, China facility and ships completed product around the world. A small number of ECDs are shipped to the Agilent Little Falls site for installation in gas chromatograph instruments which are typically sold only to US customers. The standard practice is that the ECDs are transported in bulk by air from China to JFK International Airport and turned over to a warehouse managed by Worldwide Flight Services (WFS). WFS breaks down the shipments and turns them over to a freight handler, Philadelphia Truck Lines (PTL). PTL transfers from JFK to its own warehouse and from there, ships to Agilent per UPS or FedEx. There was a deviation in the shipment containing the ECD that became lost in that, instead of turning the shipment over to Philadelphia Truck Lines, WFS warehouse turned them over to the United States Postal Service. Three of the ECDs were delivered to the Agilent Little Falls site by the USPS but the fourth never arrived. There is no record of the transfer of the number of packages turned over to USPS.

Please accept the answers provided below to the questions listed in 10 CFR 20.2201.

(i) A description of the licensed material involved, including kind, quantity, and chemical and physical form; and

Answer:

Description of licensed material: Nickel 63 (Ni-63), 15 millicuries, solid

(ii) A description of the circumstances under which the loss or theft occurred; and

06-03-2016 16:09:55

Answer: An Agilent Technologies ECD was lost in handling at an in-bound warehouse at JFK international airport. The shipment contained 4 boxes with one ECD each. Three were turned over for delivery to Agilent Technologies but one was not found within the warehouse.

(iii) A statement of disposition, or probable disposition, of the licensed material involved; and

Answer:

Agilent's freight logistics service (Kintetsu World Express) has petitioned Worldwide Flight Services (the warehouse where the ECD is believed to have been lost) for this answer but has not received one to date.

(iv) Exposures of individuals to radiation, circumstances under which the exposures occurred, and the possible total effective dose equivalent to persons in unrestricted areas; and

Answer:

There have been no known occurrences of exposure to individuals. The ECD is considered a sealed source. The Ni-63 source is embedded within a stainless steel cylinder that is kept closed by 4 tamper resistant screws. More information on the ECD and its characteristics may be found in the enclosed NRC Sealed Source & Device (SS&D) Registry NR-0348-D-111-B. Please refer to the SAFETY ANALYSIS SURVEY (page 8 of 11) in the attached SS&D Registry for a full description of possible exposure amounts to persons in unrestricted areas.

(v) Actions that have been taken, or will be taken, to recover the material; and

Answer:

Searches have been made of the Worldwide Flight Services, Philadelphia Truck Lines, and USPS warehouse, with no resolution.

(vi) Procedures or measures that have been, or will be, adopted to ensure against a recurrence of the loss or theft of licensed material.

Answer:

Worldwide Flight Services has committed to the following corrective measures:

- All mail and cargo units will be cross checked against the arrival document upon reception at the cargo facility.
- All mail units will be checked by Worldwide Flight Services management to ensure that the staff is handling in accordance with local mail SOPs to avoid the mail team's mistakenly transporting to the post office.

- All Worldwide Flight Services staff will be briefed that mail units must be checked and handled in accordance with the above process to avoid any future irregularity.

Please let me know if you have any questions.

Sincerely yours,

A handwritten signature in black ink, appearing to read "David S. Bennett". The signature is fluid and cursive, with the first name "David" being more prominent and the last name "Bennett" following in a similar style.

David S. Bennett
Radiation Safety Officer
302-636-8262
david_bennett@agilent.com

C.c. David Hoppy
EHS Manager, Eastern Region

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

NO.: NR-0348-D-111-B

DATE: May 14, 2015

PAGE 1 of 11

DEVICE TYPE: Electron Capture Detector

MODELS: G1223A, G1533A, G2310A, G2330A, G2397A, G2398A, G2404A,
G2405A, **G4597A, G4598A** (Generally Licensed)

G1224A, G1536A (Specifically Licensed)

DISTRIBUTOR:

Agilent Technologies, Inc.
Little Falls Site (previously Hewlett-
Packard, Little Falls Site)
2850 Centerville Road
Wilmington, DE 19808

MANUFACTURER:

Agilent Technologies, Shanghai Company
Limited
412 Ying Lun Road
Pu Dong
Shanghai, China

SEALED SOURCE MODEL
DESIGNATION:

QSA Global (formerly AEA
Technology) Model: NBCD

Eckert & Ziegler Isotope Products
(formerly Isotope Products
Laboratories) Model: NER-004P

ISOTOPE:

MAXIMUM ACTIVITY:

Nickel-63

18 mCi (0.67 GBq), Models G1223A, G1533A,
G1224A, G1536A

Nickel-63

15 mCi (0.56 GBq), Models G2397A, G2398A,
G2404A, G2405A, **G4597A, G4598A**

Nickel-63

5 mCi (185 MBq), Models G2301A, G2330A

LEAK TEST FREQUENCY:

6 months

PRINCIPAL USE:

(N) Ion Generator, Chromatography

CUSTOM DEVICE:

____ YES ____ X ____ NO

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

NO.: NR-0348-D-111-B

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DEVICE TYPE: Electron Capture Detector

DESCRIPTION:

The electron capture detectors (ECD's) that are registered in this certificate are devices that utilize sources manufactured by vendors listed on Page 1. The sources are registered separately and were found suitable for use in applications for chromatography ion generators.

The Models G1223A and G1224A electron capture detector (ECD) assemblies are similar to the previously approved Models 19233 and 19235. The model G1223A will be distributed to persons generally licensed and the Model G1224A will be distributed to persons specifically licensed. The two detectors are the same except that the detector label plate is different for general licenses versus specific licenses. The Models G1223A and G1224A ECDs are for use on the Model 5890 Series gas chromatographs. The manufacture of Model G1223A has been discontinued as of March 1, 2004.

The specific differences of the Models G1223A and G1224A relative to the Models 19223 and 19235 are as follows:

1. The detector heat sink is made of aluminum rather than stainless steel. The new heat sink allows the distributor to down rate their heater from 70 watts to 60 watts. This also limits the maximum temperature of the detector. In the event of a catastrophic failure mode, the 5890 gas chromatograph instrument's main processor would detect a shorted sensor fault, and turn off all heaters to devices on the gas chromatograph.
2. A 17-4 PH stainless steel will be used rather than 303 stainless steel. The supplier of the lower plated block, Amersham Corporation, has indicated that the plating quality of Ni-63 is better with 17-4 PH stainless steel. A 17-4 PH stainless steel lower block is currently being used on Models 19303 and 19312 ECD's. The inside of the lower block will be plated with non-radioactive nickel prior to plating of the Ni-63 radionuclide.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A DEVICE
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DEVICE TYPE: Electron Capture Detector

DESCRIPTION (Cont.):

3. A metal seal will be used between the lower block (cathode) and the upper block (anode) that is currently used on other ECDs being distributed (for example, Models 18713A, 19282 and 18803-60520). This particular seal uses a silver crushable O-ring. The same tamper proof screws now used on all of the distributor's distributed ECDs will be used.
4. The upper anode block design has been redesigned. The non-plated part has reduced mass, a purged anode which has been raised (withdrawn) from the region of the Ni-63 plating within the lower block (cathode). The purged anode remains cleaner and is retained with a special nut and seal removable only with the distributor's anode wrench.
5. The outer cover and insulation are different than the 19233 and 19235 merely to accommodate the new gas chromatograph. The detector label plates will have the same information as our current detectors and will remain permanently attached to a tamper proof screw.

The Models G1533A and G1536A ECD assemblies are same as the Models G1223A and G1224A with the exception of modifications to the mounting hardware and the outer cover and insulation for use with a different gas chromatograph. The Model G1533A will be distributed to persons generally licensed and the Model G1536A will be distributed to persons specifically licensed. The two detectors are the same except that the detector label plate is different for general licenses versus specific licenses. The Models G1533A and G1536A ECDs are for use on the distributor's Model 6890 gas chromatographs.

The Models G2310A and G2330A are identical to the Models G1533A and G1223A respectively, except that the G2310A and G2330A will only contain up to 5 mCi (185 MBq) of Ni-63. The sources will be plated in the same manner as those in the Models G1533A and G12723A.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A DEVICE
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DEVICE TYPE: Electron Capture Detector

DESCRIPTION (Cont.):

Models G2397A, G2398A, G2404A, and G2405A are almost identical to the ECD's described above. These ECDs still contain up to 15 mCi (555 MBq) of Ni-63, but instead of being plated onto the lower cell body the radioactive material is plated on a thin nickel cylinder. The cylinder is then press-fitted into the stainless steel lower body. The Model G2397A ECD is for use on the distributor's Models 6850, 6890, and 7890 gas chromatographs. The Model G2398A is for use on the distributor's Model 6890 gas chromatograph.

The upper body then attaches to the lower body with the same tamper-proof screws used in all designs. All ten ECDs are approximately 4" (10 cm) long and 1-1/8" (2.86 cm) in diameter at their widest location. General licensees never receive the tamper proof screws wrench or solvent cleaning/disassembly instructions.

Prior to 2000, the devices were distributed under the company name "Hewlett Packard". In 2000, the company split and the products were manufactured under the new company name of "Agilent Technologies". Agilent Technologies accepts returns of both Hewlett Packard and Agilent Technologies devices. The devices are cleaned and refurbished, then redistributed as initial distributions to new recipients.

Models G4597A and G4598A share the same internal ECD cell and tamper-resistant designs as Models G2397A, G2398A, G2404A, and G2405A. The ECD cell consists of a lower body that contains the Ni-63 capped with the upper body and sealed with an O-ring and tamper resistant screws. The ECD bottom aluminum block assembly contains a 60W Cartridge Heater/Sensor. The ECD top aluminum block contains the heater sensor, it also contains the relief bracket that protects the gas tubing, and covers the ECD cell. The ECD bottom and top blocks are fastened together with tamper-resistant screws. The main difference from the other models is that both Models G4597A and G4598A supply a path for make-up gas which is integrated into the ECD upper and lower body parts.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
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DEVICE TYPE: Electron Capture Detector

DESCRIPTION (Cont.):

Models G4597A and G4598A utilize source Model NER-004P with a maximum activity of 15 mCi of Ni-63. Agilent Technologies reported that the only difference between the Models G4597A and G4598A is the model number, which is due to marketing purposes. Models G4597A and G4598A will be distributed to persons generally licensed and is for use in the Model 9000 Gas Chromatograph System.

LABELING:

Each **ECD** is stamped with the radiation symbol, the words, "Caution-Radioactive Material," the isotope and activity. Label plates are attached by cable to a tamper proof screw on the detector body. Users are instructed not to remove these plates. The plate contains the radiation symbol, the words, "Caution-Radioactive Material," the isotope, activity, model number, serial number, date, the words, "Electron Capture Detector," and the distributor name and logo. Additionally, for the Models used by general licensees, the plate contains the labeling requirements of 10 CFR 32.51(a), and refers the user to an instruction manual that tells them not to open or chemically clean the cell.

Devices distributed as of 2000 list "Agilent Technologies". Prior to 2000, the devices were distributed under the company name "Hewlett Packard", and the distributor is listed as "Hewlett Packard". Detector cells that had initially been distributed by "Hewlett Packard", and that are redistributed by "Agilent Technologies", list the distributor as "Agilent Technologies (Original Manufacturer: Hewlett-Packard Co.)", and indicate the original Hewlett Packard serial number and manufacturing date, in order to maintain traceability and to preserve accurate age information.

DIAGRAM:

See Attachments 1-5.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
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DEVICE TYPE: Electron Capture Detector

CONDITIONS OF NORMAL USE (Cont.):

Each ECD is designed to be used in conjunction with gas chromatographs in analytical laboratories. Each ECD will be used in laboratory environment and by persons trained in the use of gas chromatography equipment. The ECD will normally be operated at temperatures up to 410°C (770°F). The working life of **all ECD Models** is 10 years.

PROTOTYPE TESTING:

Hewlett Packard tested the detector cells G1223A, G1533A, G2330A, G2310A, G1224A and G1536A to the criteria used on their presently licensed detector cells. The tests consisted of:

- Pressure test to 60 psi (414 kPa).
- Drop test from 1.5 meters (59").
- Vibration test to 55 Hz with an amplitude of 0.015" (0.38 mm).
- Freeze test to -40°C (-40°F).
- Loss of Ni-63 in carrier gas during normal use.
- Loss of Ni-63 from detector when all heat control systems fail.
- Loss of Ni-63 during solvent cleaning of the detector.
- Loss of Ni-63 at abnormally high temperatures (625°C [1157°F] and 800°C [1472°F]).

The sealed sources used in the ECD's meet the above tests and exceed the minimum ISO 2919 classification of C32211 for ion generators chromatography.

The following tests were performed on the G2397A, G2398A, G2404A, and G2405A designs: drop, impact, pressure, elevated temperature, and freeze. Because the ECDs are similar to the approved designs, no further testing was deemed necessary.

The manufacturer reported that the ECD cell for Models G4597A and G4598A have been tested to ISO 2919:2012 and achieved a classification of C42211.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
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DEVICE TYPE: Electron Capture Detector

EXTERNAL RADIATION LEVELS:

The distributor has reported that radiation levels on all accessible surfaces do not exceed background levels for measurements taken from a detector with 18 mCi (666 MBq) of Ni-63. Attachment 3 is a dose rate report showing dose rate from an opened detector cell.

QUALITY ASSURANCE AND CONTROL:

The distributor maintains an ISO 9001 quality assurance and control program which has been deemed acceptable for licensing purposes by NRC.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The Models G1224A and G1536A shall be distributed only to persons specifically licensed by the NRC or an Agreement State.
- The Models G1223A, G1533A, G2310A, G2330A, G2397A, G2398A, G2404A, and G2405A shall be distributed to persons generally licensed by the NRC or an Agreement State.
- Handling, storage, use, transfer, and disposal: To be determined by the licensing authority or as required by 10 CFR 31.5 or Agreement State equivalent.
- The devices shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 mCi (185 Bq) of removable contamination.
- The user may install the device into gas chromatographs. However, the device may not be dismantled in any way by the user unless he obtains a specific license from NRC or an Agreement State to perform such activities.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
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DEVICE TYPE: Electron Capture Detector

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

- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.
- Reviewer's Note: The use of Model NBCD source, manufactured by QSA Global, Inc., was discontinued in June 2009, by Agilent Technologies, Inc. **ECDs Models containing the Model NBCD source are no longer commercially distributed but may be approved for licensing purposes.**
- Reviewer's Note: Agilent Technologies would audit the plated source supplier every two years starting from the last audit report dated February 12, 2009.
- Reviewer's Note: In letter dated January 15, 2015, Agilent informed the NRC that the ECD Models G2404A and G2405A were never introduced to the market and that no longer plans to manufacture or commercially distribute these products.

SAFETY ANALYSIS SUMMARY:

The distributor has submitted sufficient information to provide reasonable assurance that:

- The device can be safely operated by persons not having training in radiological protection.
- Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be released or inadvertently removed from the source housing, and it is unlikely that any person will receive in any period of one year a dose in excess of 10 percent of the limits specified in Section 20.1201(a), 10 CFR Part 20.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A DEVICE
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DEVICE TYPE: Electron Capture Detector

SAFETY ANALYSIS SUMMARY (Cont.):

- Under accident conditions associated with handling, storage, and use of the source housing, it is unlikely that any person would receive an external radiation dose or dose commitment in excess of the dose to the appropriate organ as specified in the following Table:

Table 1: External Radiation Dose

PART OF BODY	DOSE
Whole body; head and trunk active blood-forming organs gonads; or lens of eye	15 rem (0.15 Sv)
Hands and forearms; feet and ankles; localized areas of skin averaged over areas no larger than 1 square centimeter	200 rem (2.0 Sv)
Other Organs	50 rem (0.50 Sv)

Based on review of the ECD Models listed in this certificate of registration, and the information and test data cited below, we continue to conclude that the devices are acceptable for licensing purposes.

Furthermore, we continue to conclude that the devices would be expected to maintain their 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 A DEVICE
(AMENDED IN ITS ENTIRETY)

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DEVICE TYPE: Electron Capture Detector

REFERENCES:

The following supporting documents for the ECDs are hereby incorporated by reference and are made a part of this registry document.

- Hewlett-Packard's letters dated January 30, 1990, February 2, 1990, May 9, 1990, September 17, 1990, October 3, 1990, October 10, 1990, June 8, 1994, August 4, 1995, April 9, 1996, May 6, 1996, June 19, 1996, August 19, 1999, and November 1, 1999, with enclosures thereto.
- Agilent Technologies' letters dated, February 21, 2002, October 24, 2001, October 19, 2001, September 4, 2001, March 9, 2001, March 5, 2001, May 24, 2000, March 2, 2000, February 18, 2000, November 21, 1999, November 15, 1999, and November 1, 1999, with enclosures thereto.
- Agilent Technologies' letter dated September 26, 2003, email dated February 27, 2004, and email dated March 31, 2004, with enclosures thereto.
- Agilent Technologies' letter dated November 6, 2006.
- Agilent Technologies' letter dated June 7, 2007, with enclosures thereto.
- Agilent Technologies' emails dated June 20, 2007, with enclosures thereto.
- Agilent Technologies' letter dated January 8, 2008, with enclosures thereto.
- Agilent Technologies' letter dated January 23, 2009, and June 1, 2009, with enclosures thereto.

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

NO.: NR-0348-D-111-B

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DEVICE TYPE: Electron Capture Detector

REFERENCES (Cont.):

- Agilent Technologies' letter dated October 14, 2009, and January 22, 2010, and enclosures thereto.
- Agilent Technologies' letter dated September 13, 2013, and February 6, 2014, with enclosures thereto.
- Agilent Technologies' email dated March 27, 2014, with enclosures thereto.
- **Agilent Technologies' letters dated January 15, 2015 (ML15021A122), and March 19, 2015 (ML15084A128), with enclosures thereto. Agilent Technologies' letters dated April 28, 2015 (ML15118A879), and May 13, 2015 (ML15133A329).**

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: May 14, 2015

Reviewer: /RA/
Maria Arribas-Colon

Date: May 14, 2015

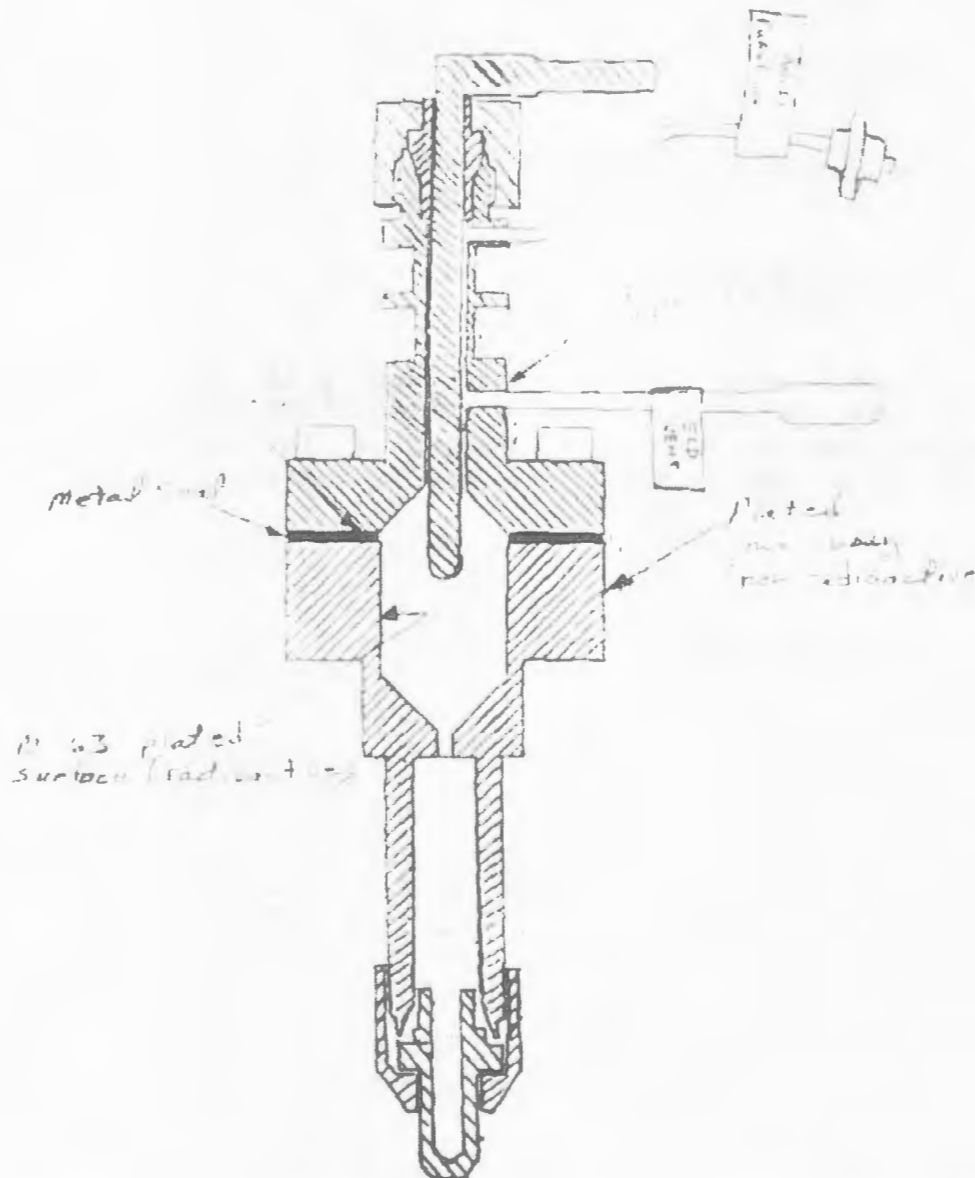
Concurrence: /RA/
Tomas Herrera

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

NO.: NR-0348-D-111-B

DATE: May 14, 2015

ATTACHMENT 1 of 5



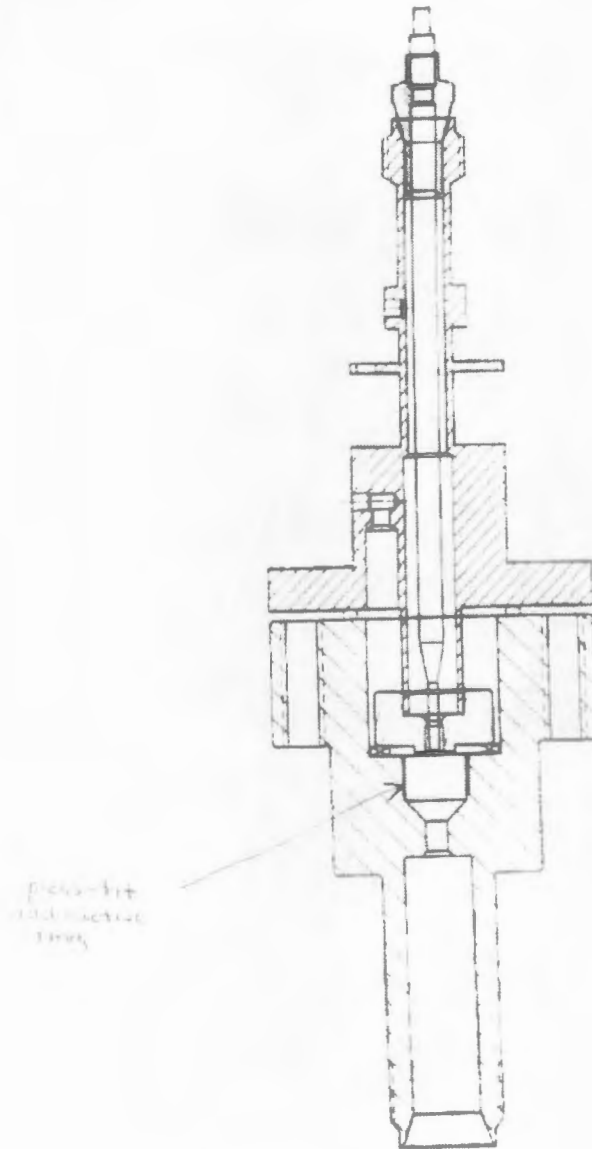
Models G1223A, G1533A, G2310A, G2330A, G1224A, and G1536A

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

NO.: NR-0348-D-111-B

DATE: May 14, 2015

ATTACHMENT 2 of 5



Models G2397A, G2398A, G2404A, and G2405A

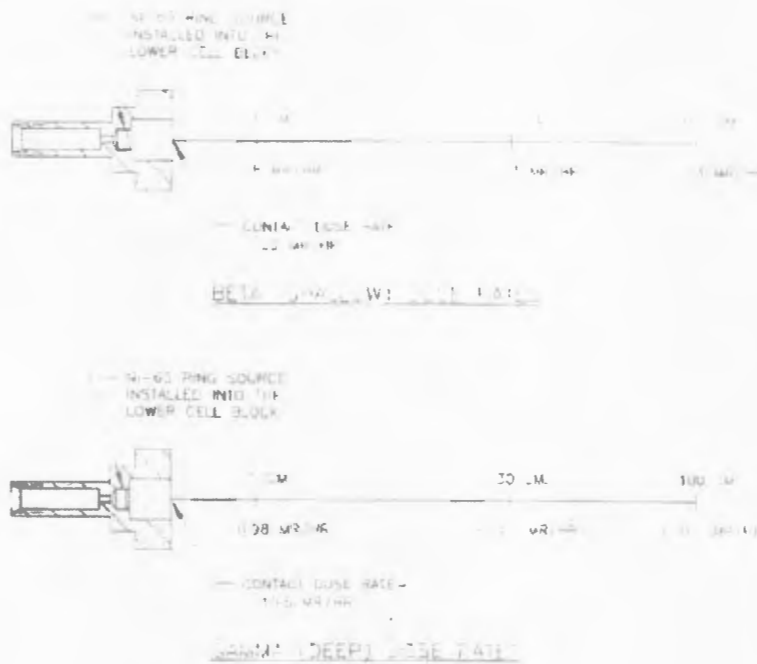
**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A DEVICE
(AMENDED IN ITS ENTIRETY)**

NO.: NR-0348-D-111-B

DATE: May 14, 2015

ATTACHMENT 3 of 5

NR-0348-D-111-B RING SOURCE DOSE RATE REPORT



NOTES

Source: NR-0348-D-111-B, 1.0 MR/HOUR, 1.0 CM

Beta dose rate measurements are performed with a standard
type of ionization chamber having 300 milligrams square centimeter foil.
Minimum detectable dose rate is 0.1 mR/hour.

Gamma dose rate measurements are performed with a standard
type of ionization chamber having 300 milligrams square centimeter foil.
Minimum detectable dose rate is 0.1 mR/hour.

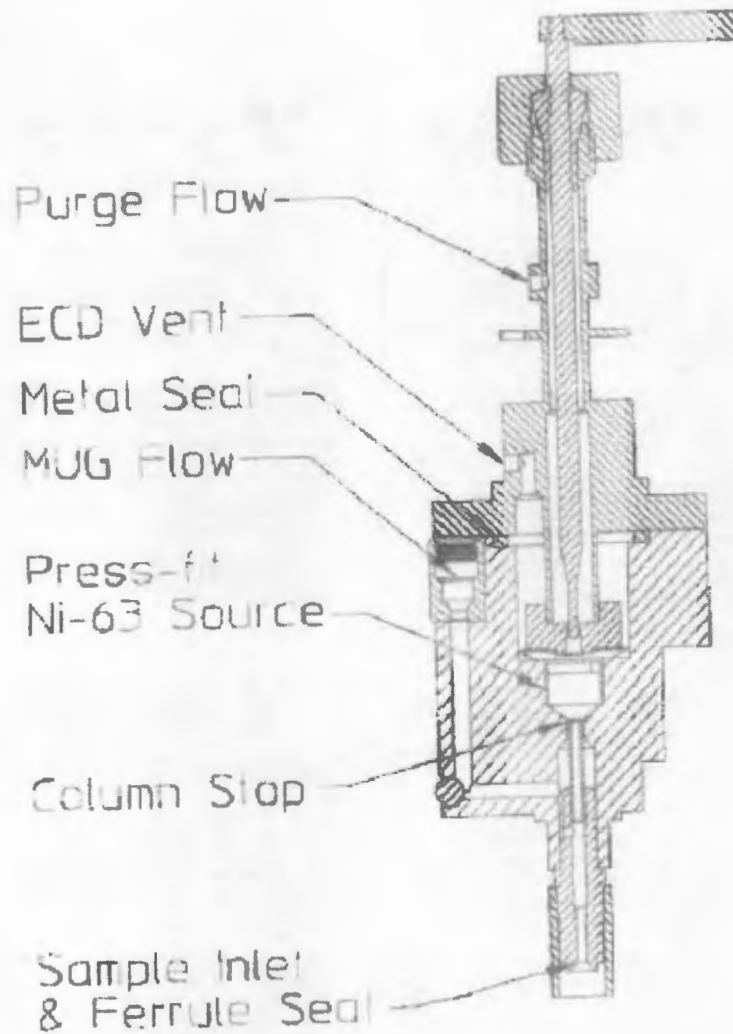
Models G2397A, G2398A, G2404A, G2405A

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

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ATTACHMENT 4 of 5






Model G4597A, G4598A




REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A DEVICE
(AMENDED IN ITS ENTIRETY)
(CORRECTED PAGE ATTACHMENT 5 - JUNE 4, 2015)

NO.: NR-0348-D-111-B




DATE: May 14, 2015

ATTACHMENT 5 of 5

 CAUTION RADIOACTIVE MATERIAL 555 MEGABECQUERELS/ 15 MILLICURIES OF NICKEL-63 G2397A ELECTRON CAPTURE DETECTOR	
<small>SERIAL NO</small>	<small>DATE</small>
 Agilent Technologies	
<p> SEE THE GC AND ECD MANUALS BEFORE OPERATING OR SERVICING THIS DEVICE.</p> <p>THIS DEVICE MUST BE WIPED (RADIOACTIVE LEAK) TESTED AT INTERVALS NOT GREATER THAN SIX MONTHS.</p> <p>THE RECEIPT, POSSESSION, USE AND TRANSFER OF THIS DEVICE ARE SUBJECT TO A GENERAL LICENSE OR THE EQUIVALENT, AND THE REGULATIONS OF THE U.S. NRC OR OF A STATE WITH WHICH THE NRC HAS ENTERED INTO AN AGREEMENT FOR THE EXERCISE OF REGULATORY AUTHORITY. OUTSIDE U.S., CONSULT THE APPROPRIATE AGENCIES TO DETERMINE THE EQUIVALENT REGULATIONS.</p> <p>THE LABEL SHALL BE MAINTAINED ON THIS DEVICE IN A LEGIBLE CONDITION. REMOVAL OF THIS LABEL IS PROHIBITED.</p> <p style="text-align: right;"><small>MADE IN CHINA</small></p>	

 CAUTION RADIOACTIVE MATERIAL 555 MEGABECQUERELS/ 15 MILLICURIES OF NICKEL-63 G2398A ELECTRON CAPTURE DETECTOR	
<small>SERIAL NO</small>	<small>DATE</small>
 Agilent Technologies	
<p> SEE THE GC AND ECD MANUALS BEFORE OPERATING OR SERVICING THIS DEVICE.</p> <p>THIS DEVICE MUST BE WIPED (RADIOACTIVE LEAK) TESTED AT INTERVALS NOT GREATER THAN SIX MONTHS.</p> <p>THE RECEIPT, POSSESSION, USE AND TRANSFER OF THIS DEVICE ARE SUBJECT TO A GENERAL LICENSE OR THE EQUIVALENT, AND THE REGULATIONS OF THE U.S. NRC OR OF A STATE WITH WHICH THE NRC HAS ENTERED INTO AN AGREEMENT FOR THE EXERCISE OF REGULATORY AUTHORITY. OUTSIDE U.S., CONSULT THE APPROPRIATE AGENCIES TO DETERMINE THE EQUIVALENT REGULATIONS.</p> <p>THE LABEL SHALL BE MAINTAINED ON THIS DEVICE IN A LEGIBLE CONDITION. REMOVAL OF THIS LABEL IS PROHIBITED.</p> <p style="text-align: right;"><small>MADE IN CHINA</small></p>	

 CAUTION RADIOACTIVE MATERIAL 555 MEGABECQUERELS/ 15 MILLICURIES OF NICKEL-63 G4597A ELECTRON CAPTURE DETECTOR	
<small>SERIAL NO</small>	<small>DATE</small>
 Agilent Technologies	
<p> SEE THE GC AND ECD MANUALS BEFORE OPERATING OR SERVICING THIS DEVICE.</p> <p>THIS DEVICE MUST BE WIPED (RADIOACTIVE LEAK) TESTED AT INTERVALS NOT GREATER THAN SIX MONTHS.</p> <p>THE RECEIPT, POSSESSION, USE AND TRANSFER OF THIS DEVICE ARE SUBJECT TO A GENERAL LICENSE OR THE EQUIVALENT, AND THE REGULATIONS OF THE U.S. NRC OR OF A STATE WITH WHICH THE NRC HAS ENTERED INTO AN AGREEMENT FOR THE EXERCISE OF REGULATORY AUTHORITY. OUTSIDE U.S., CONSULT THE APPROPRIATE AGENCIES TO DETERMINE THE EQUIVALENT REGULATIONS.</p> <p>THE LABEL SHALL BE MAINTAINED ON THIS DEVICE IN A LEGIBLE CONDITION. REMOVAL OF THIS LABEL IS PROHIBITED.</p> <p style="text-align: right;"><small>MADE IN CHINA</small></p>	

 CAUTION RADIOACTIVE MATERIAL 555 MEGABECQUERELS/ 15 MILLICURIES OF NICKEL-63 G4598A ELECTRON CAPTURE DETECTOR	
<small>SERIAL NO</small>	<small>DATE</small>
 Agilent Technologies	
<p> SEE THE GC AND ECD MANUALS BEFORE OPERATING OR SERVICING THIS DEVICE.</p> <p>THIS DEVICE MUST BE WIPED (RADIOACTIVE LEAK) TESTED AT INTERVALS NOT GREATER THAN SIX MONTHS.</p> <p>THE RECEIPT, POSSESSION, USE AND TRANSFER OF THIS DEVICE ARE SUBJECT TO A GENERAL LICENSE OR THE EQUIVALENT, AND THE REGULATIONS OF THE U.S. NRC OR OF A STATE WITH WHICH THE NRC HAS ENTERED INTO AN AGREEMENT FOR THE EXERCISE OF REGULATORY AUTHORITY. OUTSIDE U.S., CONSULT THE APPROPRIATE AGENCIES TO DETERMINE THE EQUIVALENT REGULATIONS.</p> <p>THE LABEL SHALL BE MAINTAINED ON THIS DEVICE IN A LEGIBLE CONDITION. REMOVAL OF THIS LABEL IS PROHIBITED.</p> <p style="text-align: right;"><small>MADE IN CHINA</small></p>	

Example of Labels

Non-Agreement State	Event Number: 52312
Rep Org: AGILENT Licensee: AGILENT Region: 1 City: WILMINGTON State: DE County: License #: 07-28762-01 Agreement: N Docket: NRC Notified By: DAVID BENNETT HQ OPS Officer: MARK ABRAMOVITZ	Notification Date: 10/21/2016 Notification Time: 08:28 [ET] Event Date: 09/21/2016 Event Time: [EDT] Last Update Date: 10/21/2016
Emergency Class: NON EMERGENCY 10 CFR Section: 20.2201(a)(1)(ii) - LOST/STOLEN LNM>10X	Person (Organization): CHRISTOPHER CAHILL (R1DO) NMSS_EVENTS_NOTIFICA (EMAI)

This material event contains a "Less than Cat 3 " level of radioactive material.

Event Text

LOST ELECTRON CAPTURE DEVICE

Four electron capture detectors (ECDs) were shipped at the same time from Shanghai to Wilmington, DE. The ECDs were shipped by air freight and three of the ECDs arrived at the beginning of October. The remaining ECD has not arrived and a search is ongoing.

Source: Ni-63, 15 mCi fully encapsulated

THIS MATERIAL EVENT CONTAINS A "LESS THAN CAT 3" LEVEL OF RADIOACTIVE MATERIAL

Sources that are "Less than IAEA Category 3 sources," are either sources that are very unlikely to cause permanent injury to individuals or contain a very small amount of radioactive material that would not cause any permanent injury. Some of these sources, such as moisture density gauges or thickness gauges that are Category 4, the amount of unshielded radioactive material, if not safely managed or securely protected, could possibly - although it is unlikely - temporarily injure someone who handled it or were otherwise in contact with it, or who were close to it for a period of many weeks. For additional information go to http://www-pub.iaea.org/MTCD/publications/PDF/Pub1227_web.pdf