

**Agilent Technologies**

2850 Centerville Road
Wilmington, DE 19808

Br. 2

May 18, 2015

Director
U.S. Nuclear Regulatory Commission
Region 1
2100 Renaissance Blvd, Suite 100
King of Prussia, PA 19406-2713

03032988

Re: Amendment request for license 07-28762-02G

03032988

Dear Sir or Madam,

Agilent Technologies, Inc. is introducing two new Electron Capture Detector models and requests the information below be added to line 11 of the referenced distribution license. Agilent submitted an application to add the two new model numbers to its Sealed Source & Device Registry (SS&D) on January 15, 2015 and that registry was amended on May 14, 2015 (copy enclosed).

Device Model Number	Isotope	Source Model Number	Maximum Activity Per Source
Model G4597A Detector Cell	Nickel 63	NER-004 P	15 millicuries
Model G4598A Detector Cell	Nickel 63	NER-004 P	15 millicuries

Please contact me as shown below if you have any questions associated with this amendment request or David Bennett (RSO) at 302-636-8262 if you have any technical questions.

Sincerely,

David Hoppy, CHMM, CDGP
EHS Manager, Eastern Region
2850 Centerville Road
Wilmington, DE 19808
302-636-3757 (T)
302-636-3904 (FAX)
David_hoppy@agilent.com

586996

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

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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

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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.

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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.

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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.

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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.

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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.

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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.

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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.

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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.

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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.

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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/

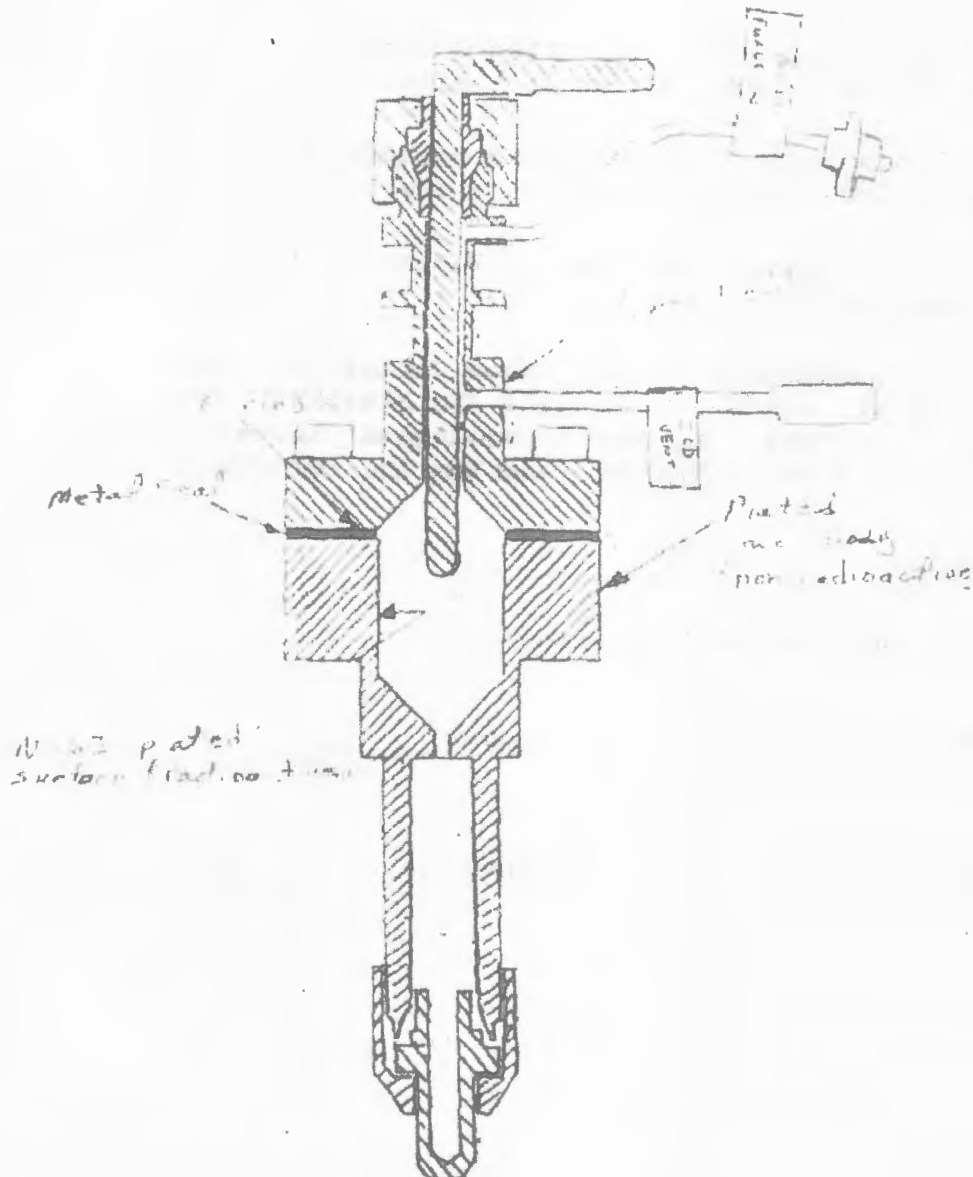
Tomas Herrera

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ATTACHMENT 1 of 5



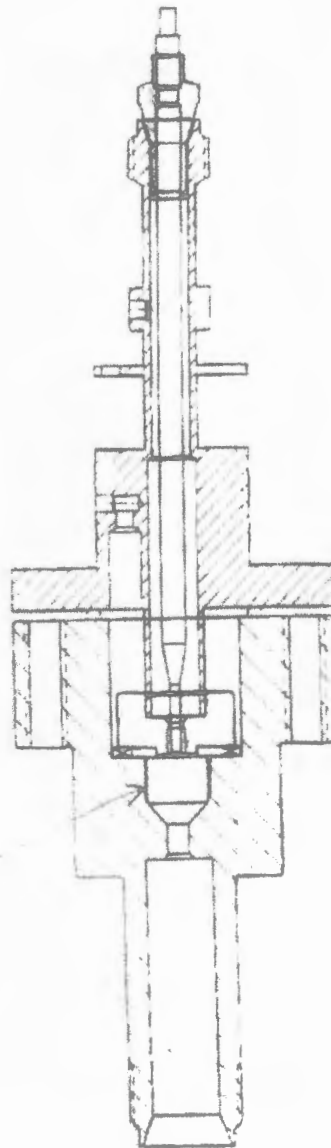
Models G1223A, G1533A, G2310A, G2330A, G1224A, and G1536A

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ATTACHMENT 2 of 5



Models G2397A, G2398A, G2404A, and G2405A

**REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF A DEVICE
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ATTACHMENT 3 of 5

BETA SHALLOW DOSE RATE REPORT



BETA SHALLOW DOSE RATE



BETA DEEP DOSE RATE

NOTES

- Source used: Ni-63, 1.1 Ci, 1.1 g, 1.1 mm diameter
- Beta dose rate measurements are performed with standard
type L film badges having 1 milligram/square centimeter filter.
Minimum detectable dose rate is 0.1 mR/hr.
- Gamma dose rate measurements are performed with standard
type L film badges having 300 milligram/square centimeter filter.
Minimum detectable dose rate is 0.1 mR/hr.

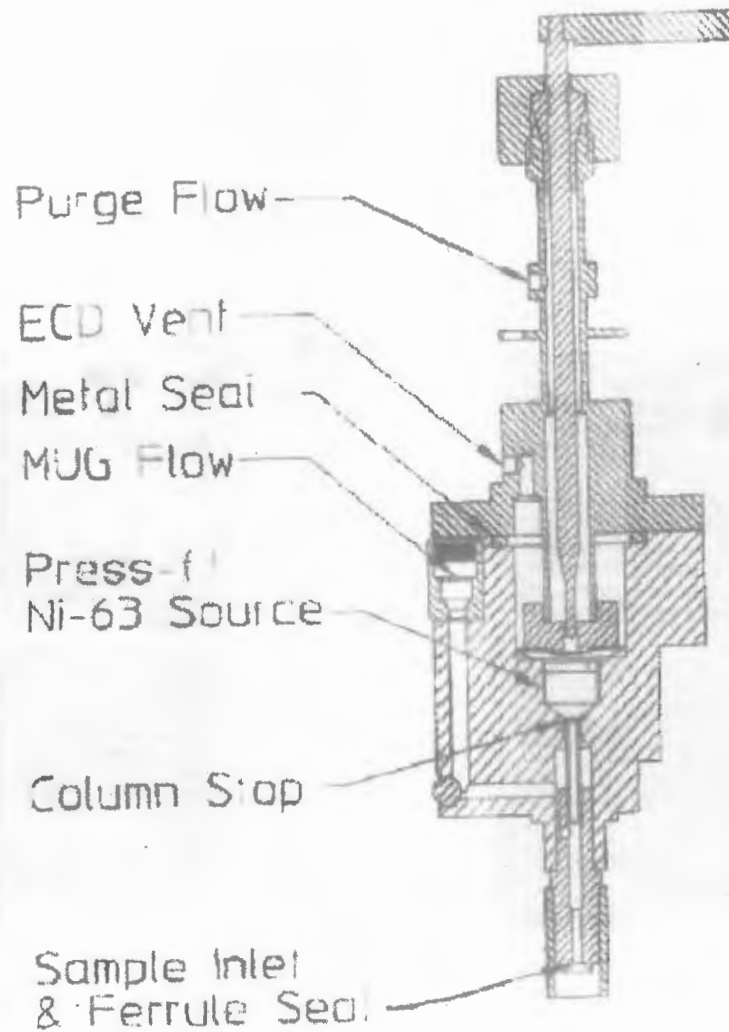
Models G2397A, G2398A, G2404A, G2405A

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Model G4597A, G4598A

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ATTACHMENT 5 of 5



Example of Labels

This is to acknowledge the receipt of your letter application dated

5/18/15, and to inform you that the initial processing which includes an administrative review has been performed.

☒ Amendment (07-28762-026)
There were no administrative omissions. Your application was assigned to a technical reviewer. Please note that the technical review may identify additional omissions or require additional information.

☐ Please provide to this office within 30 days of your receipt of this card

A copy of your action has been forwarded to our License Fee & Accounts Receivable Branch, who will contact you separately if there is a fee issue involved.

Your action has been assigned **Mail Control Number** 586996.
When calling to inquire about this action, please refer to this control number.
You may call us on (610) 337-5398, or 337-5260.