

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

NO.: NR-348-D-111-B

DATE: July 26, 1996

PAGE 1 OF 8

DEVICE TYPE: Electron Capture Detector

MODELS: G1223A, G1533A, G2310A, G2330A, G2397A, G2398A, G2404A,  
and G2405A (Generally Licensed)  
G1224A, G1536A (Specifically Licensed)

MANUFACTURER/DISTRIBUTOR: Hewlett-Packard Company  
Little Falls Site  
2850 Centerville Road  
Wilmington, DE 19808

SEALED SOURCE MODEL DESIGNATION: Amersham Corporation Model NBCD  
DuPont Merck Pharmaceutical  
Model NER-004P

ISOTOPE:

Nickel-63

MAXIMUM ACTIVITY:

15 millicuries (0.56 GBq)  
(G1223A, G1533A, G1224A, G1536A,  
G2397A, G2398A, G2404A, G2405A)

5 millicuries (185 MBq)  
(G2310A, 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 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 Hewlett-Packard Model 5890 Series gas chromatographs.

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 Hewlett-Packard 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.
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 Hewlett-Packard's distributed ECDs will be used.

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DEVICE TYPE: Electron Capture Detector

DESCRIPTION (con't):

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 nickel-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 manufacturer'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 Hewlett-Packard 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 5mCi of Ni-63. The sources will be plated in the same manner as those in the Models G1533A and G1223A.

Models G2397A, G2398A, G2404A, and G2405A are almost identical to the ECD's described above. These ECDs still contain up to 15 mCi of Ni63, 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 upper body then attaches to the lower body with the same tamper-proof screws used in all Hewlett Packard 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.

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DEVICE TYPE: Electron Capture Detector

LABELING:

Each cell 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 manufacturer name and logo. Additionally, for the Models used by general licensees, the plate contains the labeling requirements of Section 32.51, and refers the user to an instruction manual that tells them not to open or chemically clean the cell.

DIAGRAM:

See attachments 1, 2 and 3

CONDITIONS OF NORMAL USE:

Each ECD is designed to be used in conjunction with gas chromatographs in analytical laboratories. Each ECD will be used in laboratory environs 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).

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 Nickel-63 in carrier gas during normal use.
- Loss of Nickel-63 from detector is all heat control systems fail.
- Loss of Nickel-63 during solvent cleaning of the detector.
- Loss of Nickel-63 at abnormality high temperatures (625°C [1157°F] and 800°C [1472°F]).

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DEVICE TYPE: Electron Capture Detector

PROTOTYPE TESTING (con't):

The ECD's met the above tests and exceeded the minimum ANSI N542 classification of 77C32211 for ion generators, chromatography.

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

EXTERNAL RADIATION LEVELS:

The manufacturer has reported that radiation levels on all accessible surfaces do not exceed background levels for measurements taken from a detector with 15 millicuries of Ni-63. Attachment 3 is a dose rate report showing dose rate from an opened detector cell.

QUALITY ASSURANCE AND CONTROL:

The following tests are performed on each detector cell by the manufacturer prior to shipment:

- A visual inspection of the area of radioactive plating using a stereo-optic microscope.
- Measurements of the radioactivity levels by use of ionization current.
- Wipe tests of the non-radioactive surfaces to ensure non-contamination.

A copy of the Hewlett-Packard's Quality Manual is on file with the NRC.



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DEVICE TYPE: Electron Capture Detector

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 microcurie(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.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

Hewlett-Packard 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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DEVICE TYPE: Electron Capture Detector

SAFETY ANALYSIS SUMMARY (con't):

- 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 chart:

<u>PART OF BODY</u>	<u>DOSE</u>
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.

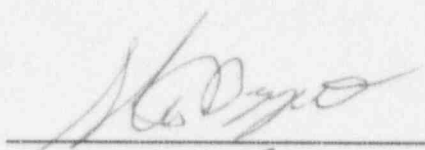
- Hewlett-Packard's letter dated June 19, 1996, May 6, 1996, April 9, 1996, August 4, 1995, and June 8, 1994, with enclosures thereto.
- Hewlett-Packard's letters dated January 30, 1990, February 2, 1990, May 9, 1990, September 17, 1990, October 3, 1990, and October 10, 1990, with enclosures thereto.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

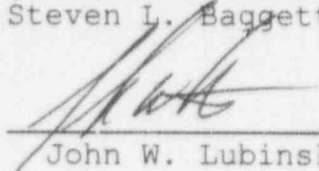
Date: July 26, 1996

Reviewer:

  
Steven L. Baggett

Date: July 26, 1996

Concurrence:

  
John W. Lubinski

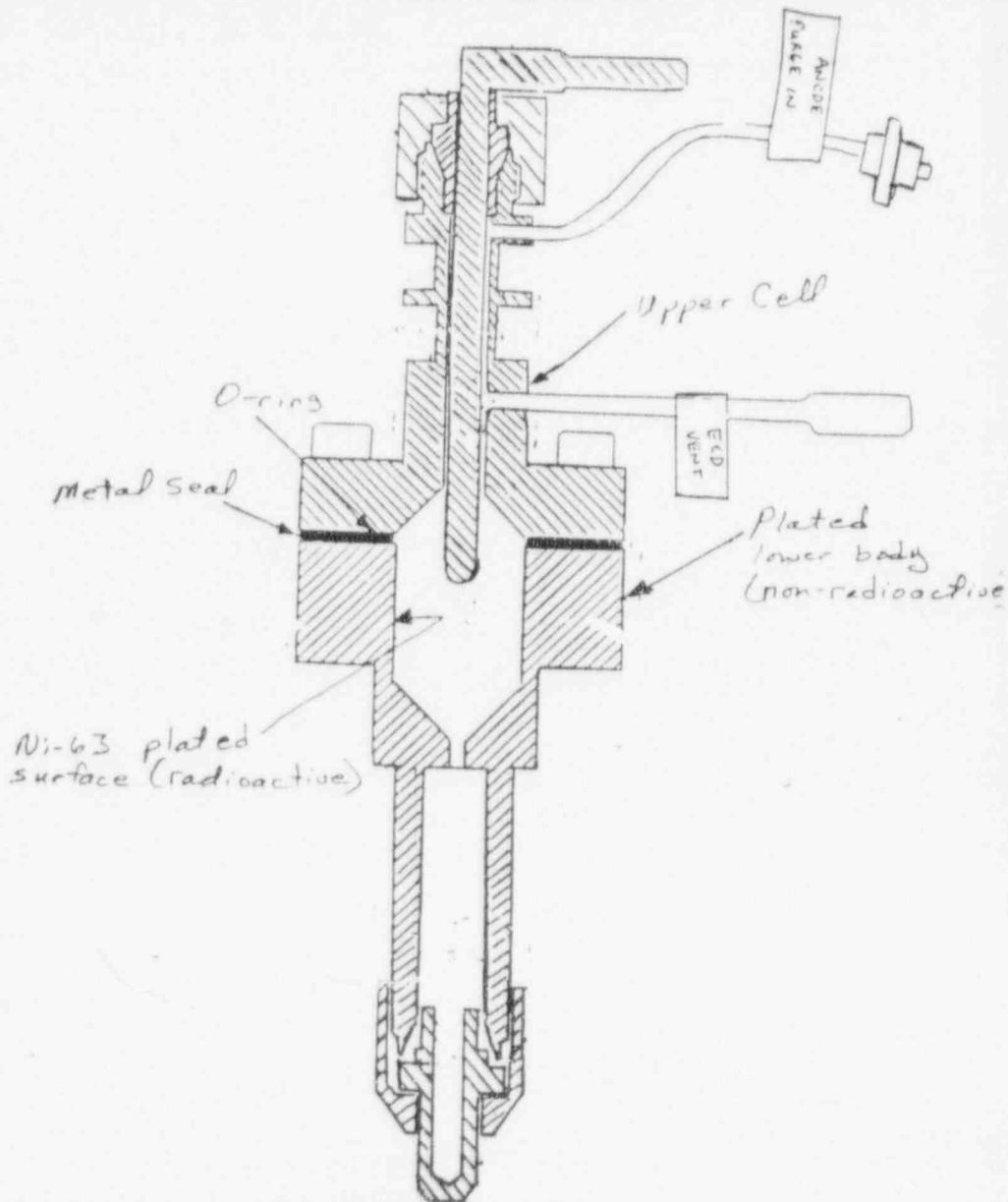


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ATTACHMENT 1

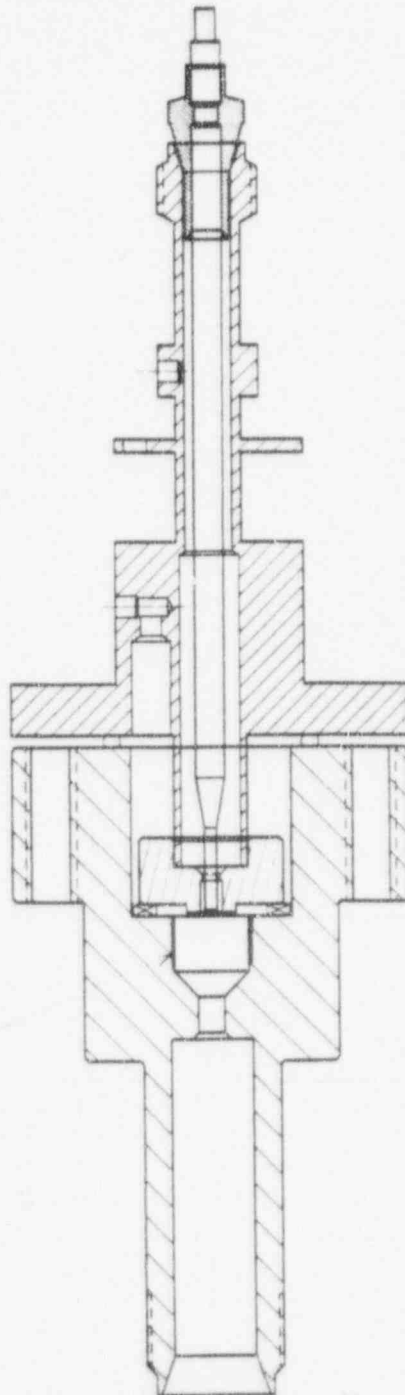


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ATTACHMENT 2



*Pressed in  
radioactive ring*

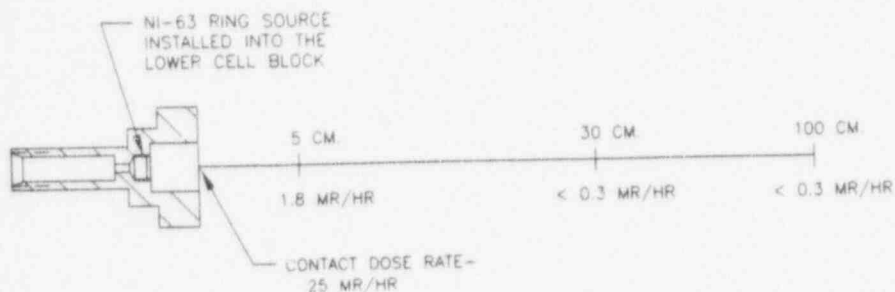
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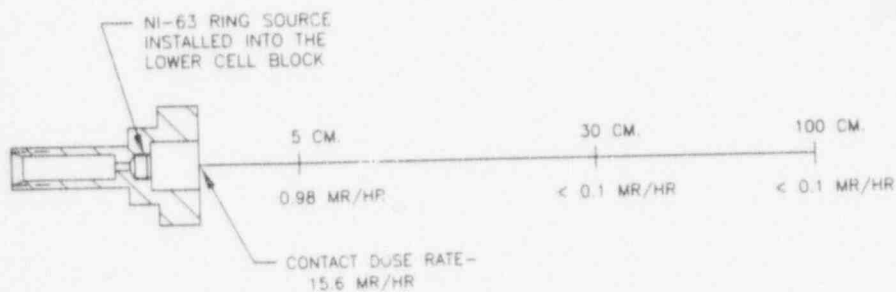
DATE: July 26, 1996

ATTACHMENT 3

NER-004P NI-63 RING SOURCE DOSE RATE REPORT



BETA (SHALLOW) DOSE RATES



GAMMA (DEEP) DOSE RATES

NOTES

1. Source used: NER-004P 15 mCi Ni-63 on 4/96.
2. Beta dose rate measurements are performed with 'Londauer' Type G film badges having 7 milligrams/square centimeter filter. Minimum detectable dose rate is 0.3 mR/hour.
3. Gamma dose rate measurements are performed with 'Londauer' Type G film badges having 300 milligrams/square centimeter filter. Minimum detectable dose rate is 0.1 mR/hour.

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DEVICE TYPE: Electron Capture Detector

MODELS: G1223A, G1533A, G2310A, G2330A, G2397A, G2398A, G2404A,  
and G2405A (Generally Licensed)  
G1224A, G1536A (Specifically Licensed)

MANUFACTURER/DISTRIBUTOR: Hewlett-Packard Company  
Little Falls Site  
2850 Centerville Road  
Wilmington, DE 19808

SEALED SOURCE MODEL DESIGNATION: Amersham Corporation Model NBCD  
DuPont Merck Pharmaceutical  
Model NER-004P

ISOTOPE:

Nickel-63

MAXIMUM ACTIVITY:

15 millicuries (0.56 GBq)  
(G1223A, G1533A, G1224A, G1536A,  
G2397A, G2398A, G2404A, G2405A)

5 millicuries (185 MBq)  
(G2310A, G2330A)

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: (N) Ion Generator, Chromatography

CUSTOM DEVICE: \_\_\_\_\_ YES \_\_\_\_\_ X \_\_\_\_\_ NO

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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 Hewlett-Packard 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.
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 Hewlett-Packard's distributed ECDs will be used.

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DEVICE TYPE: Electron Capture Detector

DESCRIPTION (con't):

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 nickel-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 manufacturer'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 Hewlett-Packard 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 5mCi of Ni-63. The sources will be plated in the same manner as those in the Models G1533A and G1223A.

Models G2397A, G2398A, G2404A, and G2405A are almost identical to the ECD's described above. These ECDs still contain up to 15 mCi of Ni63, 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 upper body then attaches to the lower body with the same tamper-proof screws used in all Hewlett Packard 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.



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DEVICE TYPE: Electron Capture Detector

LABELING:

Each cell 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 manufacturer name and logo. Additionally, for the Models used by general licensees, the plate contains the labeling requirements of Section 32.51, and refers the user to an instruction manual that tells them not to open or chemically clean the cell.

DIAGRAM:

See attachments 1, 2 and 3

CONDITIONS OF NORMAL USE:

Each ECD is designed to be used in conjunction with gas chromatographs in analytical laboratories. Each ECD will be used in laboratory environs 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).

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 Nickel-63 in carrier gas during normal use.
- Loss of Nickel-63 from detector is all heat control systems fail.
- Loss of Nickel-63 during solvent cleaning of the detector.
- Loss of Nickel-63 at abnormality high temperatures (625°C [1157°F] and 800°C [1472°F]).

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PROTOTYPE TESTING (con't):

The ECD's met the above tests and exceeded the minimum ANSI N542 classification of 77C32211 for ion generators, chromatography.

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

EXTERNAL RADIATION LEVELS:

The manufacturer has reported that radiation levels on all accessible surfaces do not exceed background levels for measurements taken from a detector with 15 millicuries of Ni-63. Attachment 3 is a dose rate report showing dose rate from an opened detector cell.

QUALITY ASSURANCE AND CONTROL:

The following tests are performed on each detector cell by the manufacturer prior to shipment:

- A visual inspection of the area of radioactive plating using a stereo-optic microscope.
- Measurements of the radioactivity levels by use of ionization current.
- Wipe tests of the non-radioactive surfaces to ensure non-contamination.

A copy of the Hewlett-Packard's Quality Manual is on file with the NRC.

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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 microcurie(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.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

Hewlett-Packard 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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DEVICE TYPE: Electron Capture Detector

SAFETY ANALYSIS SUMMARY (con't):

- 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 chart:

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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REFERENCES:

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- Hewlett-Packard's letter dated June 19, 1996, May 6, 1996, April 9, 1996, August 4, 1995, and June 8, 1994, with enclosures thereto.
- Hewlett-Packard's letters dated January 30, 1990, February 2, 1990, May 9, 1990, September 17, 1990, October 3, 1990, and October 10, 1990, with enclosures thereto.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

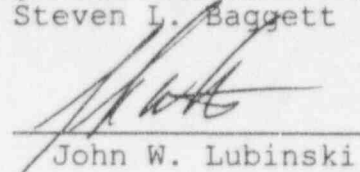
Date: July 26, 1996

Reviewer:

  
Steven L. Baggett

Date: July 26, 1996

Concurrence:

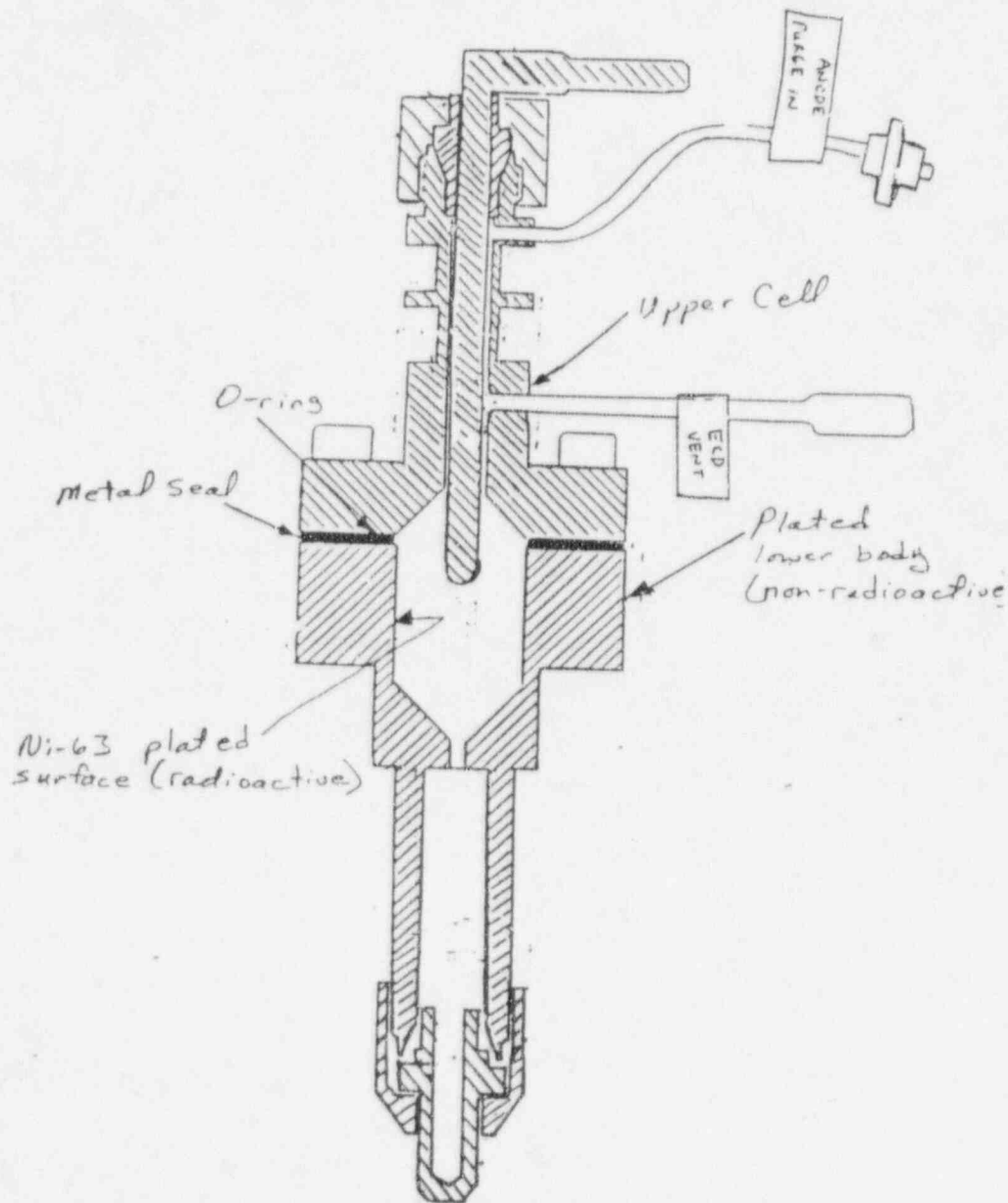
  
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ATTACHMENT 1





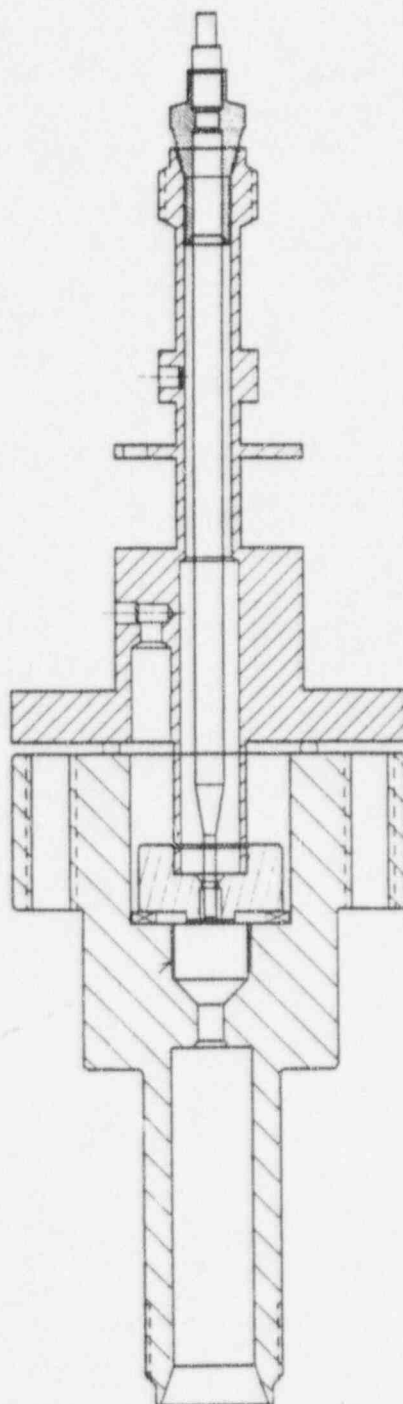
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
(AMENDED IN ITS ENTIRETY)

NO.: NR-348-D-111-B

DATE: July 26, 1996

ATTACHMENT 2

*Pressed in  
radioactive ring*



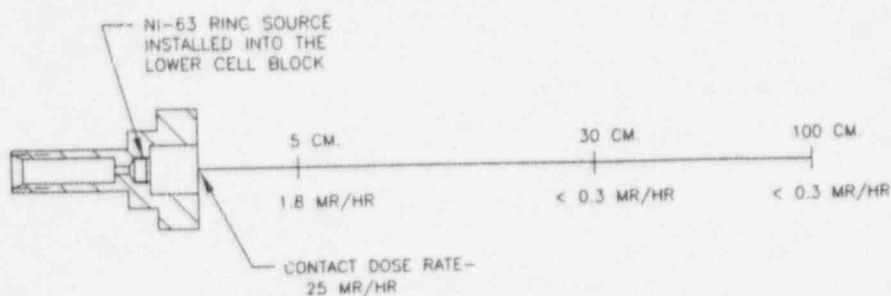
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
(AMENDED IN ITS ENTIRETY)

NO.: NR-348-D-111-B

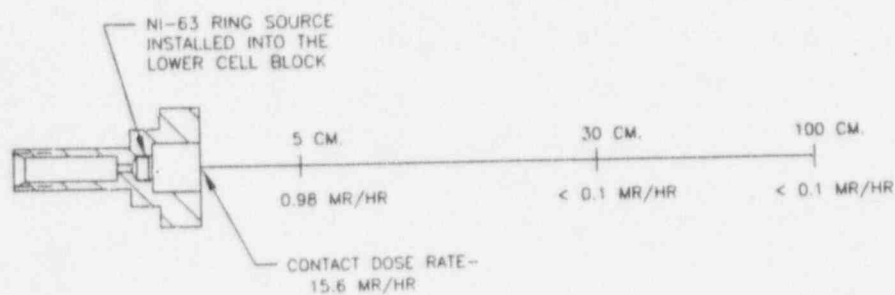
DATE: July 26, 1996

ATTACHMENT 3

NER-004P NI-63 RING SOURCE DOSE RATE REPORT



BETA (SHALLOW) DOSE RATES



GAMMA (DEEP) DOSE RATES

NOTES

1. Source used: NER-004P 15 mCi Ni-63 on 4/96.
2. Beta dose rate measurements are performed with 'Landauer' Type G film badges having 7 milligrams/square centimeter filter. Minimum detectable dose rate is 0.3 mR/hour.
3. Gamma dose rate measurements are performed with 'Landauer' Type G film badges having 300 milligrams/square centimeter filter. Minimum detectable dose rate is 0.1 mR/hour.

**FAX Transmission**

From: Brian Donnelly  
Phone Number: (302) 633-8120  
To: Mr. Steve Baggett  
Date: June 19, 1996

Hewlett Packard Company  
2850 Centerville Rd.  
Wilmington, DE 19808  
NRC  
2 pages transmitted  
(including this one)

SUBJECT: Assignment Number 96-19

Dear Mr. Baggett,

Thank you for your reply and we greatly appreciate any priority you can provide to complete this project as soon as possible.

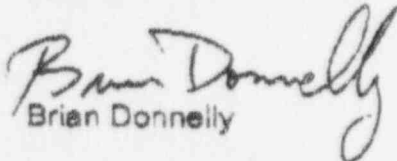
In answer to your question regarding possible scrape-off contamination during the press fit process of the Ni63 plated cylinder. The Nickel is a medium-hard electroplate and the wall thickness of the cylinder is thin enough so that it partially collapses to conform to the shape and size of the cavity of the lower body of the ECD (Electron Capture Detector). This flexibility of the cylinder should provide very little surface friction, which should prevent all but insignificant amounts of scrape-off.

The cylinders are manufactured by Dupont Merck Radiopharmaceuticals of North Billerica, MA, and they also insert the cylinders into the lower body of the ECDs. After they complete the insertion of the cylinders a wipe test (smear test) is performed on all inactive surfaces and the contamination shall not exceed 0.0006uCi.

I hope this is sufficient, but should you or your staff require any additional information, please do not hesitate to contact me at (302)633-8120.

Thank you for your assistance in these matters.

Best Regards,

  
Brian Donnelly