

 **Agilent Technologies**  
Innovating the HP Way  
2850 Centerville Road  
Wilmington, DE 19808

Michelle Burgess  
Materials Safety and Inspection branch,  
Division of Industrial and  
Medical Nuclear Safety  
Office of Nuclear Material Safety  
and Safeguards  
Washington, DC 20555-0001

September 4, 2001

Re: Response to request for additional information

Dear Ms Burgess,

To date, following are responses to your letter requesting further information for our amendment request dated March 5, 2001. The responses are numbered to match the numbers of the items in your letter. Further responses will be sent under separate cover letter.

Identify

2. Please provide full corporate name and address for all source manufacturers.

Response:

Source manufacturers are:

- AEA Technology QSA Inc. (previously Amersham Corp.)  
Headquartered at:  
40 North Ave.  
Burlington, MA 01803

Manufactured at:  
AEA Technology QSA GmbH  
Amersham Buchler Site  
Gieselweg 1  
Braunschweig

D-38110, Germany  
ISO 9001

- Isotope Products Laboratory (previously manufactured by New England Nuclear)  
24937 Avenue Tibbits  
Valencia CA 91385

3. Verify that the changes, described in item 3 of your letter dated March 5, to the metal label attached to the ECD constitute only an addition to the information currently on the label, and that you are not removing any information from the label that was previously specified.

Response:

The request to add the web site is an addition only to current information on the label. No other change has been made to the text on the label.

4. In reviewing the background information for your products, we discovered that we can not locate a copy of Hewlett-Packard's September 9, 1980, letter referenced in registration certificate NR-0348-D-106-B. Please provide a full copy, including any attachments.

Response:

Our files do not include a copy of the letter. However, the letter was in reference to a model 19312 and there are some hand written corrections with note attached that may have been the topic of the letter. A copy is included with this response.

Please contact me at 302-633-8071, or the Radiation Safety Officer, David Bennett, at 302-633-8262 if you have any questions.

Very truly yours,



Tom Zunino  
Workplace Services Manager

NRC Letter 8\_31\_01 Information for amendment

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES  
SAFETY EVALUATION OF DEVICE  
(address change 6/1/93)

NO.: NR-348-D-107-S

DATE:

PAGE 1 OF 5

DEVICE TYPE: Gas Chromatography Detector Cell

MODEL: 19312

MANUFACTURER/DISTRIBUTOR: Hewlett-Packard  
Little Falls Site  
2850 Centerville Road  
Wilmington, DE 19808-1610

SEALED SOURCE MODEL DESIGNATION: New England Nuclear Plated  
Source  
Amersham Corp. Plated Source

ISOTOPE:

Nickel-63

MAXIMUM ACTIVITY:

15 millicuries (0.555 GBq)

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: (N) Ion Generators, Chromatography

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

CERTIFICATE OF REGISTRATION  
AND SAFETY ANALYSIS SUMMARY  
DEVICE

Manufacturer and Distributor

Hewlett Packard  
Avondale Division  
Route 41  
Avondale, PA 19311

Model Designation

Model 19312

Sealed Source

Plated Source in Detector Cell

Isotope and Activity

Nickel-63, 15 millicuries

Conditions of Normal Use

This device is designed to produce an ionized atmosphere for quantitative or qualitative measurement of elements in gas streams. This device is an integral component of a gas chromatograph and will be used in ambient laboratory conditions. Normally the detector cell temperature is not allowed to exceed 370° centigrade.

Ability of Device to Withstand Loss of Containment Under Abnormal Conditions (Fire, Explosion, etc.)

If all safety controls fail at one time the cell may reach temperatures of 600°C-660°C depending on line voltage, air circulation, etc. Under these conditions the Hewlett Packard data shows that the loss of nickel-63 would be less than 0.5 microcuries. In addition, wipes of external surfaces of the detector cell showed less than 0.005 microcuries of removable contamination.

## Device Description

Nickel-63 is plated on the interior of the stainless steel lower block assembly in an identical manner as used for Hewlett Packard Models 18803-60520 and 18713A. Also the dimensions of the Model 19312 cell cavity are identical to these models. The new design has two differences. The outer shape is somewhat different to allow fitting into a smaller space. Second, a different type of stainless steel (17-4 PH) has been used to provide better strength characteristics. The two sections of the detector cell are secured by tamper proof screws to prevent access to the source by unauthorized persons (see figure 1).

The photo illustrates the detector cell and warning label.

## Prototype Testing

The Model 19312 detector cell was subjected to and passed an acceptable series of tests described in Hewlett Packard letters dated 1979. (From data provided the detector cell exceeds ANSI 77C32211 Classification *which is recommended for detector cells in gas chromatography.*) *sep 9, 1980*

## External Radiation Levels

The external radiation levels at the surface of a fully assembled detector cell do not exceed ambient background levels when measured with a G-M survey meter. *To be used*

The unshielded contact dose as measured by New England Nuclear with thermoluminescent dosimeters is reported to be  $354 \pm 19$  mr/hr and the dose rate at 4.5 inches is 2 mr/hr.

## Quality Assurance and Control

The source manufacturer (New England Nuclear or Amersham Corporation) performs a "hot" and "cold" wipe test of the lower assembly of the electron capture detector prior to return to Hewlett Packard.

The following tests are performed by Hewlett Packard on each detector cell prior to shipment:

1. A careful visual inspection of the plated surface using a stereo microscope.
2. Measurement of the ionization current of the assembled detector cell.
3. Wipe test of the cell body, inlet, and outlet. These samples are analyzed with a Beckman Model LS 100C liquid scintillation counter.
4. A standard pesticide sample is analyzed with the gas chromatograph incorporating the electron capture detector to be shipped.

Limitations and/or Other Considerations of Use

1. The Model 19312 electron capture detector may be distributed to persons, either generally or specifically licensed by the NRC or Agreement States.

2. ~~Only persons specifically licensed by NRC or Agreement States may remove the detector cell from the gas chromatograph or perform cleaning of the disassembled cell.~~

3. The device shall be leak tested at six month intervals either by:

- a. Persons specifically licensed by NRC or an Agreement State or
- b. The General licensee in accordance with procedures described in Hewlett Packard letter dated September 9, 1980.

- 5 A. Detector cells shall be used with temperature control mechanisms to limit cell temperatures to 370°C.

- 6 B. Detector cells should be vented (for example fume hood).

*Both  
see indent*

4

Safety Evaluation Summary

Based on our review of the information and test data contained in references listed below, we conclude that the Hewlett Packard Model 19312 electron capture detector device can be safely used by persons not having training in radiological protection. Furthermore, under ordinary conditions of use the nickel-63 source contained in the Model 19312 device cannot be inadvertently removed and for either routine or emergency conditions of use it is unlikely that any person will receive external radiation dose or dose commitments in excess of the limits specified in Section 20.101(a), 10 CFR Part 20 and Section 32.24 of 10 CFR Part 32.

References

This safety review and registration of the Model 19312 detector cell is based on information contained in Hewlett Packard letter dated September 9, 1980.

*Lowen case*

Date \_\_\_\_\_

Reviewed By \_\_\_\_\_

Date \_\_\_\_\_

Concurrence \_\_\_\_\_

only persons . . . . . NRC . . . . .  
may perform maintenance or cleaning of

Persons specifically

D.K. 2. The Model 19312 may be installed or removed from the gas chromatograph by the general licensee using procedures described by HP in their ltr of Sep 9, 1980. This device may also be installed and removed from the gas chromatograph by persons specifically licensed by NRC or an agreement state.

D.K. 3. Cleaning, servicing and maintenance of ~~a~~ an opened model 19312 shall be performed only by persons specifically licensed by NRC or an agreement state.