



710 Bridgeport Ave.

Shelton, CT. 06484

Phone: 203 402-5219

Email: john.widomski@perkinelmer.com

April 23, 2003

USNRC
Material Safety & Inspection Branch
Division of Industrial & Medical Nuclear safety
Office of Nuclear Material Safety & Safeguards
Washington, D.C. 20555-0001

RE: /NR536D110B/

INACTIVE STATUS

PerkinElmer LAS, Inc., by this letter, notifies you that it wishes to inactivate the following device found in NR-536-D-110-B "Registry of Radioactive Sealed Sources and Devices"

Voyager

The following supportive information is submitted:

- By "Voyager" I am referring to the portable gas chromatograph contained in the registry. This gas product has been sold to **PHOTOVAC, Inc.**, 176 Second Ave, Waltham MA 02451-1166. PHOTOVAC, Inc. has registered the device with the Radiation Control Program of the Commonwealth of Massachusetts.
- Shipments of these units ended March 12, 2002 with the shipment of serial #FGKF302.
- Approximately 75 units were distributed to US customers; of these we estimate that up to 90%, 66 units, may still be in use today.
- Gas Chromatographs will continue to be serviced by the new owner, PHOTOVAC, Inc.
- At the time of transfer, no changes were made to the product since the last certificate amendment, April 7, 1997.
- The Voyager listed in the registry has not been manufactured or distributed after March 12, 2002.



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CORRECTIONS

PAGE 1

MODEL:

REMOVE Voyager

MANUFACTURER/DISTRIBUTOR:

PerkinElmer LAS, Inc.
710 Bridgeport Ave.
Shelton, CT. 06484

REMOVE THE FOLLOWING MANUFACTURER AND LOCATIONS

MANUFACTURER:

PE Photovac
330 Cochran Drive
Markham, Ontario
Canada L3R 8E5

PE Instruments Asia PTE
13-01 Peninsula Plaza
111 North Bridge Road
Singapore 0617
Republic of Singapore

PAGE 2 & 3

Under DESCRIPTION remove "Model Voyager" and succeeding descriptive paragraph

PAGE 3 & 4

Under LABELING remove "Model Voyager" and succeeding descriptive paragraphs

PAGE 4

Under DIAGRAM remove "2 and 3"

Under CONDITIONS OF NORMAL USE remove paragraphs 2 and 3.

PAGE 5

Under PROTOTYPE TESTING remove second paragraph "The model 200155...N542-1977."



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PAGE 6

Under QUALITY ASSURANCE AND CONTROL remove paragraph 1 "With respect to...by the NRC."

Under QUALITY ASSURANCE AND CONTROL paragraph 2, remove " , and that PE Instruments Asia PTE will manufacture all units in accordance with a current ISO-9001 or ISO-9002 program" from sentence 1.

PAGE 7

Under LIMITATIONS AND / OR CONSIDERATION OF USE remove "Reviewer Note ...model Voyager"

Under SAFETY ANALYSIS SUMMARY paragraph 1, remove the two words "and Voyager"

PAGE 8

Under SAFETY ANALYSIS SUMMARY paragraph 1, remove "Voyager"

Under SAFETY ANALYSIS SUMMARY remove paragraph 2.

ATTACHMENT 2 & 3

Remove both attachments 2 & 3

If you have further questions or need clarifications please contact me at (203) 402-5219.

Sincerely,

A handwritten signature in black ink, appearing to read 'J. Widomski', written over a large, stylized loop.

John Widomski
Radiation Safety Officer

Enclosed: 2 marked up copies of the current 0registration

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

NO: NR-536-D-110-B

DATE: MAR 1 1983

PAGE: 1 of 8

DEVICE TYPE: Detector Cell Assembly

MODEL: N610-0063, N610-0134, Voyager

MANUFACTURER/DISTRIBUTOR: ~~PerkinElmer Corporation~~ LAS, Inc
761 Main Avenue 710 BRIDGEPORT AVE
Norwalk, Connecticut 06859-0098 SHELTON, CT 06484

~~MANUFACTURER: PE Photovac
330 Cochran Drive
Markham, Ontario
Canada L3R 8E5~~

~~PE Instruments Asia PTE
13-01 Peninsula Plaza
111 North Bridge Road
Singapore 0617
Republic of Singapore~~

SEALED SOURCE MODEL DESIGNATION: Nuclear Radiation Development
Model N1001

New England Nuclear Corp.
Model NER-004

Amersham/Searle Corp.
Model NBC

ISOTOPE:

Nickel-63

MAXIMUM ACTIVITY:

15 mCi (0.56 GBq)

LEAK TEST FREQUENCY: 6 months

PRINCIPAL USE: (N) Ion Generators, Chromatography

CUSTOM SOURCE: _____ YES _____ X _____ NO

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

NO: NR-536-D-110-B

DATE: MAR 1 1999

PAGE: 2 of 8

DEVICE TYPE: Detector Cell Assembly

DESCRIPTION:

Models N610-0063 and N610-0134

Perkin-Elmer Autosystem Gas Chromatographs may contain an electron capture detector (ECD) of either Model N610-0063 or N610-0134. These ECDs consist of a heater, a temperature controlling mechanism, and a Nickel-63 foil situated in a cylindrical cavity (approximately 6 inches (15.2 cm) long) of a two piece 304 stainless steel detector body (approximately 3 x 1.5 inches (7.6 x 3.8 cm)). The sealed source foil for use in the cell assembly consists of a corrosion resistant metal foil substrate which has Nickel-63 electrolytically deposited on one side. The sources used in these models are manufactured by Nuclear Radiation Development, Inc. (Model N1001), Amersham/Searle Corporation (Model NBC), and New England Nuclear Corporation (Model NER-004). The two body parts are fixed together using four tamper resistant screws. Power to the heaters is interrupted when the temperature of the foil exceeds 470°C (878°F) by a microprocessor control in the circuitry.

An effluent transfer tube (anode) is located in line with the horizontally arranged source. At the cell (cathode) the carrier gas (methane/argon or nitrogen) contacts the cylindrically formed foil and exits through a small tube at the other end of the detector.

These cell assemblies are very similar to previously evaluated and registered Models L413-0128, L413-0127, N600-0030, and N600-0113. Models N610-0063 and N610-0134 are somewhat different mechanically to meet the needs of the new Autosystem gas chromatograph. The difference between Models N610-0063 and N610-0134 is the use of a 240 volt heater in Model N610-0134 instead of a 120 volt heater in Model N610-0063. The difference is required due to the 240 volt line found in the overseas market.

~~Model Voyager~~

~~The Model Voyager is a complete gas chromatograph system which contains an ECD. The Voyager is portable and is expected to be used in all environs and has dimensions of 5.73 x 10.5 x 15.4 inches (14.6 x 26.7 x 39.1 cm). The ECD is a Model 200155 cell assembly and is identical to the two models discussed above, except that it has been modified to allow for a different mounting in the Model Voyager. The sources used in the Voyager are manufactured by Nuclear Radiation Development, Inc. (Model N1001) or Amersham/Searle Corporation (Model NBC). The Model 200155 ECD is mounted in an aluminum box~~

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

NO: NR-536-D-110-B

DATE: MAR 11 1993

PAGE: 3 of 8

DEVICE TYPE: Detector Cell Assembly

DESCRIPTION: (Cont'd)

~~within the Voyager and is insulated with foam. The aluminum box has a lid which is held in place with 4 tamper resistant screws. The ECD can be accessed through a small port for leak testing.~~

LABELING:

Models N610-0063 and N610-0134

Each ECD is stamped with an individual serial number. An aluminum plate containing the radiation symbol, the statement "DANGER RADIOACTIVE MATERIAL," the isotope, activity, date of assay, and maximum operating temperature is affixed to the cell body. The cell area of each gas chromatograph bears a label marked with the standard radioactive symbol and the words "CAUTION - Radioactive Material."

The device is labeled in accordance with the requirements of 10 CFR 32.51, if generally licensed. The label is attached to the ECD cell assembly by a wire tether similar to the one used for previously evaluated and registered models. This type of label will only be applied to those devices that are generally licensed.

The device will be labeled in accordance with 10 CFR 20.1901 when distributed to persons specifically licensed. This label is also attached to the ECD cell assembly by a wire tether similar to that used on the generally licensed devices.

~~Model Voyager~~

~~The ECD in the Voyager is stamped with an individual serial number. An aluminum plate containing the radiation symbol, the statement "DANGER RADIOACTIVE MATERIAL," the isotope, activity, date of assay, and maximum operating temperature is affixed to the cell body. The access port to the aluminum box containing the ECD of each gas chromatograph bears a label marked with the standard radiation trefoil and the words "Electron Capture Detector, CAUTION - Detector contains radioactive material, Read user's manual before accessing." In addition, the lid of the aluminum box bears a label marked with the standard radiation trefoil and the words "CAUTION - Radioactive Material."~~

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

NO: NR-536-D-110-B

DATE: MAR 1993

PAGE: 4 of 8

DEVICE TYPE: Detector Cell Assembly

LABELING: (Cont'd)

~~The Voyager device is labeled in accordance with the requirements of 10 CFR 32.51, if generally licensed. The label is attached to the outside bottom cover of the device. This label will only be applied to those devices that are generally licensed.~~

~~The device will be labeled in accordance with 10 CFR 20.1901 when distributed to persons specifically licensed. This label is also attached to the outside bottom cover of the device.~~

DIAGRAM:

See Attachments 1, ~~2,~~ and ~~3.~~

CONDITIONS OF NORMAL USE:

ECD assemblies N610-0063 and N610-0134 are designed to produce ionized atmospheres for quantitative or qualitative measurement of elements in gas streams. They are components of the Perkin-Elmer Corporation's Gas Chromatographs Systems. The ECD will be used in laboratory environs by persons trained in the use of gas chromatograph equipment. The ECD will normally be operated at temperatures up to 460°C (860°F).

~~The Model Voyager device contains an ECD that is designed to produce an ionized atmosphere for quantitative or qualitative measurement of elements in gas streams. The Voyager is portable and will be used in field environs by persons trained in the use of gas chromatography equipment. The device will normally be operated at temperatures up to 80°C (176°F), but has a rated maximum temperature of 460°C (860°F). The ECD is equipped with safety features which prevent it from exceeding 135°C (275°F).~~

~~The expected working life of the Model Voyager is anticipated to be 10 or more years. The Ni-63 source nor radiological safety aspects are a limitation with respect to the working life.~~

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

NO: NR-536-D-110-B

DATE: MAR 11 1979

PAGE: 5 of 8

DEVICE TYPE: Detector Cell Assembly

PROTOTYPE TESTING:

Model N610-0063 and N610-0134 ECDs with sealed sources installed were tested to and met the minimum classification of C42211 for chromatography sources per ANSI N542-1977. In addition, the following tests were conducted:

- Pressure test to 30 psig
- Drop test from 1.5 meters
- Temperature tests to 600°C

~~The Model 200155 ECD used in the Model Voyager, with sealed sources installed, was tested to and met the minimum classification of 77C32211 for chromatography sources per ANSI N542-1977.~~

EXTERNAL RADIATION LEVELS:

Since the walls of the ECD cell are far in excess of the range of the maximum energy beta particles emitted from the contained source, surface readings on the ECD are not expected to exceed ambient background levels.

QUALITY ASSURANCE AND CONTROL:

The manufacturer has demonstrated an acceptable QA/QC program consisting of a 100 percent inspection of the ECD's as follows:

1. Cell closure seals are inspected for leakage by pressurizing blocked off cells with dry nitrogen at 30 psi.
2. Cell saturation current is measured to specified levels.
3. Each cell is baked out for two hours in a vacuum furnace 200°C (392°F) temperature and at air pressure of less than 0.07 mm (0.003 in) of mercury.
4. 100 percent wipe tested.
5. Functional test made on each cell.

Perkin-Elmer will manufacture all units in accordance with quality assurance and control programs as accepted by the NRC.

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

NO: NR-536-D-110-B

DATE: MAR 11 1993

PAGE: 6 of 8

DEVICE TYPE: Detector Cell Assembly

QUALITY ASSURANCE AND CONTROL: (Cont'd)

~~With respect to the Model Voyagers, Perkin-Elmer Corporation has committed to auditing the quality assurance and control program of PE Photovac and PE Instruments Asia PTE on a frequency of once every 12 months. This audit will encompass a review of all the systems specified in the detailed flowcharts included with the application for amendment of this registration certificate. A copy of the audit reports will be kept on file at Perkin-Elmer for review by the NRC.~~

Perkin-Elmer commits that they will manufacture and distribute all units in accordance with a current ISO-9001 program, ~~and that PE Instruments Asia PTE will manufacture all units in accordance with a current ISO-9001 or ISO-9002 program.~~ Certificates verifying current ISO certification will be kept on file at Perkin-Elmer for review by NRC.

LIMITATIONS AND/OR CONSIDERATION OF USE:

- These devices may be distributed to persons specifically licensed or generally licensed by the NRC or an Agreement State.
- Labeling of the device shall be in accordance with the requirements of 10 CFR 20.1901, when distributed to persons specifically licensed and in accordance with the requirements of 10 CFR 32.51, when distributed to persons generally licensed.
- These devices shall be leak tested at six month intervals either by:
 - a. Persons specifically licensed by the NRC or an Agreement State; or
 - b. The general licensee using a leak test kit and following the instructions supplied with the device.
- For Models N610-0063 and N610-0134, in lieu of using the conventional radiation caution colors (magenta or purple on yellow background) as specified in 10 CFR Part 20.1901, black anodized background with silver lettering and radiation symbol is authorized for use with the ECD labels.

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

NO: NR-536-D-110-B

DATE: MAR 11 1999

PAGE: 7 of 8

DEVICE TYPE: Detector Cell Assembly

LIMITATIONS AND/OR CONSIDERATION OF USE: (Cont'd)

- ~~Reviewer Note: The Ni-63 sources that may be used in the model Voyager are the Nuclear Radiation Development, Inc. model N1001 and Amersham/Searle Corporation model NBC. The New England Nuclear Corporation model NER-004 Ni-63 source is not approved for use in the model Voyager.~~
- 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 our review of the information and test data submitted by the references cited below, we continue to conclude that the N610-0063, N610-0134, ~~and Voyager~~ models are acceptable for distribution to persons who are either specifically or generally licensed. The manufacturer has submitted sufficient information to demonstrate that the safety criteria of Section 32.51 of 10 CFR Part 32 are met:

- Under ordinary conditions of handling, storage, and use of the device, the byproduct material contained in the device will not be release 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) of 10 CFR Part 20.
- Under accident conditions (such as fire and explosion) associated with handling, storage, and use of the source housing, it is unlikely that any person would receive an external radiation dose of dose commitment in excess of the dose to the appropriate organ as specified in the following table:

<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 average over areas no larger than 1 cm ² (0.15 in ²)	200 rem (2.0 Sv)
Other organs	50 rem (0.50 Sv)

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

NO: NR-536-D-110-B

DATE: MAR 11 1999

PAGE: 8 of 8

DEVICE TYPE: Detector Cell Assembly

SAFETY ANALYSIS SUMMARY: (Cont'd)

Furthermore, we continue to conclude the Models ~~Voyager~~, N610-0063 and N610-0134, would be expected to maintain their integrity for normal conditions of use and accidental conditions which might occur during uses specified in this registration certificate.

~~In this registration certificate, two ECDs are combined with a complete gas chromatograph device. The ECD in the model Voyager (200155) is sufficiently similar to models N610-0063 and N610-0134 to combine them in one registration certificate. The radiation safety evaluation results for the three ECDs are the same. In addition, all three model ECDs are manufactured by Perkin-Elmer Corporation under the same quality assurance and control program. The model 200155 ECD is incorporated into the model Voyager gas chromatograph by PE Photovac of Canada.~~

REFERENCES:

The following supporting documents for the detector cells are hereby incorporated by reference and are made a part of this registry document:

- Perkin-Elmer Corporation letters and facsimiles dated January 17, 1990, July 6, 1990, August 2, 1996, March 18, 1997, September 22, 1997, November 10, 1997, December 29, 1997, February 4, 1998, and February 19, 1999, with enclosures thereto.
- PE Photovac letters dated February 25, 1997, February 26, 1997, and March 18, 1997, with enclosures thereto, and facsimiles dated March 20, 1997, and April 2, 1997.

ISSUING AGENCY:

U.S. NUCLEAR REGULATORY COMMISSION

Date: MAR 11 1999

Reviewer: Michele L. Burgess
Michele L. Burgess

Date: MAR 11 1999

Reviewer: John W. Lubinski
John W. Lubinski

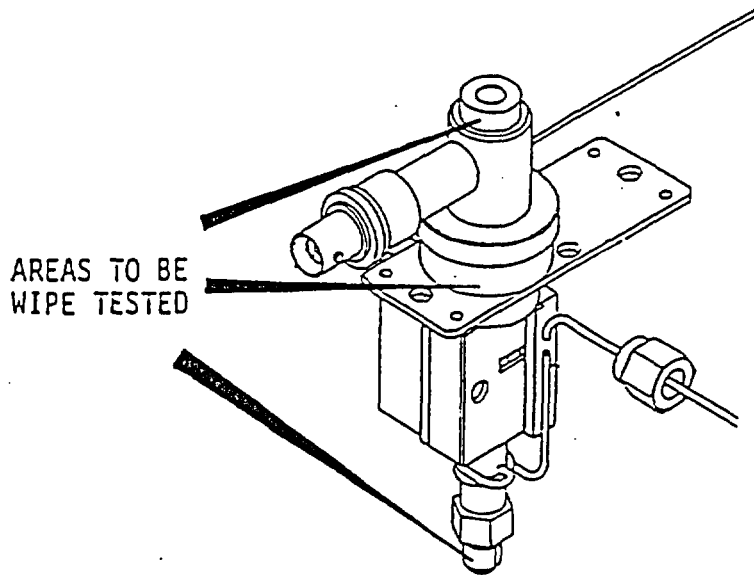
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO.: NR-536-D-110-B

DATE: MAR 1980

ATTACHMENT 1

Electron Capture Detector



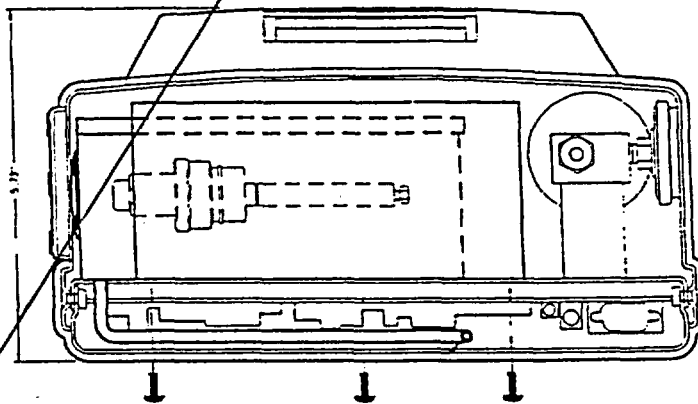
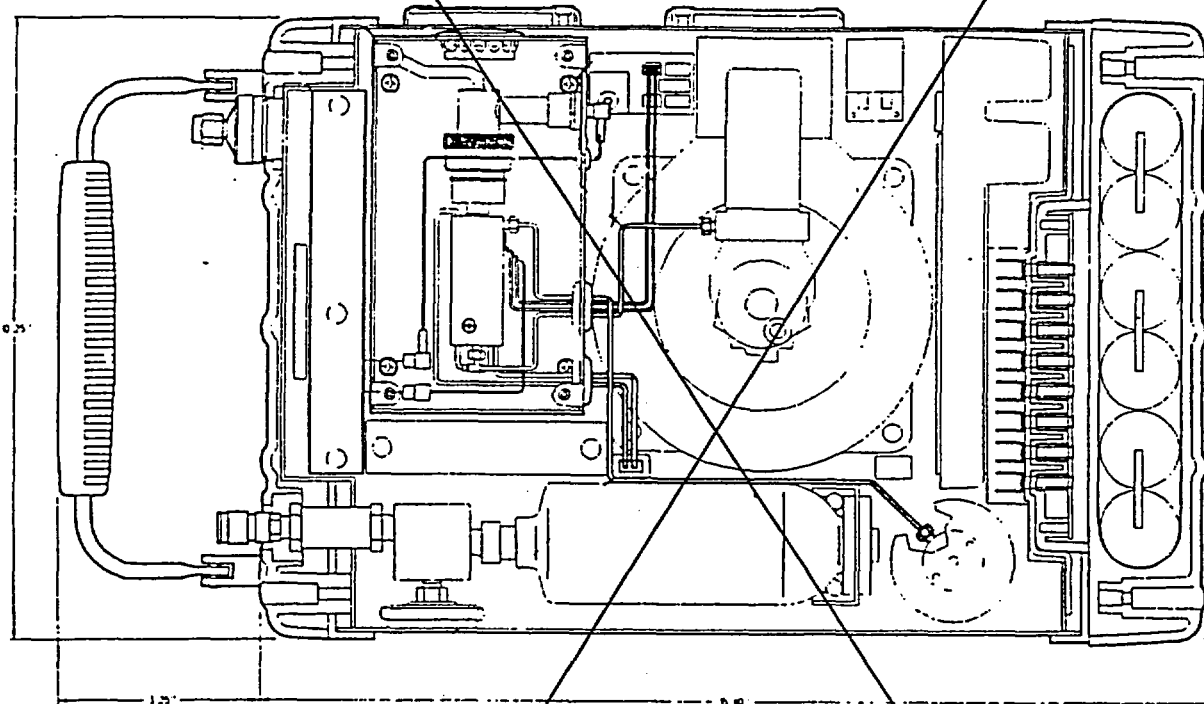
Models N610-0063 and N610-0134

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

NO.: NR-536-D-110-B DATE: 4/25 : ' 99

ATTACHMENT 2

Model Voyager ECD Module Assembly



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

NO.: NR-536-D-110-B

DATE: MAR 1962

ATTACHMENT 3

Model Voyager Gas Chromatograph

