

MATERIALS LICENSE

Amendment No. 05

Pursuant to the Atomic Energy Act of 1954, as amended, the Energy Reorganization Act of 1974 (Public Law 93-438), and Title 10, Code of Federal Regulations, Chapter I, Parts 30, 31, 32, 33, 34, 35, 36, 39, 40, and 70, and in reliance on statements and representations heretofore made by the licensee, a license is hereby issued authorizing the licensee to receive, acquire, possess, and transfer byproduct, source, and special nuclear material designated below; to use such material for the purpose(s) and at the place(s) designated below; to deliver or transfer such material to persons authorized to receive it in accordance with the regulations of the applicable Part(s). This license shall be deemed to contain the conditions specified in Section 183 of the Atomic Energy Act of 1954, as amended, and is subject to all applicable rules, regulations, and orders of the Nuclear Regulatory Commission now or hereafter in effect and to any conditions specified below.

Licensee		In accordance with the letter dated January 9, 1997,	
1. Perkin-Elmer Corporation		3. License Number 06-02135-12G is amended in its entirety to read as follows:	
2. 761 Main Avenue Norwalk, Connecticut 06859-0098		4. Expiration Date	April 30, 2003
		5. Docket or Reference No.	030-17474
6. Byproduct, Source, and/or Special Nuclear Material	7. Chemical and/or Physical Form	8. Maximum Amount that Licensee May Possess at Any One Time Under This License	
A. Nickel 63	A. As specified in Condition 11	A. Not applicable	
9. Authorized use			
A. Pursuant to 10 CFR 32.51, the licensee is authorized to distribute the devices containing sealed sources specified in Condition 11 of this license to persons generally licensed pursuant to 10 CFR 31.5, or equivalent provisions of the regulations of any Agreement State.			

CONDITIONS

10. The licensee may distribute material from 761 Main Avenue, Norwalk, Connecticut.
11. Each device distributed pursuant to the conditions of this license shall be in accordance with the following table:

Device Model Number	Isotope	Maximum Activity
Model 330-0119	Nickel 63	15 millicuries per foil
Model N600-0113 Assembly containing a Model N600-0204 detector cell	Nickel 63	15 millicuries per foil
Model L413-0128 Assembly containing a Model N600-0204 detector cell	Nickel 63	15 millicuries per foil

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PDR ADDOCK 03017474
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MATERIALS LICENSE
SUPPLEMENTARY SHEET

License Number

06-02135-12G

Docket or Reference Number

030-17474

Amendment No. 05

<u>Device Model Number</u>	<u>Isotope</u>	<u>Maximum Activity</u>
Model N610-0063 Detector Cell Assembly	Nickel 63	15 millicuries per foil
Model N610-0134 Detector Cell Assembly	Nickel 63	15 millicuries per foil
Model Voyager Detector Cell Assembly	Nickel 63	15 millicuries per foil

12. This license does not authorize possession or use of licensed material.
13. Except as specifically provided otherwise in this license, the licensee shall conduct its program in accordance with the statements, representations, and procedures contained in the documents, including any enclosures, listed below. The Nuclear Regulatory Commission's regulations shall govern unless the statements, representations, and procedures in the licensee's application and correspondence are more restrictive than the regulations.
- A. Application received March 28, 1980
 - B. Application dated December 16, 1980
 - C. Letter dated June 16, 1981
 - D. Application dated December 30, 1981
 - E. Letter dated April 2, 1982
 - F. Telegram dated April 16, 1982
 - G. Application dated June 9, 1986
 - H. Letter dated February 13, 1987
 - I. Letter dated February 17, 1987
 - J. Application dated January 17, 1990
 - K. Letter dated February 5, 1992
 - L. Letter dated January 9, 1997

For the U.S. Nuclear Regulatory Commission

ORIGINAL SIGNED BY:

JUDITH A. JOUSTRA

By

Division of Nuclear Materials Safety
Region I
King of Prussia, Pennsylvania 19406

Date

APR 21 1997

APR 21 1997

Mr. John Widomski
Radiation Safety Officer
Analytical Instruments Division
Perkin-Elmer Corporation
761 Main Avenue
Norwalk, Connecticut 06859

Dear Mr. Widomski:

This refers to your license amendment request. Enclosed with this letter is the amended license. Please note that as part of this amendment, in accordance with 10 CFR 30.36, effective February 15, 1996, the expiration date of your license has been extended by a period of five years. Your new expiration date is stated in Item 4 of the license.

Please review the enclosed document carefully and be sure that you understand and fully implement all the conditions incorporated into the amended license. If there are any errors or questions, please notify the U.S. Nuclear Regulatory Commission, Region I Office, Licensing Assistance Team, (610) 337-5093 or 5239, so that we can provide appropriate corrections and answers.

Thank you for your cooperation.

Sincerely,

ORIGINAL SIGNED BY:
JUDITH A. JOUSTRA

Judith A. Joustra
Division of Nuclear Materials Safety

License No. 06-02135-12G
Docket No. 030-17474
Control No. 124119

Enclosure:
Amendment No. 05

OFFICIAL RECORD COPY

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J. Widomski
Perkin-Elmer Corporation

-2-

DOCUMENT NAME: R:\WPS\MLTR\L0602135.12G

To receive a copy of this document, indicate in the box: "C" = Copy w/o attach/encl "E" = Copy w/ attach/encl "N" = No copy

OFFICE	DNMS/RI	<input checked="" type="checkbox"/> N	DNMS/RI	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NAME	JJoustra						
DATE	04/08/97	04/ /97	04/ /97	04/ /97			

OFFICIAL RECORD COPY

PERKIN ELMER

The Perkin-Elmer Corporation
761 Main Avenue
Norwalk, CT 06859-0001

030-17474

January 9, 1997

USNRC
475 Allendale Road
King of Prussia, PA 19406

RE: Materials License # 06-02135-08
Materials License # 06-02135-12G

The Perkin-Elmer Corp. is requesting amendments to the subject Material Licenses. First, we wish to add the following Electron Capture Detector (ECD) to each license:

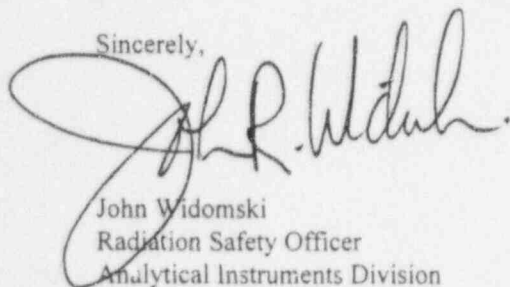
<u>Device Model Number</u>	<u>Isotope</u>	<u>Activity</u>
200155	Ni-63	15 mCi

This detector cell assembly was evolved from our currently licensed N610-0063 / N610-0134 devices. The construction has been modified to allow use of the cell assembly into a different series of Perkin-Elmer gas chromatographs. Currently, this device is undergoing safety evaluation by Mr. Brian Smith of Mr. Steve Baggett's group. Approval is expected in the next few weeks.

Second, we wish to add Cyril Fernandes to license 06-02135-08.

Amendment fees in the amount of \$580 and \$290 for fee categories 3B and 3J are enclosed, as well as two copies of our application for your files.

Sincerely,



John Widomski
Radiation Safety Officer
Analytical Instruments Division

Cc: C. Fernandes
K. Liepins

Enclosures: 6

Tel (203) 762-1000
Fax (203) 762-6700

OFFICIAL RECORD COPY

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1 2 4 1 1 9
JAN 17 1997

APPLICATION FOR MATERIAL LICENSE

INSTRUCTIONS: SEE THE APPROPRIATE LICENSE APPLICATION GUIDE FOR DETAILED INSTRUCTIONS FOR COMPLETING APPLICATION. SEND TWO COPIES OF THE ENTIRE COMPLETED APPLICATION TO THE NRC OFFICE SPECIFIED BELOW.

APPLICATIONS FOR DISTRIBUTION OF EXEMPT PRODUCTS FILE APPLICATIONS WITH:

U.S. NUCLEAR REGULATORY COMMISSION
DIVISION OF INDUSTRIAL AND MEDICAL NUCLEAR SAFETY, NMSS
WASHINGTON, DC 20555

ALL OTHER PERSONS FILE APPLICATIONS AS FOLLOWS, IF YOU ARE LOCATED IN:

CONNECTICUT, DELAWARE, DISTRICT OF COLUMBIA, MAINE, MARYLAND, MASSACHUSETTS, NEW HAMPSHIRE, NEW JERSEY, NEW YORK, PENNSYLVANIA, RHODE ISLAND, OR VERMONT, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION I
NUCLEAR MATERIALS SAFETY SECTION B
475 ALLENDALE ROAD
KING OF PRUSSIA, PA 19406

ALABAMA, FLORIDA, GEORGIA, KENTUCKY, MISSISSIPPI, NORTH CAROLINA, PUERTO RICO, SOUTH CAROLINA, TENNESSEE, VIRGINIA, VIRGIN ISLANDS, OR WEST VIRGINIA, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION II
NUCLEAR MATERIALS SAFETY SECTION
101 MARIETTA STREET, SUITE 2900
ATLANTA, GA 30323

IF YOU ARE LOCATED IN:

ILLINOIS, INDIANA, IOWA, MICHIGAN, MINNESOTA, MISSOURI, OHIO, OR WISCONSIN, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION III
MATERIALS LICENSING SECTION
796 ROOSEVELT ROAD
GLEN ELLYN, IL 60137

ARKANSAS, COLORADO, IDAHO, KANSAS, LOUISIANA, MONTANA, NEBRASKA, NEW MEXICO, NORTH DAKOTA, OKLAHOMA, SOUTH DAKOTA, TEXAS, UTAH, OR WYOMING, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION IV
MATERIAL RADIATION PROTECTION SECTION
611 RYAN PLAZA DRIVE, SUITE 1000
ARLINGTON, TX 76011

ALASKA, ARIZONA, CALIFORNIA, HAWAII, NEVADA, OREGON, WASHINGTON, AND U.S. TERRITORIES AND POSSESSIONS IN THE PACIFIC, SEND APPLICATIONS TO:

U.S. NUCLEAR REGULATORY COMMISSION, REGION V
NUCLEAR MATERIALS SAFETY SECTION
1450 MARIA LANE, SUITE 210
WALNUT CREEK, CA 94696

030-17474

PERSONS LOCATED IN AGREEMENT STATES SEND APPLICATIONS TO THE U.S. NUCLEAR REGULATORY COMMISSION ONLY IF THEY WISH TO POSSESS AND USE LICENSED MATERIAL IN STATES SUBJECT TO U.S. NUCLEAR REGULATORY COMMISSION JURISDICTION.

1. THIS IS AN APPLICATION FOR (Check appropriate item)

- ☐ A. NEW LICENSE
☒ B. AMENDMENT TO LICENSE NUMBER 06-02135-12G
☐ C. RENEWAL OF LICENSE NUMBER _____

2. NAME AND MAILING ADDRESS OF APPLICANT (Include Zip Code)

Perkin-Elmer Corporation
761 Main Avenue
Norwalk, CT 06859-0098

3. ADDRESS(ES) WHERE LICENSED MATERIAL WILL BE USED OR POSSESSED

Perkin-Elmer Corporation
761 Main Avenue
Norwalk, CT 06859

4. NAME OF PERSON TO BE CONTACTED ABOUT THIS APPLICATION

John Widomski

TELEPHONE NUMBER

(203) 762-6452

SUBMIT ITEMS 5 THROUGH 11 ON 8 1/2 x 11" PAPER. THE TYPE AND SCOPE OF INFORMATION TO BE PROVIDED IS DESCRIBED IN THE LICENSE APPLICATION GUIDE.

5. RADIOACTIVE MATERIAL

a. Element and mass number, b. chemical and/or physical form, and c. maximum amount which will be possessed at any one time.

6. PURPOSE(S) FOR WHICH LICENSED MATERIAL WILL BE USED.

7. INDIVIDUAL(S) RESPONSIBLE FOR RADIATION SAFETY PROGRAM AND THEIR TRAINING AND EXPERIENCE

8. TRAINING FOR INDIVIDUALS WORKING IN OR FREQUENTING RESTRICTED AREAS

9. FACILITIES AND EQUIPMENT

10. RADIATION SAFETY PROGRAM

11. WASTE MANAGEMENT

12. LICENSEE FEES (See 10 CFR 170 and Section 170.31)

FEE CATEGORY

3J

AMOUNT

ENCLOSED \$290.00

13. CERTIFICATION. (Must be completed by applicant) THE APPLICANT UNDERSTANDS THAT ALL STATEMENTS AND REPRESENTATIONS MADE IN THIS APPLICATION ARE BINDING UPON THE APPLICANT.

THE APPLICANT AND ANY OFFICIAL EXECUTING THIS CERTIFICATION ON BEHALF OF THE APPLICANT, NAMED IN ITEM 2, CERTIFY THAT THIS APPLICATION IS PREPARED IN CONFORMITY WITH TITLE 10, CODE OF FEDERAL REGULATIONS, PARTS 30, 32, 33, 34, 35, AND 40 AND THAT ALL INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT TO THE BEST OF THEIR KNOWLEDGE AND BELIEF.

WARNING: 18 U.S.C. SECTION 1001 ACT OF JUNE 25, 1948, 62 STAT. 749 MAKES IT A CRIMINAL OFFENSE TO MAKE A WILLFULLY FALSE STATEMENT OR REPRESENTATION TO ANY DEPARTMENT OR AGENCY OF THE UNITED STATES AS TO ANY MATTER WITHIN ITS JURISDICTION.

SIGNATURE CERTIFYING OFFICER

TYPED/PRINTED NAME

TITLE

DATE

Kaspar Liepins

Kaspar Liepins

Director,
Product Assurance

1-8-97

FOR NRC USE ONLY

TYPE OF FEE

FEE LOG

FEE CATEGORY

COMMENTS

AMOUNT RECEIVED

CHECK NUMBER

APPROVED BY

OFFICIAL RECORD COPY

REL 10

DATE

124119
JAN 17 1997

(FOR LFMS USE)
 INFORMATION FROM LTS

BETWEEN:

LICENSE FEE MANAGEMENT BRANCH, ARM
 AND
 REGIONAL LICENSING SECTIONS

PROGRAM CODE: 03240
 STATUS CODE: 0
 FEE CATEGORY: 3J
 EXP. DATE: 20030430
 FEE COMMENTS:
 DECOM FIN ASSUR REQD: N

LICENSE FEE TRANSMITTAL

A. REGION I

1. APPLICATION ATTACHED
 APPLICANT/LICENSEE: PERKIN-ELMER CORPORATION
 RECEIVED DATE: 970117
 DOCKET NO: 3017474
 CONTROL NO.: 124119
 LICENSE NO.: 06-02135-12G
 ACTION TYPE: AMENDMENT

2. FEE ATTACHED
 AMOUNT: \$290.00
 CHECK NO.: 008185

3. COMMENTS

SIGNED
 DATE

M. A. Perkins
1/12/97

B. LICENSE FEE MANAGEMENT BRANCH (CHECK WHEN MILESTONE 03 IS ENTERED 1/1)

1. FEE CATEGORY AND AMOUNT: 3J \$290

2. CORRECT FEE PAID. APPLICATION MAY BE PROCESSED FOR:
 AMENDMENT
 RENEWAL
 LICENSE

3. OTHER

SIGNED
 DATE

1997 JAN 24 10:12

I (97)

Log	<u>Jan 17</u>
Ref	<u>PERKIN-ELMER</u>
Control No.	<u>5185</u>
Amount	<u>\$290</u>
Fee Category	<u>3J</u>
Type of Fee	<u>AMO</u>
Date Check Rec'd	<u>1/12/97</u>
Date Completed	<u>1/12/97</u>
By	<u>BA</u>

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

NO: NR-536-D-110-B

DATE: April 4, 1997

PAGE: 1 of 8

DEVICE TYPE: Detector Cell Assembly

MODEL: N610-0063, N610-0134, Voyager

MANUFACTURER/DISTRIBUTOR:

Perkin-Elmer Corporation
761 Main Avenue
Norwalk, Connecticut 06859-0098

MANUFACTURER:

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

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 monthsPRINCIPAL USE: (N) Ion Generators, ChromatographyCUSTOM SOURCE:

____ YES

X

NO

124119

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

NO: NR-536-D-110-B

DATE: April 4, 1997

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 within the Voyager and is insulated with foam. The aluminum box has a lid which

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

NO: NR-536-D-110-B

DATE: April 4, 1997

PAGE: 3 of 8

DEVICE TYPE: Detector Cell Assembly

DESCRIPTION: (Cont'd)

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."

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.

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

NO: NR-536-D-110-B

DATE: April 4, 1997

PAGE: 4 of 8

DEVICE TYPE: Detector Cell Assembly

LABELING: (Cont'd)

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 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.

PROTOTYPE TESTING:

Model N610-0063 and N610-0134 ECDs with sealed sources installed were tested to and met the minimum classification of C32211 for chromatography sources per ANSI N542. 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 C32211 for chromatography sources per ANSI N542.

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

NO: NR-536-D-110-B

DATE: April 4, 1997

PAGE: 5 of 8

DEVICE TYPE: Detector Cell Assembly

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.

With respect to the Model Voyager, Perkin-Elmer Corporation has committed to auditing the quality assurance and control program of PE Photovac 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.

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.

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

NO: NR-536-D-110-B

DATE: April 4, 1997

PAGE: 6 of 8

DEVICE TYPE: Detector Cell Assembly

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

- 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.
- 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 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.

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

NO: NR-536-D-110-B

DATE: April 4, 1997

PAGE: 7 of 8

DEVICE TYPE: Detector Cell Assembly

SAFETY ANALYSIS SUMMARY: (Cont'd)

- 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)

Furthermore, we conclude the Model Voyager, and continue to conclude that Models 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.

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

NO: NR-536-D-110-B

DATE: April 4, 1997

PAGE: 8 of 8

DEVICE TYPE: Detector Cell Assembly

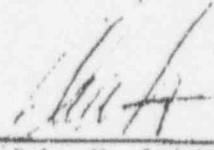
REFERENCES:

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

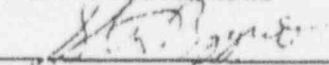
- Perkin-Elmer Corporation letters dated January 17, 1990, and July 6, 1990, with enclosures thereto.
- Perkin-Elmer Corporation amendment application received August 2, 1996, with enclosures thereto, and letter dated March 18, 1997.
- PE Photovac letters dated February 25, 1997, February 26, 1997, and March 18, 1997, with enclosures thereto, and facsimiles dated March 20, 1997, and April 2, 1997.

ISSUING AGENCY:

U.S. NUCLEAR REGULATORY COMMISSION

Date: April 4, 1997Reviewer: 

John W. Lubinski

Date: April 4, 1997Concurrence: 

Steven L. Baggett

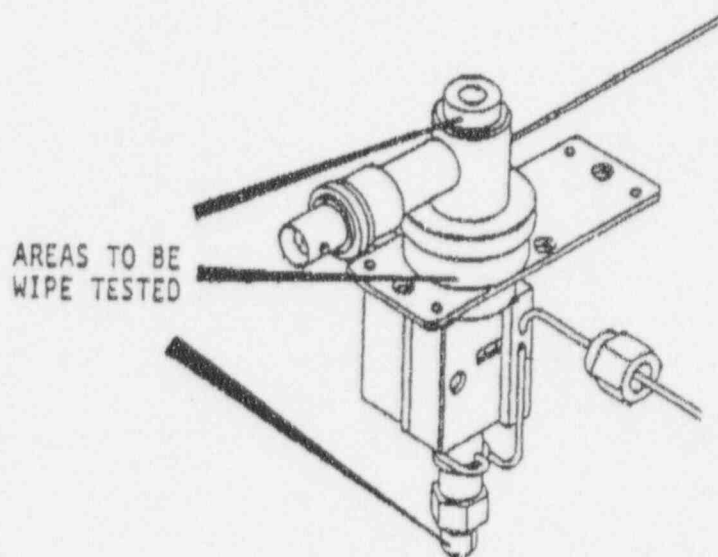
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

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

DATE: April 4, 1997

ATTACHMENT 1

Electron Capture Detector



Models N610-0063 and N610-0134

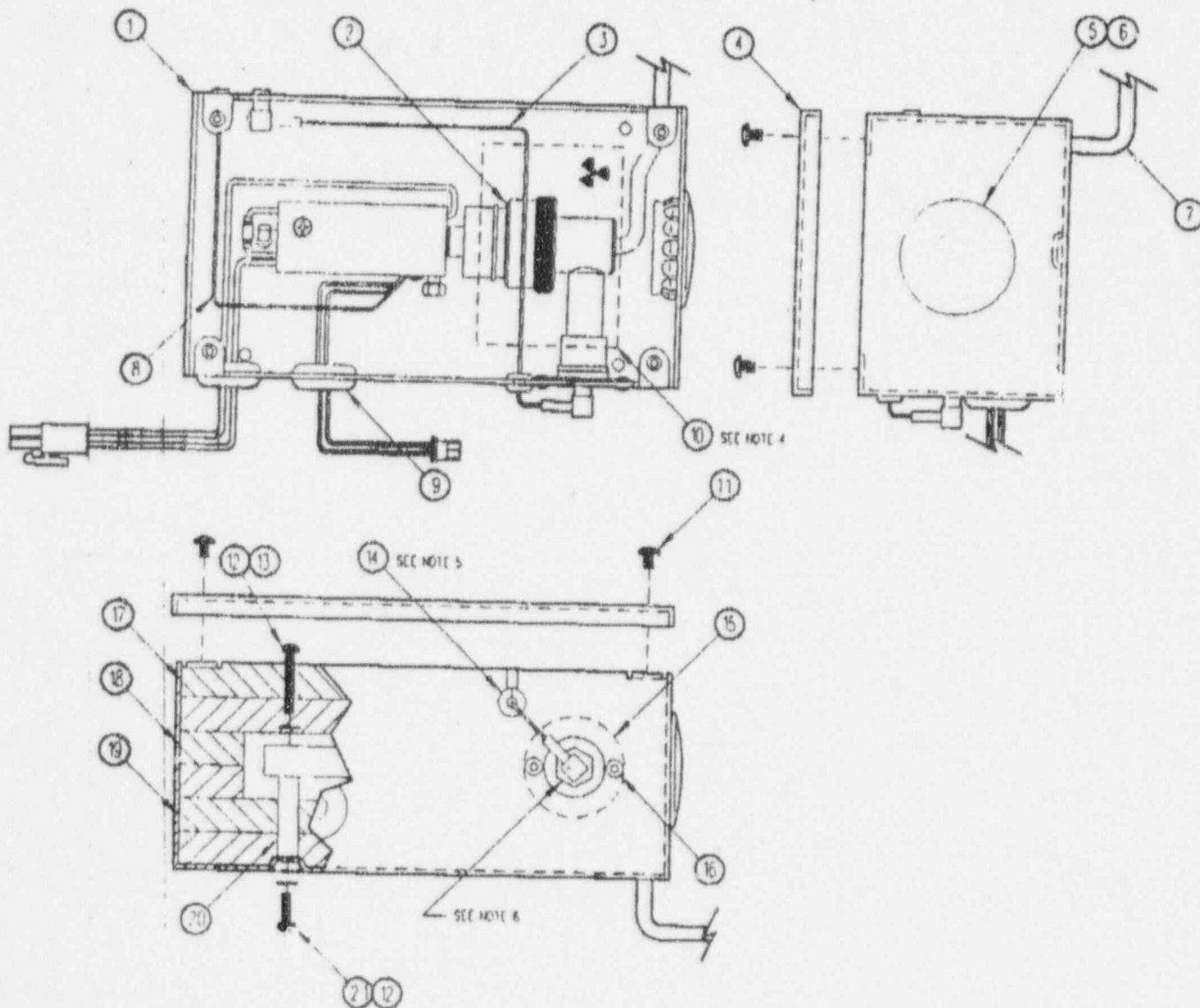
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

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

DATE: April 4, 1997

ATTACHMENT 2

Model Voyager ECD Module Assembly



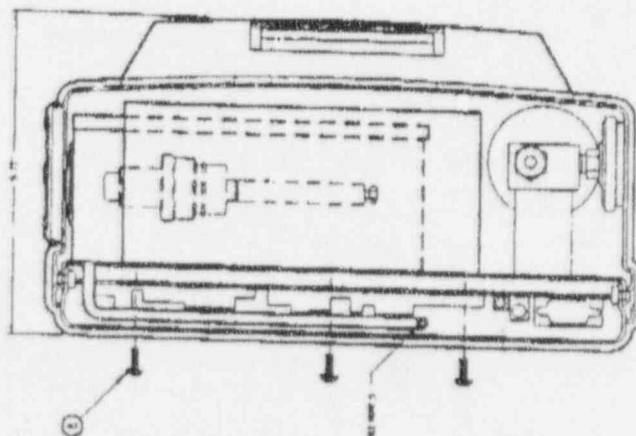
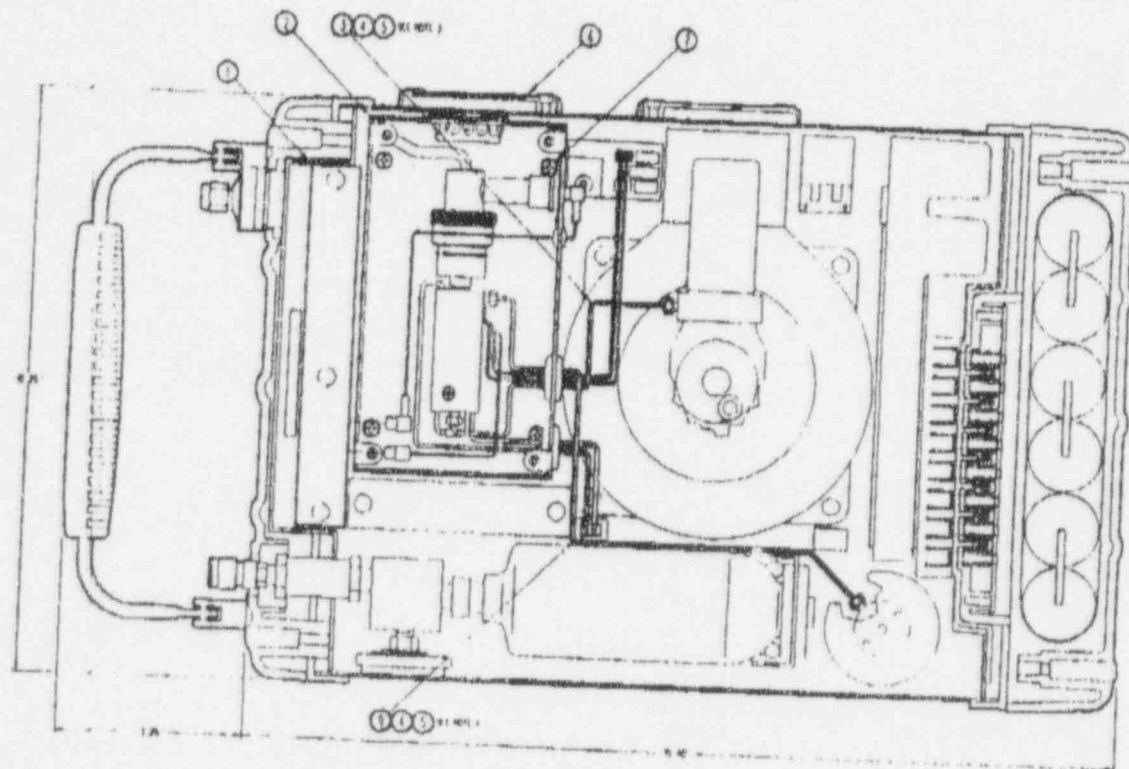
REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE
(AMENDED IN ITS ENTIRETY)

NO. NR-536-D-110-B

DATE: April 4, 1997

ATTACHMENT 3

Model Voyager Gas Chromatograph



END