

October 27, 1995

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

Dear Mr. Widomski:

Based on the information submitted in your letter dated June 5, 1995, we are in the process of updating registration certificates NR-536-D-107-B and NR-536-D-109-B. However, to continue with the process of updating the certificates, we need you to provide the following information or clarifications:

1. Please verify that the information included in the copies of the enclosed draft registration certificates (NR-536-D-107-B and NR-536-D-109-B) is accurate and complete.

For the Model 330-0119 electron capture detector (ECD):

2. Please verify that the Model 330-0119 ECD is distributed to both specific and general licensees of NRC or an Agreement State.

For each ECD listed on each of the enclosed draft registration certificates:

3. Please provide copies of the labeling that will be attached to each ECD.
4. Please provide complete drawings of each ECD. The drawings should include complete dimensions and materials of construction. Please provide details of any tamper resistant hardware that is used in the construction of the ECDs.
5. Please provide up-to-date copies of the user manuals for each ECD and copies of all instructions provided to users of the ECDs.
6. Please provide an up-to-date copy of the quality assurance and control program under which Perkin-Elmer manufactures the ECDs.

We request that you provide the above listed clarifications and information within 60 days of the date of this letter. If you have any questions, please contact me at (301) 415-7868 or Mr. Steven Baggett at (301) 415-7273.

Sincerely,
/s/

John W. Lubinski, Mechanical Engineer
Sealed Source Safety Section
Source Containment and
Devices Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosures: As stated

Distribution:

SCDB r/f	SSD-95-57	SSD-95-58	NE01
SSD File # NR-536-D-107-B ✓		SSD File # NR-536-D-109-B	///

DOCUMENT NAME: C:\FILES\SSDS\NR536107.DEF

To receive a copy of this document, indicate in the box: "C" = Copy without attachment/enclosure "E" = Copy with attachment/enclosure "N" = No copy

OFFICE	SCDB	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
NAME	JLubinski/jl								
DATE	10/27/95								

9510300003 951027
PDR RC *
SSD-95-57 PDR

OFFICIAL RECORD COPY

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

NO.: NR-536-D-107-B

DATE: DRAFT

PAGE 1 OF 6

DEVICE TYPE: Gas Chromatography Detector Cell

MODEL: 330-0119

MANUFACTURER/DISTRIBUTOR: Perkin-Elmer Company
761 Main Avenue
Norwalk, CT 06859-0001

SEALED SOURCE MODEL DESIGNATION: DuPont Merck: NER-002
NRD: N-1001
Amersham: NBC-7020

ISOTOPE:

Nickel-63

MAXIMUM ACTIVITY:

15 millicuries (0.56 GBq)

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: (N) Ion Generators, Chromatography

CUSTOM DEVICE: _____ YES _____ X _____ NO

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

NO.: NR-536-D-107-B

DATE: DRAFT

PAGE 2 OF 6

DEVICE TYPE: Gas Chromatography Detector Cell

DESCRIPTION:

The Model 330-0119 electron capture detector (ECD) consists of a heater, a temperature controlling mechanism, and a nickel-63 foil situated in a cylindrical cavity of the detector body. Its construction includes a tamper proof screw to keep users from gaining access to the source. The source foil for use in the cell assembly consist of a corrosion resistant metal foil substrate which has the radioactive material electrolytically deposited on one side.

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.

When in use in the Sigma Series gas chromatograph, a double level of temperature protection against accidental over-heating of the nickel-63 foil is provided. First, through the microprocessor temperature circuitry of the gas chromatograph. Secondly, the ECD detector block is equipped with a curie-bar thermal trip, the operation of which disconnects power to the detector block heater if the block temperature should ever exceed 450°C (842°F).

LABELING:

A wire tether is permanently attached to the ECD cell body by looping it around and crimping it in place with metal clamps. The other end of the tether is attached to the ECD cell label which is, in turn, attached to the body of the chromatograph. The angled section of the label is equipped with two screw openings to enable attachment to the body of the gas chromatograph. The label includes the radiation symbol and name of manufacturer. It also contains the following wording:

On (date of assay) this device was determined to contain millicuries of Nickel 63, a radioactive isotope. The receipt, possession, use and transfer of this device Model , Serial No. are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of a state with which the NRC has entered

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

NO.: NR-536-D-107-B

DATE: DRAFT

PAGE 3 OF 6

DEVICE TYPE: Gas Chromatography Detector Cell

LABELING (Cont.):

into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

THE ELECTRON CAPTURE DETECTOR CELL IS NOT A CUSTOMER SERVICED PART. This part is not to be removed, replaced, altered, adjusted, or tampered with by the user. Please refer to ECD section of the Customer Service Manual supplied with your gas chromatograph.

TESTING

This device must be tested at intervals of no less than six months, as required by 10 CFR 31.5(c)(2) for leakage of radioactive material. Please refer to ECD section of the Customer Service Manual for testing instructions. Note: in the event you are specifically licensed to possess this device, you may be subject to differing requirements.

CONDITIONS OF NORMAL USE:

The ECD is designed to produce an ionized atmosphere for quantitative or qualitative measurement of elements in gas streams. It is an integral component of gas chromatographs of the Perkin-Elmer Company's Sigma Series and will be used in ambient laboratory conditions.

The detector is designed for operational temperatures of up to 450°C (842°F). The foil source is fully shielded in the ECD cell and the gas chromatograph operator is not required to handle or service either the source or the detector cell.

PROTOTYPE TESTING:

Assurance of the integrity of the design of the Model 330-0119 ECD was provided by comparison of the design to previously approved designs. In addition to the comparison, Perkin-Elmer performed a test that consisted of simulated thermal runaway. The test indicated that the ECD heater block, under worst-case conditions, can never achieve the melting point of the radioactive source.

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

NO.: NR-536-D-107-B

DATE: DRAFT

PAGE 4 OF 6

DEVICE TYPE: Gas Chromatography Detector Cell

EXTERNAL RADIATION LEVELS:

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

QUALITY ASSURANCE AND CONTROL:

Perkin-Elmer submitted the quality control program followed for manufacture of the devices and the program was deemed acceptable for licensing purposes by NRC.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The device may be used persons specifically or 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 device shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

SAFETY ANALYSIS SUMMARY:

Perkin-Elmer submitted sufficient information to provide reasonable assurance that:

- The device can be safely operated by persons not having training in radiological protection.

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

NO.: NR-536-D-107-B

DATE: DRAFT

PAGE 5 OF 6

DEVICE TYPE: Gas Chromatography Detector Cell

SAFETY ANALYSIS SUMMARY (Cont.):

- 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.
- 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 cm ² (0.15 in ²)	200 rem (2.0 Sv)
Other organs	50 rem (0.50 Sv)

Based on review of the electron capture detector, and the information and test data cited below, we continue to conclude that the device is acceptable for licensing purposes.

Furthermore, we continue to conclude that the device would be expected to maintain its containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

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

NO.: NR-536-D-107-B

DATE: DRAFT

PAGE 6 OF 6

DEVICE TYPE: Gas Chromatography Detector Cell

REFERENCES:

The following supporting documents for the Model 330-0119 are hereby incorporated by reference and are made a part of this registry document.

- Perkin-Elmer Company's letters dated June 5, 1995, August 6, 1991, February 13, 1987, February 18, 1986, June 16, 1981, and December 16, 1980, with enclosures thereto.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: _____

Reviewer: _____
John W. Lubinski

Date: _____

Concurrence: _____
Steven L. Baggett

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

NO.: NR-536-D-109-B

DATE: DRAFT

PAGE 1 OF 7

DEVICE TYPE: Gas Chromatography Detector Cell

MODEL: N600-0113, N600-0030, L413-0127, L413-0128

MANUFACTURER/DISTRIBUTOR: Perkin-Elmer Company
761 Main Avenue
Norwalk, CT 06859-0001

SEALED SOURCE MODEL DESIGNATION: DuPont Merck: NER-002
NRD: N-1001
Amersham: NBC-7020

ISOTOPE:

Nickel-63

MAXIMUM ACTIVITY:

15 millicuries (0.56 GBq)

LEAK TEST FREQUENCY: 6 Months

PRINCIPAL USE: (N) Ion Generators, Chromatography

CUSTOM DEVICE: _____ YES _____ X _____ NO

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

NO.: NR-536-D-109-B

DATE: DRAFT

PAGE 2 OF 7

DEVICE TYPE: Gas Chromatography Detector Cell

DESCRIPTION:

The Model N600-0113 electron capture detector (ECD) is similar to the previously approved Model 330-0119 (registered separately). Differences in the two models may be described as follows:

- (1) In the Model 330-0119, the ECD is distinct from its heating device which is incorporated within the body of the gas chromatograph; the Model N600-0113 has been incorporated with its heating element into a single module.
- (2) The heater block in the Model N600-0113 is constructed of aluminum rather than an alloy of aluminum and bronze. Because of the lower melting point of aluminum, it is expected that the heater block would self destruct before a temperature sufficient to damage the ECD or the source was reached.
- (3) In consideration of the lower melting temperature and smaller mass of the heater block, a lower powered heater has been employed (100 watts versus 300 watts).
- (4) Four tamper proof screws seal the two halves of the cylindrical detector body and keep users from gaining access to the inner cavity which houses the corrosion resistant metal foil substrate with the radioactive material electrolytically deposited on one side. The previously approved Model 330-0119 has one tamper proof screw in the secreted collar of the ECD which prevents access to the source.

When in use in the Perkin-Elmer Sigma Series gas chromatograph, a double level of temperature protection against accidental overheating of the nickel-63 foil source of the ECD is provided. The first level of protection is provided through the microprocessor temperature circuitry of the gas chromatograph. The second level of protection through the differential expansion thermostat mounted on the ECD and heater assembly. This thermostat disconnects power to the heater if the heater block temperature exceeds temperatures within the range of 453°C to 502°C (847°F to 936°F).

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

NO.: NR-536-D-109-B

DATE: DRAFT

PAGE 3 OF 7

DEVICE TYPE: Gas Chromatography Detector Cell

DESCRIPTION (Cont.):

The Model L413-0128 is identical to the N600-0113 detector with the exception of an electrical connector used for the heater/sensor harness connection.

The Model N600-0030 is essentially the same as the Model N600-0113 with the exception that it uses a 240 volt heater in the Model N600-0030 instead of a 120 volt heater. The change is required due to the 240 volt line found in overseas markets.

The Model L413-0127 is identical to the Model N600-0030 with the exception of an electrical connector used for the heater/sensor harness connection.

LABELING:

A wire tether is permanently attached to the ECD cell body by looping it around and crimping it in place with metal clamps. The other end of the tether is attached to the ECD cell label which is, in turn, attached to the body of the chromatograph. The angled section of the label is equipped with two screw openings to enable attachment to the body of the gas chromatograph. The label includes the radiation symbol and name of manufacturer. It also contains the following wording:

On (date of assay) this device was determined to contain millicuries of Nickel 63, a radioactive isotope. The receipt, possession, use and transfer of this device Model , Serial No. are subject to a general license or the equivalent and the regulations of the U.S. Nuclear Regulatory Commission or of a state with which the NRC has entered into an agreement for the exercise of regulatory authority. This label shall be maintained on the device in a legible condition. Removal of this label is prohibited.

THE ELECTRON CAPTURE DETECTOR CELL IS NOT A CUSTOMER SERVICED PART. This part is not to be removed, replaced, altered, adjusted, or tampered with by the user. Please refer to ECD section of the Customer Service Manual supplied with your gas chromatograph.

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

NO.: NR-536-D-109-B

DATE: DRAFT

PAGE 4 OF 7

DEVICE TYPE: Gas Chromatography Detector Cell

LABELING (Cont.):

TESTING

This device must be tested at intervals of no less than six months, as required by 10 CFR 31.5(c)(2) for leakage of radioactive material. Please refer to ECD section of the Customer Service Manual for testing instructions. Note: in the event you are specifically licensed to possess this device, you may be subject to differing requirements.

CONDITIONS OF NORMAL USE:

The ECD is designed to produce an ionized atmosphere for quantitative or qualitative measurement of elements in gas streams. It is an integral component of gas chromatographs of the Perkin-Elmer Company's Sigma Series and will be used in ambient laboratory conditions.

The detector is designed for operational temperatures of up to 450°C (842°F). The foil source is fully shielded in the ECD cell and the gas chromatograph operator is not required to handle or service either the source or the detector cell.

PROTOTYPE TESTING:

Assurance of the integrity of the design of the Model 330-0119 ECD was provided by comparison of the design to previously approved designs. In addition to the comparison, Perkin-Elmer performed a test that consisted of evaluation of five ECD thermal trips for proper operations of microswitches to turn off AC power to the ECD heater within an operational temperature range. All of the thermal trips operated within the temperature range 453°C (847°F) minimum and 502°C (936°F) maximum.

EXTERNAL RADIATION LEVELS:

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

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

NO.: NR-536-D-109-B

DATE: DRAFT

PAGE 5 OF 7

DEVICE TYPE: Gas Chromatography Detector Cell

QUALITY ASSURANCE AND CONTROL:

Perkin-Elmer submitted the quality control program followed for manufacture of the devices and the program was been deemed acceptable for licensing purposes by NRC. The program includes the following inspections on each ECD distributed:

1. Cell closure sealed are inspected for leakage by pressurizing blocked off cells with dry nitrogen at 30 psi (207 kPa).
2. Cell saturation current is measured to specified levels.
3. Each cell is baked out for two hours in a vacuum furnace at 200°C (392°F) temperature and at air pressure of approximately 4×10^{-6} mm (0.16×10^{-6}) of mercury.
4. 100 percent wipe tested.
5. Functional test made on each cell.

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The device may be used persons specifically or 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 device shall be leak tested at intervals not to exceed 6 months using techniques capable of detecting 0.005 microcurie (185 Bq) of removable contamination.
- This registration sheet and the information contained within the references shall not be changed without the written consent of the NRC.

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

NO.: NR-536-D-109-B

DATE: DRAFT

PAGE 6 OF 7

DEVICE TYPE: Gas Chromatography Detector Cell

SAFETY ANALYSIS SUMMARY:

Perkin-Elmer 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.
- 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 cm ² (0.15 in ²)	200 rem (2.0 Sv)
Other organs	50 rem (0.50 Sv)

Based on review of the electron capture detector, and the information and test data cited below, we continue to conclude that the device is acceptable for licensing purposes.

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

NO.: NR-536-D-109-B

DATE: DRAFT

PAGE 7 OF 7

DEVICE TYPE: Gas Chromatography Detector Cell

SAFETY ANALYSIS SUMMARY (Cont.):

Furthermore, we continue to conclude that the device would be expected to maintain its containment integrity for normal conditions of use and accidental conditions which might occur during uses specified in this certificate.

REFERENCES:

The following supporting documents for the Model 330-0119 are hereby incorporated by reference and are made a part of this registry document.

- Perkin-Elmer Company's letters dated June 5, 1995, April 13, 1989 (two letters), March 4, 1987, February 23, 1987, April 16, 1982, April 13, 1982, April 2, 1982, December 30, 1981, June 16, 1981, and December 16, 1980, with enclosures thereto.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: _____

Reviewer: _____
John W. Lubinski

Date: _____

Concurrence: _____
Steven L. Baggett