John Widomski
Perkin Elmer Instruments
710 Bridgeport Avenue
Shelton, CT 06484

January 8, 2003

SUBJECT: INACTIVATION OF REGISTRATION CERTIFICATE NO. NR-536-D-109-B

Dear Mr. Widomski:

This letter is in reference to your letter dated September 17, 2002, requesting the transfer of certificate no. NR-536-D-109-B to inactive status. Based on the information submitted in your letter dated December 2, 2002, this certificate has been transferred to inactive status as you requested. The registration number for this inactive certificate is NR-536-D-808-B.

A copy of the inactive certificate is enclosed for your review and records. Please read over the certificate in its entirety and notify us immediately of any errors or omissions.

If you have any questions, please contact me at (301) 415-5810 or Ujagar S. Bhachu at (301) 415-7894.

Sincerely,

/RA/

Jonathan Rivera, General Engineer
Materials Safety and Inspection Branch
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Enclosure: As stated
cc w/encl: RJones, LFARB

Distribution: NMSS13 SSD-02-06 SSD File #: NR-0536-D-109-B
ADAMS accession number for package: ML023090438

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	MSIB	E	MSIB	E	MSIB	E				
NAME	JRivera		USBhachu		JJankovich					
DATE	1/3/03		1/08/03		1/8/03					

OFFICIAL RECORD COPY

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

No.: NR-536-D-808-B DATE: January 8, 2003
(Previously NR-536-D-109-B)

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 06859-0429

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

ISOTOPE: MAXIMUM ACTIVITY:

Nickel-63 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

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 separate and 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 secured 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 in the ECD module.

DEVICE TYPE: Gas Chromatography Detector Cell

DESCRIPTION (Cont.):

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).

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.

The fabrication of the models were discontinued in 1994. Between 1994 and 2002 the sale of the devices has been strictly for replacement service usage.

LABELING:

For devices distributed to general licensees, 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 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 the 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 No. _____, Serial No. ____ are subject to a general license or the equivalent and

DEVICE TYPE: Gas Chromatography Detector Cell

LABELING (Cont'd):

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 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 longer 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.

Devices distributed to specific licensees are labeled with the model number, serial number, isotope, activity, radiation symbol, the words "Danger Radioactive Material," and the name of the manufacturer.

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 2000 and 8000 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.

DEVICE TYPE: Gas Chromatography 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.

QUALITY ASSURANCE AND CONTROL:

Perkin-Elmer submitted the quality control program for the manufacture of the devices and the program was found 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.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: Gas Chromatography Detector Cell

LIMITATIONS AND/OR OTHER CONSIDERATIONS OF USE:

- The device may be used by 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.
- 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:

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: Gas Chromatography Detector Cell

SAFETY ANALYSIS SUMMARY (Cont'd):

PART OF BODY	DOSE
Whole body; head of 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 concluded that the device was acceptable for licensing purposes.

Furthermore, we concluded 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.

REVIEWER NOTE: The manufacturer is committed to continue to service the gas chromatographs.

REGISTRY OF RADIOACTIVE SEALED SOURCES AND DEVICES
SAFETY EVALUATION OF DEVICE

DEVICE TYPE: Gas Chromatography Detector Cell

REFERENCES:

The following supporting documents for the Models N600-0113, N600-0030, L413-0127, L413-0128 are hereby incorporated by reference and are made a part of this registry document.

- Perkin-Elmer Company's letters dated May 7, 1996, December 20, 1995, 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.

- Perkin-Elmer Company's letters dated September 17, 2002, and December 2, 2002, with enclosures thereto.

ISSUING AGENCY:

U.S. Nuclear Regulatory Commission

Date: 01/08/2003 Reviewer: U.S. Bhachu
Ujagar S. Bhachu

Date: January 8, 2003 Concurrence: John P. Jankovich
John P. Jankovich