



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

February 14, 1997

John Widomski
Perkin-Elmer Corporation
761 Main Avenue
Norwalk, CT 06859-0046

Dear Mr. Widomski:

This letter is in response to your application dated August 1, 1996 requesting registration of the Model PE Photovac 200155 electron capture device and the meeting held with Cyril Fernandes of PE Photovac on January 30, 1997. This letter contains the deficiencies identified during the review of your application. These deficiencies were discussed with Cyril Fernandes. Therefore, in order to continue our evaluation, the following information is necessary:

1. Your application was received without a cover letter. Please provide a cover letter for the application asking for an amendment to registration certificate NR-536-D-110-B to include the model Voyager gas chromatograph, signed by a responsible Perkin-Elmer individual.
2. Through discussions with Mr. Fernandes and observing the sample device, it was determined that the entire device, not the model 200155 electron capture device, should be registered. This model device, as stated by Mr. Fernandes, is called the Voyager. This model name will be used for the device unless we are informed otherwise. The registration certificate NR-536-D-110-B will be amended to include the model Voyager gas chromatograph, similar to the request made in your application. With the entire gas chromatograph being included in the registration certificate, additional engineering drawings are required of the device. Please provide engineering drawings of the outer case and the box that contains the model 200155 electron capture device, including dimensions, materials of construction, and method of containment (i.e., tamper proof screws, etc.). Please also provide a narrative description of the entire device, including how the model 200155 electron capture device is mounted inside the device.
3. As required in 10 CFR 32.51(b), leak test intervals of longer than six months require sufficient justification that the longer interval is warranted (i.e., performance characteristics of the device and design features which have significant bearing on the probability or consequences of leakage of radioactive material from the device). Therefore, please provide sufficient information concerning the operating experience of the Models N610-063 and N610-0134 that verifies the longer interval is warranted. You should include years of use of the devices, the number of leak tests performed on the sources, results of the leak tests, and information on any sources that tested positive when subjected to leak testing.
4. Your application requests that the device be registered for distribution as both generally and specifically licensed. Therefore, please provide the wording of the labels used for both generally and specifically licensed devices and the location of each label on the device.
5. Please verify that there are no limitations on the effluents or cleaning agents the device can be exposed to.

February 14, 1997

6. Please provide a description of prototype testing performed on the model 200155 electron capture device and the results.
7. Please verify that the expected working life of the device is 5 years and the basis for this determination is that the product will be outdated, advanced technology will be available, and that neither the Ni-63 source nor radiological safety aspects of the device is a limitation.
8. Please provide the specific quality control inspections that will be performed by Perkin-Elmer, NRD, and PE Photovac, to ensure the device is manufactured and distributed in accordance with the statements and representations of your application and the registration certificate. The inspections must include in-process inspections, the final inspection of the device prior to distribution to the end user, and identify the company that will be performing leak testing. The final inspection must be performed by Perkin-Elmer, or a U.S. representative of Perkin-Elmer, and Perkin-Elmer must commit to retain copies of all essential quality control records.
9. The user's manual provided in the application contains outdated NRC regulations and Agreement State and NRC Region information. Please provide a new user's manual with corrected information.
10. It was noted in the engineering drawings submitted that a statement was made on each that it is considered to be the property of the Perkin-Elmer Corporation. The NRC can handle information submitted by licensees on a company proprietary manner (i.e., not to be disclosed to the public) when the materials are submitted in accordance with 10 CFR 2.790(b). In addition to the markings on the material to be considered proprietary, an affidavit is required to be submitted requesting that the materials be considered proprietary. Once this has been received, the NRC will consider the request on its merits.

Please provide the requested information within 30 days. If you have any questions, please contact me at (301) 415-5723 or Mr. John Lubinski at (301) 415-7868.

Sincerely,
 Brian W. Smith, Health Physicist
 Sealed Source Safety Section
 Medical, Academic, and Commercial
 Use Safety Branch
 Division of Industrial and
 Medical Nuclear Safety
 Office of Nuclear Material Safety
 and Safeguards

cc: Cyril Fernandes, PE Photovac

Distribution:

SSSS r/f

SSD-96-68

NE01 SSD File # NR-536-D-110-B

DOCUMENT NAME: C:\96FILES\SSSS\PEPHOTO\NR536110.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	SSSS	IMAB						
NAME	Brian Smith	John Lubinski						
DATE	02/14/97	02/14/97						

OFFICIAL RECORD COPY