UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

October 16, 1996

Ronald Martone
Manager of Regulatory Affairs
Picker International
595 Miner Road
Cleveland, OH 44143

Dear Mr. Martone:

This letter is in response to your application dated August 1, 1996, requesting registration of the Model Prism 2000XP STEP transmission line source device and our telephone conversations on September 18 and 24, 1996. This letter contains the questions that were discussed during our telephone conversation on September 14 which require additional information to be submitted and additional questions which need to be addressed. This information is necessary for us to continue our review of your application.

After reviewing this application and comparing this model with the previously registered STEP transmission line source housing, it has been determined that the two cannot be combined on a single registration certificate. Although the two models perform basically the same function, the design, operation, and sources used differ significantly. It is for this reason that the two cannot be combined on the same registration certificate.

In your letter submitting the application, you requested that certain portions of the application be withheld from public disclosure on the grounds that release of this information would do irreparable commercial harm to Picker International. Our determination on this will be addressed under a separate cover.

Previously Discussed Questions

The questions marked with a single asterisk (*) indicate those questions where verification of information relayed during our phone conversation on September 24 is required by Picker. The remaining questions were to be addressed by you in a written correspondence.

1.* Per our telephone conversation, please verify that engineering drawing 210671 referenced in section 3.2.1.6 of your application should actually be engineering drawing 13066.

2. Please provide information on the clips used to hold the source in place such as the materials of construction and an engineering drawing.

3. During our phone conversation on September 24, 1996, I stated that a label is required on the outside of the device that is similar to that attached to the source housing. With the device having two radioactive material warning labels in view while attached to the scintillation camera head, this label may be placed on the bottom of the device. This label should be visible while the device is in storage. Please provide the wording and placement for this label.

4. During prototype testing of the device, did the source holder ever become stuck? The application stated that prototype testing is continuing; how many cycles have been completed so far?

5. It was not evident in the application that a drop test, one that is representative of a drop that is likely during use or storage of the device, was performed on the device. In addition, it was not evident in the application, including the registration certificate provided, that a bend test was performed on the Isotope Products Laboratories' model 3411 sources. Please provide information that verifies the device and source will withstand representative testing. An engineering analysis or comparison to a similar device is permitted in place of actual testing.

6.* Per our telephone conversation, please verify that the devices will be manufactured and distributed in accordance with the U.S. Food and Drug Administration's quality assurance program committed to for the STEP device.

7. The user's manual for the device inaccurately lists the maximum activity for the Co-57 source in several places. Please correct.

8. Section 3.3.1.3 of the application states the useful life of the device as being 10 years or longer. Appendix A of addendum 4 of the application states the useful life of the device as being 7 years. Please clarify.

Additional Questions

Please respond to the following questions.

1. In your application, Addendum 6, it states that the Gd-153 source will be changed a maximum of twice per year. If the source used in the device is dependent upon the procedure performed on the patient and the radiopharmaceutical used, why can't this number be greater?

2. Is it anticipated that a hospital would use all three sources in a single device?

3. If a Tc-99m source is used each day the device is used (you estimate that the device will be used 300 days in a year), and it is estimated that the exposure per source exchange could be as much as 200 mrem, the resulting cumulative exposure would be 60 rem to the extremities, greater than the regulatory limit in 10 CFR 20.1201(a)(2)(ii). Please explain how users will not exceed this limit.

4. Your previous device, the STEP model, was estimated to provide a dose to the patient of 2 mrem per scan. The estimate for the Prism 2000XP STEP model is 1 mrad per scan with sources of significantly greater activity than those in the STEP. Please explain the difference. Does the word "scan" refer to the complete patient imaging procedure or each time the device scans across the detector head?

5. The label attached to the source holder needs to contain the manufacturer's name. In addition, the model name should be corrected to read Prism 2000XP STEP. Please verify this information will be included on the label.

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,

Original Signed by

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

Distribution:
SSSS r/f SSD-96-83 NE01 SSD File # NR-104-D-102-S

DOCUMENT NAME: P:\SSSS\PICKER\104D102S.DF2
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		SSSS							
NAME	Brian Smith		John Lubinski							
DATE	10/16/96		10/16/96							

OFFICIAL RECORD COPY