



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

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 conversation on January 2, 1997. This letter contains the questions that were discussed during our telephone conversation. This information is necessary for us to continue our review of your application.

1. Please provide material of construction for the labels that will be attached to the device.
2. Please provide information indicating how the source will react to forces likely to be encountered during installation and use. It is expected that only a small amount of force is required to bend the sealed source. Therefore, repeated installation of the source may lead to failure. Please indicate what actions will be taken to protect against source failure. As discussed, one of the following actions may be considered appropriate:
 - 1) decreasing the risk of deformation and failure of the sealed source (i.e., design change); or
 - 2) sensitizing the user to the hazards associated with handling the sealed source and providing appropriate procedures for installation and in cases where the sealed source has become deformed or failed.
3. Your application indicated that the sealed source would be removed by the user prior to a Picker International service technician performing maintenance on the device. Does Picker International have a specific license to perform maintenance on these devices? If not, the licensee would have to remove the sealed source as stated in your application. However, the Picker International service technician may remove the sealed source if the licensee's license permits such actions.
4. A reviewer note will be added to the registration certificate that will indicate that the sealed source must be leak tested each time it is installed in a source housing assembly. However, please note that sealed sources in storage (not in a source housing assembly) would not need to be leak tested until installed in the device.

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5. The leak test procedure provided in Chapter 4 of the user's manual should be revised as follows:

- 1) The sealed source does not have to be removed from the source housing assembly to be wiped - wipe the sealed source installed in the source housing assembly. This will reduce the amount of exposure to the hands of the individual performing the test and it will also give adequate assurance as to whether the sealed source is leaking. You may recommend that the user periodically take a swipe of the source housing assembly when no source is installed to check for leakage.
- 2) If a sealed source is in storage, it does not have to be leak tested every six months, however it must be leak tested when installed in the device.

In addition to the above, please note the following: In the cover letter of the application dated August 1, 1996, you stated that other source manufacturers may receive authorization in the future to distribute sealed sources for use in the device. However, prior to the use of any of these sealed sources in your device, the registration certificate for your device must be amended to show that these new sources are approved for use in the device.

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,

BS
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

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