From: Lanzisera, Penny
To: Fulford, Greg
Subject: Request for Additional Information
Date: Wednesday, May 24, 2017 2:53:00 PM

Licensee: Nordion (Canada)
License No. 54-28275-02MD
Docket No. 03030793
Mail Control 594718

In order to continue our review of your amendment request to add the new source model to your Medical Distribution license, we require the following additional information:

As requested in Appendix U of NUREG-1556, Volume 12, please provide the following additional information:

1. the maximum activity in each source, and the anticipated use of the sources. If the sealed sources are usually used in a device, specify the manufacturer's name and the model number of the device (e.g., ViewRay).

2. confirm that the activity per source will not exceed the maximum activity listed on the approved certificate of registration issued by NRC (when issued).

As requested in NUREG-1556, Vol. 13, please provide the following additional information:

1. Submit copies or facsimiles of the labels that will accompany the sources and specify where each label will be placed (e.g., on the source shield).

2. Submit copies of all leaflets and brochures that will accompany the sources.

3. Provide a copy of correspondence to and from the FDA that clearly shows that the FDA finds the source to be safe for medical use (e.g., 510(K) approval).

4. For shipping containers used, describe the type of shipping container, container shielding, maximum radiation level expected for a fully loaded container, and maximum activity allowed per container.

5. If you do not plan to offer a source return program, so state; no additional information is necessary. However, if you offer a source return program, you must have developed, and must supply to your customers, sufficiently detailed instructions (including instructions on labeling and shipping documents) to ensure that the shipper can comply with 10 CFR 71.5 and with DOT regulations. You must also submit to NRC copies or facsimiles of all forms, labels, and instructions that you will provide to customers for shipping sources back to your facility separately licensed for possession. As a minimum, the instructions must:

a. Establish the user's responsibility and liability as the shipper;
b. Provide step-by-step instructions for completing each item on each form and label that is involved in the shipping process; and
c. Discuss all the customer's responsibilities as a shipper under 49 CFR Parts 170 to 189.

This discussion of the customer's responsibilities should include (but is not limited to):
• The requirements to survey and wipe-test packages;
• The distance at which to survey packages;
• The action levels for the package wipe-test results;
• The dose rate limitations on the particular shipping label that you will provide; and
• The need for sealing tape or another mechanism to fulfill the security seal requirement.

As discussed previously, the sealed source review is underway. To complete our review, we need the final sealed source review and the additional information described above. You may submit the above information to my

attention via a signed pdf letter; signed by senior management. Alternatively, you may fax the signed letter to 610-337-5269. Please reference Mail Control No. 594718 in your reply. Sincerely,

Penny Lanzisera
Senior Health Physicist
U.S. NRC, Region I