## **NEUTRON PRODUCTS Inc**

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July 26, 2011

Mr James Dwyer, Chief
U.S. Nuclear Regulatory Commission
Region I Office
Division of Nuclear Materials Safety
Commercial and R&D Branch
475 Allendale Road
King of Prussia, PA 19406-1415

03038295

Re: License No. 19-25203-01 amendment 1

Via fax: 610/337-5269

Dear Mr. Dwyer,

The purpose of this letter is to seek clarification on whether or not an amendment to the referenced license is required to sell refurbished teletherapy units, unit components, and used cobalt-60 sources. Over the past eighteen months or so, we have had various conversations with NRC personnel regarding whether or not this activity should be listed in our license.

For more than three decades, Neutron Products refurbished and sold close to 100 teletherapy units under our Food and Drug Administration registration. However, during a visit by the FDA in October of 2009, we were informed that an FDA registration was no longer required for that activity. Over the years, we have made our regulators (both the Maryland Department of the Environment for our MD-31-025-03 license, and the NRC for our SUB-1551 license) aware of our teletherapy equipment operations and we have not been required to have any special license conditions related to those activities.

In addition, although we are no longer authorized by MDE to manufacture cobalt-60 sources at our Dickerson, MD facility, we occasionally have an opportunity to sell used sources which we remove from teletherapy units and store at an authorized licensee's facility.

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We have a customer that wants to replace a Picker head, collimator, and cobalt-60 source with a newer model and a higher activity source. They use the device for instrument calibration and are concerned that due to its age and the fact that there is a very limited supply of replacement parts available, future servicing may not be possible. The head and collimator we propose to provide were originally manufactured by Picker, and the cobalt-60 source was manufactured by Theratronics. Refurbishing of the head would be done in accordance with our written procedures and would include but is not limited to replacement of the front and rear source wheel bearings, power return spring, v-belt, bulbs, and source drive motor. In addition, we would inspect the source wheel, adjust all switches and mechanical stops, and inspect all moving parts replacing them as needed. Our license authorizes us to perform all of the services previously mentioned in the field at customer sites, however, we would be performing them in our shop while the head does not contain a source. The cobalt-60 source will be wipe/leak tested by SwRI at their facility in accordance with their procedures prior to shipment to the customer.

Please advise whether or not a license amendment is required for us to conduct this activity.

Thank you for your attention to this matter.

Sincerely,

Edmond J. DeRosa, R.S.O.

Neutron Products, Inc.