February 8, 2022

Mr. Tomas Herrera
E-License and SSD Team Leader
U.S. Nuclear Regulatory Commission
NMSS/MSST/MSTB

Subject: Request for Amendment to SS&DR Certificate NR-1490-D-101-S

BWXT Medical's customer is working with a radiopharmacy in the U.S. to re-dispense TheraSphere into low doses for First In Human (FIH) clinical studies of TheraSphere for use in treatment of glioblastoma tumors and potentially other ailments. As the current description of use of TheraSphere in BWXT Medical's Sealed Source and Device Registration (SSDR) is very specific in terms of treatment of liver tumors, BWXT Medical requests an amendment to revise the use to a generic description.

BWXT Medical is requesting an amendment to update the information in the DESCRIPTION and CONDITIONS OF NORMAL USE section of the registration certificate.

Section	**Current statement**	**New statement**
DESCRIPTION	TheraSphere is used to treat cancerous liver tumors via a catheter inserted into a tumor site through the patients' blood vessels. The Administration Set (to be used with the TheraSphere device) and Administration Accessory Kit (supplied to new user sites) facilitate the transfer of the radioactive microspheres from their container into the tumor.	TheraSphere is used to treat cancerous liver tumors **and for clinical trials approved by the FDA.** The Administration Set (to be used with the TheraSphere device) and Administration Accessory Kit (supplied to new user sites) facilitate the transfer of the radioactive microspheres from their container into the tumor **via a catheter inserted into the tumor site through the patients' blood vessels**. For FDA approved Investigational Device Exemption (IDE) studies, modification to the administration system may be required.
CONDITIONS OF NORMAL USE	TheraSphere Y-90 glass microspheres are designed for use in hospital or clinical environments for the treatment of cancerous liver tumors.	TheraSphere Y-90 glass microspheres are designed for use in hospital or clinical environments.

An FDA Investigational Device Exemption (IDE) is being sought by the customer for the glioblastoma treatment clinical trials. Modifications to the Administration Set for the clinical trials may be required. A copy of any new Administration Set schematics can be provided once determined.

The radiopharmacy in the U.S. is to be licensed by either the US NRC or their State to distribute the TheraSphere doses. BWXT Medical will be looking at the impact on our distribution license with the Commonwealth of Virginia when the license is available for review.

Please contact myself, Tim Mahilrajan at tmahilrajan@bwxt.com or 613-963-2416 or Steve Schilthelm at swschilthelm@bwxt.com or 434-316-7517 if you have any questions or require any additional information regarding this request.

Respectfully,

Tim Mahilrajan

Digitally signed by Tim Mahilrajan
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Tim Mahilrajan
Senior Manager - Nuclear Regulatory & EHS
BWXT Medical Ltd.

cc: S.W. Schilthelm, BWXT Advanced Tech LLC
Shannon Lacasse, BWXT Medical Ltd.