



May 21, 2021

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 Ltd. has been manufacturing and distributing TheraSphere according to NR-1490-D-101-S dated September 20, 2018 with shipments conducted under Nordion (Canada) Inc.'s Canadian export authorization issued by the CNSC. This commercial arrangement was to continue until such time as BWXT Medical Ltd. obtained a similar authorization. BWXT Medical Ltd. anticipates being granted their own Canadian export authorization on November 1, 2021.

Under the current arrangement, Nordion (Canada) Inc. remained on the shipping labels to clearly identify the shipper as Nordion and BWXT as the U.S. distributor ^[1]. As a result of BWXT obtaining their own export authorization, the label will be revised to indicate only BWXT Medical Ltd.

BWXT is requesting an amendment to update the information in the LABELING section of the registration certificate.

Current statement: "All shipping boxes have a standard shipping label identifying Nordion (Canada) Inc. as the shipper and BWXT Medical Ltd. as the manufacturer and distributor."

New statement: "All shipping boxes have a standard shipping label identifying BWXT Medical Ltd. as the Shipper."

We will advise you immediately upon receiving our export authorization so that an amended certificate can be issued to BWXT Medical Ltd. A copy of the export authorization will be provided to you when it becomes available. A copy of the revised shipping label will be provided to you when it is available.

Please contact myself, Jackie Kavanagh at jkavanagh@bwxt.com or 613-963-2265 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,

A handwritten signature in blue ink that reads "J. Kavanagh".

Jackie Kavanagh
Senior Manager - Nuclear Regulatory & EHS
BWXT Medical Ltd.

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

References:

[1] Letter to Mr. H. Gonzales, US NRC, from T. Burnett, BWXT, "Response to NRC Request for Information Regarding Transfer of Registration Certificate and Request for Amendment Registration Certificate NR-0220-D-131-S", June 26, 2018.