Enclosure 2

Confidential Information Submitted Under 10 CFR 2.390

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SUBJECT: REQUEST FOR EXTENSION OF IMPLEMENTATION OF AUTHORIZED USER TRAINING AND PROCTORING FOR THERASPHERE Y-90 MICROSPHERE BRACHYTHERAPY

Dear Dr. Tapp:

On November 8, 2019, and March 20, 2020, the U.S. Nuclear Regulatory Commission (NRC) published updates to the Yttrium-90 Microsphere Brachytherapy Sources and Devices, TheraSphere® and SIR-Spheres® Licensing Guidance related to training and experience for physicians seeking Authorized User (AU) status. The revised guidance (Section 5.1.A.1.3.iv.) states that interventional radiologists must complete work experience or training under the supervision of an AU for the following topics: preparing and administering patient dosage; using administrative controls to prevent a medical event; and evaluation of each patient treatment to determine whether the administered dosage was in accordance with the written directive. The revised guidance (Section 5.1.B.) also states that physicians seeking AU status must complete training in the operation of the delivery system, safety procedures, and clinical use of the product and that the clinical use cases must be supervised by an AU.

Boston Scientific is requesting that NRC continue to allow manufacturer representatives to provide the training in Section 5.1.A.1.3.iv. or that an AU provide this training in conjunction with proctored clinical use cases starting after November 8, 2022. If training from Section 5.1.A.1.3.iv. must be provided by an AU, as the guidance is currently written, this will require an additional, separate training session from an AU in advance of the radioactive materials license amendment. [redacted] Boston Scientific's preference is that training described in Section 5.1.A.1.3.iv. continue to be provided by a manufacturer representative instead of an AU proctor. [redacted] Finally, if an AU must provide this training, Boston Scientific requests that the guidance be revised to allow this training to be given in conjunction with onsite proctored cases instead of occurring prior to the submission of the radioactive materials license amendment request.

10 CFR 2.390(a)(4) Privileged Commercial Information

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Boston Scientific is also requesting that NRC extend the implementation date for AU supervision of clinical use cases from November 8, 2021, to November 8, 2022. [redacted] If manufacturer representatives are not allowed to continue to provide these services beyond the November 8, 2021 implementation date, this will directly impact patient care, as cases will be cancelled. This will also further delay a training physician's ability to achieve AU status.

10 CFR 2.390(a)(4) Privileged Commercial Information

Boston Scientific is requesting the NRC re-evaluate the need for attestations for Y-90 microsphere training and experience. Some residency directors/existing AUs are unwilling to provide the required attestations in Part C of the revised guidance, especially for potential AUs who completed parts of the training and experience at different locations or during a time when the current director/AU was not overseeing the program. This means the potential AU must obtain up to six separate attestations: 1) diagnostic radiology plus 80 hours of training; 2) interventional radiology; 3) work experience in topics listed in 5.1.a.3.iii.; 4) work experience in topics listed in 5.1.a.3.iv; 5) training in the operation of the delivery system, safety procedures, and clinical use cases, including supervised cases; and 6) confirmation of ability to fulfill the radiation safety-related duties. Under the guidance, these attestations are being required regardless of the potential AUs board certification status, which does not align with NRC's existing regulations in 10 CFR Part 35 for other similar therapies. Gathering these signatures causes delays in patient treatments, as potential AUs are unable to schedule patients until at least the first four attestations have been obtained. Further, this has created an additional burden on NRC and Agreement license reviewers, as they request verification that the individual attesting is an AU for the type of Y-90 microspheres being requested. This verification can done by providing the name of the AU's facility and radioactive materials license (RAML) number, but in other cases it requires providing a copy of the AU's RAML, which must be requested from the site Radiation Safety Officer (RSO). Even when a copy of the RAML is provided, this may not be sufficient since broad scope licenses do not name individual AUs. When this occurs, the site RSO must write a letter to the regulator confirming the AUs credentials and status. This additional paperwork does not enhance patient, occupational, or public safety and causes delays in patient treatments because physicians are collecting documentation instead of practicing medicine.

In summary, Boston Scientific is requesting the following: 1) for NRC continue to allow manufacturer representatives to provide the training in Section 5.1.A.1.3.iv. or that an AU provide this training in conjunction with proctored clinical use cases starting after November 8, 2022; 2) for NRC to delay implementation of AU-to-AU proctoring until November 8, 2022; 3) for NRC to re-evaluate the need for attestations.

Sincerely,

DocuSigned by:

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Regional Medical Director
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