UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

April 20 , 2021

ALL AGREEMENT STATES, CONNECTICUT

NOTIFICATION OF ISSUANCE OF REVISION 10.2 OF YTTRIUM-90 MICROSPHERE BRACHYTHERAPY SOURCES AND DEVICES THERASPHERE® AND SIR-SPHERES® LICENSING GUIDANCE (STC-21-020)

Purpose: To inform the Agreement States that the U.S. Nuclear Regulatory Commission (NRC) issued a revision to the Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® licensing guidance.

Background: On March 21, 2021, Boston Scientific received its premarket approval (PMA) from the U.S. Food and Drug Administration (FDA) for TheraSphere®. Previously, TheraSphere® was approved by the FDA under the provisions of a Humanitarian Device Exemption (HDE) which require unique restrictions on the medical use of the device. Sirtex Medical's PMA for the Sir-Sphere® Y-90 resin microspheres was approved by the FDA March, 5, 2002.

Discussion: In previous revisions of the licensing guidance, Section 7.3 provides information on the TheraSphere® HDE, and the associated requirements for use of the device under an HDE. Specifically, an Institutional Review Board (IRB) must review and approve initial use of an HDE device before it is used at a facility. Further, if the IRB determines that the particular use is for research purposes, the licensee must meet the requirements in Title 10 *Code of the Federal Regulations* (10 CFR) 35.6, "Provisions for the protection of human research subjects." Because TheraSphere® now has a PMA, an IRB review and approval is no longer required. Therefore, Section 7.3, which described the HDE and IRB requirements for TheraSphere®, was removed the licensing guidance. Note requirements in 10 CFR 35.6 would still apply if a licensee conducts research described in 10 CFR 35.6(b).

If you have any questions regarding this correspondence, please contact me at 301-415-3340 or the individual named below:

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Office of Nuclear Material Safety and Safeguards

Enclosure:
Revision 10.2, Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® licensing guidance

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