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

April 19, 2021

MEMORANDUM TO: Blake D. Welling, Director
Division of Radiological Safety and Security
Region I

David L. Pelton, Director
Division of Nuclear Materials Safety
Region III

Mary C. Muessle, Director
Division of Nuclear Materials Safety
Region IV


Signed by Einberg, Christian
on 04/19/21

FROM: Christian E. Einberg, Chief
Medical Safety and Events Assessments Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

SUBJECT: NOTIFICATION OF ISSUANCE OF REVISION 10.2 OF YTTRIUM-90 MICROSPHERE BRACHYTHERAPY SOURCES AND DEVICES THERASPHERE® AND SIR-SPHERES® LICENSING GUIDANCE

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.

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.

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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).

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

Regional Memo for Issuance of Y-90 Microsphere Brachytherapy license guidance revision 10.2 DATE April 19, 2021

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