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

November 13, 2019

MEMORANDUM TO:

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FROM:

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SUBJECT:

NOTIFICATION OF ISSUANCE OF YTTRIUM-90 MICROSPHERE BRACHYTHERAPY LICENSING GUIDANCE, REVISION 10

Yttrium-90 (Y-90) Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance, Revision 10, was published on November 8, 2019. The licensing guidance for Y-90 microsphere brachytherapy was initially published in October 2002 and subsequently revised in 2004, 2007, 2008, 2011, 2012, and 2016 as operational experience was gained with the novel technology. A revision 10 to the guidance was sought to evaluate previous stakeholder comments not addressed in the 2016 revision and Authorized User (AU) training and experience (T&E) requirements. The T&E pathway which allows AUs to be added to a license prior to completing their first 3 patient cases was evaluated because Agreement State and the U.S. Nuclear Regulatory Commission (NRC) licensing staff thought that after over 10 years of licensing Y-90 microspheres, there should be enough AUs to train future AUs and that the manufacturer was no longer needed.

This revision makes significant changes to the T&E section based on public and stakeholder comments and the recommendations of the Advisory Committee on the Medical Uses of Isotopes. Specifically, the T&E criteria was changed to require physicians to receive work experience or training related to the medical use of Y-90 microspheres under the supervision of an AU and to conduct their first three cases in the physical presence of an AU. Previous

revisions to the guidance allowed manufacturer representatives to provide all Y-90 microspheres specific training or supervision. The working group determined this change was supported and that training in topics related to medical use of the Y-90 microspheres should be given or supervised by an AU, consistent with other modalities regulated by the NRC. The AU supervising the training may still be an employee or contractor of the manufacturers. It is expected that there may be physicians who are in the process of using a previous revision of this guidance to become an AU; and therefore, we are implementing a 180-day implementation period, resulting in an effective date of **May 6, 2020** for this guidance.

Revision 10 was also revised to include the recentness of training requirements, including a reference to 10 CFR 35.59 to be consistent with other modalities and a 1-year timeframe for individuals to finish their first three patient cases for physicians who have not yet completed them. These changes ensure all training occurs in a reasonable timeframe. In addition, revisions were made throughout the document based on comments, including clarifications on medical event reporting, applicable regulations, and waste disposal issues.

The guidance was not revised to remove the option to allow a physician to become an AU prior to completing their first three patient cases. This option was not removed due to significant industry and medical licensee comments that this could cause delay or harm in patient care. Please see the working group response to public comments for more information (Agencywide Documents Access and Management System Accession No.ML19030B536).

This licensing guidance revision is available at http://www.nrc.gov/materials/miau/med-use-toolkit.html.

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