



Informational Bulletin 2020-04

May 11, 2020

To: Radioactive Materials Medical Licensees

From: David M. Howe, Program Director
Radiation Protection Services

Subject: Updated Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance, Revision 10; and Nuclear Regulatory Commission's (NRC) Training and Experience Form 313A Series .

The Center for Health Protection, Radiation Protection Services (RPS) is releasing this informational bulletin to advise licensees who provide medical or therapeutic radioactive material services of updated licensing guidance effective May 6, 2020 for Yttrium (Y-90) and physicians applying to become a licensed authorized user for a specific medical modality.

The NRC's licensing guidance for Y-90 microsphere brachytherapy updates the criteria for training and experience, medical event reporting, inventory requirements, and waste disposal issues. Updated guidance also outlines the training and education criteria, and now requires a physician to perform clinical cases under the personal supervision (physically present in the treatment venue during the procedure) of an authorized user. In addition, Revision 10 adds a new section regarding surveys and guidance for patient release criteria, cremation, and autopsy procedures.

Revision 10 is available at <https://www.nrc.gov/materials/miau/med-use-toolkit.html>

NRC Form 313 series have been revised and will be implemented June 1, 2020. The new Form series can be downloaded at <https://www.nrc.gov/materials/miau/med-use-toolkit.html>

The NRC 313 forms were updated in January 2020 to complement 10 CFR Part 35 regulation amendments and future Oregon rulemaking within chapter 333, division 116. Guidance for the "Final Rule Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments" is available at <https://www.nrc.gov/docs/ML1817/ML18176A377.pdf>.

These instructions outline the training and experience requirements in 10 CFR Part 35 that went into effect on January 14, 2019. In addition, the forms provide training and experience attestation for an Associate Radiation Safety Officer. Physicians who possess a medical specialty board recognized by the Nuclear Regulatory Commission will be excused from completing specific portions of the NRC 313 form series.

If you have questions or need further clarifications, please contact Erin DeSempé at (971) 673-0510 or email at erin.desemple@dhsosha.state.or.us