



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

November 15, 2017

ALL AGREEMENT AND NON-AGREEMENT STATES

FEDERAL REGISTER NOTICE – YTTRIUM-90 (Y-90) MICROSPHERE BRACHYTHERAPY SOURCES AND DEVICES THERASPHERE® AND SIR-SPHERES® (STC-17-078)

Purpose: To provide notification that the U.S. Nuclear Regulatory Commission (NRC) has published a *Federal Register* notice (FRN) inviting public comment on the draft revision of the Yttrium-90 (Y-90) Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® licensing guidance (Rev. 10).

Background: 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. Following years of using the current licensing guidance, the NRC staff, stakeholders, and the Advisory Committee on the Medical Uses of Isotopes identified numerous issues that need to be addressed. A working group composed of Agreement State representatives and NRC staff was formed to address identified issues.

Discussion: The NRC issued an FRN on November 7, 2017 (82 FR 51655) to request comment on the draft revision. The licensing guidance for Y-90 microsphere brachytherapy has been revised to update criteria for training and experience, medical event reporting, inventory requirement specifications, and waste disposal issues. The revised draft guidance provides new information regarding cremation and autopsy.

The FRN (82 FR 51655) is enclosed. A copy of the FRN is available online at the following link: <https://www.federalregister.gov/d/2017-24129>. If you would like to respond to the FRN, please submit your comments to <http://www.regulations.gov> using docket number NRC-2017-0215. The comment period closes January 8, 2018.

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

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Enclosure:
Yttrium-90 (Y-90) Microsphere Brachytherapy
Sources and Devices TheraSphere® and
SIR-Spheres® licensing guidance (Rev. 10)

SUBJECT: *FEDERAL REGISTER* NOTICE – YTTRIUM-90 (Y-90) MICROSPHERE BRACHYTHERAPY SOURCES AND DEVICES THERASPHERE® AND SIR-SPHERES® (STC-17-XXX). DATE: NOVEMBER 15, 2017.

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