



UNITED STATES
NUCLEAR REGULATORY COMMISSION
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March 7, 2016

ALL AGREEMENT STATES, VERMONT, WYOMING

NOTIFICATION OF ISSUANCE OF YTTRIUM-90 MICROSPHERE BRACHYTHERAPY
LICENSING GUIDANCE (STC-16-020)

Purpose: To inform the Agreement States that the Yttrium-90 (Y-90) Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance, Revision 9, was published in February 2016.

Background: The licensing guidance for Y-90 microsphere brachytherapy was initially published in October 2002 and subsequently revised in 2004, 2007, 2008, 2011, and 2012. Based on recommendations from the Advisory Committee on the Medical Uses of Isotopes (ACMUI), a joint Organization of Agreement States and U.S. Nuclear Regulatory Commission (NRC) working group revised this licensing guidance. The document is intended to be guidance in licensing Y-90 microsphere brachytherapy for applicants, licensees, NRC staff, and Agreement States.

Discussion: This current licensing guidance revision has three major changes based on ACMUI recommendations. These changes (1) remove specifications for gastrointestinal tract and lung dose/activity in the written directive and exclude reporting dose/activity to an organ or tissue other than the treatment site as a medical event when the dose/activity is caused by shunting when the shunting was evaluated prior to treatment in accordance with manufacturer's procedures, (2) specifically exclude reporting of events due to stasis or emergent patient conditions, and (3) allow for interventional radiologists certified by the American Osteopathic Board of Radiology to become Authorized Users.

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

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

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