# PUBLIC SUBMISSION

**As of:** 2/8/18 2:05 PM
**Received:** February 08, 2018
**Status:** Pending_Post
**Tracking No.** 1k2-91du-ys8n
**Comments Due:** February 08, 2018
**Submission Type:** Web

**Docket:** NRC-2017-0215
Yttrium-90 Microsphere Brachytherapy Sources and Devices Therasphere and SIR-Spheres

**Comment On:** NRC-2017-0215-0024
Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres; Draft Guidance; Extension of Comment Period

**Document:** NRC-2017-0215-DRAFT-0132
Comment on FR Doc # 2017-28271

## Submitter Information

**Name:** Richard Martin
**Organization:** American Association of Physicists in Medicine

## General Comment

See attached file(s)

## Attachments

AAPM Comment NRC Y-90 Guidance Final RM

137
83 FR 159
1/2/2018

**SUNSI Review Complete**
**Template = ADM – 013**
**E-RIDS= ADM-03**
**Add=** Lisa Dimmick (lcd1)
Katherine Tapp (kns1)

AMERICAN ASSOCIATION
*of* PHYSICISTS IN MEDICINE

February 8, 2018

May Ma
Office of Administration
Mail Stop: OWFN-2-A13
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

RE: Request for Comment: Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Draft Guidance (NRC-2017-0215)

Dear Ms. Ma:

The American Association of Physicists in Medicine (AAPM)[1] is pleased to submit comments to the U.S. Nuclear Regulatory Commission (NRC) regarding Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Draft Licensing Guidance (Revision 10). The AAPM commends the NRC on its work in providing the NRC with a set of standard criteria for evaluating a medical use license application for the use of TheraSpheres and SIR-Spheres.

The AAPM is generally supportive of the draft guidance, but the AAPM does not support the elimination of the alternate pathway, which allows applicants to gain clinical experience and achieve Authorized User (AU) status under the supervision of a manufacturers' Representative who is an AU.

The AAPM has the following specific comments:

[1] The American Association of Physicists in Medicine (AAPM) is the premier organization in medical physics, a broadly-based scientific and professional discipline encompassing physics principles and applications in biology and medicine whose mission is to advance the science, education and professional practice of medical physics. Medical physicists contribute to the effectiveness of radiological imaging procedures by assuring radiation safety and helping to develop improved imaging techniques (e.g., mammography, CT, MR, ultrasound). They contribute to development of therapeutic techniques (e.g., prostate implants, stereotactic radiosurgery), collaborate with radiation oncologists to design treatment plans, and monitor equipment and procedures to ensure that cancer patients receive the prescribed dose of radiation to the correct location. Medical physicists are responsible for ensuring that imaging and treatment facilities meet the rules and regulations of the U.S. Nuclear Regulatory Commission (NRC) and various state regulatory agencies. AAPM represents over 8,700 medical physicists.

**Recommended Minimum Clinical Experience**

The AAPM supports the licensing guidance's current recommendation that a prospective AU demonstrate clinical experience with the device. We recognize the complexity of delivery of Y-90 microspheres, and agree with the current recommendation that a prospective AU complete 3 patient cases for each type of microsphere prior to approval. The AAPM believes 3 patient cases provide adequate clinical experience for a physician to gain AU status for Y-90 microspheres.

**Adding Authorization for Other Microsphere Type**

The AAPM believes that 3 additional cases are adequate as additional training when an AU who is already authorized to use one type of microsphere requests authorization for use of another type of microsphere.

**Written Attestation from Preceptor**

The AAPM supports requiring written attestation for individuals trained by an AU, but expresses concern that obtaining written attestation may be challenging for those individuals trained through the alternate pathway. In the past, the NRC states it has not required a written attestation, signed by a preceptor AU, because there was not a sufficient number of AUs to supervise the training and sign the written attestation, and the alternate pathway allowed manufacturers' representatives to provide clinical training and experience to the prospective AU. The AAPM believes the alternate manufacturers' training pathway should be maintained and written attestation should not be required for those applicants using the alternate pathway.

**Clinical Experience Under the Supervision of a Manufacturer Representative**

The AAPM believes the alternate training pathway, which allows an applicant to achieve AU status for Y-90 microsphere brachytherapy by committing to completing the first three patient cases under the supervision of a manufacturer's representative, is valuable and should not be discontinued. While this manufacturer supervision is a unique pathway specific to Y-90 microspheres, it provides uniform training that includes a thorough didactic review of the therapy as well as clinical training experience. Moreover, we believe there are some differences and advantages to continuing manufacturers' training. The manufacturers'

representatives can have significant experience with these devices, often exceeding that of a newly licensed AU. A representative that has completed hundreds of cases may be much more familiar with the device to assist with administration of microspheres than a physician who has done only three administrations. Moreover, the manufacturers' representatives can draw on significant data including pharmaco- and device- vigilance feedback that often is not readily available to others.

The AAPM questions whether there are now sufficient AUs to ensure adequate patient access to these procedures, particularly in rural communities without AUs. If the alternate pathway provided by manufacturers' representatives is eliminated, physician training will have to be performed solely by direct proctoring from AUs. We believe that securing physician trainers will be a challenge. These procedures are labor- and time- intensive. The AAPM expresses concern as to whether current AUs, physicians with limited time and availability away from their own clinical practices, will have the commitment, time and other resources to provide the training and clinical experience to future AUs. The AAPM cautions against eliminating the alternate pathway because doing so could have a negative impact on patient safety and access to care.

The alternate pathway has been an effective means of gaining AU status for more than 10 years. We believe that the collaboration between physicians and industry exhibited by this pathway has helped to ensure safe and comprehensive training in the delivery of Y-90 microspheres to patients.

**Timeliness for Completion of In-Vivo Cases**

The AAPM is supportive of the NRC's proposal to require one in-vivo case prior to treating patients if 6 months has passed to ensure recentness of training.

**Medical Event Definition**

The AAPM believes the definition of medical events (ME) for Y-90 microspheres requires great care given the complexity and variability of the delivery of microspheres to each patient. While Y-90 microspheres can be delivered to a sub-lobe location, unanticipated events, including dissection and embolization, can occur that can modify the delivered dose. Accordingly, AAPM believes flexibility in a written directive is needed to address these

circumstances. We believe the AU should be given the flexibility to perform the treatment even when it is determined in the interventional radiology suite that some dose or activity may go to the lobe opposite the lobe documented in the written directive. Use of a dose or activity range in the written directive prior to administering the Y-90 microspheres may be an appropriate method of addressing this issue.

**In summary,** the AAPM believes the alternate pathway--the manufacturers' training pathway--provides a valuable means for authorized user applicants to gain didactic training and clinical supervision experience in the use of TheraSpheres and SIR-Spheres, and accordingly, AAPM does not support the elimination of this pathway. The AAPM hopes that the NRC will consider AAPM's comments and adopt AAPM's recommendations when crafting the final guidance on Y-90 Microsphere Brachytherapy.

Thank you for the opportunity to comment. If you have any questions or require additional information, please contact Richard J. Martin, JD, Government Relations Project Manager, at 571-298-1227 or Richard@aapm.org

Sincerely,

Bruce R. Thomadsen, PhD, FAAPM, FACMP
President, AAPM