



HEALTH PHYSICS SOCIETY

Specialists in Radiation Safety

December 22, 2017

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

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Docket ID No. NRC-2017-0215

Subject: Request for comment on Yttrium-90 (Y-90) Microsphere Brachytherapy Sources and Devices TheraSphere and SIRSpheres

The HPS appreciates the opportunity to provide comments in response to the published information request in the attached document.

The Health Physics Society¹ (HPS) is a professional organization whose mission is to promote excellence in the science and practice of radiation safety.

If you have any questions regarding these comments, please contact the HPS Agency Liaison, Craig Little, at 970-260-2810 or by email to agencyliaison@hps.org.

Sincerely,

Abelquist, Eric

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Eric Abelquist, Ph.D., CHP

President

cc: Craig Little, PhD, HPS Agency Liaison
Brett Burk, HPS Executive Director
Linda Kroger, HPS Medical Section
Joseph Ring, HPS Government Relation Committee

¹ The Health Physics Society is a non-profit scientific professional organization whose mission is to promote the practice of radiation safety. Since its formation in 1956, the Society has grown to include over 4,000 scientists, physicians, engineers, lawyers, and other professionals representing academia, industry, government, national laboratories, the Department of Defense, and other organizations. Society activities include encouraging research in radiation science, developing standards, and disseminating radiation safety information. Society members are involved in understanding, evaluating, and controlling the potential risks from radiation relative to the benefits. Official position statements are prepared and adopted in accordance with standard policies and procedures of the Society.

Background

On November 7, 2017, the Nuclear Regulatory Commission requested comment on a proposed revision 10 to “Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance”. The maturing of the Yttrium-90 therapy program now offers a wider range of professionally qualified clinicians and many years of clinical experience. As a result, the proposed revision represents changes to bring the licensing guidance into closer alignment with standard brachytherapy licensing guidance that is consistent with this unique therapy.

Summary Position:

The Health Physics Society supports the proposed revision 10 of “Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance”.

Specific Comments

The following are responses to the specific questions raised by the Federal Register Notice:

(1) Recommended Minimum Clinical Experience

We support the current recommendation for each prospective Authorized User (AU) to participate in three patient cases for each type of Y-90 microsphere prior to approval. This should be sufficient for the AU to acquire the necessary clinical experience with the device, and it is consistent with the requirements for other therapy modalities in 10 CFR 35.

(2) Adding Authorization for Other Microsphere Type

The two Y-90 microsphere products currently available are significantly different in their dose treatment plan and delivery apparatus. A prospective AU should have training and experience in the operation of the delivery system, safety procedures and clinical use for each type of Y-90 microsphere for which authorization is sought. This should also include participation in three patient cases for each type of Y-90 microsphere.

(3) Written Attestation from Preceptor:

We support the requirement for a written attestation signed by a preceptor AU. This is consistent with other therapy modalities under 35.1000.

(4) Clinical Experience under the Supervision of a Manufacturer Representative:

We support the removal of the alternate pathway, which allows an individual to become an AU for Y-90 microsphere brachytherapy prior to completing any patient cases. There should currently be enough AUs who are authorized for each type of Y-90 microsphere for

physicians who were seeking authorization to complete the necessary clinical experience under the supervision of another AU already authorized for the use of Y-90 microspheres. This is also consistent with other therapy modalities under 35.1000.

(5) Timeliness for Completion of In-Vivo Cases:

To ensure recentness of training, we support the proposed one mentored in-vivo case prior to treating patients, if 6 months has passed since issuing the license naming an individual as an AU who followed the alternate pathway.

(6) Medical Event Definition:

There must be flexibility in the written directive to avoid reporting of events, such as stasis of arterial flow and shunting, which cannot be controlled using the current technology. We support that these events should be included as “patient intervention”. Occlusion of the patient arterial catheter could also be included in this category. Prescribing a dose range should also be permitted as long as it is within the clinically accepted dose.