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Yttrium-90 Microsphere Brachytherapy Sources and Devices Therasphere and SIR-Spheres

Comment On: NRC-2017-0215-0001
Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres; Draft Guidance for Comment

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Submitter Information

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General Comment

(1) Recommended Minimum Clinical Experience: The NRC is seeking specific comments on whether 3 patient cases provide adequate clinical experience for a physician to gain AU status for Y-90 microspheres.

Yes - Interventional Radiologists receive training in Y-90 microspheres during fellowship. 3 cases is sufficient to demonstrate competency in Y-90 dosimetry, handling and administration.

(2) Adding Authorization for Other Microsphere Type: The NRC is seeking comments to determine additional training needed when an AU who is already authorized to use one type of microsphere requests authorization for use of another type of microsphere. For instance, are 3 additional cases for the other type of microsphere necessary for the AU to gain the knowledge to safely administer the new microsphere, or should the number of cases be left to the discretion of the supervising AU?

Discretion of the supervising AU - Interventional Radiologists receive training in both types of Y-90 microspheres during training. 3 or less cases should be sufficient to demonstrate

competency.

(3) Written Attestation from Preceptor: Is there anything unique about Y-90 microsphere brachytherapy compared to other types of manual brachytherapy that would obviate the need for a written attestation.

Yes - Y-90 brachytherapy is being performed on a larger scale than any prior brachytherapy and Interventional Radiologists are trained to safely perform the the procedure during fellowship.

(4) Clinical Experience under the Supervision of a Manufacturer Representative: The NRC is seeking comments on whether completing the recommended clinical experience under the supervision of AU(s) authorized for the type of microsphere for which the new physician is seeking authorization still presents an undue burden on physicians.

Yes - Individually proctoring each new AU would place an undue burden on existing AUs, who must attend to their own patients and practice demands. Additionally, the complication rate from radioembolization according to the MAUDE database is extremely low - this is a solution to a problem that doesnt exist.

The NRC is seeking comments on whether finding licensed facilities at which the physicians could complete this clinical experience would be difficult.

Yes - Finding facilities to complete this training would be difficult. More importantly, it would be very disturbing to the facilities workflow and patient care to have constant trainees present.

Attachments

SIR NRC Letter Gonzalez

I am writing to you as a current interventional radiologist, current authorized user and a member of The Society of Interventional Radiology (SIR), a physician association comprised of over 6,100 members representing the majority of practicing interventional radiologists in the United States.. I am corresponding to voice my strong opposition to the proposed changes to the "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance" that would eliminate vendor involvement from the Interventional Radiology pathway to Authorized User (AU) status.

The current process, known as Pathway 2, has been in place since the concept evolved that Interventional Radiologists are the natural AU's of these devices. For these procedure, Interventional Radiologists:

- Perform required dosimetry to deliver appropriate activity to the patient
- Oversee and ensure appropriate Yttrium-90 (Y90) device handling and preparation
- Directly administer the therapy to the patient
- Coordinate the longitudinal care of patients following these procedures

Interventional Radiologists are **the only Authorized Users capable of performing all four steps above**. The existing collaboration between physicians and industry helps ensure safe and comprehensive training in the use of Y90 devices.

The existing guidelines have been tremendously successful while maintaining impeccable safety. Manufacturer And User facility Device Experience (MAUDE) reports have remained $\leq$ 10/year for both devices since 2013. The majority of the MAUDE reports focus on procedural complication and treatment toxicities seen with all types of hepatic embolization, not specific to the Y90 devices. It seems statistically implausible that reduced vendor involvement will result in a measurable improvement in safety.

Proposed changes to the current arrangement, in which physicians and industry work closely together to ensure the appropriate training of interventional radiologists in the safe use of these devices will make it exceedingly difficult for Interventional Radiologists developing a clinical practice in radioembolization. Without the current direct training provided offsite by the device vendors, physician training will have to be solely performed by direct proctoring. Securing physician proctors is a challenge and can result in the delay in care, impacting cancer outcomes; physicians have limited time and availability away from their own clinical practices. Placing additional responsibilities on physician proctors may also have the untoward effect of limiting access to care, particularly for programs in underserved areas. **The unanticipated consequence of the proposed changes is that training Interventional Radiologists in the safe and effective use of these devices will suffer greatly and patient access to care will diminish.**

In summary, Interventional Radiologists deliver high quality minimally invasive care via imaging guidance, employing a variety of technologies. Training with other devices, such as aortic stent grafts, spinal augmentation devices, and atherectomy tools frequently

involves a combination of vendor and physician collaboration. These relationships are a supplement to core training in hepatic embolization that is accomplished in fellowship. However, fine details regarding all devices may not be included in all programs. The existing NRC guidelines have facilitated training Interventional Radiologists in the safe and effective use of the Y90 devices, benefiting patients, physicians, and the government. There is no evidence of a need for change to the current NRC guidelines.

Regards,

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