

PUBLIC SUBMISSION

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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Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres; Draft Guidance; Extension of Comment Period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-0118

Comment on FR Doc # 2017-28271

82 FR 51655
11/7/2017

Submitter Information

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Name: Scott Schwartz

General Comment

I am writing to voice my strong opposition to proposed changes to the "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres Licensing Guidance". Specifically, I am opposed to the section that would eliminate vendor involvement from the Interventional Radiology (IR) pathway to Authorized User (AU) status. Changing the current Pathway 2 process will make it exceedingly difficult for Interventional Radiologists to become Authorized Users. Interventional Radiologists are the primary operators and providers of these services. Especially in smaller practices and communities, the pathway for AU status needs to be accessible and reasonable to obtain. Removing the vendor involvement will have the unintended consequence of compromised patient care and patient access to care.

Please see attached letter.

SUNSI Review Complete
Template = ADM - 013
E-RIDS= ADM-03
Add=Lisa Dimmick (1c1)

Attachments

NRC letter



DEPARTMENT OF RADIOLOGY
Henry Ford Hospital & Health Network

Scott Schwartz, M.D.

Senior Staff Interventional Radiologist
2799 West Grand Blvd.
Detroit, Michigan 48202-2689
(313) 916-1363 Office
(313) 916-1253 Fax
E-mail: scotts@rad.hfh.edu

I am writing to you as a current interventional radiologist 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 ≤ 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



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Scott Schwartz, M.D.
Senior Staff Interventional Radiologist
2799 West Grand Blvd.
Detroit, Michigan 48202-2689
(313) 916-1363 Office
(313) 916-1253 Fax
E-mail: scotts@rad.hfh.edu

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.

Sincerely,

A handwritten signature in black ink, appearing to read "Scott Schwartz".

Scott Schwartz, M.D.
Clinical Assistant Professor, Wayne State University School of Medicine
Program Director, Interventional Radiology Residency
Program Director, Vascular and Interventional Radiology Fellowship
Henry Ford Hospital
Detroit, Michigan



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