PUBLIC SUBMISSION

As of: 12/7/17 10:54 AM
Received: December 05, 2017
Status: Pending_Post
Tracking No. 1k1-906f-j370
Comments Due: January 08, 2018
Submission Type: Web

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

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Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres; Draft Guidance for Comment

Document: NRC-2017-0215-DRAFT-0096
Comment on FR Doc # 2017-24129

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11/7/2017
82 FR 51655
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General Comment

See attached file(s)

Attachments

Brian Stainken Comments Docket NRC-2017-0215

SUNSI Review Complete
Template = ADM – 013
E-RIDS= ADM-03
Add= L Dimmerick (LCD1)

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Brian Stainken, MD

Chair, Department of Radiology | Stamford Hospital

I am writing in response to the request for comments related to the guidance for licenses authorizing the use of Yttrium-90 (Y-90) Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres®. (Docket ID NRC-2017-0215)
I understand that the goal is to harmonize this device with others covered under 10CFR part 35. While harmonizing the rules is reasonable for many aspects of the device, the requisites for safe delivery of this new class of device are unique and cannot be satisfied by providers who coincidentally carry AU status for other isotopes but do not have the skill set and fluency for optimal dosimetry and administration. There is only one community of providers that possess all the requisite qualifications in vascular physiology, catheterization, trans arterial therapy and embolization to provide safe delivery of a radioactive liquids and particulates into the circulatory system. Since the last licensing guidance modification, this discipline has been recognized by the ACGME as a primary specialty and the first class of residents is now beginning their five year training program. It is a unique benefit that these trainees coming from the new DR/IR program, are both radiation experts and proceduralists. As such, they can be residency qualified both as an AU and as an IR.

As these trainees graduate and the field matures, there may no longer be a need for an alternative pathway for licensure of practicing Interventional Radiologists as they should be able to qualify based on their training. Perhaps a solution is to attach a grandfathering stipulation to the guidance for those trained prior to the primary certificate era. Alternatively, for the following reasons, the horizon (if any) for eliminating the alternative pathway should be extended.

- The first IR residents will not graduate in 202??. With a career span of 30 years, we should not expect this group of providers to become the majority for at least 20-30 years. .
- The clinical adoption of this therapy is growing and has not plateaued. This is driving a demand for more qualified licensed providers, especially in low population/underserved areas. In these regions, besides the aforementioned issues with non IR AU administration, it is less even less likely that a two providers fluent in this technology will be found (one to supervise and one to deliver treatment). Allowing industry to continue to support the preceptor/proctoring process will help preserve the opportunity for treatment in these environments.
- Trans arterial isotope infusion therapies are likely to expand and the unique qualifications and experience required for safe administration will probably continue to diverge from those devices delivered into more 'static' territories (such as the Oral administration, trans perineal, and transcavitary). This may ultimately drive the need for an expanded licensing guidance for therapies selectively administered in the circulatory system as the field matures.

RESPONSES TO QUESTIONS:

(1) *Recommended Minimum Clinical Experience:* The "complexity' of delivery of y 90 microspheres is primarily related to the nature of the approach to delivery. Practitioners authorized to use the device should be intimately familiar with hepatic/visceral arterial anatomy, techniques for micro catheterization and embolization. The challenge for on target delivery with this device relates to technical skill and fluency in the delivery of drugs and devices through catheters in the liver. Per the ABMS this skill set falls to the newly recognized specialty of Interventional Radiology exclusively. An authorized user must be able to understand what they are looking at and present enough to understand evolving flow dynamics. Otherwise, the patient is at risk. *For a board certified Interventional Radiologist, three supervised patient cases is adequate. In my opinion, other providers may be competent in the pre administration process but not for device handling and safe delivery.*

(2) *Adding Authorization for Other Microsphere Type:* The differences in the devices in terms of administration are relatively minimal. The approach to dissymmetry is different although this is variable within the AU community and evolving for both devices. The requisites for handling and safe delivery are the same. I do not believe that

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additional AU training for the same isotope delivered the same way is necessary. I do think that is is reasonable to demonstrate competency with dose management prior to administration as there is some variability in that aspect of the procedure.

(3) *Written Attestation from Preceptor:* Reasonable.

(4) *Clinical Experience under the Supervision of a Manufacturer Representative:* The best person to plan and deliver this (in my opinion) is a board certified, preferably experienced, IR. The alternative pathway has allowed this 'organic' approach to flourish and we have succeeded in developing a community of experts. But this group has not reached critical mass in terms of size and geographic distribution. The field is evolving and it continues to grow. While I believe there will be a time where all IR trainees will be reasonably competent in this treatment, we are not there yet. The system put in place has worked well. It has produced a community of expert, safe providers. It should not be prematurely dismantled.

The concept of finding "licensed facilities" to 'complete the recommended supervised clinical experience would be nearly impossible from the perspectives of licensure/credentialing/risk management, local competition, and noninterference with training programs. Not to mention patient preference. The alternative pathway simply recognizes that this device is new, different than others, and has a unique but effective path in place that recognizes this reality. The absence of this pathway places an undue burden on physicians and patients.

Moreover, being proctored 'on site' at your lab, with your team is infinitely more relevant and much more likely to guarantee safe outcomes compared to being proctored at a remote university which probably looks nothing like your lab/hospital.

(5) *Timeliness for Completion of In-Vivo Cases:* This again illustrates the problem with the elimination of the onsite proctored approach. Is there really any question that timely on site proctoring is better than a remote recollection?. Perhaps it makes sense to not eliminate the solution. On site proctoring of those beyond a reasonable window makes sense. Reasonable is probably 1year.

(6) *Medical Event Definition:* Again here the unique nature of this therapy is the issue. The vascular supply of the liver is variable, complex, and dynamic. Best care often requires decision making 'on the table'. The proposed changes in the guidance makes sense in that regard. Probably we should move to standard nomenclature that describes where the catheter tip was placed and intent (selective vs lobar vs whole liver).

Sincerely,

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Chairman, Department of Radiology