As of: 1/9/18 1:27 PM
Received: January 02, 2018
Status: Pending_Post
Tracking No. 1k2-90p8-y239
Comments Due: January 08, 2018
Submission Type: Web

PUBLIC SUBMISSION

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Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres; Draft Guidance for Comment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-0114
Comment on FR Doc # 2017-24129

Submitter Information

82 FR 51655
11/7/2017
113

Name: Janice Campbell, PhD
Address:
Beaumont Hospital
3601 West 13 Mile Road
Royal Oak, MI, 48073
Email: janice.campbell@beaumont.edu

General Comment

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

COMMENTS ON DOCKET ID: NRC-2017-0215
Number 6: Medical Event Definition
Comment: Yes, there are instances when the AU may determine in the interventional radiology suite that they may be
unable to deliver the amount of Y-90 microspheres to the intended lobe, but still wish to perform the treatment knowing
some dose or activity may go to a lobe or segment of a lobe not documented in the written directive. We agree that flexibility
in the written directive is necessary to avoid reporting of events that cannot be controlled using the current technology. We
would like the authorized user or individual under the supervision of the authorized user to be

allowed to revise the written
directive before, during or after (within 24 hours of treatment) the dose administration to account for patient condition or
changes to the treatment plan. This revision could be made verbally by the AU, as long as the revision is documented in
writing and signed by the AU within 24 hours of providing the revision verbally, consistent with other uses in 10 CFR, part 35.

Number 4: Clinical experience under the supervision of a manufacturer representative
Comment from one of our current Y-90 AUs:
I am writing to you as an 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 procedures, 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 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.

Attachments

Beaumont Comments to NRC on Y-90 Microspheres

Beaumont

Beaumont Hospital, Royal Oak
3601 West 13 Mile Road
Royal Oak, MI 48073

January 2, 2018

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

COMMENTS ON DOCKET ID: NRC-2017-0215

Dear Ms. Ma,
I am a Medical Physicist in Nuclear Medicine at Beaumont since 1998. During this time, I have been part of a health care team that has treated over 900 Y-90 microsphere patients. This program has been very successful. Our team would like to comment on a couple of the sections in the proposed licensing guidance as follows:

***Number 4**: Clinical experience under the supervision of a manufacturer representative*

Comment from one of our current Y-90 AUs:
I am writing to you as an 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 procedures, 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 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.

***Number 6**: Medical Event Definition*

Comment: Yes, there are instances when the AU may determine in the interventional radiology suite that they may be unable to deliver the amount of Y–90 microspheres to the intended lobe, but still wish to perform the treatment knowing some dose or activity may go to a lobe or segment of a lobe not documented in the written directive. We agree that flexibility in the written directive is necessary to avoid reporting of events that cannot be controlled using the current technology. We would like the authorized user or individual under the supervision of the authorized user to be allowed to revise the written directive before, during or after (within 24 hours of treatment) the dose administration to account for patient condition or changes to the treatment plan. This revision could be made verbally by the AU, as long as the revision is documented in writing and signed by the AU within 24 hours of providing the revision verbally, consistent with other uses in 10 CFR, part 35.

Thank you for your time and consideration,

Janice M. Campbell, PhD, DABR, FAAPM

Corporate Nuclear Medicine Physicist
Professor, Oakland University William Beaumont School of Medicine
Adjunct Professor, Wayne State University School of Medicine
Beaumont Health

Diagnostic Radiology and Molecular Imaging, Nuclear Medicine Section
3601 West 13 Mile Road | Royal Oak | MI | 48073
Phone: 248-898-4118 | Page: 248-992-2235
Janice.Campbell@beaumont.edu

Beaumont