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Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres; Draft Guidance; Extension of Comment Period

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General Comment

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Washington, DC 20555- 0001

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Katherine Tapp (KNSI)

RE: [NRC-2017-0215]YTTRIUM-90 MICROSPHERE BRACHYTHERAPY SOURCES AND DEVICES TheraSphere and SIR-Spheres; FEDERAL REGISTER VOL. 82, NO. 214; NOVEMBER 7, 2017

The Council on Radionuclides and Radiopharmaceuticals, Inc. (CORAR) is pleased to provide comments regarding the proposed revisions to NRC licensing guidance for licenses authorizing the use of Yttrium-90 (Y-90) Microsphere Brachytherapy Sources and Devices TheraSphere and SIR-Spheres as published in the Federal Register, Vol. 82, No. 214, published on November 7, 2017 for Docket ID NRC-2017-0215. CORAR is an industry association of firms that manufacture diagnostic and therapeutic radiopharmaceuticals, radionuclides, and other radioactive products primarily used in medicine and research, and also includes firms

that operate nuclear pharmacies that prepare and dispense radiopharmaceuticals in patient-ready doses for administration to patients in health care facilities.

Attachments

CORAR Final Comments to NRC-2017-0215 (1-31-18) - Signed

CORAR

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January 31, 2018

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RE: [NRC–2017–0215] YTTRIUM-90 MICROSPHERE BRACHYTHERAPY SOURCES AND DEVICES TheraSphere® and SIR-Spheres®; FEDERAL REGISTER VOL. 82, NO. 214; NOVEMBER 7, 2017

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CORAR has reviewed the draft Y–90 Microsphere Brachytherapy Sources and Devices Licensing Guidance, Revision 10, and has addressed the NRC's request for comments posed in NRC-2017-0215 in the enclosed.

Respectfully,

Michael J. Guastella
Executive Director

MJG:gps,mdl
Enclosure

cc: Council on Radionuclides and Radiopharmaceuticals, Inc.

Council on Radionuclides and Radiopharmaceuticals, Inc.

COMMENTS ON YTTRIUM-90 MICROSPHERE BRACHYTHERAPY SOURCES AND DEVICES TheraSphere® and SIR-Spheres®; PUBLISED IN FEDERAL REGISTER VOL. 82, NO. 214; NOVEMBER 7, 2017

1. **Recommended Minimum Clinical Experience:**

   CORAR supports a level of training and experience in the clinical use of Yttrium-90 microspheres that ensures that Interventional Radiologists licensed as Authorized Users (AU) are capable in:

   - Performing required dosimetry to deliver appropriate activity to the patient;
   - Overseeing and ensuring appropriate Yttrium-90 (Y90) device handling and preparation;
   - Administering the therapy directly to the patient;
   - Coordinating the longitudinal patient care following these procedures.

   This clinical use experience training should be conducted under the supervision of a qualified AU or manufacturer representative, in conjunction with the Interventional Radiology multidisciplinary team, and should include three hands-on cases for each type of Y-90 microsphere for which the individual is seeking AU licensure. This is consistent with clinical training requirements for alpha and beta emitters, used for radiotherapy, under 10 CFR § 35.390 (b)(1)(ii)(G)(3) or § 35.390 (b)(1)(ii)(G)(4).

   Therefore, CORAR encourages the NRC to continue to provide opportunities for Interventional Radiologists to seek AU certification through an alternate licensing pathway in order to complete the training and experience criteria listed in Section B of the training and experience section of the draft guidance "Yttrium-90 (Y-90) Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres®."

2. **Adding Authorization for Other Microsphere Type:**

   In the case when an AU is already authorized for one type of microsphere and requests authorization for the use of another type of microsphere it is important to note that each type of microsphere has slightly different processes of handling as well as contamination control and emergency procedures. Gaining clinical experience with a different type of microsphere through three different patient cases will allow the AU to ensure appropriate training and experience with the additional microsphere. Therefore, CORAR supports applying the minimum clinical experience requirements when adding authorization for another microsphere type.

3. **Clinical Experience under the Supervision of a Manufacturer Representative:**

   The current Y-90 microsphere licensing guideline has been successful increasing patient access to these devices while maintaining a high level of patient safety to health care providers, patients, and the community. It is important to note that in the Manufacturer and User Facility Device Experience (MAUDE) Report, manufacturer data provided to CORAR, no more than 10 medical events per year were listed for both Y-90 devices

since 2013. The majority of the MAUDE report events focus on procedural complications and treatment toxicities seen with all types of hepatic embolization, and not specific to the Y-90 devices.

CORAR members are concerned that removing the alternative pathway for Y-90 licensing, will jeopardize patient access in rural and underserved areas. This is due to the challenge of scheduling busy Interventional Radiologists (current AUs) who cover multiple health care facilities in these areas. This results in less time to devote to their current practices and patients. Therefore, CORAR requests that the NRC maintain the alternate Y-90 licensing pathway for situations where prospective AU candidates cannot secure a current AU to proctor the required clinical cases.

4. **Timeliness for Completion of In-Vivo Cases:**

CORAR believes that under the alternate pathway, the individual should complete the last of three patient cases within 6 months following the license issuance or amendment that names the individual as an AU for Y-90 microsphere use.

In closing, CORAR would like to thank the NRC for the opportunity to provide comments regarding the proposed revisions to NRC licensing guidance for licenses authorizing the use of Yttrium-90 (Y-90) Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® as published in the *Federal Register,* Vol. 82, No. 214.