

**U.S. Nuclear Regulatory Commission
Advisory Committee on the Medical Uses of Isotopes**

Interventional Radiology Subcommittee

Final Report

April 6, 2020

Subcommittee membership:

Dr. Vasken Dilsizian, Dr. Ronald Ennis, Dr. Hossein Jadvar, Dr. Darlene Metter, and Ms. Megan Shober (chair). The NRC staff resource is Dr. Katie Tapp.

Subcommittee charge:

At the Fall 2019 Advisory Committee on the Medical Uses of Isotopes (ACMUI) meeting, Chairman Dr. Christopher Palestro, created a subcommittee to investigate the need for an interventional radiologist on the ACMUI and to determine whether this position should be a non-voting consultant or full ACMUI member. This question was raised due to the ongoing licensing issues involving yttrium-90 (Y-90) microspheres, concerns over medical events resulting from the administration of Y-90 microspheres, the potential for other emerging radiotherapies to be administered by interventional radiologists, and a relative lack of expertise among present ACMUI members regarding interventional radiology.

Background:

The ACMUI's role is to provide advice on policy and technical issues that arise in regulating the medical use of radioactive material for diagnosis and therapy, to comment on changes to NRC's regulations and guidance, to evaluate non-routine uses of radioactive material, to provide technical assistance when requested by NRC staff, and to bring key issues to the attention of the Commission for appropriate action.

The ACMUI reviews its charter on a biannual basis. In preparation for a charter review, ACMUI considers the balance of its membership. At the September 2019 ACMUI meeting, members identified a potential knowledge gap in interventional radiology.

The composition of ACMUI membership was last changed in 2009, when the ACMUI was expanded by one position to include a diagnostic radiologist¹. Such a change in ACMUI membership requires Commission approval. For approximately one year prior to the Commission approval, the NRC staff invited a diagnostic radiologist to serve as a consultant (non-voting member) to the ACMUI.

Discussion:

The Subcommittee considered the areas of expertise of current ACMUI committee members. In 2009, when the Diagnostic Radiologist position was added to ACMUI, it was thought that this position could provide expertise in the area of existing and emerging diagnostic and image-guided therapeutic techniques, including interventional radiology. Over the past ten years, the field of interventional radiology has continued to mature and specialize. Practicing diagnostic

¹ ML092290414, SECY-09-0170, "Addition of a Diagnostic Radiologist on the Advisory Committee on the Medical Uses of Isotopes."

radiologists may not be able to provide the detailed knowledge on microspheres and other emerging technologies designed for therapeutic use by interventional radiologists.

Subcommittee members noted:

- Diagnostic radiologists and nuclear medicine physicians have familiarity with and may be part of the team that participates in microsphere therapies. However, it is the interventional radiologist who places the catheter for the intravascular administration of the dose to the treatment site.
- Radiation oncologists have training and experience to perform general intravenous radiation delivery and image-guided brachytherapy and may be part of the team that delivers microsphere therapies. Radiation oncologists typically have less experience with complex vascular liver infusions and procedures. Therefore, it is the interventional radiologist who is generally responsible for placing the catheter so the dose can be delivered to the treatment site.
- Of all medical uses of radioactive material, administration of Y-90 microspheres continues to have the greatest number of reported medical events².
- Many Y-90 medical events are due to problems with interventional equipment (i.e., tubes, catheters), and interventional radiologists are the subject matter experts with this equipment.
- Y-90 microspheres have the most complicated authorized user training requirements of any medical modality³.

Subcommittee members also discussed the relative merits of adding an interventional radiologist as a consulting (non-voting) member versus adding this position as a full ACMUI member. At this time, the Subcommittee does not know whether the value of the interventional radiologist expertise is significant enough to seek Commission approval to permanently add the position to the ACMUI. However, the Subcommittee acknowledges the expertise gap currently present on the ACMUI with respect to microsphere therapy.

Recommendations:

1. The Subcommittee does not recommend adding an interventional radiologist as a full voting member of ACMUI at this time.
2. The Subcommittee recommends inviting an interventional radiologist to be a consulting (non-voting) member of the ACMUI for a trial period of 2-3 years, after which this issue should be re-assessed.
3. This invitation should be extended to a practicing interventional radiologist who regularly uses both types of Y-90 microspheres and who is an authorized user.

The ACMUI unanimously approved this report and its recommendations, as presented, during its spring 2020 meeting on March 30, 2020.

Respectfully submitted,
Megan Shober for the Interventional Radiology Subcommittee
Advisory Committee on the Medical Uses of Isotopes
U.S. Nuclear Regulatory Commission

² There were 47 medical events in calendar years 2017 and 2018 involving yttrium-90 reported to the Nuclear Material Events Database (NMED), <https://nmed.inl.gov/>.

³ ML15350A099, "Yttrium-90 Microsphere Brachytherapy Sources and Devices TheraSphere® and SIR-Spheres® Licensing Guidance," Rev. 9, February 2016.