

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

**Subcommittee on the Review of Yttrium-90 (Y-90) Microsphere Gastrointestinal (GI)
Deposition**

Draft Report

Submitted on April 7, 2025

Subcommittee Members:

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Subcommittee Charge: The subcommittee on the Review of Yttrium-90 (Y-90) Microsphere Gastrointestinal (GI) Deposition was established by Dr. Hossein Jadvar, MD, PhD on January 15, 2025. The subcommittee was charged to review Y-90 microsphere gastrointestinal deposition on medical events involving significant GI deposition of microspheres.

Background: Y-90 microsphere brachytherapy has been performed for approximately 20 years using Sir-Spheres® and Theraspheres®. Five events have been reported to the NRC's Medical Event Database (NMED) system since May 2024, with one event being retracted, indicating significant deposition of Y-90 microspheres to the gastrointestinal (GI) system. GI deposition is a known possible complication of microsphere brachytherapy but the NRC receives very few reported events with GI deposition. The previously mentioned five medical events occurred with Theraspheres® but similar events have occurred with Sir-Spheres.

Discussion: Prior to Y-90 microsphere treatment, a mapping procedure with Tc-99m MAA is performed to predict microsphere flow dynamics and liver deposition. Mapping may be performed the same day or prior to day of treatment with no clinical relevance to treatment success or flow dynamics. Additionally, mapping is not performed prior to every treatment if time between prior mapping and treatment does not require it. Differences between Tc-99m MAA and Y-90 microspheres particle size are not significant. Any pharmaceuticals that may affect flow dynamics should be temporarily arrested prior to treatment.

Incidence rates of Y-90 medical events reported to the NRC via NMED are less than 0.5% relative to the number of vials sold (internal data) and their rate has remained consistent even as the number of treatments is increasing. But there was an increase in the crude number of NMED events that resulted in GI deposition. Improved technology and imaging techniques may have resulted in more events being identified. These treatments remain complicated and challenging with no standardization of the procedure.

No clear root cause has been identified for these medical events due to the modest number that have occurred and inconsistent nature of the events. Continued monitoring of these events and evaluation by this committee and Medical Events subcommittee may prove valuable in assessment of Y-90 medical events with significant GI deposition.

The ACMUI subcommittee on the Review of Yttrium-90 (Y-90) microsphere gastrointestinal (GI) deposition recommends the following.

Subcommittee Recommendations to NRC:

1. NRC should determine the number of Y-90 procedures being performed on an ongoing basis
2. Continued surveillance of Y-90 medical events with emphasis on GI deposition by NRC and this subcommittee
3. NRC should consider methods to inform licensees of these events.

Subcommittee Recommendations for Industry Consideration:

1. Licensees may consider performing post-therapy imaging (i.e. SPECT, PET or planar imaging) to assess extent of GI deposition
2. Manufacturers should inform users and provide additional training to prevent similar medical events
3. Training should be documented by the licensee

References:

1. NRC Medical Events Involving Y-90 Microsphere Gastrointestinal Deposition Summary
2. NMED Medical Events

Respectfully submitted, March 7, 2025

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Advisory Committee on the Medical Uses of Isotopes (ACMUI)
U.S. Nuclear Regulatory Commission (NRC)

The ACMUI unanimously approved this report as presented during its public meeting on April 7, 2025.