

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

Subcommittee on Medical Events

Draft Report

Submitted on September 21, 2023

Subcommittee Members:

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Subcommittee Charge: Review medical events (MEs) to advise the Advisory Committee on the Medical Uses of Isotopes (ACMUI) and U.S. Nuclear Regulatory Commission (NRC) about emerging trends that may need regulatory attention.

Background: The subcommittee reviewed medical events from Fiscal Years 2021 and 2022 as part of its ongoing biannual review.

Findings: Medical events in Fiscal Years 2021 and 2022 were relatively low but there appears to be an increase in medical events related to 10 CFR 35.300 and 10 CFR 35.1000 uses. The volume of procedures involving ¹⁷⁷Lu radiopharmaceuticals has increased during this period and this has resulted in an increased number of medical events in the category of 10 CFR 35.300.

Medical events related to 10 CFR 35.1000 uses have increased for treatments involving ⁹⁰Y microspheres (for both TheraSpheres and SIR-Spheres). Reducing the number of medical events involving ⁹⁰Y microspheres may be accomplished through improved education with emphasis on appropriate administration of the microspheres and proper set-up of the delivery device. In addition, a “time-out” may be a tool that can be implemented to reduce the number of medical events for procedures using ⁹⁰Y microspheres.

The committee recognizes past effort and continues to discuss medical events that may benefit from a “time-out” or those that may be the result of infrequent/inexperience use. Improved education and use of a “time-out” may be beneficial in preventing medical events.

The subcommittee will continue to examine medical events involving radiopharmaceuticals approved for use under 10 CFR 35.300 as well as treatments performed with ⁹⁰Y microsphere procedures (10 CFR 35.1000). Furthermore, the subcommittee will monitor trends that may continue and appear to be significant during the biannual review periods.

Concluding Remarks: The ACMUI Subcommittee on Medical Events appreciates the opportunity to continue reviewing these events. Emphasis will be placed on radiopharmaceuticals in 10 CFR 35.300 and 10 CFR 35.1000, specifically ⁹⁰Y microsphere procedures, to discern if there are emerging trends in medical events involving these treatments. The subcommittee welcomes any comments and/or recommendations.

Respectfully submitted, September 21, 2023
Subcommittee on Medical Events
Advisory Committee on the Medical Uses of Isotopes (ACMUI)
U.S. Nuclear Regulatory Commission (NRC)