

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

Subcommittee Final Report

Submitted On: October 4, 2021

Subcommittee Members: Mr. Richard Green, Dr. Ronald D. Ennis (Chair), M.D., Dr. Darlene F. Metter, Mr. Zoubir Ouhib, Mr. Michael Sheetz, Dr. Harvey Wolkov

Charge

The specific charge of this subcommittee is to annually review the medical events (MEs) with an eye to advising the Advisory Committee on the Medical Use of Isotopes and the U.S. Nuclear Regulatory Commission (NRC) about emerging trends needing regulatory attention.

Background

The subcommittee reviewed medical events from the Fiscal year 2020 as part of its ongoing annual or biennial review.

Findings

The MEs during 2020 were similarly low as in years past. This issue regarding time outs and checklists as a method to minimize MEs was again noted. In the committee's discussion regarding the category that it had previously called "infrequent/inexperience use" the point was made that some of these events may be due to inattention at the time of the procedure rather than infrequent or inexperience use. So, this category has been renamed to highlight this ambiguity. The NRC has issued an Information Notice in 2019 advising the user community about these issues. <https://www.nrc.gov/docs/ML1924/ML19240A450.pdf>

The concern raised by this subcommittee last year that emerging, more complex, radiopharmaceuticals may lead to an increase in MEs was not seen. There was only one such event in 2020.

The MEs involving Y-90 microspheres continue to be the most common, although as a proportion of all such procedures an ME is very rare. The MEs occur with both Therasphere and Sirsphere, although more commonly with Therasphere, despite reportedly equal market share of the two products. Because of this, the subcommittee recommends the appointment of a subcommittee specifically focused on investigating the MEs associated with this therapy and to propose, in consultation with the vendors, methods to decrease these MEs.

Concluding Remarks

The subcommittee looks forward to performing an in-depth trend analysis in 2022.
The subcommittee welcomes any comments and/or suggestions.

Respectfully Submitted,
The Medical Event Subcommittee