

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

***Final Report***

October 23, 2019

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

**NRC Staff Resource:** Ms. Lisa Dimmick

**Charge**

The specific charge of this subcommittee is to annually review the medical events (MEs) with an eye to advising the ACMUI and NRC about emerging trends needing regulatory attention.

**Background**

At the Fall 2018 ACMUI meeting this subcommittee presented an in-depth trend analysis of MEs over a four-year period and made specific recommendations. Because there are relatively few MEs each year and trends in MEs tend to emerge slowly, it was decided that the subcommittee would perform an in depth trend analysis every two years. In the intervening year, the subcommittee would perform a review of MEs of the previous fiscal year looking for urgent issues that need to be addressed immediately and cannot wait for the in-depth review of the following year. The subcommittee herein provides such a report.

**Findings**

The Subcommittee on Medical Events reviewed the Medical Events from FY 2018. Events from each section were reviewed in detail by a subcommittee member with expertise in the area. There were no new notable event types. There were no apparent marked increases in any of the event categories or types compared to prior years.

One area identified by the subcommittee that could emerge in coming years involves new radiopharmaceuticals which have a high activity and are given in a relatively large volume of fluid (i.e. more than a few milliliters). These characteristics increase the risk of MEs and of their potential for serious medical consequences. There are two newer agents that have these features: lutetium-177 dotatate (Lutethra) and iobenguane Iodine-131 (Azedra). The subcommittee will pay particular attention to these agents when it does its next review. The Subcommittee does not recommend any action regarding these agents at this time.

**Concluding Remarks**

The subcommittee looks forward to performing an in depth trend analysis in 2020.  
The subcommittee welcomes any comments and/or suggestions.

**The ACMUI unanimously approved this report during its fall 2019 meeting on September 10, 2019.**

Respectfully Submitted on October 23, 2019,  
*The Medical Event Subcommittee*