U.S. Nuclear Regulatory Commission

Advisory Committee on the Medical Uses of Isotopes

Subcommittee on Medical Events

Draft Report

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

NRC Staff Resource: Dr. Donna-Beth Howe

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 initiated a new approach to reporting on MEs such that every 2 years the subcommittee will review medical events (MEs) occurring in the previous 4 years with the goal of identifying common themes within each section of 10 CFR Part 35 and discuss possible ways to prevent these MEs. The report herein is the second such in-depth 4-year review of MEs.

Findings

The Subcommittee on Medical Events reviewed the Medical Events from FY 2016-19. Events from each section were reviewed in detail by a subcommittee member with expertise in the area. In the subcommittee's review two years ago, we noted that a significant proportion of MEs might be prevented by the universal implementation of a time out prior to the procedure/treatment. In addition, we noted that a considerable number of events seemed to occur in situations in which the authorized user and team were performing a procedure/treatment with which they do not have much recent experience.

In the current review, the subcommittee found that the number of MEs, the types and the proportion possibly preventable by a time out and the proportion related to lack of experience, were about the same.

One new emerging trend was noted. In the delivery of unsealed byproduct material for which a written directive is required (10 CFR 35.300), there was an increase in the number of MEs related to equipment (e.g., catheter) issues. This is thought to be attributable to the increasing use of agents with more complex delivery (e.g., Lu-177 dotatate). The subcommittee anticipates this trend will continue and warrants close observation. However, no specific intervention by NRC staff is recommended at this time.

A new Y-90 microsphere delivery device has been introduced by Sirtex. We will be watching for trends in MEs related to this problematic area with the introduction of this new device.

Concluding Remarks

The subcommittee looks forward to performing an in-depth trend analysis in 2022 and next year will perform a focused one-year review of FY2020.

The subcommittee welcomes any comments and/or suggestions.

Respectfully Submitted,
The Medical Event Subcommittee
Ronald Ennis, MD, Chair