Nuclear Regulatory Commission (NRC)

Advisory Committee on the Medical Uses of Isotopes (ACMUI)

Subcommittee on the Appropriateness of Medical Event Reporting

Subcommittee Draft Interim Report

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Charge

The specific charge of this subcommittee is review the appropriateness of the required elements of medical event (ME) reporting; the adherence to these requirements; and recommend actions to improve reporting.

Background

An ME is reported to an Agreement State or NRC in accordance with Title 10 *Code of Federal Regulations* (10 CFR) 35.3045, "Report and Notification of a Medical Event". The purpose of medical event reporting[1] was initially published May 14, 1980. Back then, a medical events was known as a "misadministration". In the Federal Register, dated May 14, 1980, the following statement is made **"The Commission's purpose in requiring misadministration reports to NRC was to identify their causes in order to correct them and prevent their recurrence. The Commission was able to notify other licensees if there was a possibility that they could make the same errors" (45 FR 31701, May 14, 1980).**

Similarly, as summarized in "Event Reporting Schedule for Agreement States 7/29/12" and SA-300, "Reporting Material Events" – "The information collected on … medical events … is invaluable in *assessing trends or patterns,* identifying generic issues or generic concerns, and *recognizing any inadequacies or unreliability of specific equipment or procedures.* The reported information is critical for initiating a timely and effective response to security-related events and *will significantly aid in understanding why the event occurred and identifying any actions necessary to improve the effectiveness of NRC and Agreement State regulatory programs."*

Each year, an NRC staff member and an ACMUI subcommittee conducts a review of the Nuclear Materials Events Database (NMED) of the MEs reported within the immediate past Fiscal Year (FY). The most common and repetitive statement made amongst the ACMUI members is the lack of uniformity of information reported. Specifically, some States provide the bare minimum information, as required in SA-300, while others provide much greater detail.

[1] https://www.nrc.gov/materials/miau/med-use-toolkit.html#report

During the fall 2018 ACMUI meeting, the ACMUI raised this concern once again. The NRC staff referenced SA-300 and how that particular procedure specifies the type of information to be reported by the Agreement States. The NRC staff also mentioned that SA-300 could undergo revision, if necessary. Therefore, the Subcommittee intends to make recommendations for changes, if warranted.

Current Status

The Subcommittee reviewed the following documents:

- SA-300 - FSME Procedure Approval Reporting Material Events
- SA-105 - Reviewing the Common Performance Indicator, Technical Quality of Incident and Allegation Activities
- Event Reporting for Agreement States of July 29, 2012
- NMED Annual Report of 2017
- OAS Letter 7/2/14 regarding proposal for a public NMED
- Root cause and corrective action pick lists
- NMED content

Based on our review of the above, the Subcommittee has identified the following issues with NMED.

- Frequently, the narrative is inadequate for an ACMUI reviewer to understand an ME, its root cause and contributing factors, and the adequacy of the corrective action.
- At times, there appears to be a disconnect between the narrative and the chosen root cause from the "cause pick list."
- At times, there appears to be a disconnect between the narrative and the chosen corrective action from the "corrective action pick list."
- NMED lacks information from some follow-up inspections that have been conducted by the respective NRC region or Agreement State.
- In 23% of MEs from FY 2017-18, there was either no cause or no corrective action indicated in NMED report.
- Of all 2017 MEs, 11% are incomplete and an additional 11% are pending additional information.
- Members of the public, including authorized users and radiation safety officers, only have access to an NMED annual report.

General Recommendations Under Consideration by the Subcommittee

Note: The items contained below are not official recommendations of the Subcommittee at this time.

- Root cause and corrective action sections on NMED – In addition to the pick lists, a narrative, searchable, section should be required.

- Require root cause and corrective action sections in NMED, both pick list and narrative sections always be completed.
- Require information gathered from any investigation be added to NMED.
- Require that a report in NMED be completed within 12 months.
- Require ACMUI and NRC staff to promulgate the findings of annual report of the ACMUI Subcommittee on Medical Events to the medical and medical physics communities.
- Modify how Event Reports are written:
    - Require the report use additional guidelines to be developed by this subcommittee to assure more complete and useful information is provided.
    - Require the report be initially written by the AU and clinical physicists and subsequently reviewed by the inspector.
    - Require the inspector interview all involved in the ME.
    - Require a report from the manufacturer be included if the event involved a device.
    - Corrective action should include medical as well as technical.
    - Require the final report must be signed off by the AU, physicist and inspector.

Concluding Remarks

Significant opportunities exist to enhance the utility of ME reporting, the NMED database, and the promulgation of the information to the user community.

The Subcommittee asks that it be able to continue evaluating these issues in more detail with a goal of creating a set of specific recommendations.

The Subcommittee welcomes any comments and/or suggestions.

Respectfully Submitted,
The Appropriateness of Medical Event Reporting Subcommittee