Nuclear Regulatory Commission
Advisory Committee on the Medical Uses of Isotopes
Subcommittee on the Appropriateness of Medical Event Reporting

Draft Report

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Charge

The charge of this subcommittee is to 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 event 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 conduct a review of the Nuclear Materials Events Database (NMED) of the MEs reported within the immediate past Fiscal Year (FY). The ACMUI members have come to find the information in NMED lacking in a way that impedes the ability of NMED to be a source of information to prevent future MEs.

Specifically, at the spring, 2019 meeting the Subcommittee 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.

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

- 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 the 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.

At the spring 2019 meeting, the subcommittee made some preliminary recommendations and was tasked with making final recommendations at the fall 2019 meeting.

Subcommittee Findings

The Subcommittee has determined that the regulatory requirements for reporting an ME (as per 10 CFR 35.3045) are:

- An initial report must be made within 24 hours of discovery of the event
- A written report must be submitted by 15 days
    - The elements required for the 15-day report are:
        - (i) The licensee's name
        - (ii) The name of the prescribing physician;
        - (iii) A brief description of the event;
        - (iv) Why the event occurred;
        - (v) The effect, if any, on the individual(s) who received the administration;
        - (vi) What actions, if any, have been taken or are planned to prevent recurrence; and
        - (vii) Certification that the licensee notified the individual (or the individual's responsible relative or guardian), and if not, why not.

Guidance regarding the expectations of reporting into NMED is provided in SA-300 Reporting Material Events" and the "Handbook on Nuclear Material Event Reporting in the Agreement States Final Report March 2013". This guidance is:

- Follow-up information for nuclear material event reports (e.g., providing additional information regarding initial event reports) *should* (italics added by this report) provide the results of investigations as to what, where, when and how the event or conditions occurred. Agreement States should provide the items below when reporting follow-up information:
- *On a monthly basis,* (italics added) follow-up reports through the closeout of the event *should* (italics added) be provided in writing to the RMSB Branch Chief … or electronically to the NMED
- The minimum elements for a complete NMED report are:
    - Narrative event description including source, radionuclide, activity, manufacturer, model, serial number, equipment problems, type of procedure, dose intended, actual dose, target organ
    - Was patient and referring notified

- Report number, event date, notification date, licensee, location of event, whether it is reportable and the applicable reporting requirement
- Cause and corrective action
- Notifications to police, FBI, etc.
- Indicate Generic implications

The subcommittee's conclusions regarding the reporting requirements are:

- The minimal requirements re: data elements in the medical event reports as given by 35.3045 are vague and limited
- There is no actual requirement that NMED reports be completed
- If incomplete, a Request of Additional Information (RAI), per NMED Coding Manual Appendix D) as an automatic email goes out to the responsible agency 57 days after a report was first created, but no further outreach is done
- The only oversight related to this is the Integrated Material Performance Evaluation Program (IMPEP) in which the NRC and Agreement States are reviewed every 4 years

Subcommittee Recommendations

The Subcommittee recommends two enhancements to NMED to increase the value of information in the database.

1. The NMED programmers should add a narrative field to the root cause and corrective action sections, in addition to the existing pick lists. This new narrative field should be a searchable free text section. (At a subcommittee meeting, an NMED representative has assured the subcommittee that this can be done.)

2. NRC, in coordination with the ACMUI, should provide additional information to NMED users on best practices for writing NMED reports for medical events.

For the second recommendation, a two stage approach should be implemented:

First, develop educational materials to be shared with the regulator and user communities regarding what constitutes an optimal NMED report along with the rationale for why this is important.

Specifics elements of this educational program are:

- The elements that make a useful root cause analysis narrative include:
  - What happened – with enough detail that an uninvolved AU and uninvolved radiation safety personnel would have full understanding of the ME.
    - When in the process of radiation delivery did the event occur?
    - Who was present at the time of the ME?
    - What preceded the ME?
    - How did the ME occur?
    - What helped catch the ME?
    - Who/what detected the ME?
    - Was the manufacturer notified?
- The elements that make a useful corrective action narrative include:
  - Short term and long term corrective actions undertaken
  - Specify how the corrective action is linked to the events of the ME

- Importance of adding information provided by manufacturer (when applicable)
- Importance of including medical as well as technical information about the event
- Importance of including the 15 day report in the submission (stored in ADAMS).
- Importance of completing the report within 12 months

The subcommittee recommends this information be promulgated via:

An Informational Notice from the NRC

Presentations at OAS, CRCPD and medical professional society meetings.

Second, if the educational approach is not successful at improving the quality of NMED reporting, then the subcommittee recommends implementation of specific *requirements* to improve the reporting

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 as detailed above.

If these efforts prove ineffective at improving the quality of NMED reporting, then regulatory approaches should be considered.

The Subcommittee welcomes any comments and/or suggestions.

Respectfully Submitted,
The Appropriateness of Medical Event Reporting Subcommittee