Advisory Committee on the Medical Use of Isotopes (ACMUI)

Medical Event Reporting and Impact on Medical Licensee Patient Safety Culture Final Report

Report Date: September 11, 2017

Subcommittee Members: V. Dilsizian, R. Ennis, S. Langhorst (Chair), and L. Weil

Charge: To 1) explore the impact of medical event reporting and its impact on self-reporting (safety culture); 2) identify potential ways to improve effectiveness of self-reporting in support of a culture of safety; and 3) suggest ways to share medical event (ME) reports and lessons-learned with the medical community to promote safety.

I. ACMUI April 2017 Discussion of Interim Report

This ACMUI Subcommittee began its work with an interim report[1] to provide a common perspective of the fundamental principles of radiological protection, of the U.S. Nuclear Regulatory Commission (NRC) regulatory history regarding patient safety, of the development of safety culture programs in healthcare, and of the current patient safety groups influencing medical use of byproduct materials. The ACMUI and NRC Staff discussed the interim report at its April 27, 2017 meeting[2] and how the NRC could better support medical licensees in promoting a positive patient safety culture. The Committee decided to continue exploration of how NRC ME reporting impacts a licensee's patient safety culture. The ACMUI asked the Subcommittee to provide a final report for presentation at the fall 2017 ACMUI meeting which provides specific options the NRC may take to encourage a licensee's patient safety culture, while maintaining its regulatory authority to protect patients during medical use of byproduct materials.

II. Major Topics Identified for Consideration

During the ACMUI's discussion of the interim report, issues related to ME reporting were identified as having a negative impact on a licensee patient safety culture. Additional ideas were suggested on how the NRC could make changes to better encourage a licensee patient safety culture. These were the major topics from the April 2017 ACMUI discussion which the

[1] Advisory Committee on the Medical Uses of Isotopes, "Medical Event Reporting and Impact on Medical Licensee Patient Safety Culture – Interim Report", April 27, 2017 – https://www.nrc.gov/docs/ML1713/ML17138A370.pdf (last accessed 8/8/2017).

[2] Advisory Committee on the Medical Uses of Isotopes, Transcript of the April 27, 2017 ACMUI meeting, pages 66-111 – https://www.nrc.gov/docs/ML1716/ML17164A217.pdf (last accessed 8/8/17).

Subcommittee considered in developing recommendations for improved patient safety review and reporting.

- NRC ME reporting criteria are set at conservative levels, which NRC describes as rarely causing patient harm[3]. Other types of patient safety events typically require that a patient is harmed or is at identified risk of harm to reach the criteria for patient safety reporting to the applicable organization (e.g., The Joint Commission, Food and Drug Administration, Centers for Medicare & Medicaid Services, etc.). These different levels of reporting criteria lead to inconsistent levels of response to a patient safety event and cause confusion in the medical community. For example, reporting an ME to the NRC compels a medical licensee also to provide information on the event to other outside organizations who oversee the licensee's patient safety program. The licensee makes this additional reporting because they do not want these outside organizations to first learn from others of the ME report made to a federal agency. This additional reporting to other organizations can lead to confusion when the patient risk from the NRC ME is insignificant and on par with other patient safety events that a licensee would normally evaluate in-house.

- Despite recognition that NRC MEs rarely cause patient harm, a licensee is required to notify the NRC Operations Center no later than the next calendar day after discovery of the ME. Soon after this notification, an NRC inspection generally takes place looking for violations as cause of the ME.

- In discussion of alternative ways in which byproduct material patient safety events could be evaluated consistent with other patient safety events, patient safety requirements established under professional organization accreditation programs, such as the American College of Radiology (ACR) or the American Society for Radiation Oncology (ASTRO), should be considered along with Patient Safety Organizations and Accrediting Organizations discussed in the interim report.

- Given the length of time needed to make medical use regulatory changes, the NRC staff suggested that the Subcommittee explore the Reactor Oversight Process program[4] and the

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[3] NRC NMSS Newsletter, "Purpose of Medical Event Reporting", Spring 2016, NUREG/BR-0117 No. 16-02 - https://www.nrc.gov/docs/ML1609/ML16091A236.pdf (last accessed 8/8/17).

[4] NRC Reactor Oversight Process, NUREG-1649, Rev 6 – https://www.nrc.gov/docs/ML1621/ML16214A274.pdf (last accessed 8/8/17).

> The NRC "does not operate nuclear power plants. Rather, it establishes requirements for the design, construction, operation, and security of commercial nuclear power plants in the United States. The agency ensures the plants are operated safely and securely within these requirements by licensing the plants to operate, licensing control room personnel, establishing technical specifications for operating each plant, and inspecting plants on a daily basis.
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> The NRC uses the Reactor Oversight Process (ROP) to assess a licensee's ability to safely operate a nuclear power plant in accordance with the NRC rules, regulations, license requirements, and adopted licensee standards. If the ROP identifies problems, the NRC can provide additional inspections and other actions in order to protect public health and the environment. The ROP benefits from what the NRC has learned from 30 years of improvements in nuclear industry performance, as well as improved approaches to inspecting and evaluating the safety and security performance of NRC-licensed plants."

way in which the NRC and reactor community developed and tested this change in regulatory oversight[5] for possible methods of implementing NRC medical event oversight improvements using current regulations.

In discussing this final report preparation, the Subcommittee was reminded of past ACMUI discussions in which the requirement to report MEs to the referring physician and to the patient for most MEs serves no productive purpose and may be harmful. The reporting requirement can cause unnecessary patient worry. Discussions with referring physicians are medical and like any other medical aspect, the licensee physician will discuss with the referring physician if there is a medical impact from the event. The Subcommittee questioned the rationale of telling the referring physician that the number of millicuries delivered was 21% more or less than prescribed, but this has no medical effect.

III. Recommendations to Change NRC Oversight of Current Medical Event Criteria

Given the development of patient safety regulations[6] and other requirements[7] resulting in the establishment of patient safety programs, we recommend the NRC take the following actions to change its oversight of current medical event criteria.

- Establish a program allowing a medical use licensee to evaluate MEs as described in 10 CFR 35.3045, in NRC 10 CFR 35.1000 licensing guidance, and in 10 CFR 35.3047 with an approved patient safety program. An approved patient safety program is any one or combination of the following:

    + A licensee patient safety program which commits to reporting MEs to a Patient Safety Organization approved under 42 CFR Part 3 (Department of Health and Human Services, Patient Safety and Quality Improvement) and which has expertise in medical use defined in 10 CFR 35.
    + A licensee patient safety program evaluated by an Accrediting Organization approved by the Centers for Medicare & Medicaid Services-approved accreditation program.
    + A licensee patient safety program which is established as part of accreditation by a professional organization for medical use defined in 10 CFR 35.

- NRC licensees with an NRC-approved patient safety program will continue to report medical events as required with the following conditions:

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[5] NRC SECY-99-007, "Recommendations for Reactor Oversight Process Improvements," January 8, 1999 – https://www.nrc.gov/reading-rm/doc-collections/commission/secys/1999/secy1999-007/1999-007scy_attach.pdf (last accessed 8/8/17).

[6] Department of Health and Human Services, "Patient Safety and Quality Improvement; Final Rule" established 42 CFR 3, 73 FR 70732, November 21, 2008 – https://www.gpo.gov/fdsys/pkg/FR-2008-11-21/pdf/E8-27475.pdf (last accessed 8/8/2017).

[7] Example: The Joint Commission, "Patient Safety Systems Chapter for the Hospital program" - https://www.jointcommission.org/patient_safety_systems_chapter_for_the_hospital_program/ (last accessed 8/8/17).

+ The NRC will not include this event notification in the Event Notification Report posted on its website. If this is not possible, the ME notification posted on the website will leave the licensee information and location anonymous[8].
+ The NRC will not conduct a reactive inspection of the ME unless the event results or will result in death, unintended permanent harm, or unintended significant temporary harm for which medical intervention was or will be required to alleviate the harm or reduce radiation effects.
+ The medical use licensee will write a report available for the next NRC inspection describing the event cause and corrective action taken.
+ NRC will develop, with ACMUI advice, new temporary inspection procedures for NRC review of licensee patient safety event reports, and will evaluate, with ACMUI advice, need to change enforcement manual procedures regarding MEs to support a test of this program.

- NRC should test out this pilot program with a variety of medical use licenses (such as large medical center, community hospital, rural hospital, patient clinic, etc.), with the number and duration of the pilot test to be determined later. During this test period, the NRC, with advice from the ACMUI, should evaluate the pilot licensees' ME reports and do the following:
  + Develop the minimum criteria for patient safety program reviews, such as –
    - Patient safety event and related issues are well defined, the relevant facts and circumstances are identified and collected, and the findings and conclusions are identified and substantiated by the information and evidence associated with the ME or incident
    - Cause(s) and program weaknesses or shortcomings are identified for the patient safety incident, and corrective actions taken
    - Evaluation of past patient procedures is made to determine the extent of condition for similar patient safety incidents.
  + Assess how this change in ME reporting impacts the NRC's ability to protect patient health and to minimize danger to the patient's life.
  + Evaluate the different types of patient safety programs in how lessons learned from their patient safety incident reviews are shared with the medical community.

- After completion of the test year, the NRC should consider opening the program to all NRC medical use licensees who request approval of their patient safety program, and to Agreement States who request to implement the program with their medical licensees.

IV. Recommendation for NRC Policy and Regulatory Changes Regarding Patient Safety

[8] The NRC may want to consider the following points when deciding whether to not to post these event notifications or to keep the licensee information anonymous: (a) a medical event seldom involves more than one or a few patients and is not ongoing for the licensee; (b) the majority of medical events do not result in patient harm; (c) this change would be consistent with other patient safety event reporting and may improve reporting and near-miss reporting; (d) lack of licensee information does not diminish the medical event information provided in the event report; and (e) NRC event reports are not a very good way to share medical event information.

The NRC has historically developed regulations to promote patient safety in the medical use of byproduct materials with very few ME causing patient harm. However, the NRC ME reporting criteria are inconsistent with the level of patient safety event reporting criteria established in other areas of medical practice. The focus of NRC regulatory oversight and expertise on the medical use of byproduct material does not include oversight of the practice of medicine. Regulators and the medical community continue to debate where the demarcation of NRC oversight of medical use ends and the practice of medicine begins. At the heart of this debate is the intent by both the regulators and the medical community to support patient safety and deliver effective patient care.

Given the increased complexities associated with medical use of byproduct materials, especially with regard to therapeutic procedures, and the development and sophistication of patient safety programs, we recommend the NRC take the following actions to modify the NRC Medical Use Policy and medical use regulations and guidance.

- Redefine the NRC perspective of patient safety to be different from occupational safety and from public safety. As described in the ACMUI interim report[9], the NRC has departed from the fundamental principles of radiation protection by setting patient dose limits in 10 CFR 35.3045 and 35.3047. The NRC has applied dose limits to patients which are the same as those applied to exceeding occupational dose limits. And, the NRC has explicitly stated that the Commission considers a patient to be a member of the public to be protected by the NRC. We believe the Commission should re-evaluate its perspective on patient safety to be more in line with the fundamental principles of radiation protection and the ICRP exposures categories[10] of "occupational exposures, public exposures, and medical exposures of patients (and comforters, carers, and volunteers in research)".

- Partner with the Department of Health and Human Services (HHS), specially the Agency for Healthcare and Research and Quality (AHRQ)[11], and ACMUI to develop a national database taxonomy specific for reporting patient events involving medical use of byproduct material. Due to its strong regulatory authority, the NRC has been a leader in shaping a licensee's positive safety culture. The NRC has considered its patient safety model as part of its public health and safety charge. The recent development and sophistication of patient safety laws, regulations, and programs could be utilized by NRC in reviewing patient safety events and sharing lessons learned in support of improve overall patient safety and medical outcomes.

[9] Advisory Committee on the Medical Uses of Isotopes, "Medical Event Reporting and Impact on Medical Licensee Patient Safety Culture – Interim Report", April 27, 2017 – https://www.nrc.gov/docs/ML1713/ML17138A370.pdf (last accessed 8/8/2017).
[10] ICRP Publication 103, "The 2007 Recommendations of the International Commission on Radiological Protection" – http://www.icrp.org/publication.asp?id=ICRP%20Publication%20103 (last accessed 8/8/2017).
[11] HHS Agency for Healthcare Research and Quality – https://www.ahrq.gov/ (last accessed 8/8/17).

The long-standing Public Health Service Act[12] has recently been amended "to provide for the improvement of patient safety and to reduce the incidence of events that adversely effect [sic] patient safety" by inclusion of the Patient Safety and Quality Improvement Act of 2005[13]. The Department of Health and Human Services (HHS) implemented a final rule[14] to establish "a framework by which hospitals, doctors, and other health care providers may voluntarily report information to Patient Safety Organizations (PSOs), on a privileged and confidential basis, for the aggregation and analysis of patient safety events". The HHS is also working through its Agency for Healthcare Research and Quality[15] to develop sets of common definitions and reporting formats (Common Formats) for reporting on health care quality and patient safety as directed by the Patient Safety Act Sec. 923 to "facilitate the creation of, and maintain, a network of patient safety databases that provides an interactive evidence-based management resource for providers, patient safety organizations, and other entities"[12].

The NRC should explore partnering with HHS/AHRQ in developing a segment of the network of patient safety databases to which NRC medical use licensee patient safety programs would be required to report medical event information. The event taxonomy should include the criteria for which the licensee is required to report the event to NRC and the national database, the criteria for which the licensee is required to report the event to the national database, and the criteria for which the licensee is encouraged to report to database. In addition, the taxonomy should define the minimum specific information required to be reported by the licensee to ensure the reports are interpretable and meaningful. The information shared with the national database would be anonymous and used for the purpose of: reducing errors by identifying causes of preventable errors; developing, demonstrating, and evaluating strategies for reducing errors and improving patient safety; and disseminating effective strategies to all medical licensees.

- Update the NRC Medical Use Policy and 10 CFR 35 event reporting regulations. NRC medical use regulations should continue to support patient safety by establishing training and experience requirements, equipment requirements, radiopharmaceutical and sealed source requirements, and medical radiation safety program requirements. The NRC policy and regulations should update the requirements for patient safety programs to verify the active involvement of the licensee's patient safety program review of medical errors and reporting of reviews to the national patient safety database.

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[12] Public Health Service Act, as amended through P.L. 114-255, Enacted December 13, 2016 - https://legcounsel.house.gov/Comps/PHSA-merged.pdf (last accessed 8/8/17).
[13] PUBLIC LAW 109–41—JULY 29, 2005 "Patient Safety and Quality Improvement Act of 2005" – https://www.congress.gov/109/plaws/publ41/PLAW-109publ41.pdf (last accessed 8/8/2017).
[14] Department of Health and Human Services, "Patient Safety and Quality Improvement; Final Rule" established 42 CFR 3, 73 FR 70732, November 21, 2008 – https://www.gpo.gov/fdsys/pkg/FR-2008-11-21/pdf/E8-27475.pdf (last accessed 8/8/2017).
[15] HHS Agency for Healthcare Research and Quality, "Program Brief – Network of Patient Safety Databases – Lessons From PSOs on Applying the AHRQ Common Formats for Patient Safety Reporting," November 2015 – https://pso.ahrq.gov/sites/default/files/wysiwyg/npsd-common-formats-brief.pdf (last accessed 8/8/17).

The ACMUI unanimously approved this report during its public meeting on September 11, 2017.

Addendum to

Medical Event Reporting and Impact
on
Medical Licensee Patient Safety Culture
Final Report

from

ACMUI Patient Intervention Subcommittee

Subcommittee Members: V. Dilsizian (Chair), R. Ennis, J. Suh, and L. Weil

Subcommittee Charge: Clarify 2017 ACMUI recommendation from the April 27, 2017, Advisory Committee on the Medical Uses of Isotopes (ACMUI) presentation of "Patient Intervention Subcommittee Report – Part II" by specifying how Unintentional Treatment Outcome events reporting to the Nuclear Regulatory Commission (NRC) can be modified in order to be less punitive and more informative and educational.

2015 ACMUI Recommendations, Issue II: Relates to ALL Treatments and not limited to Y-90 microspheres

- Unintentional Treatment outcome due to anatomic or physiologic anomaly and/or imaging uncertainty falls into the category "the Art of Medical Practice" provided that the standards of medical practice are met.
- Reporting such unpredictable and unavoidable patient-specific medical events will not help to prevent such events in the future, and therefore cannot be regulated.

Clarification - Recommendation for NRC Policy and Regulatory Changes for Unintentional Treatment Outcome Events Reporting

1. Define "High" vs. "Low" Impact Events
2. High Impact events will require timely notification to NRC, NRC reactive inspection, and timely written report to NRC
3. Low Impact events will not require notification to NRC
4. Low Impact events will undergo self-evaluation and corrective action reporting through NRC-approved Patient Safety Organizations, Accrediting Organizations or institutional robust patient safety program

5. Ideally, only high impact events should be made public. Low impact events should be anonymous to licensee information and location

These clarified recommendations should be considered in the implementation of Sections III. and IV. recommendations of the Medical Event Reporting and Impact on Medical Licensee Patient Safety Culture Final Report.