Nuclear Regulatory Commission (NRC)
Advisory Committee on the Medical Use of Isotopes (ACMUI)

Subcommittee on

Patient Intervention Report, Part II

***Draft* Report**
April 27, 2017

Subcommittee Members:
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I. Charge

The ACMUI Chairman, Dr. Alderson, re-established the Patient Intervention Subcommittee on October 6, 2016. The subcommittee's new charge was to clarify Issue II recommendation from the October 8, 2015, Advisory Committee on the Medical Uses of Isotopes (ACMUI) presentation of "Unintentional Treatment Outcome".

II. Introduction

The reportable medical event that results from intentional/unintentional patient action dates back to the 2002 Final Rule - 10 CFR 35.3045(b) – which states that "***A licensee shall report any event resulting from intervention of a patient or human research subject in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician***". On the subsequent 2014 Proposed Rule, no changes were proposed to the reportable medical event that results from intentional/unintentional patient action. However, during the spring of 2015 ACMUI deliberations, the question of "passive" rather than "active" patient intervention was raised. That is, what about unintentional treatment outcome due to anatomic or physiologic anomaly rather than intentional or unintentional action taken by a patient or human research subject? Does that constitute patient intervention?

In the 2015 ACMUI fall meeting, the committee proposed the following 2 sentences (as Issue II) to address the question of "passive" rather than "active" patient intervention. "***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".***

III. What is the Problem that we are trying to Solve?

The issue of "passive" unintentional treatment outcome was addressed by the NRC staff for Yttrium-90 microsphere brachytherapy sources and devices (TheraSphere® and SIR-Spheres® Licensing Guidance, Revision 9, issued on February 12, 2016) by making an exception for 1) shunting when shunting was evaluated prior to the treatment in accordance with the manufacturer's procedures, and 2) emergent patient conditions that prevent administration in accordance with the written directive (e.g. artery spasm or sudden change in blood pressure) (Rev 8, June 2012). However, these exceptions were limited toYttrium-90 microspheres. The ACMUI committee's intention was to have a broader "passive" unintentional treatment outcome exception that relates to ALL current and future treatments, and not limited to Y-90 microspheres.

IV. Medical "Event" vs Medical "Error": Should the Reporting be Similar?

Unintentional treatment outcome due to anatomic or physiologic anomaly is a "medical event". While a medical event is not a violation, failure to report a medical event is a violation. Misadministration of the wrong radiopharmaceutical and/or dose in the wrong patient is a "medical error". Medical "events" may be interpreted as medical "errors". Because a "medical event" requires reporting to the NRC or Agreement States, it is taken to mean "fault". Reporting such medical events by a physician may be perceived negatively. It captures the attention of most medical centers leadership. It requires reporting to the legal counsel in some institutions, and in reality becomes a big deal (out of proportion to the issue at hand when it comes to patient intervention). NRC needs to think creatively about a term that will not carry with it the same weight as a medical "error".

V. 2017 ACMUI Recommendations and Specific Comments

Establish a "Registry" of unintentional treatment outcome events due to anatomic or physiologic anomaly that is educational rather than punitive in nature, with the goals of 1) Tracking, 2) Trending, 3) Identifying the problem, 4) Reporting it back to the medical community, 5) Taking corrective action, 6) Developing a feedback loop, 7) Suggesting constructive improvement, and 8) Learning from the mistakes. Is there any other registry (alternative reporting systems – ROILS, etc.) that the Authorized Users can use without calling it a medical event?

VI. Concluding Remarks

The idea of reporting an unintentional and /or unavoidable medical event due to anatomic or physiologic anomaly and having punitive consequences is the problem that we are trying to solve. The authorized users are not trying to avoid the reporting process, but rather they are trying to avoid the punitive process of reporting a medical event. The committee's intention for proposing issue II in the 2015 ACMUI fall meeting was to recommend that these "passive" rather than "active" patient interventions should not be considered as reportable medical events. Reporting such unpredictable patient-specific medical events will not help to prevent such events

in the future, and therefore cannot be regulated. Such unintentional treatment outcome exception should apply to ALL current and future treatments, and not limited to Y-90 microspheres.

Respectfully submitted, March 24, 2017
***Subcommittee on* Patient Intervention**
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The Patient Intervention Subcommittee will amend its Subcommittee Report and report at the ACMUI fall 2017 meeting or by teleconference to discuss the amended report.