ACMUI's Specific Suggestions for Improving Public Understanding of the Risks Associated with Medical Events

From ACMUI final recommendations document, received July 19, 2005

1. The patient reporting requirement in 10 CFR 35.3045(e) should be amended to require informing the patient and/or friends and relatives of the ME only if the licensee determines that the ME may have harmed the patient, could potentially harm the patient, or is materially relevant to the patient's future medical treatment decisions.

Staff does not support this ACMUI recommendation because the Commission has repeatedly stated and endorsed its position that a patient or human research subject involved in any ME should be notified of the occurrence, based on the individual's right to know information about himself or herself that is contained in records both inside and outside the Federal sector [43 FR 2927 (May 7, 1978); 63 FR 43516 (August 13, 1998); 67 FR 20332 (April 24, 2002)]. Further, this requirement codifies existing medical ethical standards obligating physicians to provide complete and accurate information to their patients, so the patients can be actively involved in any decisions about any remedial or prospective health care that may be appropriate following MEs, as indicators of technical or QA problems in prescription delivery.

2. NRC staff should strive to make the ME reporting and subsequent enforcement processes more like the regulated community's own QA practice of followup and QA process review that occurs after detection of a delivery error or potential error. Specific suggestions for accomplishing this objective are as follows.

    a. NRC's ME reporting and follow-up procedures should be designed so as to not increase licensee liability. Keeping ME reports, or at least the licensee's identity, out of the public record is probably the single most useful improvement NRC could make in this regard.

Staff does not support this ACMUI recommendation because it is counter to the Commission's policy of public openness and transparency in the conduct of its business, except in cases of National security or personal privacy of patients and human research subjects. Further justification for continuing the public release of ME information is NRC's concern that technical or QA failures identified through ME reports might result in harm to individuals at the reporting licensee's facility or at other licensee facilities if ME reporting thresholds are significantly exceeded and should therefore be publicized.

    b. NRC is encouraged to develop a more graded and risk-informed process for responding to ME reports that ties the intensity and immediacy of its inspection response to individual patient risk and public health implications of the event. For example, for a relatively minor ME, where public health and safety are not in question, NRC could minimize reactive inspection of the licensee pending a satisfactory investigation and quality-improvement response on the part of the licensee.

Enclosure 3

NRC's approach to ME assessment in Management Directive 8.10, "NRC Medical Event Assessment Program," is already graded and risk-informed. For example, NRC already has a variable time frame for initiation of ME assessments that reflects the known or potential seriousness of each occurrence, with generally acceptable delay times ranging from 2 working days (for the most serious events) to 10 working days, or longer. Also, the degree and type of follow-up are based on the type of ME reported, with NRC taking enforcement action only when appropriate.

Once the ME assessment is initiated, the purpose of the inspector's site visit is to confirm and/or gather information to ensure that all required facts are available to complete the assessment. The staff continues to believe that this assessment is necessary for all MEs so that (1) the NRC is aware of events that trigger the thresholds for MEs, to determine what actions, if any, need to be taken to prevent recurrence; (2) other licensees can be made aware of generic problems that result in MEs; and (3) patients can, when appropriate based on the ME reporting criterion being significantly exceeded, make timely decisions regarding remedial and prospective health care. Staff believes that the most effective and efficient approach to ensure the timely availability of information necessary for completion of these assessment process tasks is the assessment group inspector's visit of the site, to confirm and/or gather information. Even for an ME that the licensee considers to be relatively minor, staff does not support this ACMUI recommendation.

c. NRC is encouraged to change the 24-hour Operations Center reporting procedure. Specifically, MEs that have not harmed the patient, have little potential for harming the patient, and are not materially relevant to the patient's future medical treatment decisions, as evaluated by the licensee, are to be reported to NRC by means of written notification within 7 days of their discovery.

The Commission has previously endorsed staff's position opposing different reporting periods, depending on the licensee's initial assessment of the event [67 FR 20331 (April 24, 2002)] for several reasons. First, a requirement that allows for different reporting periods, depending on the initial assessment of the event, would lead to differing interpretations and confusion as to whether the magnitude of the event requires notification of the NRC no later than the next calendar day. In addition, there may be a medical event where the seriousness of the consequences would not be immediately apparent and which, therefore, would not be reported. Further, medical events need to be evaluated as soon as possible to determine if any immediate follow-up or corrective actions are necessary.

Additionally, the 24-hour reporting requirement, intended to permit NRC to conduct a *timely*, thorough, systematic, and formal assessment is consistent with NRC's 24-hour reporting requirements for other events involving licensed material. For example, 10 CFR 30.50, "Reporting Requirements" [byproduct material]; 10 CFR 40.60, "Reporting Requirements" [source material]; and 10 CFR 70.50, "Reporting Requirements" [special nuclear material] all require 24-hour reporting of: (1) an unplanned contamination event that requires access to the contaminated area to be restricted for more than 24 hours and involves a quantity of material greater than five times the lowest annual limit on intake specified in Appendix B of 10 CFR Part 20 for the material; (2) an event in which equipment is disabled or fails to function as designed when the equipment is required by regulation or license condition to prevent releases exceeding regulatory limits, to prevent exposures to radiation and radioactive materials exceeding

regulatory limits, or to mitigate the consequences of an accident, and the equipment is required to be available and operable when it is disabled or fails to function, and no redundant equipment is available and operable to perform the required safety function; (3) an event that requires unplanned medical treatment at a medical facility of an individual with spreadable radioactive contamination on the individual's clothing or body; (4) an unplanned fire or explosion damaging any licensed material or any device, container, or equipment containing licensed material, when the quantity of material involved is greater than five times the lowest annual limit on intake specified in Appendix B of Part 20 for the material; and the damage affects the integrity of the licensed material or its container.

The 24-hour reporting requirements for all these material use events, which enable NRC to promptly assesses the potential health and safety consequences for individuals or actual impact on licensed operations, serve a parallel purpose to NRC's 24-hour reporting requirement for medical use events, which enable NRC to promptly evaluate the circumstances of the MEs to determine if any immediate follow-up or corrective actions are necessary.

From ACMUI October 2005 meeting

> Recommendation: NRC should treat event information supplied by a licensee to the NRC Operations Center, pursuant to the next-calendar-day reporting requirement in 10 CFR 35.3045(c), and contained in an Event Summary, as preliminary raw data, and the Event Summary as a draft document. This information should not be disclosed/released to the public until the event has been confirmed to be a reportable ME.

This recommended procedure, as applicable to events reported by NRC medical use licensees, parallels a procedure NRC follows, upon Agreement State request, for releasing event information reported by an Agreement State for any type of event. Therefore, the staff endorses and supports the intent of this ACMUI recommendation. However, similar to Event Summaries received by NRC from Agreement States, there must be a limit on the delay time for fact-finding and assessment, before release of information to the public, if appropriate. Therefore, if the event has not been confirmed to be a reportable ME within 5 calendar days from initial reporting by the licensee, the staff recommends that the information available on the event at that time should be released to the public since it represents a potential ME.[1]

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[1]It has been suggested by Regional staff from each region, who are involved in implementing Part 35, that any delay in releasing information on potential MEs is inappropriate, since licensee-supplied information on other types of events at NRC-licensed facilities is released promptly upon receipt by NRC. NMSS/IMNS does not accept this position, since 1) there is often more informational uncertainty (re: the need for reporting) for events involving medical use than there is for most events involving other uses, and 2) for consistency, Event Summaries for NRC medical use licensees should be handled by NRC in the same way as Event Summaries for Agreement State medical use licensees. Whether, for further consistency, Event Summaries for other types of events reported by NRC licensees should be considered for delayed release when there is uncertainty, due to the need to acquire additional information (e.g., to analyze a personal dosimeter), as to the appropriateness of reporting, is outside the scope of this paper, unless the Commission directs otherwise.

Suggestion: NRC should footnote each Event Summary disclosed/released to the public as a reportable ME to indicate that NRC's ME definitions provide thresholds for identifying events that are indicative of technical or QA problems in accurately realizing the clinical intentions (prescriptions) of AUs and that thresholds in NRC's ME definitions, if exceeded, are not necessarily indicative of patient harm, or even of increased probability of patient harm.

The staff endorses and supports the intent of this ACMUI suggestion.