From: <SiegelB@mir.wustl.edu>
To: <rez@nrc.gov>
Date: 8/23/04 7:46AM
Subject: Re: Fwd: Consultancy, on Medical Event Criteria

Ron:

I have reviewed the material you sent to me and have discussed this matter briefly with Cathy Haney. Based on my recollections of the discussions by the ACMUI, during the Part 35 public workshops, and at the Part 35 Working Group meetings, there were no rigorous evidence-based criteria for retaining the 20% variance threshold in the revision of Part 35. In large part, the threshold was retained because it was in the prior version of the rule, because the reporting frequency associated with that threshold did not appear to be causing a significant burden for licensees, and because there was a general consensus that an error of 20% or more definitely had the potential to cause harm (although by no means was certain to do so). Thus, the Working Group's posture was to strike a balance such that the reporting burden would not be excessive, while nonetheless capturing all events likely to cause harm and capturing a large enough fraction of other signal events to provide NRC with information that could be evaluated and used to improve safety practices (through such mechanisms as Information Notices).

Whether a variance of more than 20% will cause harm to a patient is highly dependent on the modality. In general, the consensus of the ACMUI during my tenure as chair and that of the working group was that a 20% error in a cancer treatment regimen could lead to inadequate treatment of the cancer (underdosing) or to an increased likelihood of complications (overdosing). However, a threshold of only 10% was thought to be too low, since such differences were well within the range of standard of care variations from one practitioner to another. In contrast, a diagnostic radiopharmaceutical dosing error of more than 20% that led to an increase in EDE of just over 5 rem or to an organ dose of just over 50 rem would probably lead only rarely to actual harm, yet the magnitude of the error would likely be so large to cause such an excessive dose as to warrant reporting for that reason alone. For example, it would be of legitimate generic interest to the NRC to understand how a patient could be overdosed with Tc-99m MDP sufficient to cause an excess EDE of 5 rem, since this would require giving a dosage of nearly 240 mCi.

Finally, I think the Working Group recognized that there simply was not enough hard information in the scientific literature to allow for selection of different thresholds on a modality-by-modality basis that would be predicated on the risk of harm. If one realizes that such data would need to be specific to treatment site and radiopharmaceutical as well as to modality, it becomes clear that such an evidence-based approach would be daunting, if not simply impossible, to develop. Moreover, it wold have been extremely confusing to licensees

Please let me know if you need additional information.

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