Radioactive Materials Unit
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Date: January 2, 2008

To: Medical Licensees With Therapeutic Uses

From: Radioactive Materials Unit

Subject: Understanding of the Risks Associated with Medical Events

Information Notice 2008-01

This information notice is being issued to aid in the understanding of the risks associated with medical events as described in Radioactive Material Rule, Chapter 4732.4525. No specific action or written response is required.

For all medical uses, without exception, there are two criteria that apply to reporting a medical event. These criteria appear in 4732.4525. One criterion is the difference between the delivered dose and the prescribed dose exceeding a 20 percent threshold. The other criterion is the difference between the delivered dose and the prescribed dose (or dose that would have resulted from the prescribed dosage) exceeding a threshold.

The threshold for licensee submission of a medical event report is an administered total dose that differs by ±20 percent from the prescribed dose defined in the authorized user physician's written directive. Since written directives are required primarily for administrations intended for therapeutic purposes, a ±20 percent deviation can correspond to intended target doses reduced by or exceeded by approximately 50 rads (0.5 Gy) to 1800 rads (18 Gy). The basis for this threshold for reporting a medical event is that deviations of this magnitude may reflect quality assurance (QA) problems with the licensees' programs and also have the potential, though not the certainty, to result in harm to the involved patients or human research subjects.

The basis for the threshold for reporting a medical event, in part, reflects a general consensus among members of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). The consensus is that a deviation in total delivered dose of 20 percent or more from that prescribed

(1) has a significant potential, though not a certainty, to cause harm to the involved patient or research subject; and

(2) could indicate a deficiency in the licensee's program for ensuring that byproduct material is used as directed by the authorized user, even if the deviation did not necessarily indicate a significant risk to the involved patient or research subject.

The rationale for this position is that the ±20 percent threshold is a reasonable threshold for identifying events indicative of treatment delivery problems in accurately realizing authorized users' clinical intention.

The consensus of the ACMUI was that a total dose error of 20 percent in a cancer treatment regimen could lead to inadequate treatment of the cancer (under-dosing) or to an increased likelihood of complications (over-dosing). However, a threshold of 10 percent was considered to be too low for reporting medical events, since such differences were well within the range of the standard-of-care variations from one practitioner to another. In contrast for the difference-in-dose thresholds criterion for medical events, a diagnostic radiopharmaceutical over-dosing error that resulted in either the excess effective dose equivalent slightly exceeding 5 rem (0.05 Sv) or the excess organ, tissue, or skin dose slightly exceeding 50 rem (0.5 Sv) would only rarely, if ever, result in actual harm to the patient or research subject. However, the absolute magnitude of the dosage error would likely be large enough to warrant reporting. The consensus of the ACMUI was that there was a legitimate interest in over-dosages where either of these difference-in-dose thresholds for medical event reporting was exceeding.

A recommendation from the ACMUI in 2002 was to consider medical events as performance indicators of technical or quality assurance problems in accurately realizing clinical intentions of authorized users, but not as indicators of actual or probable patient harm. In 2005, the ACMUI offered an additional recommendation and a suggestion on the issue of improving public understanding of the risks associated with medical events. This recommendation was that this event information not be disclosed or released to the public until the event has been confirmed to be a reportable medical event, with one modification. Specifically in the interest of openness and timeliness, the information should be provided to the public about events reported as medical events when the events have been confirmed to be medical events or after five calendar days have passed, even if the events have not yet been confirmed as medical events. Suggestion was made and implemented that a footnote to each event summary that is released to the public as a reportable medical event to indicate that the thresholds in the criteria, if exceeded, are not necessarily indicative of patient harm.