Medical Use Events in 2003 That Prompted the Staff to Reconsider the Appropriateness and Adequacy of the Regulations for WDs and MEs

A medical use event involved the implantation of 40 Iodine-125 (I-125) sources for permanent implant brachytherapy in the wrong implantation site. The staff determined that this occurrence was not a ME because: 1) the AU revised the WD in the operating room after the erroneous source placement was discovered but before completion of the procedure and also documented the actual number of sources implanted into the prostate (34 instead of the intended 74); and 2) the unintended dose to the bladder (the wrong site) did not exceed 50 percent of the dose expected to this organ from a properly conducted procedure because the 40 I-125 sources in the bladder were promptly removed when their incorrect placement was discovered. However, the staff considered the written directive rule to be flawed because 10 CFR 35.40 permits the AU to revise the WD for permanent implant brachytherapy, thereby avoiding reporting the incident as an ME.

An event nearly identical to the one just described occurred in October 2005 at the same facility, involving erroneous placement of 45 (of 90) I-125 sources into the bladder instead of the prostate. In this event, the AU discovered the incorrect placement, removed the sources from the bladder, and revised the WD before the patient left the operating room. Although the staff is still evaluating this event, the staff anticipates that this event will not constitute a reportable ME, again because 10 CFR 35.40 permits the AU to revise the WD for permanent implant brachytherapy, thereby avoiding reporting the incident as an ME.

Another event in 2003 also involved the implantation of I-125 sources, for permanent implant brachytherapy of the prostate, into the wrong site. At this facility, 21 patients received source implants to the wrong site between January 22, 2001 and January 10, 2002, because of a systematic error. The licensee identified these occurrences in June 2003, and the staff determined that they were MEs. The dose to the prostate ranged from 0 percent to 76 percent of the intended dose using a definition of target-organ dose for the prostate recommended by the ACMUI in November 2003.

The measure used for determining if a prostate brachytherapy treatment misadministration/ME had occurred was the dose received by 90 percent of the target volume (D90), in comparison to the prescribed dose.* Although the ME criterion for underdosing of -20 percent (D90 < 80 percent of the prescribed dose) is generally satisfactory, D90s exceed 120 percent of the prescribed dose for many standard treatments. Such treatments would therefore be inappropriately classified as overdosing MEs (+ 20 percent) if the criterion D90 > 120 percent of the prescribed dose is used. Accordingly, the staff recognized the need to develop an appropriate criterion for comparison to the dose-based reporting requirement in 10 CFR 35.3045. To determine such a criterion, the staff consulted the ACMUI and requested its recommendation.

*The regulation requires that the delivered dose be compared to the prescribed dose. Of the various measures used for specifying the practitioner's intention, the one that is commonly used and is dose-based is D90. The NRC is obligated to use "industry standards" when they exist and can be used in regulation; D90 is such a "standard."