Staff's Recommendations for Modifying the Requirements in Title 10 of the *Code of Federal Regulations* (10 CFR) Part 35, "Medical Use of Byproduct Material," for Permanent Implant Brachytherapy Programs

The staff is proposing certain recommendations for modifying the requirements in 10 CFR Part 35 for permanent implant brachytherapy programs. As directed by the Commission in SRM M090625B, these recommendations were formulated in close cooperation with the Advisory Committee on the Medical Uses of Isotopes (ACMUI), as well as with substantial input from stakeholders.

The recommendations, with comments and explanations, are as follows.

A. The staff's recommendations for modifying the regulatory requirements that appear in 10 CFR 35.3045 for permanent implant brachytherapy medical event (ME) reporting are:

1. *Define separate ME criteria exclusively for permanent implant brachytherapy utilizing radioactive seeds, for all treatment sites.*

   The ME criteria recommended in this paper for permanent implant brachytherapy use are primarily source-strength based, while the ME criteria currently appearing in 10 CFR 35.3045, "Report and Notification of a Medical Event," for all use modalities are primarily dose based. Accordingly, separate ME criteria are recommended.

   Also, the recommended ME criteria are intended for permanent implant brachytherapy use involving radioactive seeds, but not for use of radioactive microspheres, which are currently regulated under 10 CFR 35.1000, "Other Medical Uses of Byproduct Material or Radiation from Byproduct Material."

2. *For the treatment site, an ME has occurred[1] if 20 percent or more of the implanted seeds are located outside of the intended implant location.*

   Source strength/positioning is the measurable metric/surrogate for dose, as related to harm/potential harm. Twenty percent is the variance limit (from physician intention) that was approved by the Commission, on the recommendation of the ACMUI, for all medical uses of byproduct material.[2]

[1] With exceptions for seed migration, edema and other patient-related factors, or source displacement following placement, as long as the criterion is not violated.
[2] See SRM-SECY-05-0234, available on the NRC public web site, at www.nrc.gov.

3. *For normal-tissue structures, an ME has occurred[3] if: a) For neighboring structures (such as the bladder or rectum in prostate implants as an example), the dose to at least 5 contiguous cm^3 exceeds 150 percent of the absorbed dose prescribed to the treatment site; or b) For intra-target normal structures (such as the urethra in prostate implants as an example), the absorbed dose to at least 5 contiguous cm^3 exceeds 150 percent of that structure's expected absorbed dose based on the approved pre-implant dose distribution. These dose determinations are to be made within a time frame to be determined by the authorized user consistent with prevailing medical practice, but not to exceed 60 days unless accompanied by written justification.*

   Because of this dose-based ME criterion for organs and tissues other than the treatment site, there is an implicit operational requirement for post-implant imaging, as strongly recommended during the public workshops and as practiced in most clinical facilities.

4. *An ME has occurred if a treatment is executed: a) using the wrong radionuclide; b) using the wrong activity or source strength (+/- 20%) as specified in the WD; c) with delivery to the wrong patient; d) with seeds implanted directly into the wrong site or body part, i.e., into other (distant from the treatment site) locations;[3] e) with delivery using the wrong modality; or f) using leaking sources*.

   For this criterion, +/- 20% is used for the ME threshold for source strength variance because +/- 10% is considered too close to the actual variance associated with this quantity in clinically acceptable implant procedures.

   Criterion A.4.d., for other (distant from the treatment site) locations, directly reflects an ACMUI recommendation but appears more restrictive on acceptable practice than the current regulation, as the proposed criterion is based on direct deposition only, without a minimum required dose for ME declaration. However, the localized dose associated with any misplaced seed far exceeds the 0.5 Sievert (50 rem) dose threshold in the current regulation.

   Note that if seeds are directly deposited into the urinary bladder, because prompt removal typically follows, rather than permanent residency at the implantation site, exceeding criterion A.3.a. (dose to neighboring tissue structures) would be the basis for an ME, rather than criterion A.4.d. (direct delivery to the wrong site).

B. The staff notes that the WD requirements for brachytherapy that currently appear in 10 CFR 35.40(b)(6) would require only minor modification for compatible applicability with the recommended modifications to 10 CFR 35.3045, listed above, for permanent implant brachytherapy. These modifications with comment and explanation are summarized as follows.

1. *Have separate WD criteria exclusively for permanent implant brachytherapy utilizing radioactive seeds, for all treatment sites.*

2. *Delete "total dose" as an option for completion of the WD, leaving the other option, "total source strength and exposure time," as the required entry field (along with entry fields for radionuclide, treatment site, and number of sources).*

[3] With exceptions for seed migration, edema and other patient-related factors, or source displacement following placement.

3. *Replace "before completion of the procedure" with "before the patient is released from the AU's control and leaves the post-procedure recovery area."*

   The wording of this recommendation reflects the ACMUI position that "released from the AU's control" equates to "released from the post-procedure recovery area."[4]

   This recommendation is offered to remove uncertainty that has been encountered in interpretation of the existing requirement.

C. Additional Comments and Explanations

1. Consistent with ACMUI recommendations, all of the proposed ME criteria reflect circumstances in which there is actual or potential harm to patients being treated.

2. The ACMUI final recommendations in its October 2011 report are collectively more prescriptive than those in its interim (2010) report. The ACMUI revised final recommendations for MEs (2012) are based on the 2011 source-strength positioning ME criterion recommendation of American Society for Radiation Oncology (ASTRO)[5] but include some dose-based components for tissues other than the treatment site.

3. The ACMUI revised final recommendations for MEs (2012) are a modification of the ASTRO recommendations (2011). Although the ACMUI considers its revised final recommendations to be a more workable version of the ASTRO recommendations,[6] unlike the ASTRO recommendations, the ACMUI ME criteria include explicit consideration of doses received by normal tissues and organs. This approach clearly would introduce additional licensee obligations if the ACMUI, rather than the ASTRO recommendations, were adopted as regulatory requirements. However, the staff believes that these additional criteria are warranted, in that they address the need to identify and report high doses to normal tissue.

[4] See page 71 of the transcript for the 10/18/11 ACMUI teleconference, in ADAMS at ML11318A333.
[5] ASTRO ACMUI Meeting Testimony on Permanent Implant Brachytherapy available in ADAMS at ML111010724.
[6] See page 71 of the transcript for the 10/18/11 ACMUI teleconference.