STAFF'S RESPONSE TO THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES' NOVEMBER 6, 2015, RECOMMENDATIONS ON THE PROPOSED REVISION OF THE U.S NUCLEAR REGULATORY COMMISSON POLICY STATEMENT ON REPORTING ABNORMAL OCCURRENCES TO CONGRESS

This document provides the U.S. Nuclear Regulatory Commission (NRC) staff's detailed positions and responses to the recommendations of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on the proposed final revision of the NRC policy statement on reporting abnormal occurrences (AOs) to Congress, published in Volume 80 of the *Federal Register*, dated August 17, 2015 (80 FR 49177). In a public meeting on October 9, 2015, the ACMUI Full Committee voted to forward the following recommendations to the staff:

1. **ACMUI Recommendation:** Statement Introduction—The Subcommittee agrees that the general descriptions of what constitutes an AO should be included in the Statement of Policy and recommends no additional changes be made to this proposed change.

   STAFF POSITION: No response needed.

   STAFF RESPONSE: No response.

2. **ACMUI Recommendation:** AO Criteria I. Title and Footnote—The Subcommittee agrees with the change in title for this AO Criteria I. and the addition of footnote 2. The Subcommittee recommends the wording for footnote 2 be changed as follows with deletions noted with ~~strikeout~~ and additions noted in **bold**:

   > [2] Medical patients **and human research subjects** are excluded from consideration under this criterion and these criteria do not apply to ~~medical~~ events defined in § 35.3045 **and § 35.3047** of Title 10 of the Code of Federal Regulations (10 CFR), which are considered in AO Criteria III.C, ''Events involving the Medical Use of Radioactive Materials in Patients or Human Research Subjects.''

   This change addresses the Subcommittee's recommendation that medical-related events reported under § 35.3047 be screened under AO Criteria III.C. to maintain consistency with NRC regulations because the event exposure was due to the medical use of byproduct material.

   STAFF POSITION: Partially agree.

   STAFF RESPONSE: The staff agrees with adding the phrase "and human research subjects."

   However, the staff disagrees with removing "medical" and adding "and § 35.3047." The staff disagrees with excluding events reported under § 35.3047 from Criterion I.A.2 because the change would establish two different thresholds for reporting an AO involving exposure to an embryo/fetus; one for an embryo/fetus unintentionally exposed due to a medical administration to a pregnant individual and one for an embryo/fetus exposed from all other sources of licensed material. The NRC agrees with the statement in the dissenting vote justification in the ACMUI report, that the argument that the embryo/fetus has an indirect benefit, pertaining to the health of the mother, is not a

compelling argument for establishing two thresholds for reporting an AO for exposure to an embryo/fetus.

3. **ACMUI Recommendation:** AO Criteria III.A. Title—The Subcommittee agrees with the change in title for this AO Criteria III.A.

   STAFF POSITION: No response needed.

   STAFF RESPONSE: No response.

4. **ACMUI Recommendation:** AO Criteria III.C. Title—The Subcommittee agrees with the change in title for this AO Criteria III.C., but recommends changing "Radioactive" to "Byproduct" to be consistent with 10 CFR 35 regulations.

   STAFF POSITION: Disagree.

   STAFF RESPONSE: The staff believes that using the term "Byproduct" would improperly restrict reporting. As proposed by ACMUI, the medical uses of isotopes of "special nuclear material" or "source material" would not be subject to the AO criteria as defined in 10 CFR Part 40, "Domestic Licensing of Source Material," and 10 CFR Part 70, "Domestic Licensing of Special Nuclear Material."

5. **ACMUI Recommendation:** AO Criteria III.C. Footnote—The Subcommittee agrees with the addition of footnote 16 clarifying that AO Criteria III.A.2, III.A.3, and III.A.4 also apply to medical licensees. The application of these criteria will allow the NRC to identify as an AO those circumstances involving the loss of management controls demonstrated by multiple medical-related events even in the absence of any one event meeting the AO Criteria III.C.

   STAFF POSITION: No response needed.

   STAFF RESPONSE: No response.

6. **ACMUI Recommendation:** AO Criteria III.C.1. and 2.—The Subcommittee recommends that the proposed AO Criteria III.C.1. and 2. be replaced with the following modified wording for III.C.1.:

   > A**n** ~~medical~~ event, as defined in 10 CFR 35.3045 **or 35.3047**, which results in ~~a dose that,~~ **unintended permanent functional damage to an organ or a physiological system as determined by an independent physician[FN] deemed qualified by the NRC or an Agreement State.**
   > **[FN]Independent physician is defined as a physician not on the licensee's staff and who was not involved in the care of the patient or human research subject involved in the event**.

   This wording modification removes use of a dose criterion which may have identified events which have no evidence of probable consequence while possibly missing significant events which did not exceed the dose criterion but may have resulted in damage to an organ or physiological system. The addition of the requirement for an independent physician and the associated footnote is consistent with the statement and footnote used in AO Criterion I.A.3.

STAFF POSITION: Disagree.

STAFF RESPONSE: The staff is not proposing to revise these criteria. The Commission does not agree with the use of unintended permanent functional damage to an organ or a physiological system, as determined by an independent physician, to classify AOs for medical events in Criterion III.C because of the potential significance associated with such events, and believes that the current criteria are appropriate.

7. **ACMUI Recommendation:** Cost of Independent Physician Review—The Subcommittee recommends that NRC Staff evaluate whether implementation of the Subcommittee's recommended AO Criterion III.C.1. would trigger additional cost beyond the cost of providing independent medical consultation in support of the regulatory review conducted for a § 35.3045 or § 35.3047 event.

STAFF POSITION: Disagree.

STAFF RESPONSE: As noted in response 6, the NRC staff does not agree with the change, thus the NRC staff has not evaluated the potential costs associated with the proposed change.

8. **ACMUI Recommendation:** Appendix B. Re-Designation and New Description—The Subcommittee agrees with the change in re-designating the previous AO Criteria IV. as the proposed Appendix B with the additional description for this new appendix to clarify that it is not part of the proposed AO Criteria.

STAFF POSITION: No response needed.

STAFF RESPONSE: No response.