STAFF'S RESPONSES TO THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES' APRIL 15, 2013 RECOMMENDATIONS TO UPDATE SECTIONS I.A AND III.C OF THE ABNORMAL OCCURRENCE CRITERIA IN 71 FR 60198 (DATED OCTOBER 12, 2006)

(Slightly revised to include the date ACMUI voted to forward these recommendations to the NRC Staff)

This document provides the staff's detailed positions and responses to the recommendations of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), regarding changes to the abnormal occurrence (AO) criteria in 71 FR 60198, dated October 12, 2006. In an April 15, 2013, public meeting, the ACMUI voted to forward the below recommendations to the staff. Immediately following the staff's response to the recommendations is the staff's response to the ACMUI's philosophical views on the AO criteria and reporting.

STAFF RESPONSE TO ACMUI RECOMMENDATIONS

ACMUI Recommendation: Adjust the Section IA criteria, "For All Licensees - Human Exposure to Radiation from Licensed Material" to add a new paragraph 4 which states the following: *"These criteria do not apply to medical events included in criteria III.C involving medical administrations using byproduct material to patients or human research subjects."*

Staff Position/Response: AGREE.

ACMUI Recommendation: Adjust the title of the Section III.C criteria from "*For Medical Licensees*" to *"For Events Involving Patients or Human Research Subjects."*

Staff Position/Response: AGREE. The staff initially made this suggestion to the ACMUI. However, refinements to the language are shown in bold font below:

"*For Events Involving **the Medical Use of Radioactive Materials in** Patients or Human Research Subjects."*

ACMUI Recommendation: Replace the dose and error criteria in Section III.C.1 and III.C.2 with the criteria shown below.

A medical event as determined by a consultant physician(s) deemed qualified by NRC or an Agreement State that results in one or more of the following:

a. Unintended or unexpected permanent functional damage to an organ;
b. Unintended or unexpected permanent functional damage to a physiological system;
c. A significant unexpected adverse health effect or
d. Death.

Staff Position/Response: PARTIALLY AGREE. The staff agrees that the above harm criteria should be adopted, but disagrees that it should replace the dose and error criteria. The following background and explanation are offered.

In 2008 and 2011 public meetings, the staff briefed the ACMUI on the numbers and types of medical AOs and requested its views on the staff's proposal to change the reporting threshold so that any medical event determined to be an AO must demonstrate that harm occurred. The staff believes that, in the medical arena only, in order for the intent of AO reporting to be met, it is necessary to demonstrate that harm occurred because of the high radiation doses given to

patients. The staff suggested that replacing the conservative dose thresholds in the current Section III.C.1 criteria (e.g., 1,000 rad to the wrong treatment site) with criteria that will require actual harm be observed (e.g., "adverse health effect *as determined by a physician*") would capture only the most safety-significant medical events as AOs. The ACMUI agreed with the staff's rationale and, in both the 2008 and 2011 public meetings, the ACMUI made recommendations that the staff adjust the AO criteria accordingly.

However, subsequent to the 2011 public meeting, staff realized that because initial event reports tend to have limited information, the staff will incur difficulty in making preliminary determinations and a particular event might need to be forwarded to a consultant to make adverse health effect determination. Consequently, staff decided that the dose thresholds in the current Section III.C criteria should be retained for use as screening criteria. Staff believes that events that meet these dose thresholds have the most potential for also meeting the qualitative harm criteria. Therefore, in a 2012 public meeting, staff briefed the ACMUI with a proposal to retain the dose thresholds in the Section III.C.1 criteria for the staff's use as screening criteria.

The ACMUI formed a subcommittee to review the staff's proposal. In a 2013 public meeting, the ACMUI provided staff its final report, "Advisory Committee on the Medical Use of Isotopes (ACMUI) Report on Abnormal Occurrence Criteria for Medical Use, April 15, 2013" (see ML13161A253), in which it forwarded to staff its determination that there are no practical and implementable criteria that it could recommend to the staff for use as screening criteria.

After considering the ACMUI's determination, the staff decided to evaluate fiscal year (FY) 2010 and 2011 AOs against the current dose threshold criteria and consider whether these AOs also would likely meet the proposed adverse heath effect (i.e., the new III.C.3) criteria. The staff determined that had these criteria been in effect, half of the AOs reported in the FY 2010 and FY 2011 reports would have been appropriately screened out. Based on this outcome, the staff concluded that the current dose criteria can be used as screening criteria, as long as: (1) the proposed Section III.C.3 adverse health effect criteria are also considered, and (2) conservative assumptions about the possibility of medical events meeting those criteria are also made. Therefore, the staff recommends the following approach for identifying medical AOs:

- Retain the current dose criteria in Section III.C.1 for use as screening criteria. The staff will evaluate medical events against the Section III.C.1 criteria.

- For medical events that meet the Section III.C.1 criteria, the staff will further evaluate them against the error criteria, outlined in the current Section III.C.2.

- For those events that also meet the Section III.C.2 criteria, the staff will forward them to the medical consultant. The independent physician will evaluate them against the proposed harm criteria which will be captured in the new Section III.C.3. Based on the consultant's harm determination, the staff will identify events that it will recommend to be forwarded to the Commission to be approved as AOs.

ACMUI Recommendation: Add a new embryo/fetus criterion to Section III.C. Use the following language: "*Notification under 10 CFR 35.3047 of an event involving an unintended dose to an embryo/fetus or a nursing child that results in a significant adverse health impact to the embryo/fetus or child, as determined by a consultant physician(s) deemed qualified by NRC or an Agreement State."*

Staff Position/Response: DISAGREE. The staff acknowledges that the ACMUI's rationale for the above recommendation involves the fact that the mother is undergoing a medical treatment and therefore (in the ACMUI's view) the unintended dose to the embryo/fetus and nursing child should not be considered separate from the treatment. Based on this view, the ACMUI considers it inappropriate to capture embryo/fetus and nursing child AOs under the Section I.A AO criteria. The ACMUI also believes that in a regulatory sense, this is consistent with notification of embryo/fetus and nursing child dose under 10 CFR 35.3047.

However, with respect to this view, the staff notes that: (1) the purpose of notification under 10 CFR 35.3047 is to alert NRC of cases where medical administrations *inadvertently* resulted in embryo/fetus and nursing child exposures; (2) the standard of care (not NRC's regulatory requirement) is to assess the possibility of pregnancy prior to administration of a radiopharmaceutical, and (3) the present AO criteria I.A.2 and I.A.3 adequately capture inadvertent embryo/fetus and nursing child doses (to include those that could cause a significant adverse health impact). Therefore, there is no need for an additional embryo/ fetus and nursing child criterion under Section III.C.

STAFF RESPONSE TO ACMUI PHILOSOPHICAL VIEWS ON AO CRITERIA AND REPORTING

ACMUI AO Subcommittee Comment, Page 5: "…The past five years of AO reports included notifications of unintended dose to an embryo/fetus… due to I-131 therapy patients unknowingly being pregnant at the time of their therapy… These incidents were reported as abnormal occurrences due to the low dose threshold criterion defined the "For All Licensees" AO criteria I.A.3." [(*Sic*). Emphasis added].

Staff Response: DISAGREE. The staff disagrees with the assertion that the dose threshold for the embryo/ fetus and nursing child in AO criteria I.A.2 is a "low dose threshold" criteria. The dose threshold stated in I.A.2 is 5 rem, and the public dose limit in 10 CFR 20 is 100 millirem. Thus, the threshold of 5 rem in the I.A.2 criterion is 50 times greater than what 10 CFR 20 members of the public to receive. Particularly after considering the radio-sensitivity of the embryo/fetus or nursing child, the staff believes an accidentally administered dose of 5 rem is a high dose to this population and warrants being labeled as an "abnormal occurrence."

ACMUI AO Subcommittee Comment, Page 5: "The Subcommittee recommended that the AO criteria III.C. also include the unintended dose reported under 10 CFR 35.3047… which results in a significant medical harm to the embryo/fetus or child because this abnormal occurrence can only happen as a result of medical administration to a patient or human research subject."

Staff Response: **AGREE.** The staff agrees that 10 CFR 35.3047 captures incidents of fetal exposure (resulting only from a medical administration to the patient). However, there are other exposure scenarios that could cause an accidental administration, such as an environmental accident or occupational exposure to a pregnant woman. The staff notes that AO criteria I.A.2 and I.A.3 adequately captures all non-patient accidental exposures.

Concerning the ACMUI's position that a dose to a fetus or nursing child associated with a medical administration to the pregnant or nursing patient be captured as an AO only if significant harm results, the staff notes that the threshold of "significant harm" is not applied to

any other unintentionally exposed population in order for an AO to have occurred. As elaborated in the staff's response below, the basic criterion for defining an AO is that an exposure be "significant from the standpoint of public health or safety."

ACMUI AO Subcommittee Comment Attachment 2 Pages 8-9: "The Subcommittee considered that…events should have the potential for significant medical harm to more than one individual to be considered as significant…The NRC has used this sort of threshold criteria for determining whether an… IIT or… an AIT is warranted for a Medical Event Assessment… Subcommittee members did not see a conflict between using a threshold number of individuals as a screening criterion and the NRC's regulatory philosophy.

Staff Response: Management Directive (MD) 8.10 (in part) provides guidance to NRC staff for assessing the need to elevate the inspection response to an Incident Investigation Team (IIT) or Augmented Inspection Team (AIT) based on evidence of a systematic breakdown, generic problem, or one-time significant breakdown in a licensee's performance.

The Background section of the AO Policy Statement[1] says: "Section 208 of the Energy Reorganization Act of 1974 defines an AO as an unscheduled incident or event which the NRC determines to be significant from the standpoint of public health or safety… The policy reflects a range of health and safety concerns and applies to incidents and events involving **a single individual,** as well as those having overall impact on the general public." Thus, neither the statute requires AO reporting nor the AO Policy Statement requires that more than one individual be affected. Rather, just one event that is believed to be significant from the standpoint of health or safety needs have occurred. Consequently, the staff does not believe that it is appropriate to apply the MD 8.10 inspection criteria to AO reporting.

[1] 71 FR 60198, October 12, 2006