November 28, 2012

MEMORANDUM TO: Leon S. Malmud, M.D., Chairman
Advisory Committee on the Medical Uses of Isotopes

FROM: Christian Einberg, Chief **/RA/**
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Division of Materials Safety and State Agreements
Office of Federal and State Materials and
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SUBJECT: RESPONSE TO RECOMMENDATIONS FROM THE SEPTEMBER 20-21, 2012 MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Below are the recommendations from the September 20-21, 2012 meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). Following the recommendations are the U.S. Nuclear Regulatory Commission (NRC) staff response and/or position.

ITEM (1): Dr. Leon Malmud requested that NRC staff find data on events in which the radiopharmacy dispensed the incorrect amount of a radiopharmaceutical or the incorrect radiopharmaceutical.

NRC staff performed a search for fiscal years 2002 to 2012 and found 32 events reported in which the radiopharmacy dispensed the incorrect amount or type of a radiopharmaceutical. As mentioned during the September 20-21, 2012 ACMUI public meeting, other instances may have occurred where a radiopharmacy made an error; however, this additional data is not available to NRC staff because diagnostic radiopharmaceutical procedures typically do not meet the reporting criteria in Title 10 Code of Federal Regulations (CFR) 35.3045 and, therefore, may not be captured in NRC's Nuclear Material Events Database. Also, while limitations associated with NMED data entry can potentially exclude events from the search result, NRC staff believes the numbers reported fairly reflect the magnitude of radiopharmaceutical error events reported. NRC staff noted that the majority of the 32 events reported involved Technetium-99m. Other common events reported (not included in the count for radiopharmacy errors) were due to errors in the prescription or Authorized User's Written Directive (WD) or human error on behalf of the technologist (e.g. switching syringes, misreading label or WD, etc.). This item is closed.

ITEM (2): The committee recommended that radium-223 (Ra-223) dichloride be licensed under 10 CFR 35.300 and recommended (but not require) direct measurement of activity before/after administration.

The recommendation passed unanimously with twelve favorable votes. NRC staff is currently evaluating whether Ra-223 dichloride will be licensed under 10 CFR 35.300 or 10 CFR 35.1000.

ITEM (3): The committee endorsed the subcommittee report submitted on July 16, 2012 with the following changes: 1) recommend licensing of Ra-223 dichloride under 10 CFR 35.300 and recommend (but not require) direct measurement of activity before/after administration; 2) remove statement regarding applicability of report for all future alpha-emitting particles; and 3) remove statement regarding Ra-223 dichloride significantly prolonging survival. The ACMUI will submit a final report to NRC staff with the aforementioned changes.

The recommendation passed unanimously with 12 favorable votes. NRC staff is currently evaluating whether Ra-223 dichloride will be licensed under 10 CFR 35.300 or 10 CFR 35.1000.

ITEM (4): The committee requested that the reporting structure reviews remain on an annual basis.

The recommendation passed unanimously with 12 favorable votes. NRC staff will provide the committee an opportunity to discuss its reporting structure annually.

ITEM (5): Dr. Leon Malmud created a subcommittee to review the refined Abnormal Occurrence criteria and to provide recommendations to NRC staff. Subcommittee members include: Dr. Susan Langhorst (chair), Ms. Darice Bailey, Mr. Steve Mattmuller, Dr. Christopher Palestro, Dr. Bruce Thomadsen, Ms. Laura Weil, and Dr. James Welsh. The NRC staff resource person will be Ms. Angela McIntosh.

NRC staff provided a purpose statement and background information on October 5, 2012 and requested that the subcommittee report to the full committee at the April 2013 public meeting.

ITEM (6): Dr. Susan Langhorst requested NRC staff to provide direction as to whether or not the screening criteria needs to be a part of the Abnormal Occurrence criteria or if the screening criteria could be used separately.

NRC provided a response to the subcommittee on October 11, 2012 indicating that the screening criteria could be used separately and that the subcommittee should consider the pros and cons of such a system in their report.

ITEM (7): The committee planned the spring 2013 ACMUI Meeting on April 15-16, 2013, at NRC Headquarter. The back-up date is April 29-30, 2013. The ACMUI will meet separately with the Commission, if requested.

No NRC action required.