April 11, 2013

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 MARCH 05, 2013 AND MARCH 12, 2013 TELECONFERENCE MEETINGS OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Below are the recommendations from the March 05, 2013 and March 12, 2013 teleconference meetings 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): The Committee recommended NRC staff allow use of total source strength as a substitute for total dose for determining medical events for permanent implant brachytherapy until the 10 Code of Federal Regulations (CFR) Part 35 rulemaking is complete.

The recommendation passed unanimously with eleven favorable votes.

ITEM (2): The Committee recommended that NRC staff solicit feedback from stakeholders, in Supplementary Information section IV.D of the proposed rule for 10 CFR Part 35, on whether the proposed medical event (ME) definition for permanent implant brachytherapy would discourage licensees from using this form of therapy.

The Committee commented that NRC staff should use the language that NRC believed to be appropriate. The recommendation passed unanimously with eleven favorable votes.

ITEM (3): The Committee recommended the draft rule re-defining medical events in permanent implant brachytherapy be designated as Compatibility Category B.

The recommendation passed with eleven favorable votes and one opposing vote.

ITEM (4): The Committee recommended replacing the phrasing in the literature in terms of support for the 5 cubic centimeters of contiguous normal tissue provision of the ME definition, to the specific reference cited as, Nag, et al 2004.

The recommendation passed unanimously with eleven favorable votes.

ITEM (5): The Committee recommended that licensees approved to use generator systems show specific training on the requirement now listed under 35.290 (c)(1)(ii)(G) for those individuals (Authorized Users and others) who are responsible for proper

operation and testing of the generator as part of their license conditions. ACMUI further recommended that Authorized Nuclear Pharmacists who have the adequate training and experience (T&E) are able to provide the supervised work experience for Authorized Users on the elution of generators.

The recommendation passed unanimously with eleven favorable votes.

ITEM (6): The Committee recommended endorsing the language in the proposed rule for preceptor attestation requirements that states a candidate is able to independently fulfill the radiation safety related duties for which authorization is being sought.

The recommendation passed unanimously with eleven favorable votes.

ITEM (7): The Committee recommended that the work experience for parenteral administrations under Sections 35.390 (b)(1)(2)(g), and 35.396 not be separated between parenteral administrations of a beta/gamma emitting radiopharmaceutical versus an alpha emitting radiopharmaceutical, as proposed in the proposed rule.

The recommendation passed with eleven favorable votes and one abstention.

ITEM (8): The Committee recommended that the date of recognition of a certifying board should not impact individuals seeking to be named as an Authorized User, Authorized Radiation Safety Officer, Authorized Medical Physicist, or Authorized Nuclear Pharmacist through the certification pathway.

The recommendation passed unanimously with twelve favorable votes.

ITEM (9): The Committee recommended that the NRC adopt the U.S. Food and Drug Administration (FDA) approved package insert for breakthrough limits for radioisotope generators.

The recommendation passed unanimously with twelve favorable votes.

ITEM (10): The Committee recommended licensee reporting of out-of-tolerance generator breakthrough results to the NRC.

The recommendation did not pass with seven opposing votes and five favorable votes.

ITEM (11): The Committee recommended that the addition of Associate Radiation Safety Officers (ARSOs), and Temporary RSOs also be included in the exemptions in the same manner as AUs, ANPs, and AMPs.

The recommendation passed unanimously with twelve favorable votes.

ITEM (11): The Committee recommended that the rule “could be shortened and improved by eliminating redundancies and consolidating related sections and eliminating identical or nearly identical passages appearing multiple times throughout the draft rule. A further improvement would be the inclusion of a detailed “executive summary” style section summarizing, perhaps in a bullet format, the key changes introduced in the draft rule.”

The recommendation passed unanimously with twelve favorable votes.

ITEM (12): The Committee recommended approval of the Second Draft ACMUI Rulemaking Subcommittee Report (ML13071A690) with the caveat that all modifications discussed during the teleconference would be incorporated before submission to NRC staff.

The recommendation passed unanimously with twelve favorable votes.

The subcommittee chair, Dr. Pat Zanzonico, submitted the finalized report (ML13099A459) on April 09, 2013. The NRC staff will consider these recommendations during the development of the proposed revisions to 10 CFR Part 35, and will include the final ACMUI rulemaking report and recommendations in a paper to the Commission.