UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 2, 2016

MEMORANDUM TO: Philip O. Alderson, M.D., Chairman
Advisory Committee on the Medical Uses of Isotopes

FROM: Daniel S. Collins, Director ***/RA/***
Division of Material Safety, State, Tribal
and Rulemaking Programs
Office of Nuclear Material Safety
and Safeguards

SUBJECT: RESPONSES TO THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES' JANUARY 06, 2016 RECOMMENDATIONS ON THE DRAFT FINAL RULE: MEDICAL USE OF BYPRODUCT MATERIAL – MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE, AND CLARIFYING AMENDMENTS (RIN 3150-A163)

Below are the staff responses to the recommendations from the January 06, 2016 Advisory Committee on the Medical Uses of Isotopes (ACMUI) Final Report (ML16007A771) on the draft "Final Rule: Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments (RIN 3150-A163)." The Committee provided 13 recommendations, six of which endorsed items in the draft final rule, and therefore no change to the draft final rule is needed for these items. The NRC accepted two recommendations, partially accepted one recommendation and did not accept four recommendations.

1. **ACMUI Recommendation:** The Committee recommended changing the language for a "wrong-location" medical event in permanent implant brachytherapy from the current proposed language,

   "Sealed source(s) implanted directly into a location where the radiation from the source(s) will not contribute dose to the treatment site, as defined in the written directive,"

   to

   "Sealed source(s) implanted directly into a location discontiguous from the treatment site, as defined in the written directive."

   Staff Response: Accepted. The NRC staff agrees with the ACMUI recommendation and has made this revision in the final rule. The phrase "…as defined in the written directive" was revised in response to another comment to "…as documented in the post-implantation portion of the written directive." Without this revision, it was not clear if the requirement was with respect to the pre- or post-implantation portion of the written directive.

CONTACT: Sophie J. Holiday, MSTR/MSEB
(301) 415-7865

2. **ACMUI Recommendation:** The Committee recommended that NRC staff consider providing guidance in the NUREG-1556, Volume 9 update to licensees on the ways individuals with board certifications prior to NRC's board recognition date may seek authorization.

   Staff Response: Accepted. While this recommendation does not require a change to the rule text, the NRC will include additional guidance in NUREG-1556, "Consolidated Guidance about Materials Licenses," Volume 9, "Program-Specific Guidance about Medical Use Licenses," to clarify the ways in which individuals with Board certification prior to the NRC's Board recognition dates may seek authorization. The NRC will explain why different Boards have different recognition dates and the information needed when an individual was certified outside of the NRC's Board recognition dates.

3. **ACMUI Recommendation:** The Committee did *not* endorse establishing a separate category of Authorized Users for parenteral administration of alpha-emitting radiopharmaceuticals but, instead, recommends deleting § 35.390(b)(1)(ii)(G)*(4)* in the current Draft Final Rule and revising the pertinent passage in § 35.390(b)1()(ii)(G)*(3)* as follows, "Parenteral administration of any radioactive drug for which a written directive is required."

   Staff Response: Partially Accepted. After reviewing the Committee's recommendation and supporting statements, the NRC has determined that an additional three cases of administering dosages of radioactive drugs for alpha-emitting radiopharmaceuticals for parenteral administration is not necessary. Therefore, in the final rule § 35.390(b)(1)(ii)(G)(3) was revised to read: "Parenteral administration of any radioactive drug that contains a radionuclide that is primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or for its photon energy of less than 150 keV, for which a written directive is required." Further, § 35.390(b) (1) (ii) (G) *(4)* is deleted in the final rule.

   The NRC is not accepting the ACMUI recommendation to revise § 35.390(b) (1) (ii) (G) (*3*) as follows: "Parenteral administration of any radioactive drug for which a written directive is required." This revision would mean that any radioactive drug for parenteral administration could be encompassed within § 35.390(b) (1) (ii) (G) (*3*) with no opportunity for the NRC to evaluate new radionuclides that are developed for parenteral administration, including evaluating necessary training. While it may appear that all new radioactive drugs would be encompassed within the category of "primarily used for its electron emission, beta radiation characteristics, alpha radiation characteristics, or for its photon energy of less than 150 keV for which a written directive is required," the NRC would lose flexibility to review new radionuclides under § 35.1000, "Other medical uses of byproduct material or radiation from byproduct material," for health and safety issues. The NRC needs to maintain this flexibility for emerging medical uses.

4. **ACMUI Recommendation:** The Committee recommended revising the passage in § 35.3045(a)(2)(iii)(D) in the Draft Final Rule as follows, thereby eliminating the dose-based criteria for a "leaking-source" medical event

   > "3) An administration that includes the wrong radionuclide; the wrong individual or human research subject; a leaking sealed source; or a sealed source or sources implanted into a location discontiguous from the treatment site, as defined in the written directive."

   Staff Response: Not Accepted. The NRC acknowledges that measuring dose from leaking sealed sources can be difficult. However, no change was made to the rule text based on this recommendation. NRC has retained the dose-based criteria for leaking sealed sources, and these calculations can and are made. Further, doses in excess of 50 rem to organs or tissues can cause deterministic effects, while doses below this threshold do not pose a risk to the patient sufficient to require reporting as a medical event.

5. **ACMUI Recommendation:** The Committee did *not* endorse the new requirement in the Draft Final Rule that licensees report to the NRC as well as to the manufacturer/vendor generator elutions with out-of-tolerance parent-breakthrough but, instead, recommends a single reporting requirement to the manufacturer/vendor.

   Staff Response: Not Accepted. The NRC does not support the ACMUI recommendation of revising § 35.3204(a) to only retain the single reporting requirement to the manufacturer/vendor. This recommendation does not ensure all relevant information will be reported to the NRC. There are no requirements for manufacturers/distributors to report generator failures to the NRC in the current regulations or in the proposed rule. In order for the NRC to receive such information, a new rule would have to be proposed requiring manufacturers/distributors to make reports to the NRC. NRC believes it is important to retain the requirement that licensees report generator failures directly to the NRC because this will permit the NRC to identify if the failure is limited or more widespread and address the failure in a timely manner.

6. **ACMUI Recommendation:** The Committee recommended that the designation of a board-certified authorized user, authorized medical physicist, or authorized nuclear pharmacist as the RSO or as an ARSO required their board certification to include the designation "RSO Eligible."

   Staff Response: Not Accepted. The "RSO Eligible" designation is not needed for those individuals board-certified for their respective specialties because all AUs, AMPs, or ANPs are already eligible to be an RSO or ARSO under the training and experience provisions of § 35.50(c) (2) or (c) (3). The "RSO Eligible" designation is only needed for individuals who are board-certified under the American Board of Radiology and American Board of Medical Physics.

7. **ACMUI Recommendation:** The Committee recommends changing the "medical-events" language in §35.3045(a) in the Draft Final Rule *from*, "A licensee shall report any event, except for an event that results from patient intervention…,"*back to the language in the Proposed Rule as presented for public comment,* "A licensee shall report as a medical event, any administration requiring a written directive, except for an event that results from patient intervention…" The Committee believed the wording change proposed in the current version of the Proposed Rule should not be made without further public review and opportunity for comment."

   Staff Response: Not Accepted. The NRC is retaining the language in the draft final rule, "A licensee shall report any event as a medical event…." It is important for the NRC to learn of any event that meets the criteria for a medical event, not just those for which a written directive is required. If the NRC were to accept the ACMUI's recommendation, then the NRC would not learn of events in which the administration did not require a written directive but otherwise met the criteria to be reported as a medical event.

   The NRC deleted the phrase "any administration requiring a written directive" in § 35.3045(a) because its insertion into the proposed rule was an error. The Statement of Considerations (SOC) for the proposed rule did not identify limiting medical event reporting at § 35.3045(a) (1) to procedures requiring a written directive as a proposed revision nor did the SOC explain the NRC's regulatory basis for making such a revision.

ACMUI Endorsements That Did Not Require a Change to the Rule or Staff Response:

ACMUI Endorsement: The Committee endorsed that component of the current proposed rule redefining medical events in permanent implant brachytherapy in terms of activity (i.e., source strength) rather than radiation dose.

ACMUI Endorsement: The Committee endorsed, with reservations, designating the current proposed rule re-defining medical events in permanent implant brachytherapy as Compatibility Category C, with activity-based medical event metrics defined as an essential program element.

ACMUI Endorsement: The Committee endorsed the elimination of the preceptor-statement requirement for Board-certified individuals for an individual seeking regulatory authorization as an authorized user, authorized medical physicist, Radiation Safety Officer, or authorized nuclear pharmacist

ACMUI Endorsement: With respect to the amended requirements for preceptor attestation for an individual seeking regulatory authorization as an authorized user, authorized medical physicist, Radiation Safety Officer, or authorized nuclear pharmacist through the alternate pathway, the Committee endorsed changing the language for the preceptor attestation *from*

the individual "…has achieved a level of competency to function independently…" for the authorization *to*

the individual can "…independently fulfill the radiation safety-related duties…" associated with the authorization being requested.

ACMUI Endorsement: The Committee endorsed allowing Associate Radiation Safety Officers (ARSO) to be named on a medical license.

ACMUI Endorsement: The Committee endorsed the elimination of the requirement to submit copies of NRC Form 313, Application for Material License, or a letter containing information required by NRC Form 313 when applying for a license, an amendment, or a renewal.

The NRC staff transmitted the final rule, SECY-16-0080, "Final Rule: Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments (RIN 3150-A163; NRC-2008-0175)," to the Commission on June 17, 2016. Enclosure 4 contains the Committee's unfettered comments (Final Report). Enclosure 5 contains the NRC staff's response to the Committee's comments.

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ML16211A442 ***email concur**

OFC	MSTR/MSEB	MSTR/MSEB	MSTR/MSEB	MSTR
NAME	SHoliday	MFuller *	DBollock *	DCollins
DATE	7/22/2016	7/26/2016	7/28/2016	8/2/2016

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