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

February 1, 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: U.S. NUCLEAR REGULATORY COMMISSION ACTION IN RESPONSE TO THE JANUARY 06, 2015, TELECONFERENCE MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Below are the recommendations from the January 06, 2016, teleconference meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). Following the recommendation is the U.S. Nuclear Regulatory Commission (NRC) staff response and/or position.

**ITEM (1):** The Committee endorsed that component of the current proposed rule re-defining medical events in permanent implant brachytherapy in terms of activity (i.e. source strength) rather than radiation dose).

The recommendation passed unanimously with ten favorable votes.

**ITEM (2):** The Committee endorsed, with reservation, 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.

The recommendation passed unanimously with ten favorable votes.

**ITEM (3):** 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*

CONTACT: Sophie Holiday, NMSS/MSTR
404-997-4691

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

The recommendation passed unanimously with ten favorable votes.

**ITEM (4):** The Committee recommended revising the passage in lines 4182-4186 on page 167 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."

The recommendation passed unanimously with ten favorable votes.

**ITEM (5):** 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.

The recommendation passed unanimously with ten favorable votes.

**ITEM (6):** 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.

The recommendation passed unanimously with ten favorable votes.

**ITEM (7):** The Sub-Committee recommended that the date of recognition by the NRC of a certifying board should *not* impact individuals seeking to be named as an authorized user, authorized medical physicist, Radiation Safety Officer, or authorized nuclear pharmacist through the certification pathway.

During the discussion, this recommendation was modified in the final report as follows:

The Sub-Committee recommends 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.

The recommendation passed unanimously with ten favorable votes.

**ITEM (8):** The Committee recommended that the NRC adopt the parent-breakthrough limits for radioisotope generators specified in the relevant Food and Drug Administration (FDA)-approved package inserts.

During the discussion, the Committee recommended to *eliminate* this recommendation and instead, revise the general comments section of the report to suggest that NRC consider, in *future* rulemaking, establishing conformity with the FDA breakthrough-limit regulations.

The recommendation passed with nine favorable votes and one dissenting vote.

**ITEM (9):** 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.

The recommendation passed unanimously with ten favorable votes.

**ITEM (10):** The Committee endorsed allowing Associate Radiation Safety Officers (ARSO) to be named on a medical license.

The recommendation passed unanimously with ten favorable votes.

**ITEM (11):** The Committee recommended that the designation of a board-certified authorized user, authorized medical physicist, or authorized nuclear pharmacist as the Radiation Safety Officer (RSO) or as an ARSO requires their board certification to include the designation, "RSO Eligible."

The recommendation passed unanimously with ten favorable votes.

**ITEM (12):** 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."

The recommendation passed unanimously with ten favorable votes.

**ITEM (13):** 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 renewal.

The recommendation passed unanimously with ten favorable votes.

**ITEM (14):** The Sub-Committee recommended changing the "medical-events" language in lines 5531-5532 (page 232) of the Draft Final Rule *from*,

"A licensee shall report as a medical event, any administration requiring a written directive, except for an event that results from patient intervention…," *back to the language in the current Draft Final Rule,*

"A licensee shall report any event, except for an event that results from patient intervention…"

During the discussion, the recommendation was modified in the final report as follows:

The Sub-Committee recommends changing the "medical-events" language in lines 5531-5532 (page 232) of the current version of the Draft Final Rule *from*,

"A licensee shall report any event, except for an event that results from patient intervention…" back to the language published 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 recommendation passed unanimously with ten favorable votes.

The ACMUI submitted their final report to the NRC staff on January 07, 2016. The NRC staff will consider the ACMUI's recommendations for possible changes to the 10 CFR Part 35 draft final rule. Staff will also submit the ACMUI's report as an attachment as part of its paper to the Commission for the proposed final rule.

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| **OFC** | MSTR/MSEB | MSTR/MSEB | MSTR/MSEB | MSTR |
|---|---|---|---|---|
| **NAME** | SHoliday | MFuller | DBollock | DCollins |
| **DATE** | 1/20/2016 | 1/21/2016 | 1/21/2016 | 2/1/16 |

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