UNITED STATES
NUCLEAR REGULATORY COMMISSION
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August 23, 2019

MEMORANDUM TO: Christopher J. Palestro, M.D., Chairman
Advisory Committee on the Medical Uses of Isotopes

FROM: Christian E. Einberg, Branch Chief ***/RA/***
Medical Safety and Events Assessment Branch
Division of Materials Safety, Security, State
and Tribal Programs
Office of Nuclear Material Safety
and Safeguards

SUBJECT: RESPONSES AND UPDATES TO OPEN RECOMMENDATIONS AND ACTION ITEMS SUBMITTED TO THE U.S. NUCLEAR REGULATORY COMMISSION FROM THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES RANGING FROM 2007 TO 2019

Below are the U.S. Nuclear Regulatory Commission (NRC) staff responses and updates to open recommendations and action items from the Advisory Committee on the Medical Uses of Isotopes (ACMUI) ranging from 2007 to 2019 that have not been covered under a separate response memorandum:

1. **ACMUI Recommendation/Action Item from 2007, #33:** NRC staff should modify 10 CFR 35.491(b)(2) to specify 'superficial' ophthalmic treatments. Additionally, NRC staff should change the title of 10 CFR 35.491 to specify 'superficial' ophthalmic treatments.

   Staff Response: Not Accepted. The NRC staff added the potential rulemaking change to the user need memorandum to the Rulemaking Group, dated December 12, 2007 (ADAMS Accession No. ML073470227 (non-public)), to revise the name of 10 CFR 35.491 to add superficial ophthalmic uses of strontium-90. According to the memorandum of acceptance of regulatory bases dated July 22, 2010 (ADAMS Accession No. ML101940339 (non-public)), this recommendation was not included because of the prioritization determination made by the medical team staff. Therefore, this recommendation was not included as part of the January 14, 2019 revisions to 10 CFR Part 35.

2. **ACMUI Recommendation/Action Item from 2007, #34:** NRC staff should not revise 10 CFR 35.491 (intended for ophthalmologists) to include training and experience for the new intraocular device. Instead, NRC staff should regulate the new intraocular device under 10 CFR 35.490.

CONTACT: Irene Wu, NMSS/MSST
301-415-1951

Staff Response: Not Accepted. The NRC staff reviewed the medical use of the NeoVista, Inc's Epi-Rad$_{90}$™ (Sr-90) Ophthalmic System and determined adopting the ACMUI recommendation would exclude the ophthalmologists as authorized users. The NRC staff concluded that the ophthalmologist is the preferred physician to provide treatment inside the eye but that the training and experience (T&E) requirements in 10 CFR 35.491 were not sufficient for delivery of a therapy dose inside the eye. The NRC staff determined that the device would be regulated under 10 CFR 35.1000.

The NRC staff also concluded that the medical use of the device could be incorporated into 10 CFR Part 35 and recommended this action as a potential change to the regulations and it was included in the December 12, 2007 user need memorandum to the Rulemaking Group. According to the July 22, 2010 memorandum of acceptance of regulatory bases, this recommendation was not included because of the prioritization determination made by the medical team staff. Therefore, this recommendation was not included as part of the January 14, 2019 revisions to 10 CFR Part 35.

3. **ACMUI Recommendation/Action Item from 2008, #19:** NRC staff should accept the six recommendations of the Permanent Implant Brachytherapy Subcommittee report with one modification. Recommendation six should be modified to read, "When a Written Directive (WD) is required, administrations without a prior WD are to be reported as regulatory violations and may or may not constitute an ME."

   Staff Response: Partially Accepted. Below are the staff responses to the seven recommendations in this report[1]:

   a. The word "preimplantation" be deleted from "preimplantation written directive" in sections §35.3045 (a)(2)(i), (ii), (iii), and (iv).

      The word "preimplantation" no longer appears in 10 CFR 35.3045 (a)(2).

   b. §35.3045(a)(2)(ii) be clarified to read "The total source strength implanted outside the treatment site (including the gross tumor, the clinical target volume plus a variable planning margin as defined by the Authorized User) exceeding 20 percent of the total source strength documented in the written directive."

      The text in parentheses was not added to the medical event criteria because the current definition of the treatment site provides flexibility in allowing the AU to define the treatment site in the written directive.

   c. §35.3045(a)(2)(iii) will become superfluous and therefore should be eliminated.

      The NRC staff restructured the permanent implant brachytherapy criteria and 10 CFR 35.3045(a)(2)(iii) became 10 CFR 10 CFR 35.3045(a)(2)(iii)(C). In addition, 10 CFR 35.3045(a)(2)(iii)(C) was reworded to "Sealed sources(s) implanted directly into a location discontiguous from the treatment site, as documented in the post-implantation portion of the written directive."

[1] The ACMUI's comments on the proposed rule on medical use of byproduct material for permanent implants are dated November 5, 2008 (ADAMS Accession No. ML092220766).

d. The word “activity” should be replaced by the term “source strength” whenever it is applied to permanent brachytherapy in the document.

The NRC staff accepted this recommendation and used the phrases “source strength” and “total source strength” when referring to permanent implant brachytherapy in 10 CFR 35.40, 35.41, and 35.3045.

e. §35.40(B)(6) should be clarified that for any two part WD, **an** authorized user (AU) (though not necessarily **the** same AU) needs to approve all required information on both parts of the WD.

The recommendation for a signature of an AU on the post-implantation portion of the WD was included in the draft proposed and the draft final rule for 10 CFR Part 35. However, based on comments received by the Agreement States, this added specificity was removed in the final rule for consistency with the WD requirement formats and because §35.40(a) *already requires that a WD must be dated and signed by an AU before administration.*

f. The ACMUI should be given an opportunity to review proposed rules before they are published.

The ACMUI is provided this opportunity on NRC proposed rules before they are published.

g. When a WD is required, administrations without a WD are to be reported as regulatory violations and may or may not constitute an ME.

The NRC staff did not add a requirement for the licensee to report administrations without a WD when a WD is required as regulatory violations or expand the medical event reporting criteria to include the reporting of administrations without a WD when a WD is required as medical events.

4. **ACMUI Recommendation/Action Item from 2008, #26:** NRC staff should revise 10 CFR 35.40 to clarify that the AU should sign and date both the pre-implantation and post-implantation portions of the WD for all modalities with two part WDs.

Staff Response: Not Accepted. The recommendation for a signature of an AU on the post-implantation portion of the WD was included in the draft proposed and the draft final rule for 10 CFR Part 35. However, based on comments received by the Agreement States, this added specificity was removed in the final rule for consistency with the WD requirement formats and because §35.40(a) already requires that a WD must be dated and signed by an AU before administration.

5. **ACMUI Recommendation/Action Item from 2008, #27:** NRC staff should revise 10 CFR 35.40 to clarify that an AU, not the AU, should sign and date both the pre-implantation and post-implantation portions of the WD for all modalities with two part WDs. [Note this allows for one AU to sign the pre-implantation portion of the WD and another AU to sign the post-implantation portion of the WD]

Staff Response: Not Accepted. The recommendation for a signature of an AU on the post-implantation portion of the WD was included in the draft proposed and the draft final

rule for 10 CFR Part 35. However, based on comments received by the Agreement States, this added specificity was removed in the final rule for consistency with the WD requirement formats and because §35.40(a) already requires that a WD must be dated and signed by an AU before administration.

6. **ACMUI Recommendation/Action Item from 2011, #6:** ACMUI created an action item to reevaluate its satisfaction with the reporting structure annually.

   Staff Response: Accepted. The NRC staff plans to revise Section 5.3.1, page 10 of NMSS Policy & Procedure (P&P) 6-15, "Administration of the Advisory Committee on the Medical Uses of Isotopes," to include this as a standard agenda item. The NRC staff also plans to include this item in its next update to NUREG/BR-0309, "Serving on the Advisory Committee on the Medical Uses of Isotopes (ACMUI): A Member's Guide." A division-level ticket was issued to track the completion of the revisions to P&P 6-15 (anticipated completion date is December 2019) and NUREG/BR-0309 (anticipated completion date is January 2020).

7. **ACMUI Recommendation/Action Item from 2016, #16:** Dr. Alderson formed a subcommittee to review and evaluate the training and experience requirements for all modalities in 10 CFR Part 35. Subcommittee members include: Dr. Langhorst, Dr. Metter, Dr. Palestro (chair), Dr. Suh, and Ms. Weil. NRC staff resource: Maryann Abogunde.

   Staff Response: Accepted. This subcommittee was established on February 25, 2016 as shown on the ACMUI Subcommittees website.[2]

8. **ACMUI Recommendation/Action Item from 2016, #24:** The ACMUI will contact their respective professional organizations to request and encourage interactions between the NRC and ACMUI with their organization.

   Staff Response: Accepted. The NRC staff plans to include this item in its next update to NUREG/BR-0309. A division-level ticket was issued to track the completion of the revision to NUREG/BR-0309 (anticipated completion date is January 2020).

9. **ACMUI Recommendation/Action Item from 2016, #39:** The Committee recommended that staff issue a generic communication (information notice) regarding tubing issues (kinking, connection, hub etc.) during the administration of Y-90 microspheres brachytherapy.

   Update: The NRC staff has drafted this information notice (IN), which is going through concurrence, and expects this IN to be published in December 2019. A division-level ticket was issued to track the completion of the IN (anticipated completion date is December 2019). The staff response to this ACMUI recommendation will be included in a separate memorandum following the issuance of the IN.

10. **ACMUI Recommendation/Action Item from 2016, #42:** The Committee recommended that Pathway 2 remain for the Y-90 Microsphere Brachytherapy Licensing Guidance. The NRC/OAS working group should determine what the requirements should be for the proctoring of cases by the manufacturer(s).

[2] https://www.nrc.gov/about-nrc/regulatory/advisory/acmui/subcommittee.html

Update: The NRC staff has addressed this recommendation in the revised Y-90 Microsphere Brachytherapy Licensing Guidance. The licensing guidance, which is going through concurrence, is expected to be issued in December 2019. The staff responses to ACMUI's specific recommendations will be included in a separate memorandum following the issuance of the licensing guidance.

11. **ACMUI Recommendation/Action Item from 2016, #43:** The Committee recommended to support the update to the waste disposal section and the review of the Y-90 radiation safety issues in autopsy and cremation in the draft revision of the Y-90 Microsphere Brachytherapy Licensing Guidance.

    Update: The NRC staff has addressed this recommendation in the revised Y-90 Microsphere Brachytherapy Licensing Guidance. The licensing guidance, which is going through concurrence, is expected to be issued in December 2019. The staff responses to ACMUI's specific recommendations will be included in a separate memorandum following the issuance of the licensing guidance.

12. **ACMUI Recommendation/Action Item from 2017, #13:** The ACMUI recommended that the NRC establish a program allowing a medical use licensee to evaluate MEs as described in 10 CFR 35.3045, in NRC 10 CFR 35.1000 licensing guidance, and in 10 CFR 35.3047 with an approved patient safety program.

    Staff Response: Not Accepted. There was a significant amount of discussion on this recommendation during the March 7, 2018 ACMUI Meeting.[3] The ACMUI also presented on this recommendation during the March 8, 2018 ACMUI Commission Meeting and received negative responses from the Commissioners during the question and answer (Q&A) session.[4] Based on the discussions during those meetings, the NRC staff does not support the use of a patient safety organization (PSO) to evaluate MEs or exempt the licensee from certain actions associated with ME reporting. The NRC staff and ACMUI conduct sufficient reviews on an annual basis (NRC's annual ME review and reviews by the ACMUI Medical Event Subcommittee).

13. **ACMUI Recommendation/Action Item from 2017, #14:** The ACMUI recommended that NRC licensees with an NRC-approved patient safety program will continue to report medical events as required with the following conditions: (1) The NRC will not include this event notification in the Event Notification Report posted on its website. If this is not possible, the ME notification posted on the website will leave the licensee information and location anonymous. (2) The NRC will not conduct a reactive inspection of the ME unless the event results or will result in death, unintended permanent harm, or unintended significant temporary harm for which medical intervention was or will be required to alleviate the harm or reduce radiation effects. (3) The medical use licensee will write a report available for the next NRC inspection describing the event cause and corrective action taken. (4) NRC will develop, with ACMUI advice, new temporary inspection procedures for NRC review of licensee patient safety event reports, and will evaluate, with ACMUI advice, the need to change enforcement manual procedures regarding MEs to support a test of this program.

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[3] Discussion begins on page 97 of the March 7, 2018 ACMUI Meeting transcript (https://www.nrc.gov/docs/ML1809/ML18099A381.pdf).

[4] The Q&A session related to the ACMUI's presentation on medical event reporting begins on page 38 of the March 8, 2018 ACMUI Commission Meeting transcript (https://www.nrc.gov/docs/ML1807/ML18071A175.pdf).

Staff Response: Partially Accepted. At the March 7, 2018 ACMUI Meeting, the NRC staff discussed the limitations and resource challenges of changing to a voluntary reporting system including the need for a regulation change, 'structural' changes to the NRC and Agreement States, and changes to existing inspections. Consistent with the staff response to ACMUI's recommendation 13 from 2017, the NRC staff does not agree with the recommendation for licensees who use a PSO as a substitute or supplement to the current ME reporting process and therefore, does not accept conditions (2), (3), and (4) of ACMUI's recommendation. However, the NRC staff plans to address condition (1) by evaluating whether licensee information can be retracted from Event Notifications prior to posting online, regardless of whether the licensee uses a PSO. A division-level ticket was issued to track the completion of this evaluation (anticipated completion date is December 2019).

14. **ACMUI Recommendation/Action Item from 2017, #15:** The ACMUI recommended that NRC should test out this program with two large medical centers, two community hospitals, two rural hospitals, and two patient clinics for a year, evaluating the ME reports with the ACMUI. During this test period, the NRC, with advice from the ACMUI, should do the following: (1) Develop the minimum criteria for patient safety program reviews; (2) Assess how this change in ME reporting impacts the NRC's ability to protect patient health and to minimize danger to the patient's life; and (3) Evaluate the different types of patient safety programs in how lessons learned from their patient safety incident reviews are shared with the medical community.

    Staff Response: Not Accepted. As stated in the responses to recommendations 13 and 14 from 2017, the NRC staff does not support the use of a PSO to evaluate MEs or exempt the licensee from certain actions associated with ME reporting.

15. **ACMUI Recommendation/Action Item from 2017, #16:** The ACMUI recommended that after completion of the test year, the NRC should consider opening the program to all NRC medical use licensees who request approval of their patient safety program, and to Agreement States who request to implement the program with their medical licensees.

    Staff Response: Not Accepted. As stated in the responses to recommendations 13 and 14 from 2017, the NRC staff does not support the use of a PSO to evaluate MEs or exempt the licensee from certain actions associated with ME reporting.

16. **ACMUI Recommendation/Action Item from 2017, #17:** The ACMUI recommended that the NRC redefine its perspective of patient safety to be different from occupational safety and from public safety.

    Staff Response: Not Accepted. The NRC's Medical Use of Byproduct Material Policy Statement[5] states that the NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public. It also states that NRC will, when justified by the risk to patients, regulate the radiation safety of patients primarily to assure the use of radionuclides is in accordance with the physician's written directions. In addition, per its regulations, the NRC collects ME information as operating experience, which is an essential element in the regulatory process for ensuring that licensed activities are conducted safely. The reporting and analysis of MEs helps to

[5] https://www.nrc.gov/reading-rm/doc-collections/commission/policy/65fr47654.pdf

identify deficiencies in the safe use of radioactive material and to help ensure that corrective actions are taken to prevent recurrence.

17. **ACMUI Recommendation/Action Item from 2017, #18:** The ACMUI recommended that the NRC partner with the Department of Health and Human Services (HHS), specifically the Agency for Healthcare and Research and Quality (AHRQ), and ACMUI to develop a national database taxonomy specific for reporting patient events involving medical use of byproduct material.

    Staff Response: Not Accepted. Per its regulations, the NRC already collects ME information. That ME information is maintained in the Nuclear Material Events Database (NMED), which is secure and non-public. The information contained within the NMED is reviewed on an ongoing basis and is specifically evaluated in detail by both the ACMUI and NRC staff, and presented during public meetings at least once a year. Operating experience is an essential element in the regulatory process for ensuring that licensed activities are conducted safely. The reporting and analysis of MEs helps to identify deficiencies in the safe use of radioactive material and to help ensure that corrective actions are taken to prevent recurrence. An ME may indicate a potential problem in a medical facility's use of radioactive materials. It does not necessarily result in harm to the patient. ME reporting thresholds are set at a conservative threshold to allow the NRC to follow up on events and determine if other licensees might be experiencing the same or similar challenges. DHHS or AHRQ staff can request access to NMED by contacting nmednrc@nrc.gov.

18. **ACMUI Recommendation/Action Item from 2017, #19:** The ACMUI recommended that the NRC update its Medical Use Policy Statement and 10 CFR Part 35 event reporting regulations for patient safety programs to verify the active involvement of the licensee's patient safety program review of medical errors and reporting of reviews to the national patient safety database.

    Staff Response: Not Accepted. The NRC's Medical Use of Byproduct Material Policy Statement informs NRC licensees, other Federal and State agencies, and the public the Commission's general intentions regarding the regulation of the medical use of byproduct material. In March 2014, the ACMUI subcommittee charged to consider if the NRC's Medical Use of Byproduct Material Policy Statement should be revised issued their subcommittee report[6], which concluded that "the current policy statement provides for the safe medical use of radionuclides for patients, subjects, staff and the general public while avoiding intrusion into the practice of medicine, and therefore no revision is warranted at this time."

    Also, consistent with the responses to ACMUI's recommendations 13 and 14 from 2007, the NRC staff does not support the use of a PSO to evaluate MEs or exempt the licensee from certain actions associated with ME reporting. However, per its regulations, the NRC already collects ME information. That medical event information is maintained in NMED, which is secure and non-public. Existing mechanisms are in place to evaluate the ME information, as well as to evaluate developing trends. The information contained within the NMED is reviewed on an ongoing basis and is specifically evaluated in detail by both the ACMUI and NRC staff, and presented during public meetings at least once a year. Operating experience is an essential element in the regulatory process for ensuring that licensed

[6] https://www.nrc.gov/docs/ML1417/ML14177A218.pdf

activities are conducted safely. The reporting and analysis of MEs helps to identify deficiencies in the safe use of radioactive material and to help ensure that corrective actions are taken to prevent recurrence. An ME may indicate a potential problem in a medical facility's use of radioactive materials. It does not necessarily result in harm to the patient. ME reporting thresholds are set at a conservative threshold to allow the NRC to follow up on events and determine if other licensees might be experiencing the same or similar challenges.

19. **ACMUI Recommendation/Action Item from 2017, #20:** The ACMUI endorsed the Medical Event Reporting and Impact on Medical Licensee Patient Safety Culture Draft Report, as amended to support the concept of the pilot program with the total number of sites and duration to be determined at a later date and to include the Patient Intervention Subcommittee recommendations as an addendum.

    Update: The final report (ADAMS Accession No. ML17281A001) includes these amendments and is available on the ACMUI Subcommittee Reports website. Based on the NRC staff's review of the recommendations in both the final report and addendum, it is unclear what ACMUI's recommendations are regarding how patient interventions should or should not be considered as reportable MEs. The NRC staff plans to discuss this with the ACMUI at the Fall 2019 meeting.

    Also, regarding the recommendations in the addendum related to the use of PSOs and consistent with the responses to ACMUI's recommendations 13 and 14 from 2007, the NRC staff does not support the use of a PSO to evaluate MEs or exempt the licensee from certain actions associated with ME reporting.

20. **ACMUI Recommendation/Action Item from 2018, #1:** The ACMUI recommended that there be no breast feeding cessation for ^{11}C, ^{13}N, ^{15}O, and ^{82}Rb; a 12 hours cessation for ^{18}F-labeled and ^{68}Ga-labeled; a 24 hours cessation for ^{99m}Tc-labeled; 7 days cessation for ^{123}I-NaI and ^{111}In-leukocytes; 14 days cessation for ^{201}Tl-chloride; 28 days cessation for ^{67}Ga and ^{89}Zr; 35 days for ^{177}Lu diagnostic; and total stop of breastfeeding for ^{131}I-NaI, ^{177}Lu therapeutic, ^{223}Ra, and all alpha emitters.

    Update: These values were updated in the January 31, 2019 final report (ADAMS Accession No. ML19038A498) by the ACMUI Nursing Mother Guidelines for the Medical Administration of Radioactive Materials Subcommittee. During the June 10, 2019 teleconference[7] on the ACMUI Regulatory Guide (RG) 8.39, "Release of Patients Administered Radioactive Material" Draft Subcommittee Report, it was discussed that these values would be further updated when RG 8.39 goes out for public comment. The draft RG was issued for public comment on July 26, 2019 (84 FR 36127). RG 8.39 is being updated in two phases. The first phase, which is anticipated to be completed in April 2020, includes an update to Table 3, "Activities of Radiopharmaceuticals That Require Instructions and Records When Administered to Patients Who Are Breastfeeding an Infant or Child."

21. **ACMUI Recommendation/Action Item from 2018, #2:** The ACMUI endorsed the Nursing Mothers Guidelines for the Medical Administration of Radioactive Materials Subcommittee Report, as amended to: (1) include recommended cessation periods for both 100 and 500 mrem limits; (2) acknowledge benefits of breastfeeding; (3) incorporate corrections as

[7] This discussion begins on page 57 of the June 10, 2019 ACMUI meeting transcript (https://www.nrc.gov/docs/ML1923/ML19231A155.pdf).

needed for gamma ray constants; (4) convert the units from conventional to SI units; and (5) correct references.

Staff Response: Accepted. The draft subcommittee report was revised on June 19, 2018 and again on September 20, 2018. The final report (ADAMS Accession No. ML19038A498) dated January 31, 2019 includes these amendments and is available on the ACMUI Subcommittee Reports website. The 2019 report was used as a reference for the updates to RG 8.39, which was issued for public comment on July 26, 2019 (84 FR 36127).

22. **ACMUI Recommendation/Action Item from 2018, #6:** The NRC staff will create an ACMUI Recommendations Web page and post the full ACMUI Recommendations and Actions charts on the ACMUI Web page from 2007 - present.

    Staff Response: Accepted. The NRC staff have created an ACMUI Recommendations and Actions public Web page[8] that contains charts dating back to 2007. The NRC staff plans to update P&P 6-15 to include a reminder to add or update the chart as part of post meeting activities. A division-level ticket was issued to track the completion of the revisions to P&P 6-15 (anticipated completion date is December 2019).

23. **ACMUI Recommendation/Action Item from 2018, #7:** The NRC staff will send out a medical list server announcement to inform subscribers of the availability of ACMUI and NRC ME slides each time that they are posted on the Medical Toolkit.

    Staff Response: Accepted. The NRC staff last sent out a medical list server announcement on May 2, 2019 to inform subscribers of the availability of the NRC ME slides that were presented to the ACMUI on April 3, 2019. In P&P 6-15, Section 5.3.15d, it states that once the slides are posted, the ACMUI Coordinator will inform licensees of the availability of the slides via the NMSS Newsletter. The NRC staff plans to update this language to state that the slides will be made available via the medical list server since the NMSS Newsletter has been discontinued. A division-level ticket was issued to track the completion of the revisions to P&P 6-15 (anticipated completion date is December 2019).

24. **ACMUI Recommendation/Action Item from 2018, #11:** The ACMUI endorsed the report of the Subcommittee on the Nursing Mothers Guidelines for the Medical Administration of Radioactive Materials with added language that this document reflects the FDA approved radiopharmaceuticals on the market at this time and that licensees are obligated to carefully evaluate radiopharmaceuticals that are not encompassed in this report to keep exposures ALARA to patients, staff, and members of the public. The recommendation passed unanimously.

    Staff Response: Accepted. This language is reflected in the January 31, 2019 final report (ADAMS Accession No. ML19038A498) by the ACMUI Nursing Mother Guidelines for the Medical Administration of Radioactive Materials Subcommittee. The 2019 report was used as a reference for the updates to RG 8.39, which was issued for public comment on July 26, 2019 (84 FR 36127).

25. **ACMUI Recommendation/Action Item from 2018, #14:** Dr. Palestro amended the membership of the Training and Experience for All Modalities Subcommittee. Subcommittee

[8] https://www.nrc.gov/about-nrc/regulatory/advisory/acmui/recomm-actions.html

membership now includes Dr. Metter (chair), Dr. Ennis, Dr. Schleipman, Ms. Weil, Ms. Shober, and Mr. Sheetz. The NRC staff resource continues to be Ms. Maryann Ayoade.

Staff Response: Accepted. This subcommittee membership was amended on September 20, 2018 and its membership is reflected on the ACMUI Subcommittees website.

26. **ACMUI Recommendation/Action Item from 2018, #15:** Dr. Palestro formed a subcommittee to review the Germanium-68/Gallium-68 Pharmacy Grade Generator Licensing Guidance. Subcommittee membership includes Ms. Shober (chair), Dr. Metter, Mr. Sheetz, and Ms. Martin. The NRC staff resource is Dr. Said Daibes.

    Staff Response: Accepted. This subcommittee was established on September 21, 2018 as shown on the ACMUI Subcommittees website.

27. **ACMUI Recommendation/Action Item from 2018, #16:** Dr. Palestro formed a subcommittee to review the revisions to Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material." Subcommittee membership includes Mr. Sheetz (chair), Ms. Shober, Dr. Dilsizian, Dr. Schleipman, Ms. Martin, and Ms. Weil. The NRC staff resource is Dr. Said Daibes.

    Staff Response: Accepted. This subcommittee was established on September 21, 2018 as shown on the ACMUI Subcommittees website.

28. **ACMUI Recommendation/Action Item from 2018, #17:** Dr. Palestro formed a subcommittee to review the Yttrium-90 Microspheres Brachytherapy Sources and Devices TheraSphere® and SIR_Spheres® Licensing Guidance. Subcommittee membership includes Dr. O'Hara (chair), Dr. Dilsizian, Mr. Ouhib. Ms. Martin, Dr. Metter, and Dr. Schleipman. The NRC staff resource is Dr. Katie Tapp.

    Staff Response: Accepted. This subcommittee was established on September 21, 2018 as shown on the ACMUI Subcommittees website.

29. **ACMUI Recommendation/Action Item from 2018, #18:** Dr. Palestro formed a subcommittee to review and update the ACMUI Bylaws as needed, including a review of the role of the ACMUI Chair and his or her participation on subcommittees. Subcommittee membership includes Ms. Weil (chair), Dr. Schleipman, Ms. Shober, and Mr. Sheetz. The NRC staff resource is Ms. Sophie Holiday.

    Staff Response: Accepted. This subcommittee was established on September 21, 2018 as shown on the ACMUI Subcommittees website.

30. **ACMUI Recommendation/Action Item from 2018, #19:** Dr. Palestro formed a subcommittee to review the appropriateness of the required elements of medical event reporting, the adherence to these requirements, and recommend actions to improve reporting. Subcommittee membership includes Dr. Ennis (chair), Ms. Weil, Ms. Martin, Mr. Ouhib, Dr. Dilsizian, and Ms. Shober. The NRC staff resource is Ms. Lisa Dimmick.

    Staff Response: Accepted. This subcommittee was established on September 20, 2018 as shown on the ACMUI Subcommittees website.

31. **ACMUI Recommendation/Action Item from 2018, #20:** The Committee recommended for the NRC to draft an Information Notice on the best practices that could help prevent medical events.

    Update: The NRC staff has drafted this IN, which is going through concurrence, and expects this IN to be published in October 2019. The staff responses to ACMUI's specific recommendations will be included in a separate memorandum following the completion of the IN.

32. **ACMUI Recommendation/Action Item from 2019, #1:** The ACMUI recommended adding language into the draft *Training and Experience Requirements for All Modalities Subcommittee report* regarding the Committee's desire to work with the NRC staff to develop curriculum for a limited-scope authorized user pathway.

    Update: This language is reflected in the subcommittee's final report (ADAMS Accession No. ML19058A598) dated February 27, 2019. The NRC staff is currently evaluating the T&E requirements for AU physicians in 10 CFR Part 35 Subpart E to determine whether to establish tailored T&E requirements for different categories of radiopharmaceuticals, and whether those requirements should be based on hours or competency. The NRC staff's evaluation, which will include ACMUI's comments, will be provided to the Commission in a notation vote paper in December 2019. The staff responses to ACMUI's specific recommendations will be included in a separate memorandum following receipt of Commission direction on the notation vote paper.

33. **ACMUI Recommendation/Action Item from 2019, #2:** The ACMUI endorsed the *Training and Experience Requirements for All Modalities Subcommittee Report*, and the recommendations included therein.

    Update: The final report (ADAMS Accession No. ML19058A598) dated February 27, 2019 is available on the ACMUI Subcommittee Reports website. The NRC staff is currently evaluating the T&E requirements for AU physicians in 10 CFR Part 35 Subpart E to determine whether to establish tailored T&E requirements for different categories of radiopharmaceuticals, and whether those requirements should be based on hours or competency. The NRC staff's evaluation, which will include ACMUI's comments, will be provided to the Commission in a notation vote paper in December 2019. The staff responses to ACMUI's specific recommendations will be included in a separate memorandum following receipt of Commission direction on the notation vote paper.

34. **ACMUI Recommendation/Action Item from 2019, #3:** The ACMUI endorsed the Yttrium-90 Microspheres Brachytherapy Licensing Guidance, Rev. 10 Subcommittee Report, and the recommendations therein, with the caveat that the term "drug" be changed to "device."

    Update: The final report (ADAMS Accession No. ML19130A103) contains this caveat on the last page of the report. The report, dated May 9, 2019, is available on the ACMUI Subcommittee Reports website. The licensing guidance, which is going through concurrence, is expected to be issued in December 2019. The staff responses to ACMUI's specific recommendations will be included in a separate memorandum following the issuance of the licensing guidance.

35. **ACMUI Recommendation/Action Item from 2019, #4:** Dr. Palestro formed a subcommittee to re-evaluate the 1980 infiltration decision and report to the Committee at the fall 2019 meeting with any recommendations. Subcommittee members include Dr. Vasken Dilsizian, Mr. Richard Green, Ms. Melissa Martin (chair), Mr. Michael Sheetz, Ms. Megan Shober, and Ms. Laura Weil. The NRC staff resource is Maryann Ayoade.

    Staff Response: Accepted. This subcommittee was established on April 3, 2019 as shown on the ACMUI Subcommittees website.

36. **ACMUI Recommendation/Action Item from 2019, #6:** The ACMUI endorsed the ACMUI Bylaws Subcommittee Report, with the following amendments: 1) amend the subcommittee's recommendation regarding the Chair's role on subcommittees in Section 1.3.6 to remove the phrase in the "in these instances;" 2) add language in Section 1.3.6 regarding the ACMUI Chairman serving on subcommittee at the subcommittee's discretion; 3) amend the subcommittee's recommendation regarding explicit language defining Conflict of Interest in Section 4.1 to instead reference the appropriate OGE reference.

    Staff Response: Accepted. The final report (ADAMS Accession No. ML19126A297) dated April 10, 2019 is available on the ACMUI Subcommittee Reports website. The ACMUI endorsed the changes to the bylaws during a teleconference on June 10, 2019. In addition, the bylaws[9] were updated on the ACMUI public Web page.

37. **ACMUI Recommendation/Action Item from 2019, #7:** The ACMUI recommended that the NRC staff request a presentation from NNSA to review their plans for isotope utilization in the United States. The presentation will be given at the Fall 2019 ACMUI Meeting.

    Update: The NNSA is on the agenda for the Fall 2019 ACMUI Meeting.

38. **ACMUI Recommendation/Action Item from 2019, #8:** The NRC staff will amend its Opening Remarks such that a statement regarding Conflict of Interest will be included at every ACMUI Meeting.

    Staff Response: Accepted. The NRC staff updated its opening remarks to include a statement regarding conflict of interest beginning with the ACMUI teleconference held on June 10, 2019.

39. **ACMUI Recommendation/Action Item from 2019, #9:** The ACMUI recommended that the NRC add a column to the Recommendation and Action Charts to include the anticipated completion date for NRC staff action.

    Update: The NRC staff plans to include the anticipated completion date for NRC staff action beginning with the 2019 Recommendation and Action Chart. These charts are made available on the ACMUI Recommendations and Action Items Web page.

40. **ACMUI Recommendation/Action Item from 2019, #10:** Dr. Palestro formed a subcommittee to improve the ACMUI's institutional memory. Subcommittee members include Dr. Ronald Ennis, Dr. Michael O'Hara, Dr. A. Robert Schleipman (chair), Ms. Megan Shober, and Ms. Laura Weil. The NRC staff resource is Ms. Kellee Jamerson.

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[9] https://www.nrc.gov/docs/ML1918/ML19184A622.pdf

Staff Response: Accepted. This subcommittee was established on April 4, 2019 as shown on the ACMUI Subcommittees website.

41. **ACMUI Recommendation/Action Item from 2019, #11:** The ACMUI tentatively scheduled its fall 2019 Meeting for September 11-12, 2019. The alternate date is September 10-11, 2019.

    Update: The ACMUI Fall 2019 Meeting has been scheduled for September 10-11, 2019.

SUBJECT: RESPONSES AND UPDATES TO OPEN RECOMMENDATIONS AND ACTION ITEMS SUBMITTED TO THE U.S. NUCLEAR REGULATORY COMMISSION FROM THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES RANGING FROM 2007 TO 2019
DATE August 23, 2019

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