The U.S. NRC's Advisory Committee on the Medical Use of Isotopes (ACMUI)

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1

Disclosures

Richard L. Green, BSPharm, RPh, BCNP, FAPhA is President of RLG Consulting Group, LLC, a private consulting firm.

- Nuclear Pharmacist member & Vice Chair of the U.S. Nuclear Regulatory Commission (NRC) Advisory Committee on the Medical Uses of Isotopes (ACMUI)
- United States Pharmacopeia radiopharmaceutical expert panel that authored General Chapter <825> Radiopharmaceuticals – Preparation, Compounding, Dispensing, and Repackaging

This presentation represents Richard's thoughts and do not represent either the USP or NRC's ACMUI.

2

Learning Objectives

1. *What is ACMUI role in the NRC?*
2. *Describe the current make-up of the ACMUI membership*
3. *Consider the topics recently taken up by the ACMUI*
4. *Identify areas of future NRC action as a result of ACMUI reports*

3

Assessment Questions

1. As is currently constituted, how many members sit on the ACMUI?
   A. 11
   B. 15
   C. 13
   D. 14

4

Assessment Questions

2. Which type of advisor is not represented on ACMUI?

   A. State Government Representative

   B. Interventional Radiologist

   C. Diagnostic Radiologist

   D. Patients' Rights Advocate

5

Assessment Questions

3. 10 CFR 35.1000 is a regulation that…

   A. Permits the use of byproduct material that require a written directive

   B. Permits the use of byproduct material that do not require a written directive

   C. Permits the use of byproduct material or a radiation source approved for medical use which is not specifically addressed in other subparts

6

Assessment Questions

4. The ACMUI recommendation on Radiopharmaceutical Extravasations and Medical Event Reporting was

   A. No Action

   B. Extravasation events that require medical attention

   C. Extravasation events that cause a significant dose

   D. Extravasation events that cause permanent functional damage

7

In the Beginning…

- In 1947, Congress created the Atomic Energy Commission (AEC), which transferred control over RAM from the military to civilian sector.
- The new AEC encompassed all parts of the Manhattan Project, including the subcommittee experts who reviewed and approved distribution of radioactive isotopes.
- The first medical regulations were developed in the 1950s. The system regulated the types of uses allowed according to their hazard and known risks. It required and provided training of those who would use radioisotopes, and it required the establishment of local radioisotope committees.

https://www.nrc.gov/about-nrc/regulatory/advisory/acmui/history.html

8

And the ACMUI was born…

- In 1959, the Oak Ridge subcommittee doing reviews and approvals was officially named the Advisory Committee on the Medical Uses of Isotopes (ACMUI). The Commission established the ACMUI under the authority of the Atomic Energy Act of 1954.
- In 1974, the Energy Reorganization Act split AEC's responsibilities between the NRC and what is now known as the Department of Energy.
- The ACMUI's name, functions, and reporting structure remained unchanged under the NRC.

https://www.nrc.gov/about-nrc/regulatory/advisory/acmui/history.html

9

Advisory Committee on the Medical Uses of Isotopes (ACMUI)

- Advises the U.S. Nuclear Regulatory Commission (NRC) on policy and technical issues that arise in the regulation of the medical uses of radioactive material in diagnosis and therapy
- The ACMUI membership includes health care professionals from various disciplines, who
  - comment on changes to NRC regulations and guidance
  - evaluate certain non-routine uses of radioactive material
  - provide technical assistance in licensing, inspection, and enforcement cases
  - and bring key issues to the attention of the Commission for appropriate action

10

13 Members in the ACMUI

- Diagnostic Radiologist *
- Food and Drug Administration (FDA) Representative
- Health Care Administrator
- Medical Physicist, Nuclear Medicine *
- Medical Physicist, Therapy *
- Nuclear Cardiology Physician *
- Nuclear Medicine Physician *
- Nuclear Pharmacist *
- Patients' Rights Advocate
- Radiation Oncology Physician, Brachytherapy *
- Radiation Oncology Physician, Gamma Stereotactic Radiosurgery (GSR) *
- Radiation Safety Officer (RSO) *
- State Government Representative
- † Vascular and Interventional Radiologist (non-voting consultant)

* Authorized Users

https://www.nrc.gov/docs/ML1001/ML100110578.pdf

11

Current ACMUI Members

•Joanna R. Fair, M.D., Ph.D.,Diagnostic Radiologist
•Michael D. O'Hara, Ph.D., Food and Drug Administration Representative
•Rebecca Allen, Health Care Administrator
•Melissa C. Martin, Medical Physicist, Nuclear Medicine
•Zoubir Ouhib, Therapy Medical Physicist
•Andrew J. Einstein, Nuclear Cardiologist
•Hossein Jadvar, M.D., Ph.D., Nuclear Medicine Physician
•Richard L. Green, Nuclear Pharmacist
•Josh Mailman, Patients' Rights Advocate
•Michael R. Folkert, M.D., Ph.D., M.D., Radiation Oncologist
•Harvey B. Wolkov, M.D., Radiation Oncologist
•Richard Harvey, Ph.D., Radiation Safety Officer
•Megan L. Shober, Agreement State Representative

Chair: Hossein Jadvar, M.D., Ph.D
Vice Chair: Richard L. Green

https://www.nrc.gov/about-nrc/regulatory/advisory/acmui/membership.html

12

Current Subcommittees

1. Y-90 Microsphere Medical Events
2. Emerging Medical Technologies/Rubidium-82 Generator Rulemaking
3. Licensing Guidance for Liberty Vision Y-90 Eye Brachytherapy Source
4. Licensing Guidance Alpha Tau Alpha DaRT™ Manual Brachytherapy
5. Licensing Guidance for Superficial Manual Brachytherapy CivaDerm Device
6. Revision 2 to Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials"
7. Medical Events
8. Emerging Radiopharmaceutical Therapy Knowledge Requirements in Theranostics

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

13

Current Subcommittees cont.

9. Radionuclide Generator Knowledge and Practice Requirements
10. NRC Staff Preliminary Evaluation of Radiopharmaceutical Extravasation and Medical Event Reporting
11. Abnormal Occurrence
12. COVID-19
13. Interventional Radiology
14. ACMUI Bylaws
15. Patient Intervention

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

14

Current Subcommittees cont.

16. Revision 1 to Regulatory Guide 8.39, "Release of Patients Administered Radioactive Materials,"
17. Training and Experience Requirements for All Modalities
18. Xcision® GammaPod™ Licensing Guidance
19. ACMUI Institutional Memory
20. Infiltrations and Medical Event Reporting
21. Using checklists to reduce medical events
22. Nursing Mothers Guidelines
23. Financial Assurance Requirements for Disposition of Category 1–3 Byproduct Material Radioactive Sealed Sources

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

15

A Deeper Dive into Recent Subcommittee Activities

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- Emerging Medical Technologies/Rubidium-82 Generator Rulemaking Dec 2022

To review and comment on the staff's regulatory basis for the Emerging Medical Technologies / Rubidium-82 Generator rulemaking.

Although NRC medical regulations in 10 CFR Part 35 cover a wide range of byproduct material uses, medical technologies continue to be developed that have radiation safety concerns not addressed by these requirements.

In 2002, the NRC established 10 CFR 35.1000 so that there would be codified regulatory requirements and a more clearly defined process to obtain regulatory approval for new medical uses of byproduct material. This section provided a mechanism for NRC to license medical technologies that had characteristics or challenges not adequately considered by the other Subparts of 10 CFR Part 35. In practice, as new medical technologies were identified which did not fit into the established Subparts of 10 CFR Part 35, NRC and Agreement States would develop licensing guidan to address the unique features of the technology. In the past 20 years, NRC has issued licensing guidance for 16 emerging medical technologies.

https://www.nrc.gov/docs/ML2235/ML22353A053.pdf

16

A Deeper Dive into Recent Subcommittee Activities

- Y-90 Microsphere Medical Events — Dec 2022

To evaluate the issue of Y-90 microspheres medical events in more depth and, in consultation with vendors, propose methods to decrease the number of Y-90 microsphere-related medical events.

In summary, the three recommendations for licensees are as follows:

1. On a regular basis, licensees should review the mechanics of Y-90 microsphere delivery and setup procedures as described by the manufacturer.
2. Licensees should confirm all data and calculations in the treatment plan, prior to administration.
3. Licensees should use a "time out" to assure all elements of the administration are in accordance with the written directive. Elements such as conformation of the patient's name, treatment location and dosage comparison to the written directive.

https://www.nrc.gov/docs/ML2235/ML22353A054.pdf

17

A Deeper Dive into Recent Subcommittee Activities

- Liberty Vision Subcommittee — Est. Oct 2021

To review the Liberty Vision technology and comment on the NRC staff's draft Liberty Vision Y-90 Eye Brachytherapy Source Licensing Guidance.

On going

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

18

A Deeper Dive into Recent Subcommittee Activities

- Licensing Guidance Alpha Tau Alpha DaRT™ Manual Brachytherapy — Jan 2022

To review the Alpha Dart technology and comment on the NRC staff's draft Alpha Dart Licensing Guidance.

The subcommittee supports the licensing of Alpha DaRT™ under 35.1000. The diffusion of radioactive particles into the interstitial tissues and blood circulation make this device significantly different from brachytherapy sources such that licensing it under 35.400 would be inappropriate. Similarly, Alpha DaRT™'s delivery via a source placed into tissue differentiates it substantially from radiopharmaceuticals to support not licensing it under 35.300. The subcommittee believes it is appropriate to draw on requirements of 35.400 regarding aspects of Alpha DaRT™ that are similar to brachytherapy and requirements of 35.300 for aspects similar to radiopharmaceuticals.

https://www.nrc.gov/docs/ML2202/ML22021B298.pdf

19

A Deeper Dive into Recent Subcommittee Activities

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- Medical Events — Oct 2021

To review the medical events (MEs) from Fiscal Year 2020 with an eye to advising the ACMUI and NRC about emerging trends needing regulatory attention.

The Medical Events during 2020 were similarly low as in years past. This issue regarding time outs and checklists as a method to minimize MEs was again noted. In the committee's discussion regarding the category that it had previously called "infrequent/inexperience use" the point was made that some of these events may be due to inattention at the time of the procedure rather than infrequent or inexperience use.

MEs involving Y-90 microspheres continue to be the most common, although as a proportion of all such procedures an ME is very rare. The MEs occur with both Therasphere and Sirsphere, although more commonly with Therasphere, despite reportedly equal market share of the two products. Because of this, the subcommittee recommends the appointment of a subcommittee specifically focused on investigating the MEs associated with this therapy and to propose, in consultation with the vendors, methods to decrease these MEs

https://www.nrc.gov/docs/ML2128/ML21288A127.pdf

20

A Deeper Dive into Recent Subcommittee Activities

- Emerging Radiopharmaceutical Therapy Knowledge Requirements in Theranostics Oct 2021

To outline the knowledge and specific or specialized practice or policy requirements needed for the safe use and handling of emerging radiopharmaceuticals in theranostics.

1) Radiopharmaceutical (RPT) Healthcare Team: Depending upon the therapy, the healthcare team administrating the RPT dose may consist of the AU, CNMT, RN, RSO, and Medical Physicist

2) AU responsibilities: AU should be present, either virtually or in person, at the time of dose administration; AU is responsible for patient concerns related to RPT, including radiation induced injuries; AU is encouraged to avail themselves of all the latest training information for each new theranostics as they emerge.

3) Radiation safety issues: Non-radiation workers of the healthcare team (e.g. oncology nurse) participating in the procedure may need to wear radiation badges for monitoring as determined by the RSO; therapy should be done in a dedicated and regulatory-approved room appropriate for radioisotope administrations; extravasation; patient release criteria.

https://www.nrc.gov/docs/ML2128/ML21287A631.pdf

21

A Deeper Dive into Recent Subcommittee Activities

- Emerging Radiopharmaceutical Therapy Knowledge Requirements in Theranostics Oct 2021

4) Regulatory issues: Radioactive waste management (refer to the facility established guidelines and regulations); ensure that emerging theranostics are performed within the regulatory guidelines.

5) Dosimetry: Dosimetry-based (as opposed to fixed-activity) may play an increasingly important role; dosimetry-based approach may optimize patient outcome while minimizing radiation toxicity; no randomized controlled trials to provide level 1 evidence for benefits of dosimetry-based approach; research is needed on impact of combined other nonradioactive therapy agents on RPT biodistribution and radiosensitivity, standardization across clinics, software and medical physicists, development of robust methodology for challenges of surrogate-imaging, microscale radiation effect and daughter distribution (relevant for alpha particles), and research on potential patient benefit versus cost and complexity of logistics; as relevant data becomes mature, AUs should stay abreast of developments in dosimetry.

6) Other relevant issues: Outreach to AUs, healthcare providers, and patients to promote accurate information about safety and efficacy of theranostics .

https://www.nrc.gov/docs/ML2128/ML21287A631.pdf

22

A Deeper Dive into Recent Subcommittee Activities

- Radionuclide Generator Knowledge and Practice Requirements — Oct 2021

To review and evaluate the knowledge and practice requirements for eluting, measuring and testing, and processing the eluate from radionuclide generator systems based on the evolution of radionuclide generator distribution.
To evaluate and determine the appropriateness of the requirements and how best to obtain the required knowledge and practice.
To evaluate whether and how additional knowledge and practice should be obtained as necessary to supervise the use of any radionuclide generator system.

Current rule language in 10 CFR 35.290(c)(1)(ii)(G): (G) "Eluting generator systems appropriate for preparation of radioactive drugs for imaging and localization studies, measuring and testing the eluate for radionuclidic purity, and processing the eluate with reagent kits to prepare labeled radioactive drugs; …"

Subcommittee proposed revision: (G) "Participating in educational sessions to gain knowledge and provide supervision of – (1) radionuclide generator systems and their operation; (2) the measurement of radionuclidic impurities and acceptable limits; and (3) the use of reagent kits with radionuclide eluate to prepare radioactive drugs."

https://www.nrc.gov/docs/ML2128/ML21288A126.pdf

23

A Deeper Dive into Recent Subcommittee Activities

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https://www.nrc.gov/docs/ML2128/ML21288A126.pdf

24

A Deeper Dive into Recent Subcommittee Activities

- Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material" Jan 2022

To review the revisions to Regulatory Guide 8.39, "Release of Patients Administered Radioactive Material"

To review the CivaDerm technology and comment on the NRC staff's draft CivaDerm additional licensing considerations memo.

Reg Guide 8.39 - 6 specific recommendations, 38 comments

CivaDerm- 6 general comments, 6 specific comments

https://www.nrc.gov/docs/ML2202/ML22021B299.pdf

https://www.nrc.gov/docs/ML2202/ML22021B300.pdf

25

A Deeper Dive into Recent Subcommittee Activities

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- Extravasation Sept 2021

To review the NRC staff's Memorandum "Preliminary Evaluation of Radiopharmaceutical Extravasation and Medical Event Reporting" dated April 1, 2021 and provide feedback and recommendations.

Option 1, "**No Action**," would maintain the status quo, and extravasations would continue to be excluded from medical event reporting. This option would continue to support the Commission's 1980 position that extravasation commonly occurs in otherwise normal injections and is difficult to avoid and predict.

Option 2, "**50-rem dose threshold**," would require medical event reporting for extravasations that exceed a localized dose equivalent of 50 rem. This option would include both diagnostic and therapeutic radiopharmaceutical administrations. Licensees would need to monitor every administration for extravasation.

https://www.nrc.gov/docs/ML2128/ML21288A125.pdf

26

A Deeper Dive into Recent Subcommittee Activities

- Extravasation — Sept 2021

Option 3, "**Administration site dose for procedures requiring a written directive**," would require that for procedures requiring a written directive, extravasations resulting in a dose 50 rem greater and 50 percent or more than the expected dose to the administration site be reported as medical events. This option would be similar to reporting requirements in 10 CFR 35.3045(a)(1)(iii), except it would be specifically applicable to extravasation. Subcommittee does not support Option 3 as it excludes all diagnostic administrations, and the dosimetry methodology is not standardized at this time.

Option 4, "**Extravasation events that require medical attention**," would be a non-dose based option for reporting extravasations that result in a radiation injury. If a patient requires medical attention for a suspected radiation injury due to extravasation which results in tissue damage at or near the administration site, and this radiation injury is confirmed by a physician authorized user of the licensee to be due to radiation from the extravasation, then this will require medical event reporting. This option would not require dosimetry to determine whether an extravasation should be reported, however, dosimetry may be required if the extravasation appears severe enough to trigger the AO criteria.

https://www.nrc.gov/docs/ML2128/ML21288A125.pdf

27

A Deeper Dive into Recent Subcommittee Activities

- Extravasation — Sept 2021

Option 5, **"Extravasation events that cause a significant dose,"** would require medical event reporting for extravasations that meet the 10 Gy (1,000 rad) dose threshold requirement for AOs. Similar to Option 4, Option 5 would not require monitoring of radiopharmaceutical administrations. Instead, this option will initially rely on patients to self-report to their physicians if they have any adverse tissue effects, like erythema, which could begin to occur at extravasated doses lower than 10 Gy. After the patient reports the adverse tissue effect to his or her physician, the authorized user physician would determine if the adverse tissue effect was cause by radiation and, if so, perform dosimetry to determine if the extravasated dose was 10 Gy or higher

Option 6, "**Extravasation events that cause permanent functional damage**," would require extravasations that result in permanent functional damage to be reported as medical events. This would be similar to the current reporting requirements for events caused by patient intervention that result in unintended permanent functional damage as determined by a physician. This option could be modified to also include extravasations that require medical intervention to prevent permanent functional damage.

The Subcommittee supported Option 4.

https://www.nrc.gov/docs/ML2128/ML21288A125.pdf

28

A Deeper Dive into Recent Subcommittee Activities

- Abnormal Occurrence — Sept 2021

To define patient harm in abnormal occurrence (AO)
To reassess the current AO criteria
To define the goals of AO criteria reporting
To determine if AO criteria is adequate for public health and safety

Subcommittee Recommendations:

1. The Subcommittee fully supports the proposed changes to the medical AO criteria as outlined in Enclosure 1.

2. The Subcommittee recommends that some type of communication be prepared for distribution to all NRC and Agreement State medical licensees to inform them of best practices in preparing a medical event report so that complete and accurate information is provided in describing the event, root cause analysis on why the event occurred, and the medical effect on the individual(s). This same recommendation was also previously made by the ACMUI Subcommittee on the Appropriateness of Medical Event Reporting.

https://www.nrc.gov/docs/ML2122/ML21227A001.pdf

29

A Deeper Dive into Recent Subcommittee Activities

- COVID-19 — Mar 2020 ★

To review the impacts of COVID-19 on the medical community and provide recommendations for any regulatory relief measures in the areas of nuclear medicine and radiation oncology during the COVID-19 pandemic.

Specific recommendations on adaptions, modifications because of COVID-19 with respect to

1) Training and Education
2) Regulatory Reporting
3) Medical Event Reporting
4) Radiation Safety Activities
5) Physical Presence
6) Inspections
7) Regulatory Fees

https://www.nrc.gov/docs/ML2012/ML20125A148.pdf

30

A Deeper Dive into Recent Subcommittee Activities

- Interventional Radiologist — Apr 2020

To investigate the need for an interventional radiologist (IR) on the ACMUI, including whether an IR should be a non-voting consultant or full ACMUI member.

Recommendations:

1. The Subcommittee does not recommend adding an interventional radiologist as a full voting member of ACMUI at this time.

2. The Subcommittee recommends inviting an interventional radiologist to be a consulting (non-voting) member of the ACMUI for a trial period of 2-3 years, after which this issue should be re-assessed.

3. This invitation should be extended to a practicing interventional radiologist who regularly uses both types of Y-90 microspheres and who is an authorized user.

https://www.nrc.gov/docs/ML2009/ML20097F625.pdf

31

A Deeper Dive into Recent Subcommittee Activities

- ACMUI Bylaws — Apr 2020 Aug 2024★

To determine (1) Should there be term limits for the ACMUI Chair and Vice Chair? If so, how long? and (2) Should the ACMUI Vice Chair automatically become the ACMUI Chair?

Recommendations

The Subcommittee recommends no changes to the existing bylaws.

The Subcommittee agrees that the ACMUI Chair and Vice Chair should be appointed by the Director of NMSS and the Director should determine the duration of the term as currently stated in the bylaws.

The Subcommittee agrees that Officer succession should be at the discretion of the Director of NMSS, as currently stated in the bylaws.

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

32

A Deeper Dive into Recent Subcommittee Activities

- Patient Intervention — Apr 2020

To evaluate the definition of patient intervention and other actions and circumstances that are exclusive of medical events. annually review the medical events (MEs) with an eye to advising the ACMUI and NRC about emerging trends needing regulatory attention.

Recommendations:

1. The current definition of "patient Intervention" in 10 CFR 35.2 should be interpreted to include both intentional (or voluntary) actions taken by the patient, such as removing an implanted brachytherapy source or applicator, or refusing to continue with a prescribed course of treatment; and unintentional (or involuntary) actions which would include medical outcomes resulting from the anatomical or physiological conditions of the patient, such as extravasation, migration of implanted radioactive seeds, arterial spasm, and the onset of other underlying medical diseases and disorders which interfere with the prescribed treatment.

2. The subcommittee agrees that Medical Events resulting from "patient intervention" should not need to be reported as it would potentially infringe on the practice of medicine, and it will not help to prevent such events in the future.

3. Medical Events resulting from patient intervention in which the administration of byproduct material or radiation from byproduct material results or will result in unintended permanent functional damage to an organ or a physiological system, as determined by a physician, should be reported as required by 10 CFR 35.3045(b).

https://www.nrc.gov/docs/ML2009/ML20097F476.pdf

33

A Deeper Dive into Recent Subcommittee Activities

- Training and Experience Requirements for All Modalities — Oct 2019

To review and comment on the staff's draft evaluation of training and experience requirements for radiopharmaceuticals requiring a written directive..

Approach One – Removal of Prescriptive T&E Requirements and NRC Review and Approval of AUs

Option 1a. "Specialty Board Credentialing," where physicians must be certified by any medical specialty board to use radiopharmaceuticals.

Option 1b. "Licensee Credentialing," where licensees must develop their own procedures to determine whether their physicians are adequately trained to use radiopharmaceuticals.

Option 1c. "NRC-Recognized Specialty Board Credentialing," where physicians must be certified by a medical specialty board recognized by the NRC.

https://www.nrc.gov/docs/ML1929/ML19296D256.pdf

34

A Deeper Dive into Recent Subcommittee Activities

- Training and Experience Requirements for All Modalities — Oct 2019

To review and comment on the staff's draft evaluation of training and experience requirements for radiopharmaceuticals requiring a written directive..

Approach Two: Maintain or Enhance the Existing T&E Framework

Option 2a. "Status Quo," would make no changes to the NRC's T&E requirements.

Option 2b. "Tailored Requirements," would tailor and reduce T&E to create additional AU pathways for administration of specific categories of radiopharmaceuticals.

Option 2c. "Emerging Radiopharmaceuticals," would conduct individual reviews of each new radiopharmaceutical to determine drug-specific tailored T&E and other related requirements.

Option 2d. "Team-Based Requirements," would create an additional alternate pathway in which T&E requirements for AUs would be reduced based on pairing AUs with other individuals with radiation safety T&E.

https://www.nrc.gov/docs/ML1929/ML19296D256.pdf

35

A Deeper Dive into Recent Subcommittee Activities

- Infiltrations and Medical Event Reporting — Oct 2019 June 2024 ★

To review the NRC's 1980 determination related to infiltrations and medical event reporting [45 FR 31703].

Subcommittee Recommendations:
Extravasation is a practice of medicine issue and not an item that needs to be regulated by the NRC.

The subcommittee recommends that, under future revisions to Part 35 rulemakings, extravasations be considered a type of passive "patient intervention", similar to the recommendations from the ACMUI subcommittee (presented during the ACMUI public meeting on October 2015 and referenced in the Patient Intervention subcommittee report dated April 27, 2017) and should be captured in the NRC's current definition of patient intervention under 10 CFR 35.2.

There is no evidence at this time for this subcommittee to recommend a reclassification of extravasation at the injection site for radiopharmaceuticals to be considered a medical event. The subcommittee recommends that extravasations that lead to "unintended permanent function damage" be reportable as a Medical Event under 10 CFR 35.3045(b).

https://www.nrc.gov/docs/ML1931/ML19316E067.pdf

36

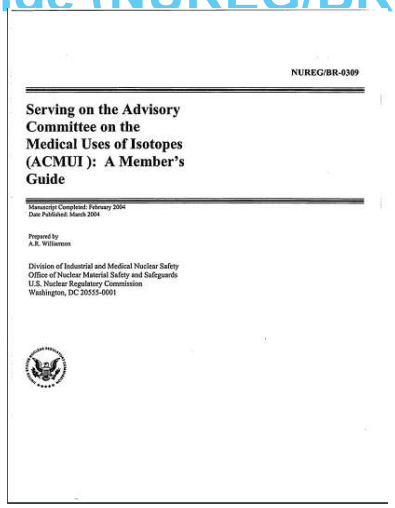
Nuclear Pharmacists Who Have Served on ACMUI

Dennis P. Swanson	Nuclear Pharmacist	1994 – 1999
Sally W. Schwarz	Nuclear Pharmacist	2000 – 2008
Steven R. Mattmuller	Nuclear Pharmacist	2008 – 2016
Richard L. Green	Nuclear Pharmacist	2016 – 2026
?	Nuclear Pharmacist	2026 – 2030

https://www.nrc.gov/about-nrc/regulatory/advisory/acmui/history.html#history

37

Serving on the Advisory Committee on the Medical Uses of Isotopes (ACMUI): A Member's Guide (NUREG/BR-0309)



NUREG/BR-0309

Serving on the Advisory Committee on the Medical Uses of Isotopes (ACMUI): A Member's Guide

Manuscript Completed: February 2004
Date Published: March 2004

Prepared by
A.R. Williamson

Division of Industrial and Medical Nuclear Safety
Office of Nuclear Material Safety and Safeguards
U.S. Nuclear Regulatory Commission
Washington, DC 20555-0001

https://www.nrc.gov/docs/ML0407/ML040790351.pdf

38

The ACMUI Plays An Essential Role

- It advises the NRC on policy and technical issues that arise in the regulation of the medical uses of radioactive material in diagnosis and therapy.
- The ACMUI membership includes health care professionals from various disciplines, who
  - comment on changes to NRC regulations and guidance
  - evaluates certain non-routine uses of radioactive material
  - provides technical assistance in licensing, inspection, and enforcement cases
  - brings key issues to the attention of the Commission for appropriate action

39

Assessment Questions

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Assessment Questions

2. Which type of advisor is not represented on ACMUI?

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41

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   A. Permits the use of byproduct material that require a written directive

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42

Assessment Questions

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   A. No Action

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43