

TELECONFERENCE MEETING OF THE
ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES

March 12, 2013

MEETING SUMMARY

PURPOSE

To discuss the draft Advisory Committee on the Medical Uses of Isotopes (ACMUI) subcommittee report on the proposed draft expanded 10 CFR Part 35 Rulemaking.

OUTCOME

The subcommittee provided a draft report for discussion with the full committee. Subcommittee members included: Dr. Susan Langhorst; Mr. Steven Mattmuller; Dr. Bruce Thomadsen; Ms. Laura Weil; Dr. James Welsh; and Dr. Pat Zanzonico (chair). During the meeting, the committee unanimously approved the draft report with minor clarifying modifications. The U.S. Nuclear Regulatory Commission (NRC) staff gained a better understanding of the views and opinions of the ACMUI. The final report will be submitted to the NRC staff, and the staff will consider the ACMUI's recommendations in its continuing effort to make 10 Code of Federal Regulations (CFR) Part 35 more useful, practical, and not overly burdensome on licensees, while maintaining public health and safety.

Full transcripts of the ACMUI meeting can be found on NRC's public website:

<http://www.nrc.gov/reading-rm/doc-collections/acmui/tr/>

Handouts from the ACMUI meeting can be found on NRC's public website:

<http://www.nrc.gov/reading-rm/doc-collections/acmui/meeting-slides/>

The final ACMUI report on the proposed draft expanded 10 CFR Part 35 Rulemaking will be available on NRC's public website under "Related Information": <http://www.nrc.gov/about-nrc/regulatory/advisory/acmui.html>

ATTENDEES

ACMUI MEMBERS

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| Darice G. Bailey | Member |
| Milton S. Guiberteau, M.D. | Member |
| Susan M. Langhorst, Ph.D. | Member |
| Leon S. Malmud, M.D. | Chairman |
| Steve R. Mattmuller | Member |
| Christopher J. Palestro, M.D. | Member |
| John H. Suh, M.D. | Member |
| Orhan Suleiman, Ph.D. | Member |
| Bruce R. Thomadsen Ph.D. | Vice Chairman |
| William A. Van Decker, M.D. | Member |
| Laura M. Weil | Member |
| James S. Welsh, M.D. | Member |

Pat Zanzonico, Ph.D.

Member

NRC STAFF

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| Brian McDermott | Director, Division of Materials Safety and State Agreements |
| Christian Einberg. | Chief, Radioactive Materials Safety Branch and Designated Federal Officer |
| Ashley Cockerham | Alternate Designated Federal Officer and ACMUI Coordinator |
| Sophie Holiday | Alternate ACMUI Coordinator |
| Neelam Bhalla | NRC staff |
| Susan Chidakel | NRC staff, Office of the General Counsel |
| Jackie Cook | NRC staff Region IV |
| Robin Elliott | NRC staff Region I |
| Sara Forster | NRC staff Region III |
| Donna-Beth Howe, Ph.D. | NRC staff |
| Ed Lohr | NRC staff |
| Dennis O'Dowd | NRC staff Region III |
| Deborah Piskura | NRC staff |
| Lester Tripp | NRC staff Region I |
| Ronald Zelac, Ph.D. | NRC staff |

MEMBERS OF THE PUBLIC

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| Sue Bunning – Society of Nuclear Medicine and Molecular Imaging | Andrew McKinley – Am. Soc. of Nuclear Cardiology |
| Dawn Edgerton – Council for Certification in Cardiovascular Imaging | Environmental Protection |
| Lynne Fairbrent – Am. Assoc. of Physicists in Medicine | Michael Peters – Am. College of Radiology |
| Karen Langley – University of Utah | Michael Stephens – FL Bureau of Radiation Control |
| Ralph Lieto – St. Joseph Mercy Hospital | Cindy Tomlinson – Am. Soc. for Rad. Onc. |
| | Michael Welling – VA Dept. of Health |
| | Gary E. Williams – Dept. of Veterans Affairs |

AGENDA TOPIC

ACMUI Rulemaking Subcommittee Report

RECOMMENDATIONS AND ACTIONS

The subcommittee discussed the following recommendations in the second draft subcommittee report:

1. Page 3, 1-D. ACMUI recommended the draft rule re-defining medical events in permanent implant brachytherapy be designated as Compatibility Category B. [10 CFR 35.3045]

The recommendation was approved by the ACMUI; however, Ms. Bailey opposed.

2. Page 4, 2-D. ACMUI 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. [10 CFR 35.390 and 396]

The recommendation was approved by the ACMUI; however Ms. Weil abstained.

3. Page 5, 3-C. ACMUI 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. [10 CFR 35.57]

The recommendation was unanimously approved by the ACMUI.

4. Page 5, 4-B. ACMUI recommended that the NRC adopt the FDA approved package insert for breakthrough limits for radioisotope generators. [10 CFR 35.204]

The recommendation was unanimously approved by the ACMUI.

5. Page 6, 4-C. ACMUI recommended licensee reporting of out-of-tolerance generator breakthrough results to the NRC. [10 CFR 30.50 and 35.204]

The recommendation was not approved by the ACMUI. Ms. Bailey, Dr. Guiberteau, Dr. Langhorst, Mr. Mattmuller, Dr. Suh, Dr. Van Decker, and Dr. Welsh opposed the recommendation. Dr. Palestro, Dr. Suleiman, Dr Thomadsen, Ms. Weil, and Dr. Zanzonico voted in favor.

6. ACMUI recommended requiring testing of molybdenum breakthrough on every elution of a molybdenum-technetium generator, rather than after only the first elution. [10 CFR 35.204]
7. Page 7, 5-A. ACMUI recommended that the addition of Associate Radiation Safety Officers (ARSOs), and Temporary RSOs also be included in these exemptions in the same manner as AUs, ANPs, and AMPs. [Multiple sections of 10 CFR Part 35]

The recommendation was unanimously approved by the ACMUI.

8. Page 8, 6-A. In reference to the plain language requirement, the ACMUI suggested 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.” [Section X. Plain Language]

The recommendation was unanimously approved by the ACMUI.

9. ACMUI 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 was unanimously approved by the ACMUI.