

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

December 13, 2010

**MEETING SUMMARY**

**PURPOSE**

To discuss issues related to the implementation of the medical regulations in 10 Code of Federal Regulations (CFR) Part 35, "Medical Use of Byproduct Material," including Advisory Committee on the Medical Uses of Isotopes (ACMUI) interactions with staff for major medical policy; patient release; rulemaking and implementation guidance for physical protection of byproduct material; and the impacts of the draft safety culture policy statement for medical licensees.

**OUTCOME**

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) made recommendations, and the U.S. Nuclear Regulatory Commission (NRC) staff gained a better understanding of the views and opinions of the ACMUI, as well as other stakeholders' views and opinions. The staff will consider these views in its continuing effort to make 10 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/>

**ATTENDEES**

**ACMUI**

|                               |                |
|-------------------------------|----------------|
| Darrell Fisher, Ph.D.         | Member         |
| Debbie B. Gilley              | Member         |
| Milton S. Guiberteau, M.D.    | Representative |
| Susan M. Langhorst, Ph.D.     | Member         |
| Leon S. Malmud                | Chairman       |
| Steve R. Mattmuller           | Member         |
| Christopher J. Palestro, M.D. | Member         |
| John H. Suh, M.D.             | Member         |
| Orhan H. Suleiman, Ph.D.      | Member         |
| Bruce R. Thomadsen Ph.D.      | Vice Chairman  |
| William A. Van Decker, M.D.   | Member         |
| James S. Welsh, M.D.          | Member         |
| Pat Zanzonico, Ph.D           | Member         |

## **NRC**

|                           |                                                             |
|---------------------------|-------------------------------------------------------------|
| Rob Lewis                 | Director, Division of Materials Safety and State Agreements |
| Chris Einberg             | Designated Federal Officer                                  |
| Mike Fuller               | Alternate Designated Federal Officer                        |
| Ashley Cockerham          | ACMUI Coordinator                                           |
| Neelam Bhalla             | NRC staff                                                   |
| James Biggins             | NRC staff                                                   |
| Elva Bowden Berry         | NRC staff                                                   |
| Lisa Dimmick              | NRC staff                                                   |
| James Firth               | NRC staff                                                   |
| Sophie Holiday            | NRC staff                                                   |
| Donna-Beth Howe, Ph.D.    | NRC staff                                                   |
| Ed Lohr                   | NRC staff                                                   |
| Maria Schwartz            | NRC staff                                                   |
| Diane Sieracki            | NRC staff                                                   |
| Dave Solorio              | NRC staff                                                   |
| Catherine Thompson, Ph.D. | NRC staff                                                   |
| Ron Zelac, Ph.D.          | NRC staff                                                   |

## **MEMBERS OF THE PUBLIC**

|                     |                                                         |
|---------------------|---------------------------------------------------------|
| Dave Adler          | American Society for Therapeutic Radiology and Oncology |
| Curtis M. Anderson  | MELE Associates                                         |
| James D. Albright   | NCDENR                                                  |
| David J. Allard     | Pennsylvania Department of Environmental Protection     |
| Christofer Alston   | Georgetown University Hospital                          |
| Maxwell Amurao      | Georgetown University Hospital                          |
| Sue Bunning         | Society of Nuclear Medicine                             |
| Robert E. Dansereau | New York State Department of Health                     |
| William Davidson    | University of Pennsylvania                              |
| Deirdre Elder       | University of Colorado Hospital                         |
| Nancy Farrington    | Iowa Department of Public Health                        |
| Dr. Thomas Huston   | Department of Veterans Affairs                          |
| Karen Langley       | University of Utah                                      |
| Andrew Mauer        | Nuclear Energy Institute                                |
| Candi McDowell      | Georgetown University Hospital                          |
| Herb Mower          | Lahey                                                   |
| Joseph Och          | Geisinger Medical Center                                |
| Mike Peters         | American College of Radiology                           |
| Melanie Rasmusson   | Iowa Department of Public Health                        |
| Gloria Romanelli    | American College of Radiology                           |
| Dr. George Segall   | Society of Nuclear Medicine                             |
| Michael Sheetz      | University of Pittsburgh                                |
| Cindy Tomlinson     | American Society for Radiation Oncology                 |
| Dr. Richard Vetter  | Health Physics Society                                  |
| Michelle White      | DMS Health Technologies                                 |
| Jenna Wilkes        | Society of Nuclear Medicine                             |
| Sandy Wolff         | Sentara                                                 |

## **AGENDA TOPICS**

1. Policy & Procedure – NRC Interactions with Staff for Major Medical Policy
2. Patient Release Following Iodine-131 Therapy
3. Rulemaking and Implementation Guidance for Physical Protection of Byproduct Material
4. Impacts of the Draft Safety Culture Policy Statement for Medical Licensees

## **RECOMMENDATIONS AND ACTIONS**

For agenda topic 1, Policy & Procedure – NRC Interactions with Staff for Major Medical Policy, the ACMUI endorsed the draft Policy and Procedure 2-5 with comments, as reflected in the meeting handout (ML103430110). The recommendation passed unanimously with ten favorable votes.

For agenda topic 2, Patient Release Following Iodine-131 Therapy, the ACMUI endorsed the Patient Release Subcommittee Report, as reflected in the meeting handout (ML103430123). The recommendation passed unanimously with ten favorable votes. NRC staff will provide the ACMUI report to Congressman Markey in response to a letter to Chairman Jaczko dated October 20, 2010.

Also for agenda topic 2, Patient Release Following Iodine-131 Therapy, the ACMUI will provide a list of action items for NRC staff based on the recommendations provided in the Patient Release Subcommittee Report.

For agenda topic 3, Rulemaking and Implementation Guidance for Physical Protection of Byproduct Material, the ACMUI will develop a draft document for further discussion at a January 2011 teleconference.

For agenda topic 4, Impacts of the Draft Safety Culture Policy Statement for Medical Licensees, the ACMUI deferred the discussion on the draft final safety culture policy statement to a January 2011 teleconference. The recommendation passed unanimously with ten favorable votes.

NRC staff will schedule a teleconference in January 2011 based on ACMUI availability and will publish a notice in the *Federal Register*.