the advisory committee on the medical uses of isotopes

march 1-2, 2004

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ACMUI Meeting
March 1-2, 2004
U.S. Nuclear Regulatory Commission
Two White Flint North Auditorium
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MARCH 1, 2004

	PRINTED NAME		PRINTED NAME
1	Roshunda Drummond	19	
2	GERACO WHITE.	20	
3	Lynne Fanahent	21	
4	William Kellegrin	22	
5	Andrew Kaup	23	
6	Raymond Herr	24	
7	James Goetz	25	
8	Lisa Dimmick	26	
9	John Coats	27	
10	Howard Griffith	28	
11	RICHARD FETIKA (FDA)	29	
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2 William Nelligan	20
3 GERALD A. GHAR	21
4 Lynne Fairobent	22
5 James A. Bayall	23
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7	25
8	26
9	27
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18	36

ACMUI SPEAKERS and PARTICIPATING STAFF
March 1 and 2, 2004

Roger W. Broseus, PhD, NMSS/IMNS/RGB

Manuel D. Cerqueira, ACMUI Chairman

Thomas H. Essig, NMSS/IMNS/MSIB, Designated Federal Official

Patricia K. Holahan, PhD, NMSS/IMNS

Donna-Beth Howe, PhD, NMSS/IMNS/MSIB

Michael Layton, NSIR

Ralph P. Lieto, ACMUI

Charles L. Miller, PhD, NMSS/IMNS

John Szabo, OGC

Angela R. Williamson, NMSS/IMNS/MSIB

Ronald E. Zelac, PhD, NMSS/IMNS/MSIB

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

March 1-2, 2004
U.S. Nuclear Regulatory Commission
Two White Flint North Building, Auditorium
Rockville, Maryland 20852-2738

AGENDA

MARCH 1, 2004

CLOSED SESSION

8:00 – 9:00	Overview of ACMUI/Staff Interactions & Reflections from Recent IAEA Meeting on the Medical Use of Radioactive Material - Charles Miller, NRC/NMSS
9:00 – 9:15	Ethical Issues Involving ACMUI Members Serving on Other Professional Entities – John Szabo, NRC/OGC
9:15 – 9:45	Materials Security Update: Licensees Other than Irradiator and Source Manufacturer Licensees – Michael Layton, NRC/NSIR
9:45 –10:00	**BREAK**

OPEN SESSION

10:00 – 10:05	Opening Remarks – Thomas H. Essig, NRC/NMSS
10:05 – 11:00	Dose Reconstruction Subcommittee Findings on St. Joseph Mercy Hospital Case – ACMUI Subcommittee
11:00 – 12:00	Status of Rulemaking; Amend 10 CFR Part 35/Recognition of Specialty Board Certifications (T&E) /Preceptor Statement/NRC Form 313A — Roger Broseus, PhD, NRC/NMSS
12:00 – 1:00	**LUNCH**
1:00 – 1:30	Emerging Technology Subcommittee Discussion on Mission and Meeting Procedures – ACMUI
1:30 – 2:30	Emerging Technology Subcommittee Discussion on SeedSelectron Licensing Guidance – NRC Staff and ACMUI
2:30 –3:15	Removing Modalities out of Pt. 35.1000 – Donna-Beth Howe, PhD, NRC/NMSS
3:15 – 3:30	**BREAK**

3:30 – 4:30	Defining Medical Events Involving Prostate Seed Implants – Ronald E. Zelac, PhD, NRC/NMSS
4:30 – 5:00	Update: Recommendations from Fall 2003 meeting – Angela Williamson, NRC/NMSS

ACMUI Meeting Agenda

MARCH 2, 2004

8:00 – 9:00	Preparation for Commission Briefing - ACMUI

COMMISSION BRIEFING
Commissioners' Hearing Room 1G16

9:30 – 9:45	Pt. 35 Licensing & Inspection Under the New Pt. 35 – Pamela Henderson, NRC/Region I
9:45 – 10:00	Commission Question and Answer Period
10:00 – 10:15	NRC Method of Dose Reconstruction – Sami Sherbini, PhD, NRC/NMSS
10:15 – 10:30	Commission Question and Answer Period
10:30 – 10:45	Pt. 35 Revision on Proposed Rulemaking – Ralph Lieto, ACMUI
10:45 – 11:00	Commission Question and Answer Period
11:00 – 11:15	ACMUI Review of NRC Method of Dose Reconstruction – Leon S. Malmud, MD, ACMUI
11:15 – 11:30	Commission Question and Answer Period
11:30 – 1:00	**LUNCH**

OPEN SESSION

1:00 – 2:00	Proposed Changes to Abnormal Occurrence Criteria – Angela Williamson, NRC/NMSS
2:00 – 3:00	Transition Issues on Pt. 35 Implementation – Ralph Lieto, ACMUI
3:00 – 3:15	**BREAK**
3:15 – 4:00	Proposed Changes to 10 CFR Part 35 – Donna-Beth Howe, PhD, NRC/NMSS
4:00 – 4:30	Next meeting date, agenda topics, meeting summary – NRC Staff/ACMUI
4:30	**ADJOURN**

Briefing of the ACMUI: Revisions to Part 35 – Recognition of Board Certifications

March 2004

Roger W. Broseus, CHP, Ph.D.
Office of Nuclear Material Safety and Safeguards,
Division of Industrial and Medical Nuclear Safety

Status of Rulemaking

- OMB approved information collection February 2, 2004
- Public comment period closed February 23, 2004
- View public comments on the NRC's rulemaking forum
  - http://ruleforum.llnl.gov/cgi-bin/rulelist?type=prule

Comments on Proposed Rule – Overview

- Fifteen commenters – five Agreement State representatives and ten public
- General support for proposed rule with five offering explicit support
  - One Agreement State
  - Four public

Questions Posed in FRN

- Do the proposed revisions to requirements for T&E provide reasonable assurance that RSOs, AMPs, ANPs, and AUs will have adequate training in radiation safety?
- Should Agreement States establish the requirements to conform with this proposed rule by October 24, 2005, or should they follow the normal process and be given a full 3 years to develop a compatible rule?
- Should the word "attestation" be used in place of the word "certification" in preceptor statements?

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Public Comments on Proposed Rule

- Preceptors should not be required to attest to candidates passing board-administered exams
- Several dealt with timing of Agreement State adoption of regulations
- Discussion of pros and cons of timing
- Use of "attest" vs. "certify" in preceptor statements
  - Commenters generally agree with ACMUI – use "attest"

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Public Comments on Proposed Rule (cont.)

- Not enough time planned for applications by boards
- Wording in proposed § 35.390(c) is unclear – implies preceptor must certify passing of certification examination
- Exempt radiation oncologists from proposed § 35.390(b)(1)(ii)
- Many comments from general public dealt with details & implementation

6

Agreement State Comments on Proposed Rule

- Agreement States seek full 3 years to develop a compatible rule
- Hours of training – want more specificity, e.g., for number of hours of didactic training and hours of supervised clinical work for AUs under 35.190, 35.290, 35.390

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Agreement State Comments on Proposed Rule (cont.)

- Clarify definitions in 35.2
- Support for retention of requirement for preceptor statements
- De-coupling of preceptor certifications from requirements for recognition of board certifications – *some mixed reactions*
  - "Unfortunate" that certification alone will be inadequate – confusing change for applicants
  - "Glad to see" burden shift from boards
- Many comments dealt with details & implementation

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Comments on Draft Implementation Procedures

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Implementation Procedures – ACMUI Comments

- Board certification purpose & process not clearly understood by the NRC
  - Boards do not determine content of training programs
  - Boards determine if candidates possess adequate understanding & knowledge of content
  - Procedures should reflect these observations

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Implementation Procedures – ACMUI Member (cont.)

- Draft includes redundant requirements
  - for boards to 'declare' that candidates must complete T&E to sit for exam
- Inappropriate for the NRC to examine board processes, e.g., exams, passing point workshops, grading procedures
- NRC should not review specific procedures of boards
- Confusion about role of Agreement States
  - Can a board apply to a State?
  - If approved, would certification approved by one State be recognized by all and the NRC?
- Do States have resources to conduct this program?

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Implementation Procedures – ACMUI Member (cont.)

- Why should boards be required to renew every 5 years (programs are static)?
- Invitation to apply should state consequences of not applying
- Board should not be delisted due to non-response to communications from NRC
- Applications by boards: NRC should hold workshop or telecon to explain procedures
- Announce in Federal Register

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Implementation Procedures – Agreement State Comments

- Need specification for number-of-hours of didactic training in 35.190, 35.290, 35.390
- Want guidelines for evaluation of training programs for certification and alternate pathways
- Need some common performance indicators for IMPEP* audits

*IMPEP: Integrated Materials Performance Evaluation Program

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Implementation Procedures – Agreement State Comments (cont.)

- Expressed doubt that boards would allow review of examinations to determine if they adequately assess radiation safety training
- Need guidance on proposed changes for users of sealed sources in medical therapy, including specialty 'modalities' such as IVB
- States should recognize State boards
  - e.g., a State Medical physicist licensing board
  - If a State were to recognize a board, would it be nationally recognized?
- Due process lacking
  - One State indicates that allowance for a hearing would be required to delist a board or to deny recognition

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Path Forward

- Resolve comments from stakeholders
- Prepare draft final rule
- Distribute for 30-day comment to
  - The ACMUI & Agreement States
- Resolve comments
- To Commissions for review and approval
- Revise implementation procedures
  - Post to web
- Publish final rule September, 2004
- Contact boards (invite application)

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Moving Modalities out of 10 CFR 35.1000

March 2004
ACMUI Meeting

Donna-Beth Howe, Ph.D.

Moving Modalities out of 10 CFR 35.1000

Requires Rulemaking

Staff plans to initiate Rulemaking

2.802 Rulemaking Petition from Stakeholders

Moving Modalities out of 10 CFR 35.1000

Rulemaking is cost effective:

Number of licensees seeking to use technology justifies the rulemaking expense

Rulemaking changes are clear and established

Degree of revision needed for Part 35

Moving Modalities out of 10 CFR 35.1000

Rulemaking changes are clear and established

The technology is no longer new

Both stakeholders and NRC have experience with the technology

The guidance has stabilized

Moving Modalities out of 10 CFR 35.1000

Both Stakeholders and NRC have experience with the technology:

Licensing experience

Inspection Experience

Medical Use experience

Medical Event experience

Moving Modalities out of 10 CFR 35.1000

The guidance has stabilized:

Revising website guidance is easy to change

Rulemaking changes are slower

Minor revisions to existing subparts of Part 35

Major revision to or entirely new subpart for Part 35

Moving Modalities out of 10 CFR 35.1000

Current "Other" or "Emerging" Technologies:

- Liquid Brachytherapy Sources
- Microsphere Brachytherapy Sources
- Beta High Dose-Rate Remote Afterloader
- Permanent Implant Low-dose Remote Afterloader

Defining Medical Events Involving Prostate Seed Implants

Ronald E. Zelac, Ph.D., NRC/NMSS

ACMUI Meeting, 3/1/04

The Regulatory Requirement

Applicable 10 CFR 35.3045 Criteria

- delivery of a dose that differs from the prescribed dose by more than 0.05 Sv (50 rem) to an organ or tissue
- a total dose that differs from the prescribed dose by 20 percent or more

ACMUI Recommendation (11/03)

Use D90 as criterion for medical event.

- OK for D90<80% (underdosing)
- Problematic for D90>120% (overdosing)
  - many standard treatments have D90s exceeding 120% of the prescribed dose
  - in standard treatments, a significant portion of the target volume receives a dose exceeding 200% of the prescribed dose

Questions for ACMUI

Regarding Criterion for "Overdosing"

- Are the previous two statements regarding D90s for standard treatments considered correct?
- If so, D90 does not appear to be a suitable criterion for defining "overdosing" medical events. Agree?
- If so, what measure is a suitable criterion?

AGENDA TOPIC: DEFINING MEDICAL EVENTS INVOLVING PROSTATE SEED IMPLANTS

January 29, 2004

MEMORANDUM TO: George C. Pangburn, Director
Division of Nuclear Materials Safety, RI

FROM: Thomas Essig, Chief /RA/
Materials Safety and Inspection Branch
Division of Industrial and Medical
Nuclear Safety, NMSS

SUBJECT: RESPONSE TO TECHNICAL ASSISTANCE REQUEST DATED NOVEMBER 5, 2003, FOR GUTHRIE HEALTHCARE SYSTEM, SAYRE, PA

Issues:

I am responding to your technical assistance request (TAR) dated November 5, 2003, regarding Guthrie Healthcare System. You requested that the response address the following: 1) Determine if the licensee's criterion for identifying a misadministration/medical event for prostate seed implants (V100<80%) is appropriate; 2) If V100<80% is not a suitable criterion, determine the appropriate criterion for identifying a medical event for an iodine-125 seed permanent implant performed with an array of sources and a volumetric target.

Action:

1. The licensee's use of V100<80% as the criterion for identifying prostate brachytherapy misadministrations/medical events is not appropriate, as it does not provide any dose information for the remaining >20% of the target volume (the prostate), for comparison to the dose-based reporting requirement in 10 CFR 35.3045.

2. For the "underdosing" events at Guthrie, the appropriate measure for determining if a prostate brachytherapy treatment misadministration/medical event had occurred is D90, the dose received by 90% of the target volume, in comparison to the prescribed dose. A misadministration/medical event occurred if D90 is less than 80% of the intended dose, as specified in the written directive.

3. For prostate brachytherapies involving potential "overdosing," [none to-date at Guthrie] an appropriate criterion for comparison to the dose-based reporting requirement in 10 CFR 35.3045 must still be determined. This will be done in cooperation with the Advisory Committee for Medical Uses of Isotopes (ACMUI).

Background:

10 CFR 35.3045 requires licensee reporting of medical events, as defined in the section. As applicable to prostate brachytherapy with implanted seeds, the criteria for a medical event includes delivery of a dose that differs from the prescribed dose by more than 0.05 Sv (50 rem) to an organ or tissue, and a total dose that differs from the prescribed dose by 20 percent or more. The total dose portion of this criterion corresponds to a criterion in the definition of a

CONTACT: Ronald E. Zelac, Ph.D., NMSS/IMNS
(301) 415-7635

medical misadministration for brachytherapy in 10 CFR 35.2 prior to October 24, 2002 (the effective date of the revised Part 35), when the Guthrie events that are described below occurred.

Since June 16, 2003, Guthrie Healthcare System has reported a total of 21 misadministrations/medical events that occurred at its facility in Sayre, Pennsylvania between January 2001 and January 2002 during the implant of iodine-125 seeds for treatment of prostate cancer. On July 28, 2003, after licensee identification and reporting to NRC of four such medical events, Region I issued a Confirmatory Action Letter (CAL No. 1-03-003). The CAL outlined the actions to be taken by the licensee. Included, in order to identify any additional such events, was performing an audit of all prostate seed implants performed at the licensee's facility from 2001 to the date of the letter and any others performed at its facility prior to 2001 by the Radiation Oncology staff members who were involved in the four reported misadministrations/medical events.

On September 15, 2003, the licensee submitted a report which included a review of the dosimetry from these treatments. Because the dose was prescribed to the entire prostate volume, rather than to a point, and the dose to any point within the prostate volume was determined by the distribution of iodine-125 seeds, the licensee evaluated the treatments by determining the percentage of the prostate volume that received at least 100% of the prescribed dose (V100). The licensee then used the 20% value referenced in the definition of a misadministration in 10 CFR 35.2 (currently, as described in 10 CFR 35.3045, a medical event) to establish the threshold for a misadministration as a V100 of <80%; i.e., a misadministration occurred if less than 80% of the prostate gland, the target organ, received at least 100% of the prescribed dose . The licensee's decision was based on its interpretation of the previous 10 CFR 35.2 definition for a brachytherapy misadministration, i.e., as noted above (in the first paragraph under "Discussion"), a calculated administered dose differing from the prescribed dose by more than 20% of the prescribed dose. This criterion matches the total dose criterion for a medical event (under the current 10 CFR 35.3045). The V100 values for the 21 misadministrations ranged from 0 to 73.3%. In other words, for the 21 reported misadministrations, 0% to 73.3% of the prostate gland, the target organ, received at least 100% of the prescribed dose.

Region I questions the licensee's use of 80% V100 as a criterion for identifying a misadministration/medical event, since less restrictive, and possibly more realistic, criteria for judging the adequacy of a treatment have been established by nationally recognized experts in brachytherapy. Region I was concerned that the use of this criterion (that Region I considered as conservative) by the licensee to report these 21 events, and potentially more events (where the administered treatment might be closer to that which was intended), will result in many other licensees using this same criterion and reporting a large number of misadministrations/medical events when this is not necessarily appropriate for conformity with the requirement of the current regulation (10 CFR 35.3045). Accordingly, Region I asked for guidance on how to evaluate these treatments.

Discussion:

In its TAR request, RI documented the results of its attempt to identify a different criterion from the licensee-utilized V100<80% for judging if a permanent implant prostate brachytherapy treatment dosimetric outcome required licensee reporting as a misadministration or medical event (depending on when it occurred relative to October 24, 2002, the effective date of the revised 10 CFR Part 35). The following three paragraphs describe established criteria from

nationally recognized experts in brachytherapy for judging the adequacy of a treatment that RI considered as less restrictive and possibly more realistic than V100<80%, and possibly suitable for identifying misadministrations/medical events:

1) The American Association of Physicists in Medicine (AAPM) Radiation Therapy Committee Task Group 64, in its review of permanent prostate seed implant brachytherapy, states: "For dosimetric evaluation performed at the optimum imaging time [approximately four weeks post-implant for I-125], it is recommended to use D90 in comparison to the prescribed dose, as an indicator of implant quality in dose coverage." D90 is the dose received by at least 90% of the prostate volume. Region I documented the D90 values for each patient reported by the licensee as a misadministration/medical event. The D90 values ranged from 11.52% to 70.7% of the prescribed dose. (Considering 80% of the prescribed dose to be an acceptable D90, all of the events reported by Guthrie thus far would remain as reportable medical events; i.e., all of the 21 reported misadministrations had 90% of the target organ, the prostrate, receiving less than 80% of the prescribed dose.);

2) The federally-funded Radiation Therapy Oncology Group (RTOG), which runs clinical trials and establishes criteria for evaluation of treatment accuracy in these trials, established for iodine-125 prostate implants that the goal is for greater than or equal to 80% of the prostate volume to receive at least 90% of the prescribed dose. This is the same as saying V90 is greater than or equal to 80%. Using this criterion, a few of the misadministrations/medical events reported by Guthrie are close to not meeting the criterion for consideration as a misadministration, but the number of misadministrations/medical events is not reduced. Note: The RTOG recognizes, as an acceptable treatment variation, when 50% or more of the prostate volume receives at least 90% of the prescribed dose. This is the same as saying V90 is greater than or equal to 50%. If this were the criterion for a misadministration/medical event, 13 of the 21 events reported by Guthrie would no longer be considered misadministrations/medical events;

3) Pro-Qura, a program of the Seattle Prostate Institute that provides independent evaluations of the quality of prostate implants, including feedback for technique improvement, recognizes the inherent difficulty in performing seed implants. This program established a standard that 80% of a radiation oncologist's treatments have V100s exceeding 75 to 80%, depending on the timing of post-implant CT images.

After MSIB staff received the RI TAR, the question of defining misadministrations/medical events for prostate brachytherapy treatments was posed at the November, 2003 ACMUI meeting, for input. The response, from Dr. Subir Nag, the radiation oncologist member, without dissent from other members, was that the appropriate measure for determining if a prostate brachytherapy treatment misadministration/medical event had occurred is D90, the dose received by 90% of the target volume, in comparison to the prescribed dose. Using this dose-based criterion vs. the requirement in 10 CFR 35.3045, a misadministration/medical event would occur for D90<80% or D90>120% of the prescribed dose.

From a regulatory point of view, D90 is a more appropriate criterion than V100 because D90 is dose-based, and permits dose comparisons, as does the regulation (10 CFR 35.3045), while V100 does not provide any dose information for the remaining >20% of the target volume (the prostate), for comparison to the dose-based reporting requirement in 10 CFR 35.3045. Accordingly, Headquarters staff agrees with the ACMUI recommendation, which reflects clinical practice considerations, to use a dose-based measure, specifically D90, as the criterion for deciding, under 10 CFR 35.3045, whether a prostate brachytherapy utilizing permanently

implanted seeds should or should not be considered a misadministration/medical event. This approach appears as a more appropriate match to the requirement (10 CFR 35.3045) than use of any of the volume-based measures (e.g., V100) as the criterion for deciding whether or not a misadministration/medical event has occurred. Use of this measure, D90, as the criterion should not result in inappropriate reporting of a large number of misadministrations/medical events by other medical use licensees performing prostate brachytherapy utilizing permanently implanted seeds, as the criterion, D90, is considered to be realistic and not overly conservative.

While this criterion, D90, is satisfactory for "underdosing," as in the Guthrie Healthcare System event, it appears that many standard treatments have D90s exceeding 120%, and would therefore be classified as "overdosing" misadministrations/medical events if the criterion D90>120% of the prescribed dose was used. In fact, in standard treatments, a significant portion of the target volume receives a dose exceeding 200% of the prescribed dose. Reference Mueller, et al., "Modification of prostate implants based on postimplant treatment margin assessment," in Medical Physics (Med. Phys.) 29(12): 2782-7 (2002). Overreporting of events, which would follow from using D90 as the sole criterion for both "underdosing" and "overdosing" misadministrations/medical events, was exactly the issue of concern to RI. Accordingly, an appropriate criterion for comparison to the dose-based reporting requirement in 10 CFR 35.3045 must still be determined for prostate brachytherapies involving potential "overdosing," [none to-date at Guthrie] . The NRC staff will determine this criterion in cooperation with the Advisory Committee for Medical Uses of Isotopes (ACMUI).

MEMORANDUM TO: Manuel D. Cerqueira, M.D., Chairman
Advisory Committee on the
Medical Uses of Isotopes

FROM: Thomas H. Essig, Chief
Materials Safety and Inspection Branch
Division of Industrial and Medical
Nuclear Safety, NMSS

SUBJECT: RESPONSE TO RECOMMENDATION FROM THE NOVEMBER 12-13, 2003, MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Below is the recommendation from the November 12-13, 2003 meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). Following the recommendation is the U.S. Nuclear Regulatory Commission (NRC) staff's response and/or position.

RADIOIODINE ACTIVITY THRESHOLD FOR THE TREATMENT OF HYPERTHYROIDISM

ACMUI recommendation: That the NRC allow those licensees, who were previously authorized to use I-131 to treat hyperthyroidism under the previous regulation, continue to use I-131 under the revised regulation in 10 CFR 35.392, as well as 10 CFR 35.394; provided that those licensees submit a written statement that contains at least three cases documenting that they have experience using greater than 33 millicuries. This statement need not be from a preceptor authorized user.

Staff response: Staff has accepted this recommendation as the professional advice of the ACMUI. Staff specifically solicited this recommendation from the ACMUI so that staff can respond to technical assistance request (TAR) number 133633, submitted to NRC Headquarters from the Region 1 office of the NRC. Staff has forwarded this recommendation to Region 1. TAR 133633 may be viewed in the Agencywide Documents and Administration System under accession number ML033570442.

Contact: Angela Williamson, NMSS/IMNS
(301) 415-5030

PROPOSED CHANGE TO ABNORMAL OCCURRENCE CRITERIA

ANGELA R. WILLIAMSON
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
U.S. NUCLEAR REGULATORY COMMISSION

ABNORMAL OCCURRENCE (AO) DEFINITION

An AO is an unscheduled incident or event which the U.S. Nuclear Regulatory Commission determines to be significant from the standpoint of public health or safety.

Source: Energy Reorganization Act of 1974, Section 208

LESS COMMON TYPES OF AOs

- AOs involving releases to the environment
- AOs involving theft or diversion of radioactive material
- AOs involving the design or construction of licensed facilities

COMMON TYPES OF AOs

- AOs involving medical events
- AOs involving overexposures

FY 04 PROPOSED CHANGE TO MEDICAL EVENT AO CRITERIA

- Appendix A, (Criterion IV, For Medical Licensees) states that a medical misadministration or medical event that:

  (a) Results in a dose that is (1) equal to or greater than 1 gray (Gy) (100 rads) to a major portion of the bone marrow, to the lens of the eye, or the gonads, or (2) equal to or greater than 10 Gy (1,000 rads) to any other organ, or to tissue which results in permanent functional damage to the tissue, and...

PURPOSE FOR THIS PROPOSED CHANGE

- Capture IVB events
- Intended to capture only those IVB events that result in serious, permanent damage to patients' vasculature

Potential 10 CFR Part 35 Rulemaking

March 2004

ACMUI Meeting

Donna-Beth Howe, Ph.D.

Potential 10 CFR Part 35 Rulemaking

10 CFR 32.74(a) states that an application will be approved under this section for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed pursuant to part 35 of this chapter for use as a calibration or reference source or for the uses listed in §§ 35.400 and 35.500, 35.600 if certain information is provided.

Recommend revision to 32.74(a) ..."to persons licensed pursuant to part 35 of this chapter for use as a calibration, transmission, or reference source ..."

1

Potential 10 CFR Part 35 Rulemaking

10 CFR 32.74(a) states that an application will be approved under this section for a specific license to manufacture and distribute sources and devices containing byproduct material to persons licensed pursuant to part 35 of this chapter for use as a calibration or reference source or for the uses listed in §§ 35.400 and 35.500, 35.600 if certain information is provided.

Recommended revision of 32.74(a) ..."to persons licensed pursuant to part 35 of this chapter for use as a calibration, transmission, or reference source or for the uses listed in §§ 35.400, 35.500, 35.600, and 35.1000."

2

Potential 10 CFR Part 35 Rulemaking

10 CFR 35.12(d) In addition to the requirements in paragraphs (b) and (c) of this section, an application for a license or amendment for medical use of byproduct material as described in § 35.1000 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of this part.

(1) The applicant shall also provide specific information on--

Recommend that 35.12(d) be revised to specifically include Subpart M.

3

Potential 10 CFR Part 35 Rulemaking

10 CFR 35.12(d) In addition to the requirements in paragraphs (b) and (c) of this section, an application for a license or amendment for medical use of byproduct material as described in § 35.1000 must also include information regarding any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C of this part.

(1) The applicant shall also provide specific information on--

Recommend that 35.12(d) be revised to specifically include appropriate radiation safety requirements in Subparts D through H.

4

Potential 10 CFR Part 35 Rulemaking

10 CFR 35.12(d) In addition to the requirements in paragraphs (b) and (c) of this section, an application for a license or amendment for medical use of byproduct material as described in §§ 35.1000 must also include information regarding:

(1) Any radiation safety aspects of the medical use of the material that is not addressed in Subparts A through C and M of this part;

(2) Commitment to follow radiation safety program requirements in Subparts D through H that are appropriate for the specific 35.1000 medical use; and

(3) The applicant shall also provide specific information not included above on--

5

Potential 10 CFR Part 35 Rulemaking

35.41 Procedures for administrations requiring a written directive...

(b) At a minimum, the procedures required by paragraph (a) of this section must address the following items that are applicable to the licensee's use of byproduct material—...

(4) Verifying that any computer-generated dose calculations are correctly transferred into the consoles of therapeutic medical units authorized by § 35.600.

Recommend revision to 35.41(b)(4) ... "...correctly transferred into the consoles of therapeutic medical units authorized by §§ 35.600 or 35.1000."

6

Potential 10 CFR Part 35 Rulemaking

10 CFR 35.610(d) requires the licensee to provide instruction, initially and at least annually, to all individuals who operate the unit, as appropriate to the individual's assigned duties, in the emergency procedures and operating procedures for the unit.

Recommend revising to add a new section on vendor training and distinguish this training from licensee provided "initial" training. The difference based upon the licensee experience with the unit, i.e., new units and units with significant manufacturer upgraded.

7

Potential 10 CFR Part 35 Rulemaking

10 CFR 35.610(d)

(1) Vendor training will be provided for all operators of a new therapy unit, or therapy unit with significant manufacturer update, prior to first use of the unit for patient treatment. The vendor training will be provided by the device manufacturer or by individuals certified by the device manufacturer.

(2) A licensee shall provide instruction, initially and at least annually, to all individuals who operate a therapy unit that is not new or recently received significant manufacturer updating.

(3) The training and instruction identified in paragraphs (d)(1) and (d)(2) will be as appropriate to the individual's assigned duties, in—

(a) The procedures identified in paragraph (a)(4) of this section; and

(b) The operating procedures for the unit.

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Potential 10 CFR Part 35 Rulemaking

35.26 Radiation protection program changes.

(a) A licensee may revise its radiation protection program without Commission approval if--

(1) The revision does not require a license amendment under §§ 35.13;

(2) The revision is in compliance with the regulations and the license ; ....

Recommend revision to permit change based upon NRC"s current guidance for the 35.1000 use posted on the NRC website.

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Potential 10 CFR Part 35 Rulemaking

35.26 Radiation protection program changes.

(a) A licensee may revise its radiation protection program without Commission approval if--

(1) The revision does not require a license amendment under §§ 35.13;

(2) The revision is in compliance with the regulations;

(3) The revision is in compliance with the license or is based on current guidance for the 35.1000 medical use posted on the NRC website;

(4) The revision has been reviewed and approved by the Radiation Safety Officer and licensee management; and

(5) The affected individuals are instructed on the revised program before the changes are implemented.

(b) A licensee shall retain a record of each change in accordance with §§ 35.2026

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Potential 10 CFR Part 35 Rulemaking

35.2026 Records of radiation protection program changes.

A licensee shall retain a record of each radiation protection program change made in accordance with §§ 35.26(a) for 5 years. The record must include a copy of the old and new procedures; the effective date of the change; and the signature of the licensee management that reviewed and approved the change.

Recommend revision of 35.2026 ...The record must include a copy of the old and new procedures; a copy of the appropriate 35.1000 medical use website guidance; the effective date of the change; ...

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UNITED STATES NUCLEAR REGULATORY COMMISSION CHARTER FOR THE ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES
(Pursuant to Section 9 of Public Law 92-463)

1. **Committee's Official Designation:**

   Advisory Committee on the Medical Uses of Isotopes

2. **Committee's objectives, scope of activities and duties are as follows:**

   The Committee provides advice, as requested by the Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Materials Safety and Safeguards, on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy. The Committee may provide consulting services as requested by the Director, IMNS

3. **Time period (duration of this Committee):**

   From March 20, 2002, to March 20, 2004

4. **Official to whom this Committee reports:**

   Charles L. Miller, Director
   Division of Industrial and Medical Nuclear Safety
   Office of Nuclear Materials Safety and Safeguards
   U.S. Nuclear Regulatory Commission
   Washington, DC 20555

5. **Agency responsible for providing necessary support to this Committee:**

   U.S. Nuclear Regulatory Commission

6. **The duties of the Committee are set forth in Item 2 above.**

7. **Estimated annual direct cost of this Committee:**

   a. $160,000.00 (includes travel, per diem, and compensation)

   b. Total staff-year of support: 1.5 Full Time Equivalent

8. **Estimated number of meetings per year:**

   Three meetings per year, except when active rulemaking is conducted, then five meetings per year.

9. **The Committee's termination date.**

April 4, 2004

10. **Filing date:**

Andrew L. Bates
Advisory Committee Management
Officer
Office of the Secretary of the
Commission

ACMUI
February 20, 2002

U.S. NUCLEAR REGULATORY COMMISSION

OFFICE OF NUCLEAR MATERIALS SAFETY AND SAFEGUARDS

ADVISORY COMMITTEE ON MEDICAL USES OF ISOTOPES

BYLAWS

CONTENTS

PREAMBLE

These bylaws describe the procedures to be used by the Advisory Committee on the Medical Uses of Isotopes (ACMUI), established pursuant to Section 161a of the Atomic Energy Act of 1954, as amended, in performing its duties, and the responsibilities of the members. For parliamentary matters not explicitly addressed in the bylaws, Robert's Rules of Order will govern.

These bylaws have as their purpose fulfillment of the Committee's responsibility to provide objective and independent advice to the Commission through the Office of Nuclear Material Safety and Safeguards, with respect to the development of standards and criteria for regulating and licensing medical uses of byproduct material. The procedures are intended to ensure that such advice is fairly and adequately obtained and considered, that the members and the affected parties have an adequate chance to be heard, tand that the resulting reports represent, to the extend possible, the best of which the Committee is capable. Any ambiguities in the following should be resolved in such a way as to support those objectives.

BYLAWS-ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

1. Scheduling and Conduct of Meetings

The scheduling and conduct of ACMUI meetings shall be in accordance with the requirements of the Federal Advisory Committee Act (FACA), as amended, 10 CFR Part 7, and other implementing instructions and regulatins as appropriate.

1.1 Scheduling of Meetings:

1.111 Meetings must be approved or called by the Designated Federal Officer. At least two regular meetings of the Committee will be scheduled each year. A spring meeting will be scheduled in April-May, and a fall meeting will be scheduled in October-November. Additionally, the Committee will meet with the Commission each year in the first or second quarter of each year.

1.1.2 Special meetings will be open to the public, except for those meetings or portions of meetings in which matters are discussed that are exempt from public disclosure under FACA or other appropriate rules or statutes.

1.1.3 ACMUI meetings will be open to the public, except for those meetings or portions of meetings in which matters are discussed that are exempt from public disclosure under FACA or other appropriate rules or statutes.

1.1.4 All meetings of the Committee will be transcribed. During those portions of the meeting that are open to the public, electronic recording of the proceedings by members of the public will be permitted. Television recording of the meeting will be permitted, to the extent that it does not interfere with Committee business, or with the rights of the attending public.

1.2 Meeting Agenda:

The agenda for regularly scheduled ACMUI meetings will be prepared by the Chair of the Committee (referred to below as "the Chair") in consultation with the Nuclear Materials Safety and Safeguards (NMSS) staff. The Designated Federal Officer must approve the agenda. The Chair will query committee members for agenda items prior to agenda preparation. A draft agenda will be provided to committee members not later than thirty days before a scheduled meeting. The final agenda will be provided to members not later than seven days before a scheduled meeting.

Before the meeting, the Chair and the Designated Federal Officer for the committee will review the findings of the Office of the General Counsel regarding

possible conflicts of interest of members in relation to agenda items. Members will be recused from discussion of those agenda items with respect to which they have a conflict.

1.3 Conduct of the Meeting:

1.3.1 All meetings will be held in full compliance with the Federal Advisory Committee Act. Questions concerning compliance will be directed to the NRC Office of the General Counsel.

1.3.2 The Chair will preside over the meeting. The Designated Federal Officer will preside if the Chair is absent, if the Chair is recused from participating from discussion of a particular agenda item, or if directed to do so by the Commission.

1.3.3 A majority of the current membership of the Committee will be required to constitute a quorum for the conduct of business at a committee meeting.

1.3.4 The Chair has both the authority and the responsibility to maintain order and decorum, and may, at his or her option, recess the meeting if these are threatened. The Designated Federal Officer will adjourn a meeting when adjournment is in the public interest.

1.3.5 The Chair may take part in the discussion of any subject before the committee, and may vote. The Chair should not use the power of the Chair to bias the discussion. Any dispute over the Chair's level of advocacy shall be resolved by a vote on the Chair's continued participation in the discussion of the subject. The decision shall be by a majority vote of those members present and voting, with a tie permitting continued participation of the Chair in the discussion.

1.3.6 When a consensus appears to have developed on a matter under consideration, the Chair will summarize the results for the record. Any members who disagree with the consensus shall be asked to state their dissenting views for the record. Any committee member may request that any consensus statement be put before the ACMUI as a formal motion subject to affirmation by a formal vote. No committee position will be final until it has been formally adopted by consensus or formal vote, and the minutes written and certified.

2. MINUTES

2.1 The Chair will prepare detailed minutes of each ACMUI meeting (excepting meetings with the Commission for which transcripts are prepared) based on the transcripts of the meeting.

2.2 A draft of the minutes will be prepared by the Chair, assisted by NRC staff, and made available as soon as practicable to the other members. After receiving corrections to the draft minutes from the committee members, the Chair will certify the minutes. By certifying the minutes, the Chair attests to the best of his or her knowledge to the completeness and technical accuracy of the minutes.

2.3 Copies of the certified minutes will be distributed to the ACMUI members. The staff will then forward the minutes to the Public Document Room, with only deletions authorized or required by law.

3. APPOINTMENT OF MEMBERS

3.1 The members of the committee are appointed by the Commission, which determines the size of the committee. The NRC will solicit nominations by notice in the Federal Register and by such other means as are approved by the Commission. Evaluation of candidates shall be by such procedures as are approved by the Commission. The Commission has the final authority for selection. The term of an appointment to the committee is three years, and the Commission has determined that no member may serve more than 2 consecutive terms (6 years).

3.2 The Chair will be appointed by the Commission. The Chair will serve for a period of two years, and will be eligible for reappointment by the Commission for two additional two-year terms.

4. CONDUCT OF MEMBERS

4.1 If a member feels that he or she may have a conflict of interest with regard to an agenda item to be addressed by the committee, he or she should divulge it to the Chair and the Designated Federal Officer as soon as possible, but in any case before the committee discusses it as an agenda item. Committee members must recuse themselves from discussion of any agenda item with respect to which they have a conflict of interest.

4.2 Upon completing their tenure on the committee, members will return any privileged documents and accountable equipment (as so designated by the NRC) provided for their use in connection with ACMUI activities, unless directed to dispose of these documents or equipment.

4.3 Members of the ACMUI are expected to conform to all applicable NRC rules and regulations.

5. ADOPTION AND AMENDMENTS

5.1 Adoption of these bylaws shall require a vote of two-thirds of the current ACMUI membership and the concurrence of the Director of the Office of Nuclear Material Safety and Safeguards.

5.2 Any member of the committee or NRC may propose an amendment to these bylaws. The proposed amendment will be distributed to the members by the Chair and scheduled for discussion at the next regular committee meeting.

5.3 The final proposed amendment may be voted on not earlier than the first regular meeting after it has been discussed at a committee meeting pursuant to Paragraph 5.2.

5.4 A vote of two-thirds of the current ACMUI membership and the concurrence of the Director of the Office of Nuclear Material Safety and Safeguards shall be required to approve an amendment.

5.5 Any conflicts regarding interpretation of the bylaws shall be decided by majority vote of the current membership of the committee.

[Federal Register: February 18, 2004 (Volume 69, Number 32)][Notices]
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From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr18fe04-74]

NUCLEAR REGULATORY COMMISSION

Advisory Committee on the Medical Uses of Isotopes: Meeting Notice

AGENCY: U.S. Nuclear Regulatory Commission.

ACTION: Notice of meeting.

SUMMARY: The U.S. Nuclear Regulatory Commission will convene a meeting of the Advisory Committee on the Medical Uses of Isotopes (ACMUI) on March 1 and 2, 2004. An announcement of this meeting was originally made in the January 28, 2004 Federal Register. However, it is necessary to re-announce this meeting because the NRC staff has since determined that parts of the meeting must be closed to the public.

A sample of agenda items to be discussed during the public sessions includes: (1) Dose Reconstruction Subcommittee Findings in the St. Joseph Mercy Hospital Case; (2) Proposed Changes to Abnormal Occurrence Criteria; (3) Status of Rulemaking--Recognition of Specialty Board Certifications; and, (4) Defining Medical Events Involving Prostate Seed Implants. To review the agenda, see http://www.nrc.gov/ reading-rm/doc-collections/ acmui/schedules/2004/ or contact arw@nrc.gov.

Date and Time for Closed Session Meeting: March 1, 2004, from 8 a.m. to 10 a.m. This session will be closed so that NRC staff and the ACMUI may discuss ethical issues and security-related issues.

Dates and Times for Public Meetings: March 1, 2004, from 10 a.m. to 5 p.m.; and March 2, 2004, from 8 a.m. to 9 a.m. and from 1 p.m. to 5 p.m.

Date and Time for Commission Briefing: March 2, 2004, from 9:30 a.m. until 11:30 a.m. The public meetings and the Commission briefing will take place at the addresses provided below.

Address for Public Meetings: U.S. Nuclear Regulatory Commission, Two White Flint North Building, Auditorium, 11545 Rockville Pike, Rockville, MD 20852-2738.

Address for Commission Briefing: U.S. Nuclear Regulatory Commission, One White Flint North Building, Commissioners' Conference Room 1G16, 11555 Rockville Pike, Rockville, MD 20852-2738.

FOR FURTHER INFORMATION CONTACT: Angela R. Williamson, telephone (301) 415-5030; e-mail arw@nrc.gov of the Office of Nuclear Material Safety and Safeguards, U.S. Nuclear Regulatory Commission, Washington, DC

20555-0001.

Conduct of the Meeting

Manuel D. Cerqueira, M.D., will chair the meeting. Dr. Cerqueira will conduct the meeting in a manner that will facilitate the orderly conduct of business. The following procedures apply to public participation in the meeting:

1. Persons who wish to provide a written statement should submit a reproducible copy to Angela R. Williamson, U.S. Nuclear Regulatory Commission, Two White Flint North, Mail Stop T8F5, 11545 Rockville Pike, Rockville, MD 20852-2738. Submittals must be postmarked by February 23, 2004, and must pertain to the topics on the agenda for the meeting.

2. Questions from members of the public will be permitted during the meeting, at the discretion of the Chairman.

3. The transcript and written comments will be available for inspection on NRC's Web site (http://www.nrc.gov) and at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852-2738, telephone (800) 397-4209, on or about March 22, 2004. Minutes of the meeting will be available on or about May 3, 2004.

This meeting will be held in accordance with the Atomic Energy Act of 1954, as amended (primarily Section 161a); the Federal Advisory Committee Act (5 U.S.C. App); and the Commission's regulations in Title 10, U.S. Code of Federal Regulations, part 7.

Dated: February 11, 2004.
Andrew L. Bates,
Advisory Committee Management Officer.
FR Doc. 04-3444 Filed 2-17-04; 8:45 am]

BILLING CODE 7590-01-P

ACMUI MEMBERS

MEMBER	SPECIALTY
VACANT	**Interventional Cardiologist**
Manuel D. Cerqueira, M.D. Georgetown University Medical Center Division of Cardiology (5-PHC) 3800 Reservoir Rd. NW Washington, DC 20007-2197	**Nuclear Cardiology** Email: cerqm@concentric.net Phone: 202-444-7190 FAX: 202-444-4593
David A. Diamond, M.D. Florida Oncology Network Walt Disney Memorial Cancer Institute Florida Hospital - Orlando 2501 N. Orange Ave., Suite 181 Orlando, FL 32804	**Radiation Oncologist** Email: dagdmail@yahoo.com Phone: 407-303-2030 FAX: 407-303-2042
Douglas F. Eggli, M.D. Dept. of Radiology, H066 Penn State University Hospital The Milton S. Hershey Medical Center Room # HG300Z P.O. Box 850 500 University Drive Hershey, PA 17033	**Nuclear Medicine Physician** Email: deggli@psu.edu Phone: 717-531-8940 FAX: 717-531-5596
Nekita Hobson National Association of Cancer Patients 2070 Ridgeline Avenue Vista, CA 92083	**Patient Advocate** Email: nohobson@aol.com Phone: 760-598-8289 FAX: 760-598-7304
Maureen Hess U.S. Food and Drug Administration 5600 Fishers Lane HFD - 6, Parklawn Building Rockville, MD 20857	**FDA Representative** The choice of FDA appointees is made by FDA. Ms. Hess chooses the FDA representative for each meeting. Email: hessm@cder.fda.gov Phone: 301-443-5573 Fax:

MEMBER	SPECIALTY
Ralph P. Lieto Radiation Safety Office St. Joseph Mercy Hospital 5301 E. Huron River Dr. Ann Arbor, MI 48106-0995	**Medical Physicist, Nuclear Medicine** Email: lietor@trinity-health.org Phone: 734 712-8746 FAX: 734-712-5344
Leon S. Malmud, M.D. Dean Emeritus, Temple University School of Medicine *Temple University Health System* 3401 N. Broad St Philadelphia, PA 19140	**Health Care Administrator** Email: martinp@tuhs.temple.edu or Malmudls@tuhs.temple.edu *Phone* : 215-707-7078 (Pat Martin) Phone: 215-885-0756 FAX: 215-707-3261
Ruth McBurney Division of Licensing, Registration and Standards Bureau of Radiation Control Texas Department of Health 1100 West 49th Street Austin, TX 78756-3189	**State Representative** Email: ruth.mcburney@tdh.state.tx.us Phone: 512-834-6689 FAX: 512-834-6716
Subir Nag, M.D. Division of Radiation Oncology Department of Radiology Arthur G. James Cancer Hospital and Research Institute Ohio State University 300 W. Tenth Avenue Columbus, OH 43210	**Radiation Oncologist** Email: nag.1@osu.edu Phone: 614-293-8415 FAX: 614-293-4044
Sally Wagner Schwarz Division of Nuclear Medicine Mallinckrodt Institue of Radiology Washington University School of Medicine 510 *south Kingshighway* Blvd. St. Louis, MO 63310	**Nuclear Pharmacist** Email: schwarzs@mir.wustl.edu Phone: 314-362-8426 FAX: 314-362-9940
Richard J. Vetter, Ph.D. Mayo Clinic Medical Sciences B-28 *or* 200 1st St. SW Rochester, MN 55905	**Radiation Safety Officer** Email: vetter.richard@mayo.edu Phone: 507-284-4408 FAX: 507-284-0150

MEMBER	SPECIALTY
Jeffrey F. Williamson, Ph.D. MCV Radiation Oncology 401 College Street, Basement B-129 PO Box 980058 Richmond, VA 23298-0058	Therapy Physicist Phone: 804-828-8451 Fax: 804 827-1670 E-mail jfwilliamson@vcu.edu Donna Manion dmanion@hsc.vcu.edu