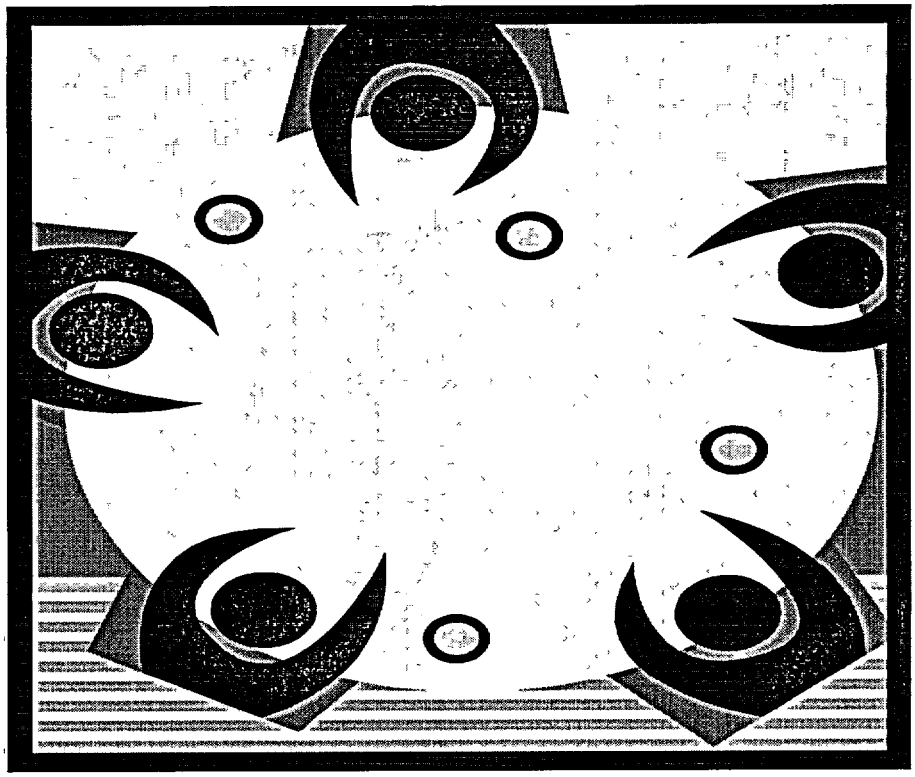
PUBLIC MEETING of the

ADVISORY COMMITTEE on the MEDICAL USES OF ISOTOPES

U.S. NUCLEAR REGULATORY COMMISSION

October 28, 2002



MEMBERS OF THE PUBLIC SIGN IN SHEET
(DO NOT REMOVE THIS FORM)

ACMUI Meeting
October 28, 2002
U.S. Nuclear Regulatory Commission
Two White Flint North, T2B3

Please print legibly, as this is a public document.

NAME	NAME
1 Michael K. Williamson	19 Paul Purtko
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18 JAMES A. BOXALL	36

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ACMUI SPEAKERS and PARTICIPATING STAFF
October 28, 2002

Manuel D. Cerqueira, ACMUI Chairman

Lloyd Bolling, OSTP

Paul Lohaus, OSTP

John Szabo, OGC

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

Frederick Brown, NMSS/IMNS/MSIB

Thomas Young, NMSS/IMNS/RGB

Angela Williamson, NMSS/IMNS/MSIB

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

October 28, 2002
U.S. Nuclear Regulatory Commission
Two White Flint North Building, Room T2B3
Rockville, Maryland 20852-2738

AGENDA

CLOSED SESSION

8:00 - 8:15 Ethics Briefing – John Szabo, NRC/OGC,
8:15 - 8:30 Security Issues Training – Lynn Silvious, NRC/NSIR
8:30 - 9:45 Administrative Review - ACMUI

9:45 - 10:00 **BREAK**

OPEN SESSION

10:00 - 10:10 Opening Remarks -Dr. Manuel Cerqueira, Chairman, ACMUI, and Thomas Essig, NRC/NMSS
GAO Presentation added
10:10 – 10:30 Update on Status of Training & Experience Recommendations from ACMUI in August 2002 – Anthony Tse, NRC/NMSS

10:30 - 11:15 Agreement State Compliance with Part 35 – Lloyd Bolling, NRC/OSTP

11:15 - 12:00 Discussion of the National Materials Program Working Group Report - Paul Lohaus, NRC/OSTP

12:00 - 1:00 **LUNCH**

1:00 - 1:20 Health and Human Services Database – Linda Psyk, NRC/NMSS

1:20 - 2:00 Status of Implementation of Revised Rule – Frederick Brown and Thomas Young, NRC/NMSS
- NUREG 1556, Vol. 9
- Update: revised inspection guidance

2:00 - 2:20 Sealed Source Model Numbers as License Conditions on NRC Licenses – Frederick Brown, NRC/NMSS

2:20 - 2:45 Discussion: Practical Issues Associated with Manual Brachytherapy Seed Implant – Frederick Brown, NRC/NMSS

2:45 - 3:00	**BREAK**
3:00 – 3:45	Implications of Intermediate Packaging and Sterilization of Brachytherapy Seeds- Frederick Brown, NRC/NMSS
3:45 - 4:00	Update: Recommendations from Spring 2002 Meeting – Angela Williamson, NRC/NMSS
4:00 – 4:15	Update: ACMUI Vacancies – Angela Williamson, NRC/NMSS
4:15 - 5:00	Administrative Conclusion ▪ Next Meeting Date ▪ Agenda Topics ▪ Meeting Summary
5:00	**ADJOURN**

GAO
Accountability * Integrity * Reliability

U.S. General Accounting Office

Review of Domestic Regulation of Nuclear Material

Presentation to the Advisory Committee on the Medical Uses of Isotopes
October 28, 2002

GAO
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Outline

- Who we are and what we do
- GAO reviews of nuclear materials regulation
- How we plan to to conduct our work
- Goals of the review

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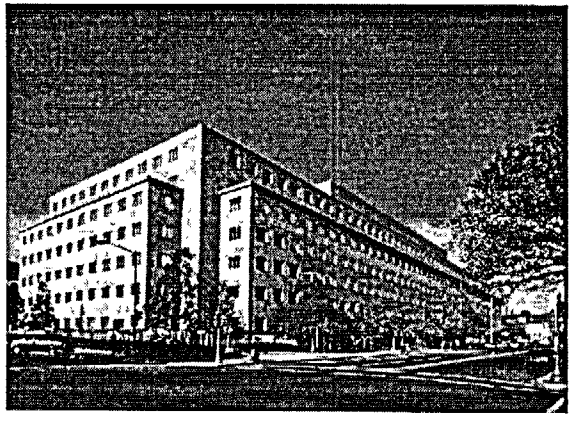
U.S. General Accounting Office
Who We Are and What We Do



- Investigative arm of the Congress.
- In the legislative branch of the federal government.
- Approximately 3,500 employees headed by the Comptroller General of the United States, currently David M. Walker.
- Conducts unbiased, objective, and non-partisan audits, investigations, and evaluations to improve efficiency, effectiveness, economy, and accountability of federal programs.

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GAO Reviews of Nuclear Materials Regulation

- Requested by Senator Daniel Akaka, Chairman of the Subcommittee on International Security, Proliferation, and Federal Services, Senate Committee on Governmental Affairs.
- 3 separate efforts: international, domestic, and narrow-scope review of DOE's Offsite Source Recovery program.
- Working with IAEA, NRC (Commissioners, STP, NMSS, NSIR, and Regions), DOE, State Department, FEMA, DOD, EPA, FBI, FDA, IC, OAS, CRCPD, and Health Physics Society.
- Reports expected in Spring 2003.

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Review of Domestic Regulation of Nuclear Material

1. What is the extent of the issue? i.e. types of material, how many licensees, maximum activities licensed, uses of materials
2. How effective is the current federal and state regulatory framework?
3. What actions have NRC and/or the states taken since September 11, 2001?

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How We Plan to Conduct Our Work

- Surveys to be sent to all agreement states and NRC regions in January.
  - Number and types of licenses
  - Materials licensed
  - Qualitative questions on effectiveness of state programs, interactions between state and NRC/EPA/FDA, participation in post-September 11th activities
- In person visits to sample of states and individual licensees.
  - Pretesting survey—November
  - Post-survey data reliability tests—January/February
- Observe IMPEP reviews of states and NRC region.

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Goals Of Our Review

- Provide an education on the regulation of nuclear materials to the Congress by a neutral third party.
- Provide the Bush Administration with best practices from federal/state relations in nuclear materials regulation that can be applied to other industries, e.g. protection of chemical facilities.
- Identify the successes of the current regulatory system, some of the challenges it faces, and perhaps provide recommendations for change.
- Examine need for legislative changes, e.g. amending the AEA to allow for NRC regulation of accelerator-produced material.

GAO
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U.S. General Accounting Office
441 G Street, NW Room 2T23
Washington, DC 20548

ETHICS BRIEFING: CLOSED SESSION
BRIEFING FOR ACMUI ONLY
NO HANDOUT PROVIDED

SECURITY ISSUES TRAINING: CLOSED SESSION BRIEFING FOR ACMUI ONLY

NO HANDOUT PROVIDED

ADMINISTRATIVE REVIEW: CLOSED SESSION BRIEFING FOR ACMUI ONLY

NO HANDOUT PROVIDED

UPDATE: STATUS OF TRAINING AND EXPERIENCE RECOMMENDATIONS FROM THE ACMUI

NO HANDOUT PROVIDED

Action: Lohaus, STP

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

OFFICE OF THE SECRETARY

STP

02 AUG 22 AM 11:5

Cys: Travers
Paperiello
Kane
Norry
Craig
Virgilio, NMSS
Droggitis, STP
Schroll, SECY

August 20, 2002

MEMORANDUM TO: William D. Travers
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary

SUBJECT: STAFF REQUIREMENTS - SECY-02-0107 - ADDENDUM TO SECY-02-0074: "NATIONAL MATERIALS PROGRAM: PILOT PROJECTS"
and
SECY-01-0112 - NATIONAL MATERIALS PROGRAM: TRANSMITTAL OF THE FINAL WORKING GROUP REPORT PRESENTING OPTIONS FOR A NATIONAL MATERIALS PROGRAM

The Commission has approved implementation of a blending of the "current program" and the "Alliance" options through the initiation of five pilot projects. The Commission's ultimate decision on the direction of the National Materials Program (NMP) will be guided by the lessons learned from the pilot projects. When carrying out the pilot projects, the staff, in collaboration with the States, should establish a process that ensures the comments and concerns from all participants are appropriately considered. The staff should also solicit comments from the broad spectrum of stakeholders, including licensees and non-Agreement States.

In addition, the Commission notes that there is another program involving the States to address security issues, particularly with regard to the security concerns with the radioactive dispersal devices. The staff should use this opportunity to study the interactions between NRC and the Agreement States and to apply any lessons learned to the work on the National Materials Program. The staff should ensure that any understandings arising from this effort are included in the evaluation of the five pilot projects.

Due to the increased financial concerns recently expressed by several Agreement States, there is concern that some State radiation control programs may not be able to participate as fully in the Alliance option as they would prefer, or as originally envisioned by the Working Group. The staff should seek to identify any equity issues that may arise during the implementation of these pilot projects and include this feedback to the Commission once the pilot projects are completed. At the end of the pilot projects, the staff should report the results to the Commission and provide an assessment of the effectiveness and efficiency of the blended option. The staff should also provide a recommended path forward for the program.

(~~EDO~~) (STP) (SECY Suspense: ~~11/14/03~~) 11/6/03 199900114

Copy to Acmul briefing book
File under "Discussion... NMP"

cc: Chairman Meserve
Commissioner Dicus
Commissioner Diaz
Commissioner McGaffigan
Commissioner Merrifield
OGC
CFO
OCA
OIG
OPA
Office Directors, Regions, ACRS, ACNW, ASLBP (via E-Mail)
PDR

NATIONAL MATERIALS PROGRAM

Paul Lohaus, Director
Office of State and Tribal Programs
October 2002

NATIONAL MATERIALS PROGRAM PROCESS

- A National Materials Program (NMP) is in Place Today
- SECY-01-0112 National Materials Program: Final Working Group Report
  - Identified range of options for NMP
  - Discussed need for additional information – pilot program

1

NATIONAL MATERIALS PROGRAM PROCESS (Cont.)

- SECY-02-0074 National Material Program. Pilot Programs
  - Described five pilot projects
  - Provided information on Working Group recommended "Alliance" option
- SECY-02-0107 Addendum to SECY-02-0074
  - NRC Staff, CRCPD, and OAS recommended use of blending the "Current Program" and the "Alliance" option

2

NATIONAL MATERIALS PROGRAM PROCESS (Cont.)

- August 20, 2002 Staff Requirements Memorandum
  - Approved blending of the "Current Program" and the "Alliance" options through initiation of five pilot projects
  - Future direction and decision will be guided by results of the pilot projects
  - Solicit comments from broad spectrum of stakeholders, including licensees and non-Agreement States.

3

INTER-RELATIONSHIP of the NATIONAL MATERIALS PROGRAM

Individual Program Activities
Licensing
Inspection
Response To Incidents
Staffing & Training
Enforcement & Investigation

Shared Program Activities
Rule Development
Guidance Development
Program Evaluation
Policy

ISSUES (SUCCESS MEASURES)

- Evolving NMP environment
- NRC ability to share establishment of priorities with States
- Ability of States to assume and carry out greater responsibility for development and maintenance of products under a NMP
- Individual State programs ability to commit resources to NMP
- NRC, CRCPD, and OAS Roles

5

PILOT PROJECTS
NEXT STEPS

- Five Pilot Projects identified jointly by NRC, OAS, and CRCPD
- Lead Assigned to Develop Pilot Project Charters
- Seeking Agreement State Pilot Project Representatives
- Report on Pilot Projects due to Commission in November 2003

Reporting of Final Adverse Actions to the Health Integrity and Protection Data Bank

Linda M. Psyk
Division of Industrial and Medical Nuclear Safety

ACMUI Meeting
October 28, 2002

1

Health Integrity and Protection DB

Discussion Outline

- What is the HIPDB
- Why the NRC reports to the data base
- What the NRC reports
- How the NRC will report
- Agreement State Reporting

2

What is the HIPDB?

- *Health Insurance Portability and Accountability Act of 1996*
  - Health care fraud
    - Burdens US with enormous financial costs and threatens health care quality and patient safety
  - Required DHHS to create a national health care fraud and abuse control program
  - Established a national data bank to receive and disclose certain final adverse actions against health care practitioners, providers, and suppliers

3

What is the HIPDB? Cont.

- Contents of HIPDB are confidential
  - No access to general public
- Entities reported to HIPDB are notified
- HIPDB information available to
  - State and Federal Agencies
  - Health plans
  - Health care practitioners, providers, and suppliers requesting information concerning themselves

4

Why Does the NRC Report to HIPDB?

- Codified in 45 CFR Part 61
- Requires reporting from:
  - State and Federal Government Agencies responsible for the licensing or certification of health care practitioners, providers, and suppliers
  - Health plans (insurance, programs that provide health benefits)

5

What the NRC Reports

- 3 Criteria for Reportable Action:
  - Final negative actions or findings
  - Actions that are publicly available
  - Related to medical practice or healthcare
- Examples
  - Revocation or suspension of a license
  - Actions that limit the scope of practice

6

What the NRC Reports cont.

- NRC reports NRC licensees and employees working under an NRC license:
  - Physicians
  - Medical physicists
  - Technologists
  - Hospitals
  - Clinics
  - Radiopharmacies
  - Medical source replacement contractors

7

How the NRC Will Report

- Management Directive
- Regional staff to collect information
- Office of Enforcement to input data into HIPDB
- Reporting actions taken since August 21, 1996

8

Agreement States

- AS required to report adverse actions as well
- NRC to provide a letter to AS when Management Directive is complete -reminder

9

Summary

- NRC to report adverse actions taken against licensees which pertain to health care
- Information submitted to HIPDB in accordance with Management Directive
- Agreement States also required to report

Copy to Acmul briefing book
File under "Revised Rule"

UNITED STATES
NUCLEAR REGULATORY COMMISSION
OFFICE OF NUCLEAR MATERIAL SAFETY AND SAFEGUARDS
WASHINGTON, D.C. 20555

October 21, 2002

NRC REGULATORY ISSUE SUMMARY 2002-19
NEW MODALITIES TO BE REGULATED UNDER 10 CFR 35.1000

ADDRESSEES

All medical licensees authorized to use byproduct material for therapeutic administration.

INTENT

The U.S. Nuclear Regulatory Commission (NRC) is issuing this regulatory issue summary (RIS) to inform addressees of how three specific new modalities will be regulated under the revised 10 CFR Part 35, "Medical Use of Byproduct Material." No specific action nor written response is required.

BACKGROUND

There are three new modalities currently authorized by the NRC on some specific licenses. These are Y-90 microspheres (e.g., MDS Nordion Y-90 TheraSphere®); liquid brachytherapy (e.g., Proxima Therapeutics' GliaSite® Radiation Therapy System); and intravascular brachytherapy (e.g., Cordis Checkmate™ System, Novoste Beta-Cath™ System, and Guidant Galileo™ Intravascular Radiotherapy System).

SUMMARY OF ISSUE

On the effective date of the revised Part 35, October 24, 2002, Y-90 microspheres, liquid brachytherapy, and intravascular brachytherapy will be governed by §35.1000, based on NRC's determination that they do not fit into §35.100 through §35.600. For licensees currently authorized to use these modalities, their existing license conditions applicable to these types of use will remain in effect after October 24, 2002.

Specific licensees that want to be authorized to use one or more of these new modalities on or after the effective date of the final rule should request license amendments in accordance with §35.1000 and §35.12(d).

ML022830802

This RIS requires no specific action nor written response. If you have any questions about this summary, please contact the individual listed below or the appropriate regional office.

/RA/

Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety
Office of Nuclear Material Safety
and Safeguards

Contact: Ivelisse M. Cabrera, NMSS
(301) 415-8152
E-mail: imc1@nrc.gov

Attachment: List of Recently Issued NRC Regulatory Issue Summaries

Part 35 Implementation Status

Frederick D. Brown
NMSS/IMNS/MSIB

NUREG 1556, Vol 9

- March 2002 draft circulated for comments
- Staff worked to address comments – internal and external
- "Pink Team" review and revision
- "Red Team" approval

NUREG 1556, Vol 9

- Review Team Philosophy:
  - Ensure no "regulation" via "guidance"
  - Ensure no unnecessary burden in submittals
  - Ensure clarity and simplicity
  - Be responsive to stakeholder comments
- Last three items above counterbalanced by maintaining adequate safety

NUREG 1556, Vol 9

- Final document on Web 10/22/02: http://www.nrc.gov/reading-rm/doc-collections/nuregs/staff/sr1556/v9/index.html (hyphens required)
- Clear differentiation between guidance on required license submissions vs. "information only" model procedures

Diagnostic Only Guidance

- Society of Nuclear Medicine developed
- NRC supports the SNM document
- The document currently available from SNM
- NRC pursuing a contract to allow making the document widely available to public

Training for NRC Staff

- Five training sessions held
  - Covered the rule, inspection, and licensing guidance
  - Stressed a continuing shift from old prescriptive approach to performance based, risk informed
  - Consistent trainers and material used for most sessions
  - Agreement State participation

INSPECTION PROCEDURES

Medical Use of Byproduct Material

Presented to:

Advisory Committee on Medical Uses of Isotopes

By: Thomas Young, Health Physicist
NMSS/IMNS/RGB
301/415-5795, tfy@nrc.gov

1

CHANGES

MEDICAL INSPECTION PROCEDURES (IPs)

- Currently 4 IPs Changed to 5 IPs
- Changed to New IP Numbers
- Changed Format to 7 Risk-Informed Focus Elements

2

New IP Numbers and Titles

MEDICAL INSPECTION PROCEDURES

- IP 87130, Nuclear Medicine Programs--Written Directive Required [Formerly IP 87115]
- IP 87131, Nuclear Medicine Programs--Written Directive Not Required [Formerly IP 87115]
- IP 87132, Brachytherapy Programs [Formerly IP 87118]
- IP 87133, Medical Gamma Stereotactic Radiosurgery and Teletherapy Programs [Formerly IP 87116]
- IP 87134, Medical Broad Scope Programs [Formerly IP 87119]

3

7 Risk-Informed Focus Elements

MEDICAL INSPECTION PROCEDURES

- 1) Security and control of licensed material;
- 2) Shielding of licensed material;
- 3) Comprehensive safety measures;
- 4) Radiation dosimetry program;
- 5) Radiation instrumentation and surveys;
- 6) Radiation safety training and practices; and
- 7) Management oversight

4

Performance-Based Approach

MEDICAL INSPECTION PROCEDURES

- Observation, Interview, Demonstration, Measurements
  - Rather than exclusive reliance on a review of the licensee's written procedures and records.
- Conduct of the inspection should not intervere with patient care or privacy
  - Unless an inspector needs to intervene to prevent an unsafe situation
- Inspectors should exercise discretion when interviewing licensee staff
  - In the presence of patients
  - When preparing or administering a dosage or dose.

5

Listing of Sources

Frederick D. Brown
NMSS/IMNS/MSIB

10 CFR 30.32(g)(1)

- An application for a specific license to use byproduct material in the form of a sealed source ..... must identify the source or device by manufacturer and model number.....
- Applicable to all registered sources

Applicability

- Applicable to all Part 30 type licenses (radiography, industrial gauging, medical, etc.)
- Applicable to all <u>specific</u> licenses unless more specific provisions within a Part
- Applicable at the time of <u>application</u>

Possible Mitigation

- Manufacturers can register a single "device" utilizing many specific "sources"
- Licensees can anticipate potential sources
- Burden to be monitored and evaluated

Manual Brachytherapy Issues

(Stakeholder concerns from public workshops)

10 CFR 35.40(b)(6) "Written Directive"

- (i) Before implantation: treatment site, the radionuclide, and dose; and
- (ii) After implantation but <u>before completion of the procedure</u>: the
  - radionuclide,
  - <u>treatment site</u>,
  - number of sources, and
  - total source strength and exposure time (or the total dose).

Identified Issues

- Inability to identify exact organ boundaries during implantation
- “Skill curve” at teaching institutions
- WD revision interference with the procedure
- “Seeds dropped from needle”???

Staff Discussion

- “Treatment Site” is not limited/limiting
- “(C)ompletion of the procedure” not limited
- “dropped” seeds from an inserted needle probably of interest

Items for ACMUI Consideration

- Is guidance necessary on treatment site?
  - If so, who should develop
- Guidance on completion of procedure?
  - If so, who should develop
- Is there a radiation safety issue with "dropped seeds" and "trainees" requiring further NRC staff action?

Packaging Manual
Brachytherapy Seeds

NRC Practice

- SSDR required if packaging can:
  - Effect spacing (cartridges and applicators)
  - Effect seed integrity through temperature or chemical reaction (strands)

- ACMUI thoughts?

Calibration Issue

- Brachy seed calibration now required
- Licensees can not calibrate “packaged” seeds to meet standards
- Use of manufacturer’s calibration data will require traceability of seed to record

- ACMUI thoughts on impacts/safety issues?

UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

July 2, 2002

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

FROM: Donald A. Cool, Director
Division of Industrial and
Medical Nuclear Safety, NMSS

SUBJECT: RESPONSE TO RECOMMENDATIONS FROM THE OCTOBER 29, 2001, AND THE FEBRUARY 20, 2002 MEETINGS OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

Below are the recommendations/resolutions of the October 29, 2001 and February 20, 2002 meetings of the Advisory Committee on the Medical Uses of Isotopes (ACMUI). Following each recommendation is the U.S. Nuclear Regulatory Commission (NRC) staff's position.

CERTIFICATION BOARD RECOGNITIONS

ACMUI October 29, 2001 recommendation: The ACMUI recommends that NRC interpret 35.57 to mean the following: that medical physicists who are listed as authorized teletherapy physicists on any Agreement State or NRC license, or by any act of a radiation safety committee within a broad scope license, be allowed to be authorized medical physicists for all modalities without qualifications, provided that they satisfy the supplementary training requirements contained in the current regulatory guides for those modalities extent on that date

Staff response: Staff deferred a response to this recommendation until the February 20, 2002 meeting, when it was discussed under the agenda topic "Board Certifications." This discussion culminated in a resolution to form a subcommittee to amend the training and experience requirements in the revised 10 CFR Part 35.

ACMUI February 20, 2002 resolution: That ACMUI form a subcommittee whose charge is to develop a draft rule to amend the revised 10 CFR Part 35 (i.e., Part 35) so that board certification in itself will become a primary pathway to qualify authorized users, radiation safety officers, and authorized medical physicists.

Contact. Angela Willliamson, NMSS/IMNS
(301) 415-5030

Staff response: The subcommittee was formed. The subcommittee met on June 21, 2002, to discuss and refine its recommendations. On July 8, 2002, the full ACMUI committee will meet in a teleconference to act on the subcommittee's recommendations, and forward final recommendations to NRC staff.

STATUS OF BOARD RECOGNITIONS

ACMUI February 20, 2002 resolution: The ACMUI recommends that the Commission retain, in the current Part 35, the training and experience requirements for authorized nuclear pharmacists, authorized medical physicists, radiation safety officers, and authorized users of Part 35.600 modalities, until such time as a rulemaking initiative can be completed to rectify the problem of recognition of the Boards as pathways for achieving this status.

Commission response: The staff, with Commission agreement, retained the training requirements in Part 35.600 and other modalities, as well as the requirements under the current Part 35, Subpart J, for a 2-year period after publication of the final rule. During that 2-year period, licensees will have the option of complying with either Subpart J or Subparts B and D-H. After the 2-year period expires, Subpart J will be deleted.

ACMUI MEETING
October 28, 2002

TOPIC: ACMUI Vacancies

NRC CONTACT: Angela R. Williamson

Background

- Five ACMUI members were reappointed in 2002 for a second term (Diamond, Nag, Schwarz, Williamson, and Vetter)
- Three members due to rotate off in 2004:

  1. Dr. Manuel Cerqueira, Chairman, and Nuclear Cardiologist
  2. Ms. Nekita Hobson, Patient Advocate
  3. Ms. Ruth McBurney, State representative

- Mr. Ralph Lieto, Medical Physicist: eligible for reappointment in 2004

NRC Action Items

- Solicit nominations late 2002/early 2003 to replace Dr. Cerqueira, Ms. Hobson, and Ms. McBurney
- Discuss possibility of reappointment with Mr. Lieto late 2003

SUMMARY MINUTES FOR THE MEETING OF THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES
February 20, 2002

The Advisory Committee on Medical Uses of Isotopes (ACMUI) held its semiannual meeting at the U.S. Nuclear Regulatory Commission (NRC) in Rockville, Maryland, on February 20, 2002. On the previous day, February 19, 2002, the Committee met with the Commission.

ACMUI members present at the meeting were:

Manuel Cerqueira, M.D.	Nuclear cardiologist, ACMUI Chairman
David A. Diamond, M.D.	Radiation oncologist
Nekita Hobson	Patients' rights advocate
Ralph Lieto	Medical physicist
Ruth McBurney	State representative
Subir Nag, M.D.	Radiation oncologist
Sally W. Schwarz	Nuclear pharmacist
Richard J. Vetter, Ph.D.	Radiation safety officer
Jeffrey F. Williamson, Ph.D.	Radiation therapy physicist

The following NRC staff were present:

Robert Ayres, Ph.D.	NMSS/IMNS/MSIB
Frederick Brown	NMSS/IMNS/MSIB
Donald Cool, Ph.D.	Division Director, NMSS/IMNS
Joseph DeCicco	NMSS/IMNS/MSIB
Susan Frant, Ph.D.	Deputy Division Director, NMSS/IMNS
Catherine Haney	NMSS/FCSS
John Hickey	NMSS/IMNS/MSIB
Patricia Rathbun, Ph.D.	NMSS/IMNS
Angela Williamson	NMSS/IMNS/MSIB

The meeting came to order at 8:12 a.m.

Opening Remarks

John Hickey, the designated Federal official, welcomed everyone to the meeting. He introduced Dr. Manuel Cerqueira, ACMUI Chairman, who made the opening remarks.

Board Certification

In this discussion, several ACMUI members expressed concern that board certifications could not be used as a vehicle to produce qualified users under the revised 10 CFR Part 35. One specific suggestion involved a proposal that NRC restore board certification as the default pathway to qualification. This discussion culminated in a motion to form a subcommittee that would make recommendations to NRC staff as how to best modify the revised Part 35 so that board certifications in themselves would qualify authorized users.

The Committee approved the following action regarding this topic:

The ACMUI will form a subcommittee whose charge is to develop a draft rule to amend the revised 10 CFR Part 35 so that board certification in itself will become a primary pathway to qualify authorized users, radiation safety officers, and authorized medical physicists.

This discussion begins on Page 104 of the transcript.

Status of NUREG 1556, Vol. 9

In this presentation, Susan Frant, PhD, discussed the need to develop NUREG 1556, Vol. 9, so that it provides the appropriate level of guidance. Toward that goal, Dr. Frant suggested that the medical community work closely with NRC staff in creating model procedures. Dr. Frant went on to outline NRC's plan to introduce an updated version of NUREG 1556, Vol. 9, to the medical community via various mechanisms including meetings, opportunities for written comments, and workshops. This discussion begins on Page 130 of the transcript.

Status of NRC Website - Security Restrictions

In this presentation, Patricia Rathbun, Ph.D., discussed the rationale for the removal of certain documents from the NRC website after the September 11 terrorist attacks. Examples of documents she discussed were fact sheets that relayed the types and strengths of sources some medical institutions possess; ACMUI transcripts, and NUREG 6642 (a document that outlines different risk scenarios). Dr. Rathbun explained that NRC staff took a conservative approach and removed these documents, as well as many others that were less sensitive, due to the extreme concern that any information, even seemingly innocuous information, may be used inappropriately. She went on to discuss the agency's plan to reintroduce certain documents back to the newly designed NRC web site. This discussion begins on Page 164 of the transcript.

Status of NRC Website - Electronic Forms

In this presentation, John Hickey relayed the Agency's desire to make NRC's website more useful by posting more electronic forms to the site, and by making documents that are currently posted to the site easier to download. This discussion begins on Page 180 of the transcript.

Distribution of ACMUI Minutes

In this presentation, John Hickey reaffirmed the staff's intent to ensure that ACMUI minutes clearly display any action items and resolutions the committee makes for staff consideration. He also affirmed that staff would respond to ACMUI resolutions in a separate paper that would then be distributed to ACMUI. This discussion begins on Page 184 of the transcript.

Update on ACMUI Bylaws

During this discussion, Angela Williamson informed ACMUI on the procedure to update the portion of the bylaws that delineates the term of service of ACMUI members. This discussion begins on Page 187 of the meeting transcript.

IAEA Patient Protection

Donald Cool, Ph.D., gave a presentation on this topic. In his presentation, Dr. Cool explained the international community's current efforts toward improving the safety of radiation medicine in the international arena, particularly in developing countries. In doing so, he provided a brief background of the activities of the International Atomic Energy Agency (IAEA). He explained that the IAEA formed a technical committee charged with making recommendations to improve the safety of radiation medicine. Dr. Cool then promised to provided ACMUI with a draft report of the recommendations of the IAEA technical committee. He also informed ACMUI that this information was being presented only to educate them. He explained that they may consider choosing to be involved in this endeavor as part of their professional societies, but that they were not to take action on this information as representatives of ACMUI. This presentation begins on Page 190 of the transcript.

Status of Board Recognitions

Robert Ayres, Ph.D., made a presentation on this topic. Dr. Ayres provided an update to ACMUI on NRC's review of requests for board recognition. Dr. Ayres discussed the following boards:

- ✓ American Board of Nuclear Medicine
- ✓ Board of Pharmaceutical Specialties
- ✓ American Board of Medical Physics
- ✓ American Board of Health Physics
- ✓ American Board of Radiology
- ✓ Certification Board of Nuclear Cardiology
- ✓ American Board of Science in Nuclear Medicine

Of these, the American Board of Medical Physics, the American Board of Health Physics, and the Certification Board of Cardiology were under review during the last ACMUI meeting (October 29, 2001). Staff completed review of these boards, resulting in the following action by staff:

- Partial recognition granted to the American Board of Medical Physics (ABMP). ABMP applied for recognition under the revised 10 CFR Part 35.51(a), Authorized Medical Physicist, but staff could not grant full recognition due to the board's lack of requirement to complete training for all modalities. However, the staff should be able to grant recognition in a specified modality if the physicist can demonstrate adequate training and experience in that modality.

- Denial of recognition to the American Board of Health Physics (ABHP). ABHP was not granted recognition because its certification process does not require one year of full-time radiation safety experience with similar types of byproduct material, and it does not require a that preceptor RSO sign a written certification of experience.

- Probable recognition granted to the Certification Board of Cardiology under 10 CFR 35.2909. Although recognition had not been granted at the time of this briefing, recognition was expected to be granted.

Dr. Ayres noted that with respect to Radiation Safety Officer recognition, a large number of the boards that requested recognition were denied because their certifying processes included insufficient medical experience requirements as well as the absence of a requirement for signed preceptor statements. Likewise, with respect to Medical Physicist recognition, many boards' certifying processes were denied recognition due to non-requirement of training in all modalities as well as the absence of a requirement for signed preceptor statements.

Regarding training and experience, the Committee approved the following resolution:

The ACMUI recommends that the Commission retain, in the current 10 CFR Part 35, the training and experience requirements for authorized nuclear pharmacists, authorized medical physicists, radiation safety officers, and authorized users, until such time that a new rule is implemented that will allow board certification as a pathway for meeting the training and experience requirements in the revised 10 CFR Part 35.

This presentation begins on Page 208 of the meeting transcript, and continues on Page 266.

Report on National Materials Program-Results

Paul Lohaus and Jim Myers made a presentation on this topic. In this presentation, Mr. Lohaus informed ACMUI that the number of Agreement States is expected to continue to rise through FY 2004. In response to this anticipated rise, NRC formed the National Materials Program Working Group, comprised of NRC staff and Agreement State personnel, who were charged with analyzing the NRC's role in a future environment where 75 percent of licensees will fall under Agreement State jurisdiction. Mr. Lohaus informed ACMUI that the Working Group developed a report recommending an "alliance option" whereby the Agreement States and NRC would work together to develop regulatory products that could be smoothly implemented by both NRC and the Agreement States. Several ACMUI members expressed concern that any regulatory products born out of this alliance option could result in fragmented applications of regulations; thereby hampering the practice of medicine. In response, Mr. Myers informed ACMUI that the structure of the alliance option was designed such that any application of jointly-developed regulatory products should ensure maximum uniformity across all Agreement States and the NRC.

Most members of ACMUI were not aware of the Working Group and strongly believed that the committee as a whole should have been involved in developing the recommendations of the Working Group. Furthermore, the ACMUI expressed keen interest in being kept up-to-date on the activities of the National Materials Program Working Group. In response, Mr. Lohaus

promised to provide them with a copy of a report that was sent to the Commission in May 2001, and also committed to keep them updated via briefings.

The Committee requested the following action regarding this topic:

That the Chairman, ACMUI, direct ACMUI members to review and develop a consensus statement - for distribution to the Commission - on ACMUI's position with respect to the National Materials Working Group's report to the Commission regarding the National Materials Program.

This discussion begins on Page 214 of the meeting transcript.

Security of Radioactive Material

Catherine Haney began this presentation by informing ACMUI that her purpose was to provide them with information they can pass along to members of the regulated community who may ask them questions concerning what NRC is doing to protect the public since the September 11 terrorist attacks.

Ms. Haney informed ACMUI that, in addition to the NRC's safety mission, which is well understood, the Agency also has the responsibility to promote the nation's defense, and does so through the security regulations it develops. She informed ACMUI that one of the mechanisms the agency has always employed to meet its security mission was the sharing of intelligence information with other government agencies such as the Central Intelligence Agency and the Federal Bureau of Investigation. However, subsequent to the September 11 terrorist attacks, this inter-governmental coordination has increased dramatically, and now also includes coordination with the newly developed Office of Homeland Security.

Regarding security, Ms. Haney mentioned several initiatives, some national, and others at the licensee and Agency level. In terms of national security, Ms. Haney informed the committee that NRC is working closely with other agencies in identifying key infrastructures that need to be protected. With respect to Agency-specific initiatives, Ms. Haney informed them of the Agency's top-to-bottom review of its security and safeguards program. At the licensee level, she explained that the Agency is requiring higher licensee security where risk warrants such action. Furthermore, she mentioned that NRC has proposed Interim Compensatory Measures that, in the long term, may require increased security at hospitals. Ms. Haney also gave ACMUI practical suggestions that the average medical facility could implement to enhance security. This presentation begins on Page 318 of the transcript.

Update on New Intravascular Brachytherapy (IVB) Devices

John Hickey gave a presentation on this subject. Mr. Hickey informed ACMUI that their previous advice to the staff regarding the use of IVB devices (e.g., advice regarding use of procedures not specifically reviewed by FDA and the physical presence issue during IVB procedures) helped NRC formulate an approach that appears to be working well. This presentation begins on Page 342 of the transcript.

Mixed Doses

Joseph DeCicco gave a presentation on this topic. In this presentation, Mr. DeCicco gave ACMUI an update on NRC's efforts to address the mixed dose issue. Specifically, he informed the committee that the agency re-evaluated its regulation in 10 CFR Part 20 that addresses mixed doses. He explained that the agency evaluated whether some method other than deep dose equivalent could be used to determine external exposure. Mr. DeCicco concluded his discussion by providing ACMUI with a pre-decisional Regulatory Issues Summary (RIS) that outlines different methodologies for calculating mixed doses than are currently offered in Part 20. He requested that ACMUI review the draft RIS and submit comments by March 14, 2002. This presentation begins on Page 353 of the transcript.

The meeting concluded at 3:20 p.m.

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.

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

   From March 20, 2002 to March 20, 2004

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

   Donald A. Cool, 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. $160,000.000 (includes travel, per diem, and compensation)

   b. Total staff-year of support: 1.5 FTE

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

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

Charter, ACMUI

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

April 4, 2002

10. **Filing date:**

March 20, 2002

/s/

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

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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: October 23, 2002 (Volume 67, Number 205)]
[Notices]
[Page 65148]
From the Federal Register Online via GPO Access [wais.access.gpo.gov]
[DOCID:fr23oc02-127]

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 October 28, 2002. The meeting will take place at the address provided below. All sessions of the meeting will be open to the public with the exception of the first session, which will be closed for a security briefing and to conduct administrative business related to internal personnel rules and/or practices of ACMUI members. Topics of discussion in the public session will include: (1) Status of the implementation of the revised title 10, Code of Federal Regulations, part 35; (2) Status of NUREG 1556, Vol. 9 (Consolidated Guidance About Materials Licensees: Program-Specific Guidance About Licenses of Broad Scope); (3) Status: ACMUI Subcommittee's training and experience recommendations as they pertain to the revised title 10 Code of Federal Regulations, part 35; and, (4) Discussion of the National Materials Program report.

DATES: The public meeting will be held on Monday October 28, 2002, from 10 a.m. to 5 p.m. The closed session will be held from 8 a.m. to 9:45 a.m on October 28.

ADDRESSES: U.S. Nuclear Regulatory Commission, Two White Flint North Building, Conference Room T2B3, 11545 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 Williamson, U.S. Nuclear Regulatory Commission, Two White Flint North, Mail Stop T8F5, Washington, DC 20555-0001. Submittals must be postmarked by October 24, 2002, 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 (www.nrc.gov) and at the NRC Public Document Room, 11555 Rockville Pike, Rockville, MD 20852-2738, telephone (800) 397-4209, on or about December 3, 2002. Minutes of the meeting will be available on or about January 7, 2003.

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: October 17, 2002.
Andrew L. Bates,
Advisory Committee Management Officer.
[FR Doc. 02-27003 Filed 10-22-02; 8:45 am]
BILLING CODE 7590-01-P