

*Advisory
Committee
on the
Medical Uses
of Isotopes*

Briefing Book

February 19-20, 2002

Rockville, Maryland

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

**ACMUI Meeting
February 20, 2002
U.S. Nuclear Regulatory Commission
Two White Flint North, T2B3**

Please print legibly, as this is a public document.

NAME	NAME
1 Angela Erickson	19 William D. McEligey
2 STEPHEN HADDOCK	20
3 Nancy Barbour	21
4 JAMES A. BOXALL, JR	22
5 Lynne Fairbent	23
6 Nancy R Daly	24
7 P. J. ILMANEN	25
8 B. UFFELMAN SNA	26
9 Lynne Fairbent	27
10 J Merchant - OE	28
11 Susan PRANT IMNS/NMSS.	29
12 XXXXXXXXXX	30
13 Lloyd Bolling, STP	31
14 Allen Howe, IMNS	32
15 Roger W. Broseus IMNS	33
16 Donna-Beth Howe IMNS	34
17 Roberto J Torres NMSS/STP	35
18 Robert Ayres NMSS/IMNS	36

Speakers & Staff

ACMUI SPEAKERS and PARTICIPATING STAFF
February 20, 2002

Robert Ayres, NMSS/IMNS/MSIB

Manuel Cerqueira, ACMUI Chairman

Donald A. Cool, NMSS/IMNS

Joseph DeCicco, NMSS/IMNS/MSIB

Susan Frant, NMSS/IMNS

Catherine Haney, NMSS/FCSS

John Hickey, NMSS/IMNS/MSIB

Patricia Rathbun, NMSS/IMNS

Angela Williamson, NMSS/IMNS/MSIB

Agenda

NO HANDOUT WAS PROVIDED FOR THE
FOLLOWING AGENDA TOPICS:

Status of NUREG 1556 Vol. 9

Status of NRC Website

- * Security Restrictions
- * Electronic Forms

IAEA Patient Protection

Update on New IVB Devices Undergoing Current
Review by NRC and FDA

Distribution of ACMUI Minutes

Update ACMUI Bylaws (Re: Term of Appointments);
Update ACMUI Charter

Status of ACMUI Vacancies

Follow-up Discussion of ACMUI Recommendation
Re: Interpretation of 10 CFR 35.57

ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES

**February 19-20, 2002
U.S. Nuclear Regulatory Commission
Rockville, Maryland 20852-2738**

AGENDA

FEBRUARY 19 – COMMISSION BRIEFING SCHEDULE

PRE-BRIEFING ACTIVITIES

Time: 11:00 a.m. – 12:30 p.m.
Location: Two White Flint North Building, Room T2B3
Agenda Item: Pre-Commission Briefing Discussion

ACMUI BRIEFING TO THE COMMISSION

Time: 2:00 p.m. - 4:00 p.m.
Location: One White Flint North Building, Room O1G16
Agenda Items: See below

Miscellaneous Items

10 CFR Part 35 Report to Congress – Manuel D. Cerqueira, M.D., Nuclear Cardiologist,
ACMUI Chairman

Coordination of State and Federal Regulation of the Medical Uses of Isotopes – Ruth E.
McBurney, State Government Representative

Staffing Issues

Issues Affecting the Availability of Nuclear Pharmacists - Sally W. Schwarz, Nuclear Pharmacist

Issues Affecting the Availability of Medical Physicists– Jeffrey F. Williamson, Ph.D., Therapy
Physicist

Issues Affecting the Availability of Radiation Safety Officers – Richard J. Vetter, Ph.D.,
Radiation Safety Officer

FEBRUARY 20 – REGULAR MEETING SCHEDULE

LOCATION: Two White Flint North Building, Room T2B3

- 8:00 - 8:15 Opening Remarks -Dr. Manuel Cerqueira, Chairman, ACMUI, and John Hickey, NRC
- 8:15 - 9:00 Follow-up Discussion from Commission Briefing
- 9:00 - 9:30 Status of NUREG 1556 Vol. 9 – Susan Frant, NRC
- 9:30 – 10:00 Status of NRC Website
* Security Restrictions – Patricia Rathbun, NRC
* Electronic Forms-John Hickey, NRC
- 10:00 -10:15 **BREAK**
- 10:15 –11:00 IAEA Patient Protection– Donald Cool, NRC
- 11:00 -11:30 Report on National Materials Program-Results, Stakeholders Involved, Effect Upon ACMUI – Paul Lohaus, NRC
- 11:30 - 1:00 **LUNCH**
- 1:00 - 1:30 Status of Board Recognitions – Robert Ayres, NRC
- 1:30 - 2:00 Update on New IVB Devices Undergoing Current Review by NRC and FDA – John Hickey, NRC
- 2:00 - 2:30 Update: Security of Radioactive Material -Catherine Haney, NRC
- 2:30 - 2:45 Mixed Doses – Joseph DeCicco, NRC
- 2:45 - 3:00 **BREAK**
- 3:00 - 3:15 Distribution of ACMUI Minutes – John Hickey, NRC
- 3:15 - 3:25 Update ACMUI Bylaws (Re: Term of Appointments); Update ACMUI Charter – Angela Williamson, NRC
- 3:25 - 3:35 Status of ACMUI Vacancies – Angela Williamson, NRC
- 3:35 - 3:50 Follow-up Discussion of ACMUI Recommendation Re: Interpretation of 10 CFR 35.57- John Hickey, NRC
- 3:50 - 4:00 Meeting Summary
- 4:00 – 5:00 Open Discussion as Needed
Next Meeting Date and Agenda Topics
Adjourn

Charter & Bylaws

**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. Advisory Committee on the Medical Uses of Isotopes:

(Committee's Official Designation)

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 appointed Chairman of the Committee will conduct all meetings and will prepare minutes summarizing the deliberations of each meeting. The minutes will include the Committee's recommendations for future actions. Subcommittees may be convened to address specific problems when it is not necessary for the full Committee to be present.

3. Time period (duration of this Committee):

From April 4, 2000, to April 4, 2002

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. \$161,000.000 (includes travel, per diem, and compensation)

b. Total staff-year of support: 1.5 FTE

8. Estimated number of meetings per year:

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

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

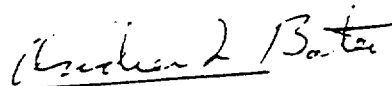
Three meetings per year except when active rulemaking is conducted, then five meetings per year.

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

April 4, 2002

10. **Filing date:**

April 3, 2000


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

ACMUI
January 5, 1995

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, and that the resulting reports represent, to the extent 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 regulations as appropriate.

1.1 Scheduling of Meetings:

1.1.1 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 two years, and the Commission has determined that no member may serve more than three consecutive terms.
- 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.**

FRN

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 February 19-20, 2002. The meeting will take place at the address provided below. The topics of discussion will relate to the status of the revised 10 CFR Part 35, Medical Use of Byproduct Material.

DATES: ACMUI will hold a public meeting on Tuesday, February 19, 2002, from 11 a.m. to 12:30 p.m. From 2 p.m. to 4 p.m. on February 19, the ACMUI will meet with the Commission in the Commissioners' conference room. On Wednesday, February 20, 2002, the ACMUI will continue its public meeting from 8 a.m. to 5 p.m.

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.

Address for Public Meeting: 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, 11545 Rockville Pike, Rockville, MD 20852-2738. Submittals must be postmarked by February 11, 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 April 22, 2002. Minutes of the meeting will be available on or about April 15, 2002.

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: January 28, 2002.

Andrew L. Bates,
Advisory Committee Management Officer.

Update: Security of RAM



OUTLINE

- **NRC Mission**
- **NRC Regulation of Nuclear Security**
- **Safeguards & Security Program**
- **NRC Immediate Response Following September 11**
- **Post September 11th Enhancements**
- **Threat Environment Review**
- **Ongoing and Future Actions**
- **Possible Implications for Materials Licensees**



NRC MISSION

- **Ensure that civilian use of nuclear material**
 - **Protects the public**
 - **Promotes the common defense and security**
 - **Protects the environment**



NRC REGULATION OF NUCLEAR SECURITY

- **Licensing**
- **Inspection and oversight**
- **Rulemaking**
- **Research**
- **Intergovernmental coordination**



SAFEGUARDS & SECURITY PROGRAM For Sensitive Nuclear Facilities

- **Design Basis Threat**
- **Security programs**
 - **Physical security – organization, physical barriers, detection and assessment systems, access controls, alarm stations and communications, response strategy, training and qualification**
 - **Personnel security – background checks, access authorization, fitness for duty**
 - **Information security – controls, handling, and storage of sensitive information**

NRC oversight program
Security levels



Existing Design Basis Threat

- **Determined and violent assault by several individuals with military training**
- **Hand-held weapons and equipment**
- **Insider assistance**
- **Vehicle bomb**



Security Principles

- **Detect and assess intrusion**
- **Communicate internally and externally**
- **Delay access**
- **Respond**
 - **Onsite force**
 - **Offsite force**



Security Programs

- **Physical security**
- **Personnel security**
- **Information security**
- **Response plans**
- **Heightened security modes**



NRC IMMEDIATE RESPONSE FOLLOWING SEPTEMBER 11TH

- **Activated NRC Emergency Response Center at Headquarters and in Regions on September 11, 2001**
- **Issued Threat Advisory and advised all sensitive nuclear facilities to go to the highest level of security**
- **Contacted licensees to discuss actions and answer questions**
- **Evaluated general and specific threats to NRC licensed facilities**
- **Coordinated with other agencies and States; staffed FBI's Strategic Information and Operations Center**
- **Enhanced NRC building security**



POST SEPT 11th ENHANCEMENTS

- **Augmented licensee capabilities**
- **Issued series of advisories, including prompt and additional actions**
- **Contacted Governors regarding deployment of State assets, including National Guard**
- **Coordinated Federal assets**
 - **Coast Guard**
 - **Combat Air Patrol (CAP)**

Coordinated FAA Flight Restrictions and Notices to Airmen

Enhanced Interagency coordination



ONGOING AND FUTURE ACTIONS

- **Top to bottom review of NRC safeguards and security program**
 - **Threat revisions**
 - **Vulnerability, consequence, and risk analysis**
 - **Short and long-term measures**
 - **Policy, program, and functional revisions**

Legislation on Federal law enforcement authority

- **Standardize force authority**
- **Criminalize sabotage**
- **Authorize necessary weapons**

Interagency coordination

- **Federal Bureau of Investigation**
- **Office of Homeland Security**
- **Intelligence community**
- **Department of Defense**
- **Others**



THREAT ENVIRONMENT REVIEW

- **Plants reported suspicious incidents since 9/11/01**
- **Hundreds of incidents reported - flyovers, threats, strange people**
- **Investigated by law enforcement agencies**
- **Most incidents resolved**
- **Some may be more serious**



Surveillance and Planning

- **High profile terrorist trials in the U.S.**
- **Reveal multi-year surveillance and planning**
 - **Information collection**
 - **Security system challenges**
 - **Insider infiltration**
 - **Credential theft**
- **Heightened security alert continues**



POSSIBLE IMPLICATIONS FOR MATERIALS LICENSEES

- **Vulnerability analyses**
- **Increased security**
- **Possible changes in regulations**

Status: NRC Website

National Materials Program

POLICY ISSUE
(Notation Vote)

June 22, 2001

SECY-01-0112

FOR: The Commissioners

FROM: William D. Travers
Executive Director for Operations

SUBJECT: NATIONAL MATERIALS PROGRAM: TRANSMITTAL OF THE
FINAL WORKING GROUP REPORT PRESENTING OPTIONS
FOR A NATIONAL MATERIALS PROGRAM

PURPOSE:

Respond to Commission direction in the November 23, 1999 Staff Requirements Memorandum (SRM), "SECY-99-250 - National Materials Program..." to examine the impacts of the increased number of Agreement States and to provide the Commission options for a National Materials Program. Request Commission approval for early release of the Working Group Report.

BACKGROUND:

Agreement State licenses currently comprise approximately 75% of the national total. With the forecast of three more States entering into agreements by the end of fiscal year 2003, Agreement State licenses will comprise more than 80% of the national total. In acknowledgment of this shift, larger portions of NRC resources have been devoted to activities in support of the national infrastructure rather than in direct interactions with applicants and licensees through licensing and inspection activities. These program activities include rulemaking and guidance development, technical support, development and maintenance of information technology systems, event follow up, and the Integrated Materials Performance Evaluation Program (IMPEP).

Although the Nuclear Regulatory Commission (NRC) and Agreement State staff have referred to a "National Materials Program," or have used similar references (e.g., coherent nationwide effort), no clear definition has been established to define what is meant by a National Materials Program (i.e., its structure, characteristics, makeup, functions and resources). To address this issue, the Commission directed the formation of an NRC/State Working Group to examine the impacts of the increased number of Agreement States and to develop options for Commission consideration. The Commission also directed that the Working Group coordinate with a Panel established by the Conference of Radiation Control Program Directors, Inc., (CRCPD), to

Contact: Frederick Combs, STP
301-415-2325

examine the structure of a National Materials Program. Section I of the Working Group Report (Attachment 1) presents the history, current status and a prediction of future challenges for the national program.

DISCUSSION:

The National Materials Program Working Group, consisting of six representatives from States, six NRC representatives and an NRC advisor, first met in early 2000. The Working Group sought guidance from its Steering Committee, input from internal and external stakeholders at several meetings, and conducted a tabletop exercise at the October 2000 Organization of Agreement States (OAS) meeting to test one of the options - a consensus-based national structure. Working Group members also made presentations and held discussions at the 2000 and 2001 annual CRCPD meetings. Office of Inspector General staff also attended Working Group and Steering Committee meetings as part of their audit of this program area.

The Working Group decided, based on an initial analysis of the issues, to develop possible options from a functional, "bottom-up" analysis rather than a programmatic "top-down" approach. This allowed the Working Group to first define the elements essential to a radiation control program and then determine how those elements could best be accomplished in a national materials program.

These elements included, but were not limited to, licensing and inspection programs, rule and guidance development, and mechanisms for communicating with stakeholders. The current methods for implementing various program elements were compared with possible alternatives using the following evaluation criteria:

- Protect Public Health and Safety
- Optimize resources of Federal, State, professional, and industrial organizations;
- Account for individual agency needs and abilities;
- Promote consensus on regulatory priorities;
- Promote consistent exchange of information;
- Harmonize regulatory approaches; and
- Recognize State and Federal needs for flexibility.

Information on this process and evaluation is contained in Section II of the Report.

Once basic program elements were identified, the Working Group next developed and evaluated a range of possible options for a national program. After defining the current national regulatory program (the base case option), five other options were developed and evaluated. Options ranged from allowing all States to independently regulate all radioactive materials without Federal oversight, to a structure with only one regulatory entity having jurisdiction over all radioactive material in the United States. The presentation and evaluation of options is contained in Section III of the Report. A matrix which summarizes and compares the options is attached (Attachment 2). The resources presented in Attachment 2 represents estimates of NRC resources under each option and do not include estimates of Agreement State resources.

Attachment 3 provides additional information on the option and resource estimates.

After evaluating comments from stakeholders, considering the advantages and disadvantages of each option, and considering potential resource implications, the Working Group recommends that the Commission adopt a cooperative, consensus option for a national program. The Working Group believes that this recommendation, the Alliance Option, has the best potential for achieving NRC's current strategic goals, as well as the goals and objectives of a future National Materials Program. The Working Group believes the Alliance Option offers the prospect of leveraging NRC's program by joining in a continuing collaborative process with other regulators (the Agreement States) to jointly establish national priorities and agendas, share resources, and develop regulatory products.

The Report recommends that an Implementation Plan be developed to guide and evaluate the transition to the alliance structure, or to develop implementing details of another option or blending of options (see discussion below).

The Working Group's Report also recommends several components (i.e., enhancements) that could be used with or without changes to the current national structure. The feasibility of these types of enhancements is also being evaluated by the staff as part of other ongoing initiatives. The recommendations and components are contained in Sections IV and V of the Report. Enhancements to the current program are also discussed in Section II of the Report.

In developing options for the Commission's consideration, the Working Group also addressed the following six issues as specified in SECY-99-250:

1. Development of an overall program mission statement with defined "top level" goals and objectives.
2. Delineation of the respective roles and legal responsibilities of NRC and the Agreement States, including the Organization of Agreement States (OAS) and the CRCPD.
3. Delineation of the scope of activities to be covered by the program and the need for statutory changes at both State and Federal levels.
4. Establishment of formal program coordination mechanisms.
5. Establishment of performance indicators and a program assessment process to both measure program performance and to ensure program evolution.
6. Provision/Budgeting of resources at both State and Federal levels.

Section VI of the report provides the Working Group's response to these issues.

COMMISSION CONSIDERATION OF THE WORKING GROUP REPORT

The Working Group Report represents a major milestone in the process of examining options and helping determine the future framework for a National Materials Program. The options reflect a range of possibilities from all States independently assuming regulatory responsibility to NRC reasserting regulatory jurisdiction across the nation. The Report also examines options between these extremes, such as the Alliance option. In addition, each option can be varied to create unique "sub-options" within an option, or program details of individual options can be combined to create an entirely new option. Therefore, the Commission may want to consider the larger universe of options that may be possible through such blending of

individual program details within each option when examining the report, its recommendations, and when examining possible options for a National Materials Program.

Blending of the program details of one or more option into a new option will change the relative level of NRC resources that might be needed to implement that new option. The resources in Attachment 2 only represent NRC's resources under each option. The matrix does not make any assumption about how each Agreement State would participate if the option was selected and thus does not include an estimate of Agreement State resources. This could have a significant implication for the net national program.

The resource estimates are directly dependent on the specific program assumptions reflected in each option. These assumptions can be varied, or individual assumptions can be combined which, in turn, will reflect a corresponding difference in the resource estimate. Thus, the Commission could examine, for example, the relative change in resources that could result from variations in the Current (Base Case) Program option by selecting different assumptions. (e.g., The Commission could choose to move towards the Alliance option only for certain activities such as guidance development and maintenance.) The matrix in Attachment 2 can be expanded to represent such other options and can help identify the resulting relative resource differences if such decisions were to be considered or directed by the Commission.

Depending on the option selected, or the blending of options selected by the Commission, additional work will be needed to further evaluate and develop implementing details for that option. To assist in helping develop additional supporting information, the Commission may wish to consider selecting an option or sub-option for further analysis through a pilot program. For example, the OAS, working through an alliance process, could be requested to assume responsibility for maintaining one or more (or all) of the NUREG-1556 consolidated materials guidance series up-to-date and available to both NRC and the Agreement States. Other examples, such as Agreement State assumption of responsibility for the development of amendments to certain materials rules, could also be considered as additional pilot programs. Continued development and testing of the approach selected for working with the Agreement States is important to gaining an understanding of the processes needed, and the resources necessary to conduct work in an efficient and effective manner. In addition, it will allow all of the organizations to understand the roles, responsibilities, and level of commitment that will be necessary for success.

PUBLIC AVAILABILITY OF THE WORKING GROUP REPORT

At the public meeting held in Arlington, Texas in February 2001, stakeholders, including individual Agreement State representatives, suggested that the Working Group's Report be released as soon as it is completed. The Working Group agrees with this suggestion and asks that the Commission give priority to releasing the Report as soon as possible.

RESOURCES:

Staff estimates that about 2-3 FTE (NMSS, STP and OGC) would be required to work with the Agreement States to further develop the next steps following Commission direction, such as development of an implementation plan for a specific option. Staff estimates that about 0.5-1.0 FTE would be required to work with the Agreement States on an additional pilot program, such as transferring one or more of the NUREG-1556 guidance documents to the Agreement States for maintenance. Resources for such follow-on work are not explicitly reflected in the Materials Arena budget, and would need to be reprogrammed from the existing budget.

COORDINATION:

The National Materials Program Steering Committee has reviewed the Report and believes it provides a sufficient range of options and analysis to facilitate Commission consideration. Committee members include the Deputy Executive Director for Materials, Research and State Programs (DEDMRS); the Chief Financial Officer; the Associate General Counsel for Licensing and Regulation; the Directors of Nuclear Material Safety and Safeguards (NMSS) and State and Tribal Programs (STP); the Director of the Division of Industrial and Medical Nuclear Safety (IMNS); Division of Nuclear Materials Safety (DNMS) Directors from Regions II and III; and Agreement State Program Managers from Massachusetts and California.

RECOMMENDATION:

Staff requests that the Commission approve the Working Group's request for early release of the Report.

/RA/

William D. Travers
Executive Director for Operations

Attachments:

1. Final Working Group Report
2. Comparison of Options Table
3. Description of Options and Assumptions
for Resource Estimate

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IRA/

William D. Travers
Executive Director for Operations

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OFFICE	OGC		NMSS:D		CFO		STP:D		DEDMRS		EDO	
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ATTACHMENT 1

**FINAL REPORT OF THE WORKING GROUP
ML011590426**

ATTACHMENT 2
COMPARISON OF OPTIONS TABLE

Comparison of Options Table

	Current Program (Base Case)	Independent States	Minimum NRC Involvement	Alliance	Delegated Program	Single Regulatory Agency
Change in AEA required	No	Yes (Agreements)	No	Yes (NARM)	Yes (Agreements and NARM)	Yes (Agreements and NARM)
Agreement States	Yes	No	Yes	Yes	No	No
# of Agreement States Assumed	32	0	32	32/50	0	0
NRC jurisdiction over federal facilities	Yes	Yes	Yes	Yes	Yes	Yes
No. of state programs possible	32	50	32	32/50	0	0
No. of states where NRC has jurisdiction	18	0	18	18/0	50	50
NRC licensing	Yes	Yes	Yes	Yes	Yes	Yes
NRC physical inspection	Yes	Yes	Policy Dependent	Yes	Yes	Yes
Guidance development	Yes	Yes	Policy Dependent	Yes	Yes	Yes
Rule development	Yes	Yes	Yes	Yes	Yes	Yes
Evaluation of state regulatory programs	Yes	No	Yes	Yes	Yes	Yes
IMPEP	Yes	No	No	Yes	No	No
Estimated NRC resources in millions and (FTE)	\$55(336)	\$3.7(23)	min. support \$36.7(269) min. program \$32.0(200)	32 states - \$51.6(315)/ 50 states - \$24.7(135)	\$76(368)	\$113(744)

ATTACHMENT 3

DESCRIPTION OF OPTIONS AND ASSUMPTIONS FOR RESOURCE ESTIMATE

DESCRIPTION OF OPTIONS AND ASSUMPTIONS FOR RESOURCE ESTIMATES

Base Case. To estimate resources for the various options, the Working Group first defined the Base Case. The Working Group began with the resource numbers in the NRC FY 2001 budget in the Materials Arena. In its Base Case the Working Group did not include resources for activities that would not be subject to regulation by Agreement States (fuel cycle activities and support for spent nuclear fuel). The Working Group then added resources for low-level waste, decommissioning, and uranium recovery activities from the Waste Arena because those activities are subject to regulation by Agreement States. The Base Case also includes resources to maintain the framework for materials regulation (State and Tribal Programs, legal advice and support, research, enforcement, investigations and event assessment) and the NRC efforts to support the materials program (resources providing policy, financial, administrative, information technology infrastructure, personnel support, rent, utilities, building maintenance). The Base Case is estimated to be about \$55 million, including salaries and benefits for 336 FTE.

Independent States Option. The first option compared to the Base Case is the Independent States option. This option assumes that a change in the Atomic Energy Act (AEA) abolishes NRC's materials program for those categories of materials which are currently subject to regulation by agreements with States. The option assumes NRC would maintain its authority over Federal entities, in areas of exclusive Federal jurisdiction and over AEA materials in Guam, Puerto Rico, U. S. Virgin Islands, and the District of Columbia (unless those entities desired to become an Agreement "State" as provided by Section 274 (n)). The Working Group included this as an extreme to bound the options, though the group determined that it probably would not meet the mandatory goal of protecting public health and safety. Resource estimates do not consider the effort necessary to achieve this statutory condition.

The option assumes an NRC licensee population of about 500 licensees, with corresponding reductions in NRC licensing and inspection direct staff and support. Because NRC's oversight of State materials regulatory programs would no longer be required (there would be no Agreement States), and virtually all AEA materials licenses would be turned over to the States, many program elements currently residing at NRC, such as the Office of State and Tribal Programs and the Office of Nuclear Material Safety and Safeguards (NMSS) support of State activities would disappear completely. Additional resource decreases are found in the areas of research, investigations, and rule and guidance development.

Minimum NRC Options. During the course of its evaluations, the Working Group examined a number of options under which the NRC would minimize its activities in materials regulation. All of the options assume that NRC would maintain authority over AEA materials, including a voluntary Agreement State program. NRC would streamline its operations to continue to meet the minimum requirements of the AEA. The Minimal Options assume NRC makes dramatic policy changes in executing its obligations. For example, the AEA requires that the NRC take a leadership role in regulation of AEA materials throughout the U.S., but does not define the level of effort required to meet that statutory obligation.

The Working Group compared two Minimum NRC Options to the Base Case. The first option, the Minimum Support Option, assumes NRC's resources in support of the national program are

significantly reduced and efforts are focused on NRC's licensees. As a result, the NRC licensing and inspection programs do not change, but rule and guidance development are reduced substantially. The general license program is assumed to support follow-up activities for a second round of registrations. The Nuclear Materials Events Database (NMED) and event evaluation support only NRC's licensees, and resources are reduced accordingly. The orphan source and low-level radioactive waste programs are eliminated and State Program activities are limited to interactions with perspective Agreement States, review of Agreement States, and reduced interactions with the Organization of Agreement States (OAS) and the Conference of Radiation Control Program Directors, Inc. (CRCPD).

The second Minimum Option, the Minimum NRC Program Option, assumes reductions in support for elements of NRC's regulatory program not specifically identified in the AEA. Consequently, the NRC's onsite inspection program is eliminated with the exception of those inspection activities associated with NRC's response to licensee incidents. Additionally, the option assumes there is no materials research, guidance development, Integrated Materials Performance Evaluation Program (IMPEP), orphan source program, grants for terminated sites in Agreement States, and no NMED.

Alliance Option. The Alliance option is the option which is most similar to the Base Case. The option is characterized by the collaborative identification, prioritization and development of regulatory products (rules and guidance) necessary for support of the national program. NRC resource changes are characterized by reductions in rulemaking and the development of licensing and inspection guidance. The Working Group considered two options, one with the current number of Agreement States, the other assumes there are 50 Agreement States.

Delegated Program. The Delegated Program assumes the Agreement States program is abolished, leaving the entire materials regulatory program to be run by the NRC. NRC is given authority to delegate licensing and inspection activities to the States, and all States voluntarily enter into such agreements. The Delegated Program is assumed to be similar to the current FDA program for mammography. As with the Independent States option, the resource estimates do not include the efforts to achieve this statutory condition. NRC staff would negotiate the terms of a delegated program with each State and set up a policing function, similar to IMPEP, to assure consistency across the delegations. NRC would also develop licensing and inspection guidance, evaluate licensee events, take enforcement actions and conduct adjudications for all licensees. Because of their specialized nature, uranium recovery activities are assumed to be outside of the delegated program.

In estimating the costs of the delegated program, State FTE are assumed to be the same as NRC FTE to license and inspect an equivalent number of licensees and State salaries were assumed to be about 60 percent of the NRC's costs for salaries and benefits.

Single Regulatory Agency Option. Under the Single Regulatory Agency Option, NRC licensing and inspection resources are assumed to increase fourfold to accommodate the licensees in the former Agreement States. Resources for investigations, enforcement and adjudications also increase proportionately to the licensee increase. Resources do not change for rulemaking and guidance development. Resources for low-level radioactive waste regulation were estimated by summing identified current Agreement State resources in this area. The Agreement States program is eliminated.

Status: NUREG 1556 Vol. 9

Status: Board Recognitions

Updated Status on NRC Board Recognitions

ACMUI Meeting

February 20, 2002

Boards Applying for Recognition

- American Board of Nuclear Medicine
- Board of Pharmaceutical Specialties
- American Board of Medical Physics
- American Board of Health Physics
- American Board of Radiology

Boards Applying for Recognition

- American Board of Nuclear Medicine
- American Board of Radiology
- American Board of Science in Nuclear Medicine
- Certification Board of Nuclear Cardiology

American Board of Medical Physics

- Recognition under §35.51(a) requested
- Full recognition not possible due to lack of requirement to complete training for all specific modalities:
 - ◆ Remote Afterloader
 - ◆ Teletherapy
 - ◆ Gamma Knife
- Partial recognition may be possible

Update on Status of Previously Discussed Board Submissions

- American Board of Health Physics
 - ◆ Problems:
 - ◆ One year of full-time radiation safety experience with similar types of byproduct materials not required
 - ◆ Written certification of experience signed by a preceptor RSO not required

American Board of Nuclear Medicine

- Letter to ABNM, dated June 29, 2001, granting NRC recognition for:
 - ◆ §35.190
 - ◆ §35.290
 - ◆ §35.390
 - ◆ §35.392
 - ◆ §35.394
- Not granting NRC recognition for RSO authorizations under 35.50(a), but pointing out alternative pathway under 35.50(c)

Certification Board of Nuclear Cardiology

- Requests recognition of the board diplomats under 35.290
- No outstanding issues – NRC recognition expected to be granted

Points for Discussion

- Key Issues:
 - ◆ RSO authorizations
 - ◆ A large number of Boards have requested recognition under §35.50(a) but none document requiring:
 - one year full time medical materials experience
 - Absence of a requirement for signed preceptor statements in board certification process
 - ◆ Many Board diplomates do qualify under §35.50(c)

Points for Discussion

- Key Issues (continued):
 - ◆ Medical physics authorizations
 - ◆ Lack of Board requirements for specified training in all modalities
 - ◆ Absence of a requirement for signed preceptor statements in board certification process
 - ◆ Partial Medical Physics Board recognition for selected modalities possible

Points for Discussion

- Key Issues (continued):
 - ◆ Generic
 - ◆ Applicable to all Boards, except ABNM and CBNC
 - Absence of a requirement for signed preceptor statements in accordance with the New Part 35 requirements in various board certification processes
 - Several Boards have certification and/or requirements for written recommendation
 - ◆ In some cases slight changes to existing certification requirements could bring these Boards into compliance

Grandfathering under §35.57(a)

- Covers RSO, medical physicist, and nuclear pharmacist
- Based on a review of the Statements of Consideration
 - ◆ Clear that presently authorized medical physicists will retain only those authorizations for which they are presently authorized at the time of conversion from old to new 10 CFR Part 35
 - ◆ Qualified individuals may obtain new authorizations prior to new Part 35

END

Update: New IVB Devices

IAEA Patient Protection

Mixed Doses

ACMUI MEETING

February 20, 2002

TOPIC: Mixed Doses

NRC CONTACT: Joe DeCicco, NMSS/IMNS (301) 415-7833
Fred Brown, NMSS/IMNS (301) 415-8731

BACKGROUND:

This very brief presentation will provide the ACMUI with the updated information of what actions have been taken since the last meeting, and the planned course of action addressing the issue of dose assessment when fluoroscopy exposure is received along with exposure to NRC-licensed sources. Regulations provide some latitude of NRC to adopt guidance, as noted in the footnote to the table of weighting factors in the definition paragraph of 10 CFR Part 20. Guidance has been developed in a draft Regulatory Issues Summary (RIS) that is currently out to State regulatory agencies for comment, prior to issuing the RIS to licensees. The draft RIS is provided to the ACMUI members; details of the Draft RIS will not be discussed because of its pre-decisional nature.

ACMUI Minutes Dist.

Oct. 24, 2001 Sum Minutes

SUMMARY MINUTES FOR THE MEETING OF THE ADVISORY COMMITTEE ON THE
MEDICAL USES OF ISOTOPES
OCTOBER 29, 2001

The Advisory Committee on the Medical Uses of Isotopes (ACMUI) held its semiannual meeting at the U.S. Nuclear Regulatory Commission (NRC) in Rockville, Maryland, on October 29, 2001.

ACMUI members present at the meeting were:

Manuel Cerqueira, MD	Nuclear cardiologist, ACMUI Chairman
David A. Diamond, MD	Radiation oncologist
Nekita Hobson	Patients' rights advocate
Ralph Lieto	Medical physicist (designee)
Leon Malmud, MD	Healthcare administrator (designee)
Ruth McBurney	State representative
Subir Nag, MD	Radiation oncologist
Sally W. Schwarz	Nuclear pharmacist
Richard J. Vetter, PhD	Radiation safety officer
Jeffrey F. Williamson, PhD	Radiation therapy physicist

The following NRC staff members were present:

Robert Ayres, PhD	NMSS/IMNS/MSIB
Frederick Brown	NMSS/IMNS/MSIB
Donald Cool, PhD	Division Director, NMSS/IMNS
Patricia Holahan, PhD	NMSS/IMNS/RGB
Donna-Beth Howe, PhD	NMSS/IMNS/MSIB
Mark Sitek	NMSS/IMNS/MSIB
John Szabo	OGC
Angela Williamson	NMSS/IMNS/MSIB

Invited guests present at the meeting:

Jeffrey Brinker, MD	Society for Cardiac Angiography and Interventions
Geoff Ibbott, PhD	American Association of Physicists in Medicine

The meeting came to order at 8:13 a.m.

Opening Remarks

Dr. Manuel Cerqueira welcomed everyone to the meeting. He introduced Mr. Ralph Lieto and Dr. Leon Malmud as new members to ACMUI.

Follow-Up to Items from Previous Meeting

Angela Williamson read the recommendations from the April 18, 2001 meeting, and gave NRC's response to each recommendation. This presentation begins on Page 22 of the meeting transcript.

10 CFR Part 35 Status/Update

Patricia Holahan updated the Committee on the current status of 10 CFR Part 35 (also known as Part 35). She informed the Committee that NRC received Office of Management and Budget (OMB) approval of the collection requirements contained within the new Part 35. OMB granted this approval on September 19, 2001. She also informed the Committee that the new Part 35 has not been published because of the Senate's proposal of language that would impact NRC's ability to implement the new rule, and informed the Committee that the House and the Senate were in conference to come to an agreement regarding the Senate's proposed language. Finally, she informed the Committee that the regulatory guide to accompany the new Part 35, NUREG 1556, Vol. 9, has been completed but is on hold pending the new Part 35's publication. This presentation begins on Page 29 of the meeting transcript.

Status of Certification Boards/Medical Physicist Qualification Criteria

Robert Ayres, NRC, and Dr. Geoff Ibbott, American Association of Physicists in Medicine (AAPM), gave presentations on this topic. Dr. Ayres informed the Committee on NRC's progress toward evaluation of various boards' abilities to certify their medical physicists' credentials against the training and experience requirements contained in the new Part 35. Dr. Ayres' presentation begins on Page 53 of the meeting transcript.

Dr. Ibbott's presentation was a discussion of what he believed would be the effects – upon the medical physicist community – of the new Part 35's training and experience requirements for physicists. This presentation begins on Page 171 of the meeting transcript.

The Committee made the following recommendation to staff on this topic:

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 needs to re-discuss this recommendation with ACMUI. Staff plans to do so during the Spring 2002 meeting. After further discussion and clarification, staff will draft a response to this recommendation, and will forward that response to the Commission.

Update on Intravascular Brachytherapy

Two persons spoke on this topic: Dr. Jeffrey Brinker of the Society of Cardiac Angiography and Interventions, and Dr. Donna-Beth Howe, NRC. Dr. Howe gave an update on NRC's latest guidance, which had already been distributed to assist professionals in safely conducting the intravascular brachytherapy (IVB) procedure. She indicated that NRC is no longer requiring the presence of three persons during IVB (i.e., the authorized user; the medical physicist; and an interventional cardiologist). The Committee discussed the advisability of no longer requiring three persons to be present during IVB. This presentation begins on Page 97 of the meeting transcript.

Dr. Brinker discussed what he believed to be the appropriate approach to determining how many professionals should be present during IVB. His comments begin on Page 103 of the meeting transcript.

Regulation of Mixed Occupational Doses involving both NRC-regulated Material and Fluoroscopy

Frederick Brown spoke on this issue. He indicated that the Agency was trying to address cases involving radiation doses from both NRC-regulated radioactive material, and NRC non-regulated radioactive material (i.e., "mixed doses"). This presentation begins on Page 147 of the meeting transcript.

Determination on when to Recommend Radiation-exposed Individuals to Physicians for Treatment

Mr. Mark Sitek made a presentation on this topic. This topic was not an agenda item, but was addressed at the Committee's request. In this presentation, Mr. Sitek outlined NRC's guidance that cites the dose thresholds at which acutely exposed individuals should be referred to a physician. He informed the Committee that NRC's guidance includes a recommendation that physicians contact the Radiation Emergency Assistance Center/Training Site for more information on how to treat acutely exposed persons. This presentation begins on Page 201 of the meeting transcript.

The meeting concluded at 2:39 p.m.

F/U: ACMUI Recommendation

ACMUI Spring 2002 Member List

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Spring 2002**

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Nuclear Medicine Physician**Interventional Cardiologist**