

**Advisory Committee on the Medical Uses of Isotopes
Reporting Structure Background Information
January 7, 2011**

This document contains pre-decisional information. The following information was provided to members of the Advisory Committee on the Medical Uses of Isotopes (ACMUI), by request of the Committee, for information only. The information was not reviewed by NRC management prior to distribution. The information in this document may or may not be reflected in a future Commission paper.

Purpose

NRC staff is seeking input from ACMUI members on the ACMUI's reporting structure. NRC staff is providing this document, "ACMUI Reporting Structure Background Information," to aid the Committee in formulating its recommendation(s) on this issue. NRC staff is not planning to send the draft Commission paper to the ACMUI for concurrence, but staff will include the ACMUI's unfettered views in the paper, as staff wishes to ensure that the ACMUI's preferences are clearly communicated to the Commission.

Background

Commission Direction

In response to Staff Requirements Memorandum dated July 21, 2010, "Briefing on Proposed Rule on Part 35 Medical Events Definitions – Permanent Implant Brachytherapy (SRM-M100708B)," the staff will work with OGC to provide the Commission a paper outlining possible improved mechanisms for providing the Commission with the ACMUI's feedback regarding medical issues, including the pros and cons of restructuring ACMUI such that it reports to the Commission. This paper will provide an implementation plan that would be used to affect such a restructuring should the Commission decide to move forward.

ACMUI

ACMUI advises NRC staff on policy and technical issues that arise in the regulation of the medical uses of radioactive material in diagnosis and therapy. The ACMUI membership includes health care professionals from various disciplines who comment on changes to NRC regulations and guidance; evaluate certain non-routine uses of radioactive material; provide technical assistance in licensing, inspection, and enforcement cases; and bring key issues to the attention of the Commission for appropriate action.

As an official advisory body to the NRC staff, the ACMUI's operational practices are governed by the provisions of the Federal Advisory Committee Act (FACA). Advisory committees are structured to provide a forum where experts representing many technical perspectives can provide independent advice that is factored into NRC's decision-making process. ACMUI members are appointed by the FSME Director in consultation with the Commission, and the majority of ACMUI activities, particularly those related to 10 CFR Part 35, are addressed by staff in FSME.

See Attachment 1 for organization chart.

ACRS

The Advisory Committee on Reactor Safeguards (ACRS) is statutorily mandated by the Atomic Energy Act of 1954, as amended. The Committee has four primary purposes: to review and report on safety studies and reactor facility license and license renewal applications; to advise the Commission on the hazards of proposed and existing production and utilization facilities and the adequacy of proposed safety standards; to initiate reviews of specific generic matters or nuclear facility safety-related items; and to provide advice in the areas of health physics and radiation protection.

At the request of the Commission, the ACRS also reviews the NRC's Research Activities and provides a biannual report (NUREG-1635) to the Commission. Upon request from the Department of Energy, the ACRS reviews and provides reports on U.S. Naval reactor designs under a reimbursable agreement. Upon request, and with the Commission's consent, the ACRS is required to provide advice to the Defense Nuclear Facilities Safety Board in accordance with Public Law 100-456.

The ACRS is independent of the NRC staff and reports directly to the Commission, which appoints its members. The operational practices of the ACRS are governed by the provisions of the Federal Advisory Committee Act (FACA). ACRS activities span across many offices at the NRC, including the Office of Nuclear Reactor Regulation, Office of New Reactors, Office of Nuclear Materials Safety and Safeguards, Office of Research, and Office of Nuclear Security and Incident Response.

See Attachment 2 for organization chart.

Options for ACMUI Structure

Staff proposes the following two options for the ACMUI reporting structure. Staff recommends Option 1.

1. Report to MSSA Director in FSME. This is the current structure with a change in procedure for providing ACMUI viewpoints to Commission. In accordance with SRM-M100708B, staff is developing internal guidance to include ACMUI recommendations and dissenting views along with the staff's assessment of the ACMUI recommendations and dissenting views for all major medical policy issues submitted to the Commission, including proposed and final rules.
 - a. Pros
 - i. Use existing FSME staff for administrative, technical, and managerial support. (Note: ACMUI has requested additional technical and administrative staff support for interactions with the Committee due to the increasing workload and use of subcommittees.)
 - ii. FSME staff access to ACMUI as medical consultants
 - b. Cons
 - i. Perception of limited Commission access to ACMUI
 - ii. Perception of diminished status of ACMUI

OR

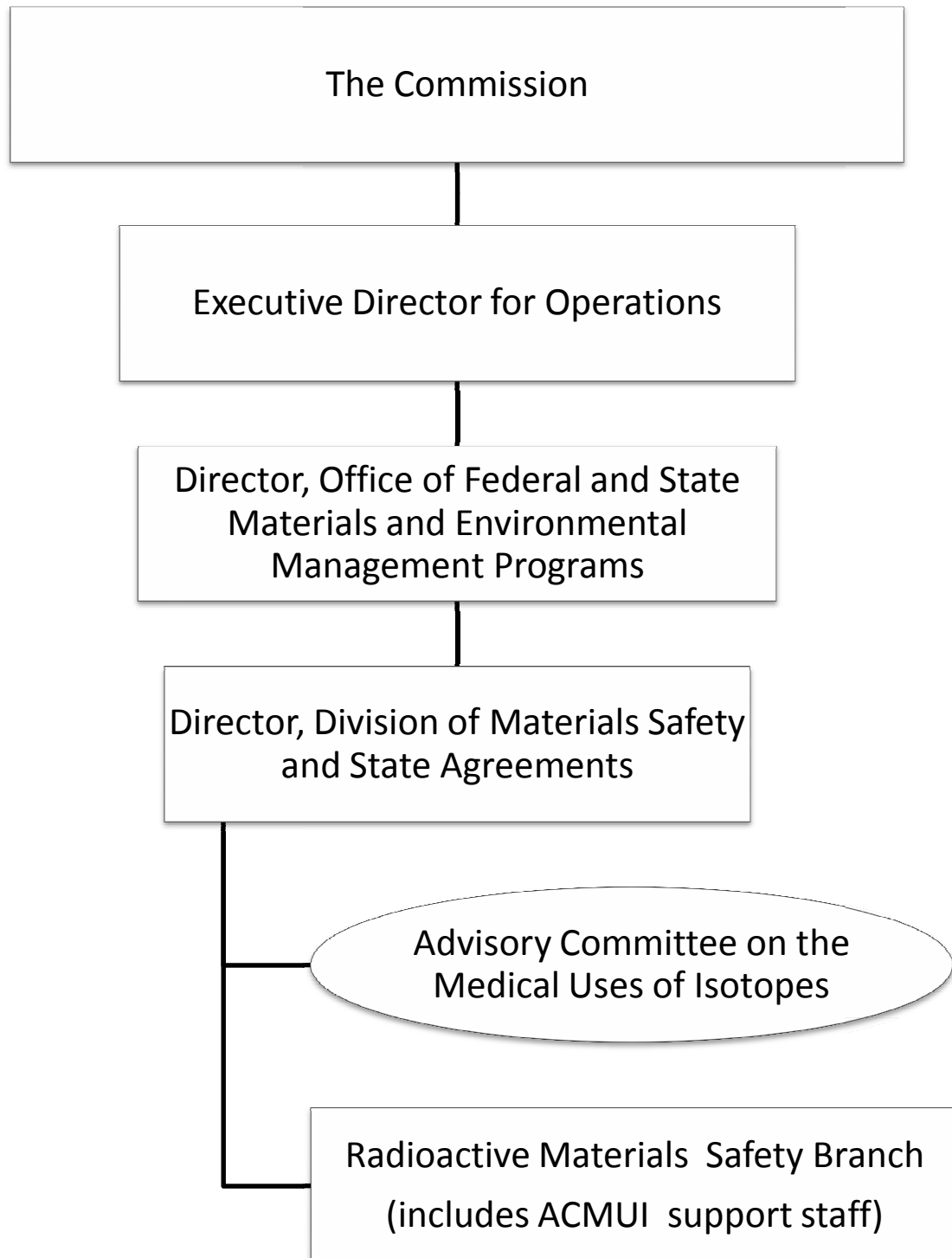
2. Report to Commission through Executive Director, Advisory Committee on Reactor Safeguards (ACRS): ACRS to provide general support for ACMUI including hiring, meetings, publications, etc., technical support, and administrative support.

- a. Pros
 - i. Enhanced Commission access to medical experts
 - ii. Enhanced ACMUI access to ACRS facilities and support staff for meetings
- b. Cons
 - i. 3-4 FTE increase in ACRS for new staff for technical and managerial support. (See Attachment 3 for justification provided by ACRS Director)
 - ii. Use of existing ACRS staff for administrative support may cause resource burden on ACRS or diminish their support for ACRS
 - iii. Potential reduced FSME staff access to ACMUI members as medical consultants due to conflict of interest or ACMUI member time constraints.
 - iv. FTE increase in FSME for hiring or contracting of FSME medical experts (e.g., radiation oncologist, nuclear pharmacist, nuclear medicine physician), due to reduced FSME staff access to ACMUI as medical consultants (FSME to provide FTE estimates).
 - v. Potential increase in ACMUI workload (>2 meetings/year, additional subcommittees, etc.) and higher expectations of members.

ACMUI Feedback from January 5, 2011 Teleconference

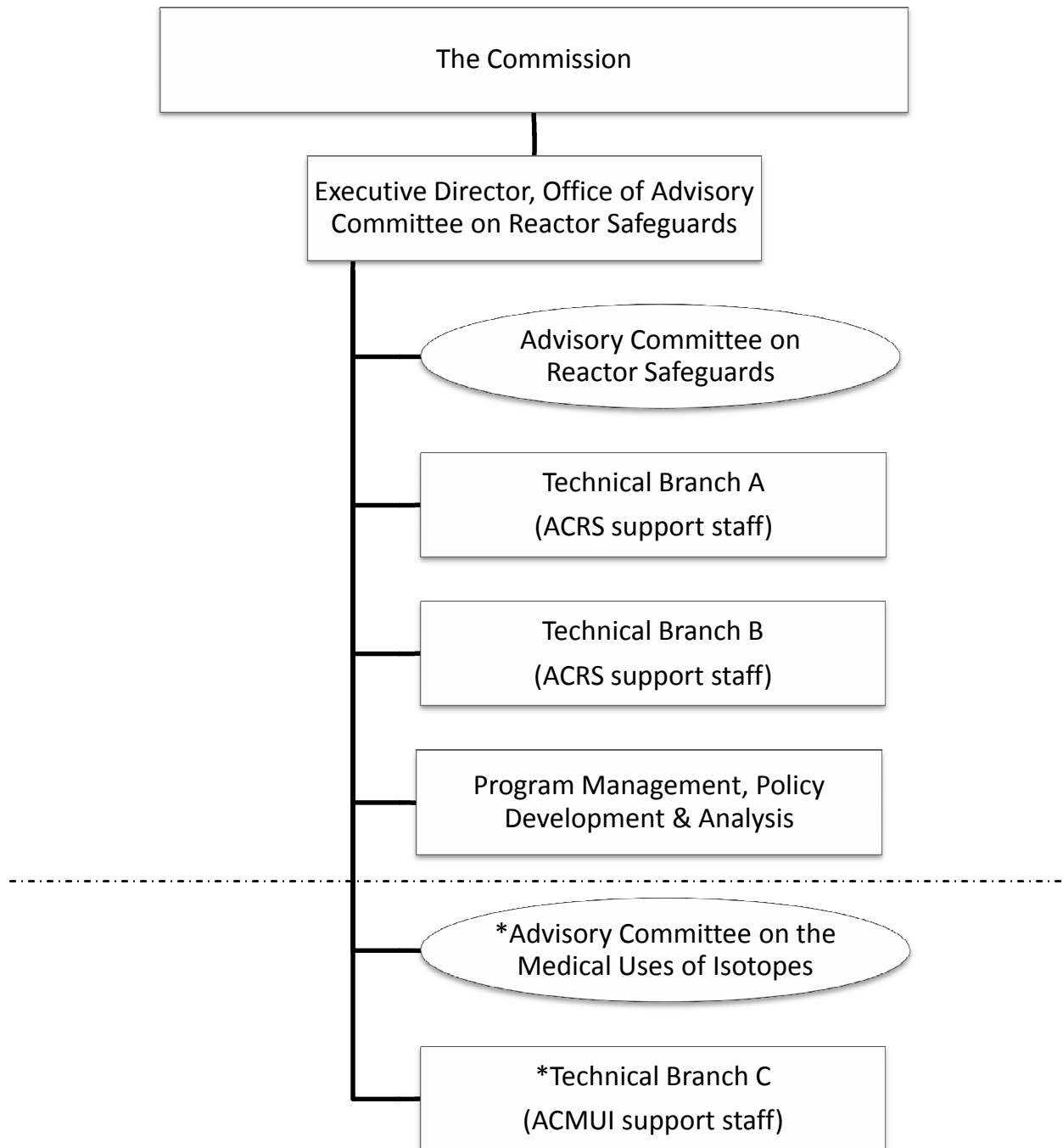
NRC staff should maintain the current reporting structure for the ACMUI with enhancements in communication, as described in FSME Policy and Procedure 2-5, and increased support staff. Dr. James Welsh made the recommendation, which was seconded by Dr. Pat Zanzonico. Drs. Susan Langhorst and Milton Guiberteau suggested the motion be tabled for further discussion at the January 12, 2011 teleconference meeting.

ATTACHMENT 1 – Current ACMUI Structure (Option 1)



ATTACHMENT 2 – Current ACRS Structure

***Proposed Structure, if ACMUI Reports to Commission (Option 2)**



ATTACHMENT 3 – Budget Increase Justification from ACRS Executive Director

Resource estimates are provided below for the FSME Commission paper to cover the eventuality that the Commission decides to bring ACMUI under the ACRS Office (Option 2). However, ACRS concurs with FSME's recommended position that the ACMUI remains under FSME (Option 1).

Assumptions

Continuation of 13 ACMUI Members;
ACMUI meets 2X per year;
ACMUI produces approximately 10 reports per year;
ACMUI meets with the Commission 1X per year;
ACRS would be responsible for all of the ACMUI logistical support and some technical support.

Level of Effort

Given the above assumptions, ACMUI would require approximately 15%-20% of the current ACRS level of effort, but it would be somewhat leveraged by resources ACRS already has in place.

Proposed Additional Resources

This level of effort would indicate an additional 3-4 FTE between technical support and logistical support and approximately \$1M additional in contract support.