

**FSME Policy and Procedures 2-5**  
**REVISION 0**  
**{DATE}**

**FSME PROCEDURE FOR INTERACTING WITH THE ADVISORY COMMITTEE ON THE MEDICAL USES OF ISOTOPES DURING DEVELOPMENT OF MAJOR MEDICAL ISSUES**

**1. PURPOSE:**

This Federal and State Materials and Environmental Management Programs (FSME) Policy and Procedure (P&P) defines and documents FSME staff guidance and procedures for interfacing with the Advisory Committee on the Medical Uses of Isotopes (ACMUI) during the development of major medical policy issues including medical rulemakings that will be reviewed by the Commission. ACMUI provides advice, as requested by the Director, Division of Materials Safety and State Agreements (MSSA) on policy and technical issues that arise in regulating the medical use of byproduct material for diagnosis and therapy. The ACMUI also raises issues of concern to the medical community to the U.S. Nuclear Regulatory Commission (NRC).

**2. BACKGROUND:**

In a Staff Requirements Memo (SRM) dated July 21, 2010 (M100708B-Briefing on Proposed Rule on Part 35 Medical Events Definitions-Permanent Implant Brachytherapy, July 8, 2010), the Commission directed the staff to develop internal guidance that requires the staff 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 that are submitted to the Commission, including proposed and final rules.

Major medical use policy issues include changes to the Code of Federal Regulations (i.e., rulemaking), as well as certain changes in medical use licensing and inspection guidance and other medical use policy issues that will require Commission review and/or approval. Determination of the status of a medical issue as a major medical policy issue will be made by the MSSA Director or the Director, Division of Intergovernmental Liaison and Rulemaking (DILR). Major medical policy issues may be legally sensitive or significantly impact the public, patients or human research subjects, medical use licensees or stakeholders, or the Agreement States.

Changing the Code of Federal Regulations (i.e., rulemaking) is a significant action. Adding, deleting, or revising regulations impacts licensees, certificate holders and other stakeholders. For this reason, MSSA staff should draft a regulatory basis as a robust foundation for the rulemaking before a rulemaking begins. The regulatory basis should contain the justification for a rule and describe the technical, legal, or policy information that supports the rulemaking and provides a basis for informed decisions during the rulemaking.

Rules that could affect medical activities would require the MSSA to seek input from the ACMUI prior to initiation of the rulemaking. The level of input may range from very little ACMUI involvement (e.g., a recommendation from the ACMUI to support MSSA's proposed revisions to the regulations) to very extensive ACMUI involvement (e.g., a report with information to be used in the regulatory basis).

If during the rulemaking process, MSSA determines it is necessary to make fundamental changes to the regulatory basis due to issues identified by MSSA or the ACMUI, such changes must be reflected in an amended regulatory basis. This will require that work must stop on the rulemaking and that the amended regulatory basis be provided to the rulemaking working group (WG). If this happens, DILR will inform the Executive Director of Operations (EDO) and the Office of the Secretary of the Commission (SECY) that rulemaking schedule needs to be rebaselined. A formal request to the EDO and SECY for rebaselining will follow when DILR has accepted the amended regulatory basis.

### **3. ROLES AND RESPONSIBILITIES**

#### **3.1 Rulemaking**

- 3.1.1** In DILR, Rulemaking Branches (RB) A, and B, have the overall responsibility for the preparation of rulemaking packages. The rule package includes the *Federal Register* notice (FRN) for the proposed or final rule, as well as the appropriate supporting documents (e.g., a regulatory analysis, an environmental assessment, a backfit analysis, Congressional letters, State liaison letters, Agreement State letters, and a press release). In addition, the Office of Management and Budget (OMB) supporting statements are needed for rules with information collection requirements.
- 3.1.2** The MSSA, Radioactive Materials Safety Branch (RMSB), has the primary responsibility of seeking input from the ACMUI on any proposed or final rulemakings that may affect medical uses of radioactive materials.

#### **3.2 Other Major Medical Policy Issues**

The MSSA, RMSB, has the primary responsibility of seeking input from the ACMUI on any proposal that constitutes a major policy issue that may affect medical uses of radioactive materials and will eventually need review or approval from the Commission.

### **4. PROCEDURES**

#### **4.1 Proposed Rules:**

After acceptance of the regulatory basis for a proposed rulemaking, the Branch Chief (RBA or RBB) will assign a project manager (PM) to lead the rulemaking in accordance with FSME P&P 6-10 entitled, "FSME Procedures for Preparation and Review of Rulemaking Packages."

The RB PM will work with the WG members to prepare a draft package for the proposed rule.

A draft version of the proposed rule FRN may be provided electronically to the ACMUI PM at the point at which the rulemaking PM and the MSSA WG member believe it to be substantially complete. The ACMUI PM will distribute the draft proposed rule FRN to the ACMUI members for their review and comment. The ACMUI PM may indicate that the documents are predecisional and cannot be publicly released, unless authorized by NRC staff. In accordance with an SRM

dated October 25, 2007 (SECY-07-0134 Evaluation of the Overall Effectiveness of the Rulemaking Process Improvement Implementation Plan), the FSME Director may authorize the release of draft rule text, statements of consideration, and the technical basis for public review and to hold workshops prior to submission of a proposed rule to the Commission.

ACMUI will review the draft rule and consolidate its comments into an ACMUI position. The ACMUI position may include dissenting views of individual ACMUI members. The ACMUI will be given 90 days to complete its review and provide comments. In some cases, the ACMUI may find that additional discussion or information is required to provide quality opinions and request that more time be allotted. The MSSA Director may grant an extension on a case-by-case basis.

The RB PM, in concert with the WG members, will address comments from the ACMUI in the preparation of the final proposed rule package. If comments are substantive or if the draft rule has significant changes, DILR will reissue the package to the appropriate offices for concurrence. The Commission Paper should include a discussion of the staff's interaction with the ACMUI. The Commission paper must specifically include ACMUI comments/recommendations, any dissenting opinions from ACMUI members, plus staff's assessment of ACMUI recommendations and dissenting views and the basis for incorporating or not incorporating ACMUI recommendations into the proposed rule.

After Commission approval, the proposed rule will be published in the *Federal Register* for public comments. The standard public comment period is 75 days.

#### 4.2 Final Rules:

After the public comment period is over, the RB PM will hold periodic meetings with the WG or with specific members to resolve all of the comments received. The RB PM will review the responses to ensure the comments have been appropriately addressed. The RB PM and WG members should identify any controversial issues to management at an early stage.

A draft version of the final rule FRN may be provided electronically to the ACMUI PM at the point at which the RB PM and the MSSA WG member believe it to be substantially complete. The ACMUI PM will distribute the draft final rule FRN to the ACMUI members for their review. The ACMUI PM may indicate that the documents are predecisional and cannot be publicly released, unless authorized by NRC staff. The SRM dated October 25, 2007 (SECY-07-0134) referenced in 4.1 above authorizes the release of the draft proposed rule documents, the FSME Director may authorize the release of draft final rule documents. ACMUI will review the draft rule and consolidate its comments into an ACMUI position. The ACMUI position may include dissenting views of individual ACMUI members. The ACMUI will be given 90 days to complete its review and provide comments. In some cases, the ACMUI may find that additional discussion or information is required to provide quality opinions and request that more time be allotted. The MSSA Director may grant an extension on a case-by-case basis.

The RB PM, in concert with the WG members, will address comments from the ACMUI, and prepare the final rule package (if the comments are substantive or if

the final rule has significant changes from the draft, DILR will reissue the package to the appropriate offices for reconcurrence). The Commission paper must specifically include ACMUI comments/recommendations, any dissenting opinions from ACMUI members, plus staff's assessment of ACMUI recommendations and dissenting views and the basis for not incorporating ACMUI recommendations into the final rule.

The MSSA WG member may also seek ACMUI's advice and guidance throughout the rulemaking process. The MSSA WG member and the ACMUI PM may share predecisional documents with the ACMUI to get their input. However, the ACMUI PM must indicate that the documents are predecisional and cannot be publicly released or discussed.

The RB PM will take the lead in briefing the ACMUI, if requested by the MSSA management on the status and progress of any medical rulemakings.

After Commission approval, the final rule will be published in the *Federal Register*.

#### **4.3    Other Major Medical Policy Issues:**

Other major policy issues that may affect medical uses of radioactive materials may arise as a result of medical use licensing and inspection findings or emerging issues brought to the staff or Commission attention by the medical community. After identification of a major policy issue that may affect medical uses of radioactive materials (other than rulemaking) that the MSSA intends to take to the Commission for review (e.g., SECY paper on a specific issue or significant licensing or inspection guidance revision for medical use licensees), the ACMUI PM will distribute the documents to the ACMUI members for review and comment. The ACMUI will be given at least 60 days to complete its review and provide comments. MSSA may also elect to obtain earlier ACMUI input by including one or more members of the ACMUI on the staff working group developing the policy issue or document. The ACMUI member serving on the WG may be the Chairman, a member most closely associated with the issue, or a member of an ACMUI subcommittee working on the issue or a related issue. It would be understood, however, that these individual members do not represent the ACMUI's collective opinion.

MSSA should provide the ACMUI's comments or recommendations on a proposed or final major medical policy issue, including dissenting views in the document provided to the Commission. MSSA should also describe how the ACMUI views were considered in the development and finalization of the major medical policy issue.

#### **4.4    ACMUI Meetings:**

The ACMUI views will be obtained during either regular or special (e.g., teleconference) ACMUI meetings. The meetings will be open to the public unless they may be closed under the provisions of 10 CFR 9.104, "Closed meetings."

### **5.    ACMUI ENDORSEMENT**

The draft procedure was presented to the ACMUI for their review and endorsement during the October 20-21, 2010, and December 13, 2010, ACMUI Meetings. The ACMUI members reviewed the draft procedure, provided comments, and unanimously approved the procedure with comments.

6. DOCUMENT HISTORY

Version	Description of Change	Responsible Division	Date Last Modified
0	Initial Procedure	DILR/MSSA	