Integrated Plan for Part 35 Guidance and Rulemaking
(WITS 201000193/ EDATS: SECY-2010-0425)

This "Integrated Plan for Part 35 Guidance and Rulemaking," (IP) identifies the outstanding Staff Requirements Memoranda (SRMs) by number and title. For each SRM, the SRM requirement is listed as a bulleted item. The Path Forward section presents the staff's intended actions to fulfill each requirement. A schedule for completion of the listed requirements is also included in each section. The IP concludes with an integrated schedule for fulfilling the requirements from the listed SRMs.

A. SRM-SECY-10-0062, "Re-proposed Rule: Medical Use of Byproduct Material – Amendments/Medical Event Definitions," dated August 10, 2010, and SRM-M101020, "Briefing on Medical Issues, 9:00 A.M., Wednesday, October 20, 2010…"

- Work closely with the Advisory Committee on the Medical Uses of Isotopes (ACMUI) and broader medical and stakeholder community to develop event definitions. Plan to be provided via Commissioner's Assistants (CA) Note. **Due: March 25, 2011 (201000192).**

- Hold a series of stakeholder workshops to discuss issues associated with the medical event definition. Plan to be provided via CA Note. **Due: March 25, 2011 (201000192).**

- Develop Integrated Plan denoting schedule and Agreement State participation, for completing this rulemaking along with other activities in the medical area such as developing guidance for incorporating ACMUI input into major medical policy issues and for licensing and inspection programs**. Due: March 8, 2011 (201000193).**

- As part of the integrated plan for completing the activities in the medical arena which was directed by the Commission in SRM-SECY-10-0062, the staff should include options and recommendations for streamlining the medical rulemaking petition and rulemaking processes without compromising the opportunities for full stakeholder involvement or the appropriate time for in-depth staff review and consideration. **Due: March 8, 2011 (201000264).**

- Include in the integrated plan a proposed schedule for completion of the final rule written directive requirements in 10 CFR 35.40(b)(6) and the medical event reporting requirements in 10 CFR 35.3045 for permanent implant brachytherapy medical use to convert from dose-based to activity-based. **Due date to be reset following receipt of 201000193 (200600079).**

- Provide revised guidance documents for final rule to amend 10 CFR Part 35, medical events and requirements for permanent implant brachtherapy (to be distributed to affected external stakeholders and made publically available) per current SRM. **Current Due Date: March 31, 2011 (200800307).** Due date to be reset following receipt of 201000193.

Path Forward:

1. **Develop Medical Event Reporting Guidance for Part 35 Current Rule and Expanded Rulemaking**:

   Obtain regional alignment on implementation issues associated with the current medical event reporting requirements for prostate brachytherapy and prepare draft inspection and licensing guidance. In addition, the staff will prepare guidance documents for the final expanded rule.

   - Share the draft licensing and inspection concept with both the ACMUI and Organization of Agreement States (OAS) for high-level feasibility review.

   - Use the draft guidance as a starting point for conducting a series of stakeholder workshops.

   - Schedule:

     A. Current rule

     - 3 months to develop and vet with regions. (Completion March 2011)
     - Provide to OAS and ACMUI for feasibility review (March–April 2011)

     B. Final Expanded Rule Guidance (200800307), pending Commission decision (proposed new due date - October 2014)

2. **Conduct Stakeholder Workshops**:

   Hold two stakeholder workshops. The locations will be determined based on consideration of factors to maximize stakeholder participation. Locations being considered include Rochester, Minnesota (Mayo Clinic), New York, New York (Memorial Sloan Kettering), and Denver, Colorado (Denver Federal Center). Additionally, the spring 2011 ACMUI meeting will be devoted to Part 35 rulemaking issues.

   The following Part 35 rulemaking topics will be discussed at the workshops to gather input from a spectrum of stakeholders:

   - Medical event reporting requirements for prostate brachytherapy – newly developed draft guidance for the current rule and the ACMUI prostate subcommittee interim report will serve as the starting point for discussions at the workshops.

   - Controversial Part 35 “expanded” rulemaking topics (e.g. modification of preceptor attestation requirements, grandfathering some certified individuals as authorized, naming assistant RSOs on medical licenses, etc.)

   - Patient release issues.

   Anticipated dates of workshops: June 2011

3. **Initiate Expanded Rulemaking:**

The currently in-progress "expanded" Part 35 rulemaking will be further expanded to include permanent implant medical event (ME) reporting requirements, because with the plan described in item 1, there may only need to be clarifications to the rule, rather than a new approach taken. Input from the workshops will be used for the expanded Part 35 rulemaking.

The staff believes that the Integrated Plan (IP) and the new procedure for addressing ACMUI views on major medical policy issues would have impacts on the current "expanded" Part 35 rulemaking schedule.

Current OEDO schedule for the Expanded Part 35 rulemaking (200900016) (per January 12, 2010 SRM re: COMSECY-09-0028) is:

Proposed Rule	March 8, 2012
Final Rule	September 23, 2013

In following the IP, the new Commission due dates for the current rulemakings (200600079 and 200900016) would be:

Proposed Rule	December 2012
Final Rule	October 2014

New Schedule for Expanded Rulemaking

1.	Conduct stakeholder workshops	June 2011
2.	Consolidate comments from the workshops	July - September 2011
3.	Complete ME rule Regulatory Basis	June 2012
4.	Complete proposed rule and provide to Commission	December 2012*
5.	Publish proposed rule	March 2013
6.	Allow 120 days for comments (typically, the Agency gives 75 days, but the large number of issues justify at least 120 days)	July 2013
7.	Conduct 3 public meetings during the comment period	April - July 2013
8.	Final Rule to Commission	October 2014**

* One year from consolidating comments, plus 3 months to accommodate the new ACMUI procedure

** One year from the close of comment period, plus 3 months to accommodate the new ACMUI procedure

B. SRM-M090625B, "Meeting with Advisory Committee on the Medical Uses of Isotopes (ACMUI), 1:30 P.M., Thursday, June 25, 2009…," dated 7/1/09.

- The Commission looks forward to the advice of the ACMUI on recommendations for improvements to the NRC's processes and regulations as an outgrowth of the investigation of the Department of Veterans Affairs medical events and any regulatory changes for permanent implant brachytherapy programs. **(200900138, due December 22, 2010 (extension sent to OEDO for March 31, 2012))**

Path Forward:

The ACMUI final report on prostate brachytherapy will be provided to the NRC staff in the fall of 2011, after the stakeholder workshops. (As noted above, ACMUI has requested to have the benefit of the stakeholder workshops before finalizing its report.) The staff would then use the ACMUI recommendations to develop recommendations that would be conveyed to the Commission in a Notation Vote SECY paper.

C. SRM-M100708B, "Briefing on Proposed Rule on Part 35 Medical Events Definitions – Permanent Implant Brachytherapy, 1:30 P.M., Thursday, July 8, 2010…," dated July 21, 2010.

- Develop internal guidance that requires that for all major medical policy issues that are submitted to the Commission, including proposed and final rules, the staff should include ACMUI recommendations and dissenting views **(201000183, complete)**.

- Staff should work with OGC to provide the Commission with a paper outlining possible improvement 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. The paper should provide an implementation plan for ACMUI reporting to Commission **(201000184, due April 1, 2011)**.

Path Forward:

1. The staff has developed a procedure for providing ACMUI input to the Commission on major medical issues. (Completed January 12, 2011)

2. The staff is preparing a SECY paper on potential improvement mechanisms, including the pros and cons of ACMUI reporting to the Commission. This paper is currently scheduled to be provided to the Commission by April 1, 2011

INTEGRATED SCHEDULE

DATE	ACTIVITY
01/21/11	Develop internal guidance on how ACMUI input will be provided to the Commission on major medical policy issues (project complete: FSME Policy and Procedure 2-5, effective January 12, 2011).
03/11	Prepare draft inspection and licensing guidance for current ME reporting requirements.
03/11-04/11	OAS and ACMUI perform high level feasibility review of inspection and licensing implementation approach for ME reporting requirements.
03/08/11	Provide to Commission - Integrated Plan plus recommendations for streamlining medical use rulemaking and petition processes.
03/25/11	Provide CA note on plans for holding stakeholder workshops associated with the development of the ME definition.
04/01/11	Provide to Commission - improvements to ACMUI reporting and implementation plan for reporting to Commission.
04/11	April ACMUI Meeting (focus on Part 35 rulemaking issues).
06/11	Conduct two stakeholder workshops.
07/11-09/11	Consolidate comments from workshops.
11/11	Revise draft licensing and inspection guidance for current ME rule and provide to regions and licensees.
04/12	Transmit Commission paper with recommendations on medical event reporting for permanent implant brachytherapy use.
06/12	Complete ME rule Regulatory Basis.
12/12	Provide to Commission-Proposed Expanded Rule (includes ME rule).
03/13	Publish proposed rule.
04/13-07/13	Allow 120 days for public comments (typically the Agency gives 75 days, but the large number of issues justify 120 days).
04/13-07/13	Conduct 3 public meetings during the comment period.
10/14	Provide to Commission- Final Rule.