# RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Chairman Allison M. Macfarlane

SUBJECT: COMSECY-14-0018 – REVISIONS TO PROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL - MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE, CLARIFYING AMENDMENTS (RIN 3150-AI63)

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached X None ___

SIGNATURE

6/10/14
DATE

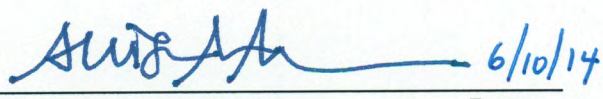
Entered on "STARS" Yes X No ___

**Chairman Macfarlane Comments on COMSECY-14-0018,**
**"Revisions To Proposed Rule: Medical Use Of Byproduct Material - Medical Event Definitions, Training And Experience, Clarifying Amendments" (RIN 3150-AI63)**

I approve publishing the notice for the proposed rule entitled, "Proposed Rule: Medical Use of Byproduct Material - Medical Event Definitions, Training and Experience, Clarifying Amendments" in the *Federal Register*, subject to the comments below. I would like to reiterate my appreciation to the staff for their dedication to developing this rule and extend my appreciation for their extensive efforts to consolidate the Commission direction into the revised *Federal Register* Notice (FRN).

In the SRM to SECY-13-0084, the Commission directed staff to change the Compatibility Category for medical event reporting from C to B. During consolidation of Commission direction into the revised FRN, staff made a change to the Compatibility Category for medical event reporting from C to B, as directed by the Commission, and removed the text soliciting comments on this issue. I believe that this particular issue is a major consideration that would benefit from a specific question being presented in the FRN. It is important to note that two of my colleagues who supported the change in the Compatibility Category from C to B specifically cited in their votes that they would reserve judgment or right to a final decision until after the public comments on the proposed rule are received and reviewed. This underscores the importance of soliciting public feedback and discussion on this topic to strengthen the public comment record. Additionally, soliciting public feedback on this topic is in keeping with the cumulative effects of regulation principles, as it directly impacts Agreement State implementation of the rule. To continue the staff's excellent public outreach efforts, staff should reinstate the specific question, with the appropriate revisions, related to the very important issue.

Within the text of the COMSECY-13-0018, staff explicitly mentions that the Commission is changing the Compatibility Category for medical event reporting from C to B. As such, I do not see the adding back in the question on the Compatibility Category as being substantially different from the language submitted to the Commission in SECY-13-0084. Therefore, staff should provide to SECY the revised FRN for publication within 30 days of the date of this SRM.




Allison M. Macfarlane Date

# RESPONSE SHEET

**TO:** Annette Vietti-Cook, Secretary

**FROM:** COMMISSIONER SVINICKI

**SUBJECT:** COMSECY-14-0018 – REVISIONS TO PROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL - MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE, CLARIFYING AMENDMENTS (RIN 3150-AI63)

**Approved** XX **Disapproved** _____ **Abstain** _____

**Not Participating** _____

**COMMENTS:** **Below** XX **Attached** ___ **None** ___

I approve publication of the revised *Federal Register* notice (FRN) and find that it is consistent with the Commission's previous direction arising from action on SECY-13-0084. The staff's deletion of the FRN language soliciting for views on the compatibility category as applied to medical event reporting is, however, an arguable point. Consequently, I support the reinsertion of this language into the FRN, as desired by some of my Commission colleagues.

**SIGNATURE**

06/16/14
**DATE**

**Entered on "STARS"** Yes ✓ No ___

# RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Apostolakis

SUBJECT: COMSECY-14-0018 – REVISIONS TO PROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL - MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE, CLARIFYING AMENDMENTS (RIN 3150-AI63)

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached ___ None X

SIGNATURE

5/22/14
DATE

Entered on "STARS" Yes ✓ No ___

# RESPONSE SHEET

**TO:** Annette Vietti-Cook, Secretary

**FROM:** Commissioner Magwood

**SUBJECT:** COMSECY-14-0018 – REVISIONS TO PROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL - MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE, CLARIFYING AMENDMENTS (RIN 3150-AI63)

**Approved** X **Disapproved** _____ **Abstain** _____

**Not Participating** _____

**COMMENTS:** **Below** X **Attached** ___ **None** ___

Once again, I appreciate staff's work in resolving the complex issues associated with the definition of medical events. The staff's successful engagement with stakeholders to develop an effective proposal that both carries out the agency's mission to protect public health and safety and avoids unnecessary intrusion into the practice of medicine is to be lauded. I approve for publication the draft Federal Register notice without further comment.

**SIGNATURE**

17 June 2014

**DATE**

**Entered on "STARS"** Yes X No ___

# RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER OSTENDORFF

SUBJECT: COMSECY-14-0018 – REVISIONS TO PROPOSED RULE: MEDICAL USE OF BYPRODUCT MATERIAL - MEDICAL EVENT DEFINITIONS, TRAINING AND EXPERIENCE, CLARIFYING AMENDMENTS (RIN 3150-AI63)

Approved _X___ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached _X__ None ___

_____
SIGNATURE

5/30/14
DATE

Entered on "STARS" Yes _X__ No ___

**Commissioner Ostendorff's Comments on COMSECY-14-0018, "Revisions To Proposed Rule: Medical Use Of Byproduct Material - Medical Event Definitions, Training And Experience, Clarifying Amendments (Rin 3150-Ai63)"**

Staff did an excellent job incorporating Commission direction in a short timeframe. I approve publishing the Federal Register Notice for the proposed rule subject to the comments below.

One aspect of the Commission's direction in the Staff Requirements Memo (SRM) to SECY-13-0084, "Proposed Rule: Medical Use of Byproduct Material – Medical Event Definitions, Training and Experience, and Clarifying Amendments," was to change the reporting of a medical event from compatibility category C to B. Staff made this change. Staff also removed the specific question in section D. of the FRN "Compatibility Category for the Agreement States on section 35.3045, Reporting and notification of a medical event" and the supporting discussion. The discussion clearly identified that there were varied opinions on this topic. I believe stakeholders' comments on the discussion and specific question will provide a balanced view of impacts of this change. Therefore, staff should revise the discussion from the perspective of medical event reporting as compatibility category B, and pose the specific question that was removed from the FRN.

Additionally, staff removed several references to reporting failed generators as directed by the Commission. However, there is still a reference in the Executive Summary. Staff should remove from the FRN the last reference to failed generators.

Finally, there has been some concern over the amount of time needed to publish this FRN after this SRM is issued. I do not see the changes as being significantly different from what was originally reviewed (adding back the question and discussion on compatibility category for medical event reporting). Therefore, staff should provide to SECY the revised FRN for publication within 30 days of the date of this SRM.