UNITED STATES
NUCLEAR REGULATORY COMMISSION
WASHINGTON, D.C. 20555-0001

August 13, 2012

SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-12-0053

TITLE: RECOMMENDATIONS ON REGULATORY CHANGES FOR PERMANENT IMPLANT BRACHYTHERAPY PROGRAMS

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of August 13, 2012.

This Record contains a summary of voting on this matter together with the individual vote sheets, views and comments of the Commission.

Kenneth R. Hart
Acting Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets

cc: Chairman Macfarlane
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
OGC
EDO
PDR

VOTING SUMMARY - SECY-12-0053

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. MACFARLANE	X				X	7/30/12
COMR. SVINICKI	X				X	7/23/12
COMR. APOSTOLAKIS	X				X	6/18/12
COMR. MAGWOOD	X				X	7/10/12
COMR. OSTENDORFF	X				X	5/31/12

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Chairman Allison Macfarlane

SUBJECT: SECY-12-0053 – RECOMMENDATIONS ON REGULATORY CHANGES FOR PERMANENT IMPLANT BRACHYTHERAPY PROGRAMS

Approved __X__ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached _X__ None ___

SIGNATURE

7/30/12

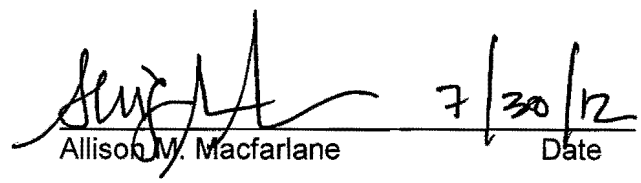
DATE

Entered on "STARS" Yes _X__ No ___

Chairman Macfarlane's Comments on SECY-12-0053, "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs"

I approve the staff's recommendations for modifying the requirements in 10 CFR Part 35 for permanent implant brachytherapy programs. I would like to echo my fellow Commissioners' praise of the staff's extensive outreach efforts on this complex issue, and I appreciate the full, open, and diverse discussion that has resulted. As the rulemaking process continues, I have great confidence that the NRC staff will continue to strike a balance among several factors, including protecting the interests of patients, allowing physician flexibility to take medically necessary actions, and allowing the NRC to detect failures in process, procedure and training or the misapplication of byproduct material.

Ahead of the current schedule for the expanded 10 CFR part 35 rulemaking, the staff should clarify medical event reporting for permanent implant brachytherapy under the existing rule. As outlined in a May 23, 2012 Commissioners' Assistants Note "Options to Clarify Medical Event Reporting for Permanent Implant Brachytherapy," the staff should pursue Options 3 and 5. I agree with the staff's assessment that clarifying licensee guidance (Option 3) is an important component for addressing the challenges that exist with the current medical events reporting. I also agree with the staff and approve the development of an interim enforcement policy for Commission review and approval (Option 5) to provide enforcement discretion to licensees where there is confusion about the meaning of the regulations.



Allison M. Macfarlane 7/30/12
Date

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER SVINICKI

SUBJECT: SECY-12-0053 – RECOMMENDATIONS ON REGULATORY CHANGES FOR PERMANENT IMPLANT BRACHYTHERAPY PROGRAMS

Approved XX Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached XX None ___

SIGNATURE

07/23/12

DATE

Entered on "STARS" Yes ✓ No ___

Commissioner Svinicki's Comments on SECY-12-0053
Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs

I approve the staff's recommendations for modifying the regulatory requirements that appear in 10 CFR 35.3045 for permanent implant brachytherapy medical event reporting, as outlined in the enclosure to SECY-12-0053, and conforming changes to the current written directive requirements in 10 CFR 35.40(b)(6). These modifications should be developed as part of the proposed rule for the expanded 10 CFR Part 35 rulemaking. Also, as outlined in the Commissioners' Assistants Note, "Options to Clarify Medical Event Reporting for Permanent Implant Brachytherapy," dated May 23, 2012, the staff should continue its implementation of Option 3, which entails the issuance of a Regulatory Issues Summary to NRC medical use licensees and to Agreement State regulatory programs to provide insights about compliance with the current NRC requirements related to permanent implant brachytherapy. As described in the Commissioners' Assistants Note, I also approve the staff moving forward with Option 5, wherein the staff would develop and provide for Commission approval an interim enforcement policy that would allow the staff and Agreement States to exercise enforcement discretion for both existing and future violations of current Part 35 that result from an otherwise appropriate use of total source strength and treatment time for determining the existence of a medical event.

Finally, I thank the NRC staff, the Advisory Committee on the Medical Uses of Isotopes, other medical experts who commented and participated in the NRC workshops, our Agreement State partners, and others for participation in the development of these proposed changes on this complex topic. In formulating these recommendations, I believe the NRC staff has done a laudable job in balancing differing viewpoints while also developing event definitions that protect the interests of patients, allow physicians the flexibility to take actions that they deem medically necessary, while continuing to enable the NRC to detect failures in process, procedure, and training, as well as any misapplication of byproduct materials by authorized users.

Kristine L. Svinicki 07/25/12

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Apostolakis

SUBJECT: SECY-12-0053 – RECOMMENDATIONS ON REGULATORY CHANGES FOR PERMANENT IMPLANT BRACHYTHERAPY PROGRAMS

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

Not Participating _____

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

I approve staff's recommendation to amend 10 CFR Part 35 to include a separate medical event reporting requirement exclusively for permanent implant brachytherapy and to use a combination of dose based and activity based criteria with one comment. I also support the staff's plan to quickly pursue issuance of regulatory guidance that will clarify medical event reporting under the existing requirements, ahead of the current schedule for the expanded 10 CFR Part 35 rulemaking. I recommend that the staff replace the term "seeds" with "sources".

The definition of medical events is a long-standing and complex issue. I thank the staff for working closely with the Advisory Committee on the Medical Uses of Isotopes and the broader stakeholder community to develop event definitions that would protect the interests of patients, allow physicians the flexibility to take actions that they deem medically necessary, while continuing to enable the agency to detect failures in process, procedure, and training, as well as any misapplication of byproduct materials by authorized users.

SIGNATURE

6/18/12

DATE

Entered on "STARS" Yes √ No ___

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MAGWOOD

SUBJECT: SECY-12-0053 – RECOMMENDATIONS ON REGULATORY CHANGES FOR PERMANENT IMPLANT BRACHYTHERAPY PROGRAMS

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

Not Participating _____

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

Will OK

SIGNATURE

10 July 2012

DATE

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

Commissioner Magwood's Comments on SECY-12-0053, "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs"

This matter has been before the agency for quite some time and has experienced significant evolution—particularly as a result of the medical events that occurred at the Veterans Affairs hospital in Philadelphia between 2002 and 2008. During this long period of consideration, staff has been very diligent in working with a broad array of stakeholders to develop a regulatory approach to assure the protection of public health and safety while allowing physicians to take the actions they believe necessary to address the medical needs of their patients. I appreciate staff's flexibility and professionalism during the agency's review of this complex issue. I also appreciate the excellent cooperation provided by the medical community and the ACMUI as the Commission has sought to find an appropriate path forward.

Staff has recommended that the Commission approve modifications to the regulatory requirements in 10 CFR 35.3045 regarding the reporting of medical events associated with permanent implant brachytherapy. Staff's recommendations, which are reflected in both SECY-12-0053 and a recent Commissioners' Assistants note on options to clarify medical event reporting for permanent brachytherapy, are well-presented and thorough. Staff's recommended approach will enable the agency to detect failures in process, procedure, and training as well as any misapplication of byproduct materials by users without interfering inappropriately with responsible medical judgments. I therefore approve staff's recommendation.

I also approve staff's recommendation that the agency issue licensee guidance and an interim enforcement policy. This interim policy will remain in place until the staff can provide clarity through the rulemaking process. I find this to be a good suggestion from the staff to improve the process quickly.

Regarding the rulemaking process, I remain concerned about keeping the final resolution of the brachytherapy matter packaged in a very complex, combined rulemaking that covers a host of less critical issues. Bringing clarity to the definition of medical events and resolving issues associated with training and experience attestation requirements will have a positive impact on patients across the country and should not be delayed. We have heard from many stakeholders regarding the vital importance of bringing an immediate conclusion to this matter. However, staff believes that developing a separate rule to resolve the brachytherapy matter would not accelerate substantial the schedule for this issue but could delay other matters.

I therefore recommend that, as the combined rulemaking proceeds, staff be required to provide the Commission with a new paper at any time a substantive delay in the completion schedule for this rule becomes apparent. This step would facilitate additional decision-making by the Commission regarding this very important rulemaking activity. Such a paper should explain the schedule delay and the impact of separating a permanent implant brachytherapy rule from the combined rulemaking. Also since Staff has done significant outreach during the development of the regulatory basis for the proposed rule, staff should, where possible, leverage this outreach to further streamline the rulemaking process.

Finally, regarding the compatibility category of 10 CFR 53.3045 reporting requirements, I reserve judgment until the proposed rule is provided to the Commission with the staff's evaluation and recommendation.

7/10/12

William D. Magwood, IV **Date**

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER OSTENDORFF

SUBJECT: SECY-12-0053 – RECOMMENDATIONS ON REGULATORY CHANGES FOR PERMANENT IMPLANT BRACHYTHERAPY PROGRAMS

Approved __X__ Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached _X__ None ___

SIGNATURE

5/31/12

DATE

Entered on "STARS" Yes __X_ No ___

Commissioner Ostendorff's Comments on SECY-12-0053, "Recommendations on Regulatory Changes for Permanent Implant Brachytherapy Programs"

I approve the staff's recommendations to modify the regulatory requirements for permanent implant brachytherapy medical event reporting in 10 CFR 35.3045 and to make conforming changes to the requirements for written directives in 10 CFR 35.40. The staff has done a commendable job of thoroughly engaging our stakeholders to develop the proposed revisions. I believe that the staff's proposal aligns with the intent of the Commission's 2000 policy statement on the Medical Use of Byproduct Material, which states that the "NRC will not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public." The staff's proposal appropriately balances the interests of patients, the flexibility for authorized users to take actions that they deem are medically necessary, and continues to enable the agency to detect failures in process, procedure, and training as well as any misapplication of byproduct materials by authorized users.

I believe it is important for the staff to address the lack of clarity and implementation challenges associated with the current rule in an expedited manner. I agree with the staff's assessment of the options to address these issues documented in a May 23, 2012 note to Commissioner's Assistants. Therefore, the staff should continue to develop a regulatory issue summary to clarify the rule requirements and issue an interim enforcement policy providing enforcement discretion for licensees that use total source strength and exposure time for dose in determining whether a medical event occurred. I believe that this approach addresses the challenges with the current rule in a timely manner, while continuing to ensure radiological safety.