



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

May 21, 2013

SECRETARY

COMMISSION VOTING RECORD

DECISION ITEM: SECY-13-0044

TITLE: INTERIM ENFORCEMENT POLICY FOR PERMANENT  
IMPLANT BRACHYTHERAPY MEDICAL EVENT  
REPORTING

The Commission (with all Commissioners agreeing) approved the subject paper as recorded in the Staff Requirements Memorandum (SRM) of May 21, 2013.

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

A handwritten signature in black ink, appearing to read "Annette L. Vietti-Cook".

Annette L. Vietti-Cook  
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-13-0044

RECORDED VOTES

|                   | APRVD | DISAPRVD | ABSTAIN | NOT<br>PARTICIP | COMMENTS | DATE    |
|-------------------|-------|----------|---------|-----------------|----------|---------|
| CHRM. MACFARLANE  | X     |          |         |                 | X        | 5/10/13 |
| COMR. SVINICKI    | X     |          |         |                 | X        | 5/16/13 |
| COMR. APOSTOLAKIS | X     |          |         |                 |          | 5/7/13  |
| COMR. MAGWOOD     | X     |          |         |                 |          | 5/15/13 |
| COMR. OSTENDORFF  | X     |          |         |                 | X        | 5/3/13  |

**NOTATION VOTE**

**RESPONSE SHEET**

**TO:** Annette Vietti-Cook, Secretary  
**FROM:** Chairman Allison M. Macfarlane  
**SUBJECT:** SECY-13-0044 – INTERIM ENFORCEMENT POLICY  
FOR PERMANENT IMPLANT BRACHYTHERAPY  
MEDICAL EVENT REPORTING

Approved  X  Disapproved   Abstain

Not Participating

**COMMENTS:** Below  X  Attached   None

I approve the staff's request to issue this Interim Enforcement Policy for Permanent Implant Brachytherapy Medical Event Reporting. I believe that this policy strikes the right balance between the radiation oncologist's need for flexibility, and the NRC's need to have appropriate medical events identified and reported.



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**SIGNATURE**

5/10/13

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**DATE**

Entered on "STARS" Yes  X  No

**NOTATION VOTE**

**RESPONSE SHEET**

TO: Annette Vietti-Cook, Secretary  
FROM: COMMISSIONER SVINICKI  
SUBJECT: SECY-13-0044 – INTERIM ENFORCEMENT POLICY  
FOR PERMANENT IMPLANT BRACHYTHERAPY  
MEDICAL EVENT REPORTING

Approved XX Disapproved \_\_\_\_\_ Abstain \_\_\_\_\_

Not Participating \_\_\_\_\_

COMMENTS: Below XX Attached \_\_\_\_\_ None \_\_\_\_\_

I approve the staff's proposed interim enforcement policy related to the reporting of certain medical events occurring under a licensee's permanent implant brachytherapy program. I approve publication of the *Federal Register* Notice, enclosed with the paper.

  
\_\_\_\_\_  
SIGNATURE

05/16/13  
\_\_\_\_\_  
DATE

Entered on "STARS" Yes  No \_\_\_\_\_

**NOTATION VOTE**

**RESPONSE SHEET**

TO: Annette Vietti-Cook, Secretary  
FROM: Commissioner Apostolakis  
SUBJECT: SECY-13-0044 – INTERIM ENFORCEMENT POLICY  
FOR PERMANENT IMPLANT BRACHYTHERAPY  
MEDICAL EVENT REPORTING

Approved  X  Disapproved \_\_\_\_\_ Abstain \_\_\_\_\_

Not Participating \_\_\_\_\_

COMMENTS: Below \_\_\_ Attached \_\_\_ None  X



\_\_\_\_\_  
SIGNATURE

7 May 2013  
DATE

Entered on "STARS" Yes  No \_\_\_\_\_

**NOTATION VOTE**

**RESPONSE SHEET**

**TO:** Annette Vietti-Cook, Secretary  
**FROM:** COMMISSIONER MAGWOOD  
**SUBJECT:** SECY-13-0044 – INTERIM ENFORCEMENT POLICY  
FOR PERMANENT IMPLANT BRACHYTHERAPY  
MEDICAL EVENT REPORTING

Approved  Disapproved  Abstain

Not Participating

COMMENTS: Below  Attached  None



\_\_\_\_\_  
**SIGNATURE**

15 May 2013

\_\_\_\_\_  
**DATE**

Entered on "STARS" Yes  No

**NOTATION VOTE**

**RESPONSE SHEET**

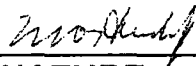
TO: Annette Vietti-Cook, Secretary  
FROM: COMMISSIONER OSTENDORFF  
SUBJECT: SECY-13-0044 – INTERIM ENFORCEMENT POLICY  
FOR PERMANENT IMPLANT BRACHYTHERAPY  
MEDICAL EVENT REPORTING

Approved  X  Disapproved \_\_\_\_\_ Abstain \_\_\_\_\_

Not Participating \_\_\_\_\_

COMMENTS: Below  X  Attached \_\_\_ None \_\_\_

I approve the interim enforcement policy that will allow the staff to exercise enforcement discretion for certain violations of the 10 CFR 35 regulations for reporting medical events under a licensee's permanent implant brachytherapy program. This enforcement discretion is needed to address hesitancy among medical practitioners to use permanent implant brachytherapy because, under the current definition, otherwise acceptable treatments may need to be reported as events. In addition to providing necessary flexibility, the interim enforcement policy continues to ensure radiation safety by limiting the use of discretion to cases in which doses to normal tissue are within the limits specified in the current definition. I also agree that enforcement discretion should be provided for doses to the treatment site that exceed 120%. I believe that this provision is consistent with the NRC's policy to not intrude into medical judgments affecting patients, except as necessary to provide for the radiation safety of workers and the general public.

  
\_\_\_\_\_  
SIGNATURE

5/3/13  
\_\_\_\_\_  
DATE

Entered on "STARS" Yes \_\_\_ No \_\_\_