SECRETARY

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

April 9, 2012

COMMISSION VOTING RECORD

DECISION ITEM: SECY-12-0011

TITLE: DATA COLLECTION REGARDING PATIENT RELEASE

The Commission acted on the subject paper as recorded in the Staff Requirements Memorandum (SRM) of April 9, 2012.

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

Annette L. Vietti-Cook
Secretary of the Commission

Attachments:
1. Voting Summary
2. Commissioner Vote Sheets

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

VOTING SUMMARY - SECY-12-0011

RECORDED VOTES

	APRVD	DISAPRVD	ABSTAIN	NOT PARTICIP	COMMENTS	DATE
CHRM. JACZKO	X	X			X	2/10/12
COMR. SVINICKI	X				X	3/30/12
COMR. APOSTOLAKIS		X			X	3/19/12
COMR. MAGWOOD		X			X	3/29/12
COMR. OSTENDORFF		X			X	3/9/12

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Chairman Gregory B. Jaczko

SUBJECT: SECY-12-0011 – DATA COLLECTION REGARDING PATIENT RELEASE

Approved __X__ Disapproved __X__ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached _X_ None ___

SIGNATURE

2/10/12

DATE

Entered on "STARS" Yes _x_ No ___

Chairman Jaczko's Comments on SECY-12-0011,
"Data Collection Regarding Patient Release"

I approve in part and disapprove in part the staff's recommendation in SECY-12-0011 regarding data collection and patient release. I appreciate the staff's work thus far and its identification of the current gaps in: 1) the empirical data on the release of patients to locations other than their primary residences such as nursing homes and hotels, and 2) the evaluation of internal doses delivered to members of the public from inhalation and/or ingestion due to the increased activities administered in today's patient release practices.

I remain concerned that under Option 3, the agency would still have no real world information as to whether members of the U.S. public really are receiving less than 500 mrem per year, as required by our regulations. As discussed by the staff in the SECY paper, current patient release practices are based on assumptions that were made at the time when patient release was based on activities at release not exceeding 30 mCi. Currently, patients are released immediately after administration of up to a few hundred mCi and these increased levels of activity may invalidate prior assumptions regarding internal doses. For the empirical studies that do exist, staff has indicated that most of those studies were in other countries and involved patients that received lower activities than are typically administered to patients in the U.S.

In May 2008, the agency issued a Regulatory Issue Summary (RIS) regarding patient release, which cautions that licensees consider not releasing patients whose living conditions may result in unnecessary exposure of infants and young children because the doses from internal exposure may be greater than previously estimated. In January 2011, the agency issued a RIS regarding patient release to locations other than private residences, such as hotels, which states the release of patients to locations other than a private residence is strongly discouraged because it may result in doses for which compliance cannot be fully assessed and that are not ALARA. In my mind, both of these RISs were necessary partly because we are unsure what doses are actually being received by members of the public due to release of patients after treatment with radioactive material. Therefore, staff should undertake Option 4, which would include revisiting calculations and methods described in our guidance as well as a limited amount of empirical data collected from field measurements.

2/16/12

Gregory B. Jaczko Date

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER SVINICKI

SUBJECT: SECY-12-0011 – DATA COLLECTION REGARDING PATIENT RELEASE

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

Not Participating _____

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

I approve the staff's recommended Option 3, to conduct a review of the methods and assumptions used in NUREG-1492 and NUREG-1556, including a review of the assumptions associated with internal dose and location of release. This option will allow NRC to enhance our guidance through the use of more modern computer codes for dose assessment and by incorporating operating experience about patient release, patient behavior after release, and adherence to medical precautions, and to accomplish these updates as a nearer-term activity. As a supplemental, follow-on activity, I also support Commissioner Magwood's proposal to direct the staff to develop a proposal for how it would implement and resource the additional activities under Option 4, and to include this plan as a component of the FY 2014 budget request.

SIGNATURE

03/30/2012

DATE

Entered on "STARS" Yes ✓ No ___

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Apostolakis

SUBJECT: SECY-12-0011 – DATA COLLECTION REGARDING PATIENT RELEASE

Approved _____ **Disapproved** __X__ **Abstain** _____

Not Participating _____

COMMENTS: **Below** _X_ **Attached** ___ **None** ___

I disapprove the staff recommended Option 3. I agree with Chairman Jaczko and Commissioner Ostendorff that Option 4 should be approved. I agree that data collection, in large part, relies on patient behavior, and that the volunteers may or may not represent members of the public. Therefore, staff should design its limited empirical research/data collection such that the information collected will be representative of members of the public to the maximum extent possible. Staff should also solicit feedback on its plan with the Advisory Committee on Medical Isotopes. If staff uses expert judgment elicitation to inform the dose assessments, it should ensure that the results of this elicitation are well documented and available for public review.

SIGNATURE

3/19/12

DATE

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

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER MAGWOOD

SUBJECT: SECY-12-0011 – DATA COLLECTION REGARDING PATIENT RELEASE

Approved _____ Disapproved X Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached X None ___

SIGNATURE

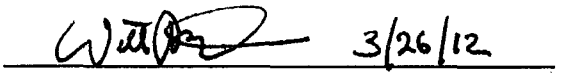
29 March 2012
DATE

Entered on "STARS" Yes X No ___

Commissioner Magwood's Comment on
SECY-12-0011, "Data Collection Regarding Patient Release"

I disapprove the staff's recommendation of Option 3. While it is at this stage unclear whether the approach described in Option 4 will, in contrast to Option 3, provide substantial improvement in our understanding of the potential doses associated with various patient release scenarios, there is a clear benefit in an effort to validate the assumptions used in our dose modeling.

I therefore approve Option 4. However, I believe it important that the Commission benefit from a more complete assessment of the resources needed for this effort and that we prioritize them appropriately. I therefore recommend that staff limit its activities in the near term to refining its approach and preparing a proposal to be submitted to the Commission as part of the FY 2014 budget request. I recommend that such a proposal detail how staff plans to interact with stakeholders, with particular emphasis on our engagement with patients. Once this proposal is submitted with the FY 2014 request, Commission approval of work beyond the planning stage can then be made in the context of our overall program of work.



William D. Magwood, IV **Date**

NOTATION VOTE

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER OSTENDORFF

SUBJECT: SECY-12-0011 – DATA COLLECTION REGARDING PATIENT RELEASE

Approved _____ Disapproved __X__ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached __X__ None ___

_____
SIGNATURE

3/9/12
DATE

Entered on "STARS" Yes __X__ No ___

Commissioner Ostendorff's Comments on SECY-12-0011, "Data Collection Regarding Patient Release"

I disapprove Option 3. Instead, I approve Option 4: to supplement the formal dose assessments of Option 3 by including a limited amount of empirical data. I continue to believe that our current regulatory requirements for the release of patients following medical isotope procedures are protective. That said, I agree with the staff that there are gaps in the empirical data. Closing these gaps by updating calculations and modeling to reflect current scenarios will provide a more complete and clear basis for the release of patients following medical isotope procedures. However, I agree with Chairman Jaczko that obtaining some real world information also has value. Collecting limited empirical data, in addition to updating calculations, will provide more direct information and enhance the transparency and credibility of the analysis. Both the Advisory Committee on Medical Isotopes, and individuals working in the medical isotope field that I spoke to during a recent facility visit, recommended obtaining some empirical data. I believe it is important to fully consider the views of such experts with experience in the field.

To ensure credibility of the empirical results, the data should be free of any factors that could skew the results. In SECY-12-0011, the staff very thoughtfully provided the logistical challenges and complexities associated with collection of data from individuals. To avoid biased results, the staff should close the gaps primarily through revision of calculations and modeling. These analyses should be supplemented with empirical data only in areas that are uncertain or that can significantly alter the results. Further, empirical studies should be limited to the use of phantoms, time motion studies, and field measurements. The scenarios used should be realistic, and should assume that patients follow the instructions provided. Any limitations with the data obtained should be fully explained.