

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER SVINICKI
SUBJECT: COMGBJ-11-0003 – DATA COLLECTION REGARDING
PATIENT RELEASE

Approved XX Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached XX None ___



SIGNATURE

06/1/11

DATE

Entered on "STARS" Yes No

Commissioner Svinicki's Comments on COMGBJ-11-0003
Data Collection Regarding Patient Release

I approve Chairman Jaczko's proposal that the staff provide a notation vote paper to the Commission with recommendations regarding the need, if any, for additional empirical data on doses received by the public resulting from exposure to patients dosed with radioactive material being released from a hospital or clinical setting. The preparation of this paper should be carried out in a manner which avoids any impact to the schedule for the ongoing 10 CFR Part 35 rulemaking.

Many of us have experienced the heart-wrenching compulsion to be near loved ones during the end stages of their terminal cancer and the desire to provide palliative care at home. I am concerned about the feasibility of collecting additional data and uncertain whether the data that could be gathered would be usable in regulatory decision making. As I understand it, the staff has, as reference, a number of already completed studies on this topic. The staff should begin its analysis by assessing whether these studies reveal any regulatory gap in our current technical basis. Staff should also weigh the direct utility of any additional data-gathering exercise against the potential for intruding upon patient privacy protections. As noted in the COM, NCRP Report No. 155 states: "the release of patients treated with therapeutic amounts of radiopharmaceuticals is not likely to expose any member of the public, inclusive of both external and internal dose contributions, [to] > 5 mSv (0.5 rem) provided that adequate instructions are provided at discharge to the patient and the family members." The staff's evaluation should assume the effective use of such instructions.



Kristine L. Svinicki

06/1/11

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: Commissioner Apostolakis
SUBJECT: COMGBJ-11-0003 – DATA COLLECTION REGARDING
PATIENT RELEASE

Approved X Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below X Attached _____ None _____

I approve the Chairman's proposal. The staff's notational vote paper should also include as an alternative or additional option, a recommendation regarding the feasibility of revisiting the dose assessment used to support the patient release rulemaking. The paper should also address the staff's recommended approach on the use of expert elicitation.



SIGNATURE

5/24/11

DATE

Entered on "STARS" Yes X No _____

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER MAGWOOD
SUBJECT: COMGBJ-11-0003 – DATA COLLECTION REGARDING
PATIENT RELEASE

Approved Disapproved Abstain

Not Participating

COMMENTS: Below Attached None



SIGNATURE

27 May 2011

DATE

Entered on "STARS" Yes No

**Commissioner Magwood's Comment on
COMGBJ-11-0003, "Data Collection Regarding Patient Release"**

I approve the Chairman's proposal to request that the staff provide the Commission with a notation vote paper with recommendations regarding the need for additional empirical data on dose to members of the public exposed to patients treated with radioactive material. I also agree with Commissioner Ostendorff that that the staff's recommendation should consider whether such information is feasible to obtain and would add value to the agency's regulatory decision making.

I believe that as the staff is evaluating the need for additional data, it is important that staff assume that existing guidance provided to the patients is being followed appropriately, including the additional guidance provided recently to the licensees regarding the use of hotels. Further, several empirical studies on dose to members of the public have been completed. The staff should consider these studies in the course of its evaluation, as well as the various International & National Council on Radiation Protection and Measurements Reports on patient release.

Finally, I recommend that staff provide the Commission with its recommendations prior to the initiation of the FY 2014 budget formulation in order to assure that any resulting proposal can be considered in the budget process.



William D. Magwood, IV 5/27/11
Date

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary
FROM: COMMISSIONER OSTENDORFF
SUBJECT: COMGBJ-11-0003 – DATA COLLECTION REGARDING
PATIENT RELEASE

Approved Disapproved _____ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached None ___

M. Ostendorff
SIGNATURE

5/16/11
DATE

Entered on "STARS" Yes No ___

Commissioner Ostendorff's comments on COMGBJ, "Data Collection Regarding Patient Release"

I approve the Chairman's proposal to request that the staff provide the Commission with a notation vote paper with recommendations on whether additional empirical data on doses to members of the public that are exposed to patients treated with radioisotopes is necessary. I also agree that the staff's recommendations should consider whether such information is feasible to obtain and would add value to the agency's regulatory decision making.

I firmly agree with the statement in the Chairman's proposal that the current release criteria for patients treated with radioactive material set appropriate limits that properly balance public health and safety with the individual necessities of medical care. The staff and our domestic and international partners have completed thorough analyses of the issues associated with the release of patients treated with medical isotopes. These analyses have demonstrated that our current requirements are appropriately protective. The staff's analysis of the need for additional empirical data should fully utilize this previous work.

We should, however, continue to assure ourselves that our regulatory decisions are fully informed by the best available information. Since the agency's guidance on the release of patients was last issued, the agency has become aware of scenarios not previously considered, such as the use of hotels by patients following treatment with radioisotopes. The Chairman's proposal is consistent with the NRC's longstanding practice of making solid decisions based on science.

I strongly believe that being open and transparent is one of the agency's strongest attributes. Regardless of the outcome of the staff's evaluation of the need for additional data, documenting this evaluation would enhance the agency's transparency and credibility. This is particularly important given the very public nature of the issues surrounding the release of patients treated with medical isotopes.