RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER SVINICKI

SUBJECT: COMAMM-14-0001/COMWDM-14-0001 – BACKGROUND AND PROPOSED DIRECTION TO NRC STAFF TO VERIFY ASSUMPTIONS MADE CONCERING PATIENT RELEASE GUIDANCE

Approved ____ Disapproved __XX__ Abstain _____

Not Participating _____

COMMENTS: Below ___ Attached __XX__ None ___

SIGNATURE

04/4/14
DATE

Entered on "STARS" Yes ✓ No ___

Commissioner Svinicki's Comments on COMAMM-14-0001/COMWDM-14-0001 Background and Proposed Direction to NRC Staff to Verify Assumptions Made Concerning Patient Release Guidance

I appreciate the evident care and concern of my colleagues in putting forward their proposal. At this time, however, I disapprove adoption of their proposals as premature. In 2012, motivated by the exact same underlying concerns articulated here, the Commission directed the staff to perform analytical and limited empirical research/data collection and to revisit the agency's fundamental calculations and methods in existing NUREG guidance for patient release. By that action, the Commission set in motion a more expansive re-examination of issues surrounding patient release than had been undertaken in over a decade and adopted the option requiring the most sweeping set of activities of any of the options proposed by the staff in SECY-12-0011. These activities were directed by the Commission with the express purpose of informing the types of activities now proposed by my colleagues. And yet, we have not awaited the result of any of it.

The Commission should demonstrate the constancy of purpose of permitting the staff to carry out our direction and receiving the results of their work, results which, in this case, consist entirely of the information we claimed we needed in order to chart a course forward. The irony is only heightened by my colleagues' admission that their basis for action is "primarily anecdotal at this point." The Commission has already directed the staff to undertake the set of activities that will supplant this anecdotal basis with a substantive, data-driven one. I suggest we let our staff get on with it.

Few Americans have escaped being personally affected in some way by the patient care issues at the heart of our consideration of this matter. I am no different. But where our work impacts so directly the health and well-being of individuals, I argue that we should proceed with greater deliberateness, not less, and with a solid foundation in the kind of facts and analysis that the staff is already preparing for us.

Kristine L. Svinicki 04/4/14

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: Commissioner Apostolakis

SUBJECT: COMAMM-14-0001/COMWDM-14-0001 – BACKGROUND AND PROPOSED DIRECTION TO NRC STAFF TO VERIFY ASSUMPTIONS MADE CONCERING PATIENT RELEASE GUIDANCE

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

Not Participating _____

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

I thank Chairman Macfarlane and Commissioner Magwood for proposing direction to the staff on this important topic. I support their proposal and also suggest that the staff leverage the communications activities of the Office of Public Affairs in addition to the activities with the advocacy groups as they develop the release guidance information. The proposal is focused mainly on NRC activities; the staff should also work with the Agreement States on these activities. The staff should consider whether the information can be made into an NRC brochure or whether a medical organization would produce a brochure for nationwide distribution. Lastly, while this effort is focused on the use of iodine-131, the staff should be encouraged to leverage this effort to address patient release guidance for other radionuclides and procedures.

SIGNATURE

March 24, 2014

DATE

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

RESPONSE SHEET

TO: Annette Vietti-Cook, Secretary

FROM: COMMISSIONER OSTENDORFF

SUBJECT: COMAMM-14-0001/COMWDM-14-0001 – BACKGROUND AND PROPOSED DIRECTION TO NRC STAFF TO VERIFY ASSUMPTIONS MADE CONCERING PATIENT RELEASE GUIDANCE

Approved _X_ **Disapproved** _____ **Abstain** _____

Not Participating _____

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

_____
SIGNATURE

4/3/14
DATE

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

Commissioner Ostendorff's Comments on COMAMM/WDM-14-0001, "Background and Proposed Direction to NRC Staff to Verify Assumptions made Concerning Patient Release Guidance"

Chairman Macfarlane and Commissioner Magwood have articulated their concern regarding release of patients who have undergone medical treatments using by-product material in an informed and thoughtful manner. They have provided a comprehensive list of actions that the staff should take to close the perceived gap in patient information regarding release after treatment using by-product material. I approve the direction to the staff in the COM subject to the comments below.

I note that there has been significant Commission attention to this issue over the last several years. For example, the Advisory Committee on the Medical Use of Isotopes' (ACMUI) "Patient Release Subcommittee Report,"[1] indicated that additional guidance to patients may be warranted. In that report the Subcommittee noted the IAEA statement[2], "The success of a patient release program is critically dependent on the quality and specificity of the information provided to the patient, the skill with which it is communicated, and whether or not the patient believes the information provided." The IAEA also advised that the precautions "should be based upon realistic models of behavior, including realistic occupancy factors, and should not be over-cautious."[3]

In COMGBJ-11-0003, the Commission stated, "While there is analytical information that our current requirements are appropriate, there does not appear to be much empirical data regarding the doses actually being received by members of the public that are exposed to these patients," and directed staff to evaluate whether there are gaps in available data regarding doses being received by the public. In SECY-12-0011, staff identified "gaps in our data that would require additional data gathering and analysis" and eventual updating of our guidance. In the SRM to SECY-12-0011, the Commission directed staff to revisit calculations and methods described in agency guidance as well as a limited amount of analytical and empirical data collection from field measurement to revise agency guidance. As discussed in my vote on SECY-12-0011, I continue to believe that our current regulatory requirements for the release of patients following procedures using by-product material are protective, but I supported efforts to close gaps including the use of empirical data.

Staff developed a plan to address this Commission direction and is in the process of evaluating current research to inform their next steps. Due to the sequestration and lack of contract dollars, it may take staff through 2016 to complete its analysis. I feel it is important for the staff to complete its assessment before undertaking any updating of guidance or regulation to address patient release.

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[1] ACMUI Patient Release Subcommittee Report, December 13, 2010
[2] IAEA Safety Reports Series No. 63, "Release of Patients after Radionuclide Therapy," International Atomic Energy Agency, 2009
[3] IAEA Position Statement, "Release of Patients after Radionuclide Therapy," International Atomic Energy Agency, February 23, 2010

Therefore, while I agree that staff should address each of the elements in this COM, I only support implementation of elements 1 and 3 at this time. The development of additional guidance for instructions (element 1) and development of a website for consistent patient information (element 3) should be done in conjunction with stakeholders that include ACMUI and professional medical organizations such as the American Society for Radiation Oncology, the Society of Nuclear Medicine, and the Health Physics Society. Further, this work should build on the information that has been developed over the last decade including NRC guidance in NUREG-1556, volume 9, Appendix U, various Information Notices, and Regulatory Information Summaries. This guidance should focus on enhancing our licensees' ability to provide clear guidance to patients on the risks of treatment with regulated materials as well as of expected behaviors after release from radioisotope therapies. Finally, I support elements 2 and 4 after the staff's current assessment is complete if that assessment identifies the need for updates to our requirements and guidance documents.