April 28, 2014

MEMORANDUM TO: Mark A. Satorius
Executive Director for Operations

FROM: Annette L. Vietti-Cook, Secretary /RA/

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

The Commission has agreed to direct the staff to do the following:

1. Develop a standardized set of guidelines that licensees can use to provide instructions to patients. Use of these guidelines would not constitute a new requirement, but would provide licensees with standard guidance which they could adopt as a best practice. The use of these guidelines would also help to reduce the variability of instructions provided to patients and eliminate some of the uncertainty regarding the type of information that is provided to the patient. The new guidelines could be issued as part of or in conjunction with a revised Regulatory Guide 8.39 (see # 2).

2. Revise Regulatory Guide 8.39, and subsequently NUREG-1556, to specify guidelines for patient information and instructional guidance. The current approach leaves the details of patient instruction to licensees. NRC could provide more detailed guidance for patients. As part of this guidance, NRC should include a model "patient acknowledgment form" that would be read and signed by the patient and countersigned by an appropriate representative of the licensee to demonstrate that the patient understands the instructions as they were communicated. The suggested form should be a very simple and clear one page form through which the patient acknowledges (for example) that he or she:

    a. Has received a clear explanation of the treatment process.
    b. Understands the need to limit the exposures to others, especially to young children and pregnant women, after treatment and has been informed how long special care must be exercised.
    c. Has worked with the licensee to develop plans for:
        1) Transportation from the clinic to home
        2) Arrangements for protecting others once arriving at home
        3) Minimizing the exposure of people both inside and outside the home
        4) Managing biological wastes and trash in accordance with NRC, state, and local requirements
        5) Emergency care
        6) Whom to contact in the event that questions arise during the recovery period.

3. Develop a website that provides information and links to relevant medical organizations and patient advocacy groups to enable patients to access clear and consistent patient information regarding:

    a. What is radioactive iodine (RAI)?
    b. Basic radiation safety
    c. RAI treatment
    d. Preparing for RAI treatment
    e. What to expect before and after receiving the treatment?
    f. Side effects of RAI treatment
    g. Precautions to take after receiving treatment
    h. Risks to others, with an appropriate statement regarding the risks to young children and pregnant women.

4. Evaluate whether significant regulatory changes to the patient release program are warranted. In parallel with the research project initiated under the SRM for SECY-12-0011, NRC staff should explore with the public, licensees, and state partners whether the agency should change 10 CFR Part 35.75 to require:

    a. Development of an activity based patient release threshold under which patients would be required to be maintained in a clinic-sponsored facility until the standard for release is met.
    b. Clarification on whether the current dose limit in 10 CFR 35.75 (a) for releasing patients who have been administered radioactive material applies to each individual treatment or to the total treatment provided in a given year.
    c. Assessment of whether the current patient release standard, which allows family members, caregivers, and hotel workers to be exposed to dose levels above that of the public, is appropriate.
    d. Development of requirements for releasing patients who are likely to expose young children and pregnant women to levels above the public dose limit.

The staff should leverage the communications activities of the Office of Public Affairs in addition to the advocacy groups as they develop the release guidance information.

The staff should work with the Agreement States on these activities.

The staff should consider whether the guidance information can be made into an NRC brochure or whether a medical organization would produce a brochure for nationwide distribution.

The staff should leverage this effort to address patient release guidance for other radionuclides and procedures.

The development of additional guidance for instructions and development of a website for consistent patient information 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 as well as patient advocacy groups, such as the American Thyroid Cancer Survivors Association or Cancer Care.

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.

cc: Chairman Macfarlane
Commissioner Svinicki
Commissioner Apostolakis
Commissioner Magwood
Commissioner Ostendorff
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Office Directors, Regions, ACRS, ASLBP (via E-Mail)
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