COMAMM-14-0001/
COMWDM-14-0001

March 10, 2014

TO: The Commission

FROM: Chairman Macfarlane /RA/
Commissioner Magwood /RA/

SUBJECT: BACKGROUND AND PROPOSED DIRECTION TO NRC STAFF TO VERIFY ASSUMPTIONS MADE CONCERNING PATIENT RELEASE GUIDANCE

Background

According to the Journal of Nuclear Medicine, each year in the United States, unsealed byproduct material (i.e., radioactive pharmaceuticals and other compounds) or implants containing byproduct material are administered to roughly 14 million to 20 million patients for medical diagnoses or the treatment of diseases[1]. For example, oral administration of iodine-131 (^{131}I) has been a commonly accepted procedure for treatment of benign and malignant conditions of the thyroid since the 1940s. Major uses of ^{131}I include the treatment of thyrotoxicosis (hyperthyroidism, such as resulting from Graves' disease) and some thyroid cancers that absorb iodine. As a result of these types of procedures, patients are significantly radioactive for several days after treatment and can expose others around them from the resulting radiation field, from direct physical contact, or from contact with waste products or other residues left by the patients such as urine, perspiration, or saliva.

On May 21, 1991, NRC published a final rule that amended 10 CFR Part 20 "Standards for Protection Against Radiation". However, the revision of 10 CFR Part 20 provided no guidance regarding whether or how the provisions of 10 CFR 20.1301 were intended to apply to the release of patients under 10 CFR Part 35.75, “Release of Patients or Human Research Subjects Containing Radiopharmaceuticals or Permanent Implants,” leaving licensees uncertain as to what effect the revised 10 CFR Part 20 would have on patient release criteria--particularly with regard to ^{131}I treatment.

Prior to 1997, NRC's patient release criteria, contained in 10 CFR 35.75, specified:

a) a licensee may not authorize release from confinement for medical care any patient or human research subject administered a radiopharmaceutical until either (1) the measured dose rate from the patient or the human research subject is less than

[1] Delbeke, D., Segall, G.M., J Nucl Med, December 1, 2011 vol. 52 no, Supplement 2, 24S-28S

5 mrem per hour at a distance of 1 meter or (2) the activity in the patient or the human research subject is less than 30 mCi; and

b) a licensee may not authorize release from confinement for medical care of any patient or human research subject administered a permanent implant until the measured dose rate from the patient or the human research subject is less than 5 millirems per hour at a distance of 1 meter.

Given the uncertainty of the applicability of 10 CFR 20.1301 (1991) to patient release, the American College of Nuclear Medicine and the American Medical Association submitted petitions for rulemaking that requested revision of 10 CFR Part 20 and 10 CFR Part 35 to address the ambiguity between the two regulations. Specifically, Part 20 placed a 1 mSv (100 mrem) total effective dose equivalent limit to the general public whereas Part 35's activity-based patient release limit of 30 mCi (or 5 mR per hour at a distance of 1 meter) could, in some instances, permit release of a patient such that public exposures would be greater than 100 mrem.

In response to the petitions, NRC developed Information Notice No. 94-09, “Release of Patients with Residual Radioactivity from Medical Treatment and Control of Areas due to Presence of Patients Containing Radioactivity Following Implementation of Revised 10 CFR Part 20” (1994), which stated explicitly that 10 CFR 35.75 governed patient release. The Commission also took the additional step of directing the staff to revise 10 CFR 35.75 to remove the 30 mCi activity-based criteria and shift patient release to a dose-based standard.

Based on Commission direction, 10 CFR 35.75 was revised in 1997 to permit licensees to release patients as long as:

a) the total effective dose equivalent to any other individual is not likely to exceed 5 mSv (500 mrem; this is interpreted by staff to apply to caregivers and family members) and

b) licensees provide the released individual with instructions, including written instructions, on actions recommended to maintain doses to other individuals as low as is reasonably achievable if the total effective dose equivalent to any other individual is likely to exceed 1 mSv (100 mrem).

Changes to the rule were partially based on NUREG-1492, "Regulatory Analysis on Criteria for the Release of Patients Administered Radioactive Material" (1997), which was developed in direct response to the petitions discussed above. The analysis in this NUREG reflects several key assumptions that formed the basis of the resulting patient release criteria. Most importantly, the analysis anticipates that patients will adhere to the following instructions in order to keep doses to other individuals as low as is reasonably achievable:

- Maintain a distance of 1 meter from others, including separate sleeping arrangements;

- Minimize time in public places (e.g., public transportation, grocery stores, shopping centers, theaters, restaurants, and sporting events);

- Take precautions to reduce the spread of radioactive contamination.

In addition, NUREG-1492 anticipates that the patient will be aware of the time period during which it will be necessary to observe these precautions.

NUREG-1492 defines an "occupancy factor" that describes the nature of exposures resulting from time spent with and proximity to a patient. Based on the assumptions in the NUREG, this value was calculated as 0.25 at 1 meter, which translates into a maximum dose of 5 mSv (500 mrem) received by a caregiver or family member. The NUREG also evaluated the cost and benefit associated with a change in the criteria for release of patients administered radioactive material. This analysis concluded that not restricting patient release to a specific activity (e.g., 30 mCi) has the benefits of reducing hospital stays, providing emotional benefits to patients and their families, and lowering health care costs. In other words, staff felt that the 5 mSv (500 mrem) exposure to family members and caregivers is justified.

NRC Regulatory Guide 8.39 “Patients Administered Radioactive Materials” (1997) and NUREG 1556, “Consolidated Guidance About Materials Licenses,” Volume 9, “Program-Specific Guidance About Medical Use Licenses,” Rev. 2, Appendix U, “Model Procedure for Release of Patients or Human Research Subjects Administered Radioactive Materials,” (NUREG-1556; 2008) outlines the acceptable methods of calculating the total effective dose equivalent to any other individual upon release of a patient and include the following computation options: (1) administered activity, (2) a measured dose rate at 1 meter, or (3) patient-specific dose calculations. NUREG 1556 also gives instructions as to the activities and dose rates requiring written instructions.

NRC has also issued several generic communications related to the patient release topic. NRC Information Notice (IN) 2003-22, “Heightened Awareness For Patients Containing Detectable Amounts of Radiation From Medical Administrations,” (2003) and IN 2003-22, Supplement 1 (2009) provide information and guidance regarding patient release and exposures to other individuals. These INs emphasize that licensees should consider the destination to which a patient may be released, consider the potential for potential exposure to others, and provide written release instructions specific to the patient’s circumstances. Regulatory Issue Summary (RIS) 2005-24, “Control of Radiation Dose to Visitors of Hospital Patients”, RIS 2008-11, “Precautions to Protect Children Who May Come in Contact with Patients Released After Therapeutic Administration of I-131,” and RIS 2011-01, “NRC Policy on Release of Iodine-131 Therapy Patients Under 10 CFR 35.75 to Locations Other Than Private Residences,” provide additional guidance on the release of patients following treatment with ^{131}I. Specifically, RIS 2008 -11 instructs licensees to consider <u>not</u> releasing patients administered ^{131}I whose living conditions may result in unnecessary exposure of infants and young children. These guidance documents take into consideration the most current recommendations of the National Council

on Radiation Protection and Measurements and the International Commission on Radiological Protection related to patient release.

Current Situation

Over the years that this regime has been in place, operational experience, while primarily anecdotal at this point, has brought into significant question whether the assumptions at the basis of the 1997 rule correctly reflect the actual behavior of most patients. At the core of the matter are two questions: Are patients receiving consistent and useful instructions from clinics and hospitals? Are patients following correctly those instructions when they are provided? Direct discussions with patients who have received ^{131}I treatments are instructive. Information provided by members of the Thyroid Cancer Survivors Association[2]–as well as patient advocates and state regulators - reveals the following:

- While some patients receive carefully-provided, personalized instructions from clinics and hospitals, the quality of instructions provided varies significantly.

- While a few patients with sufficient resources are able to isolate themselves effectively, patients are often provided instructions that both patients and clinics know will be impractical to follow. Examples of behaviors that have been reported include:

    - checking into hotels despite being discouraged by NRC (while, in some cases, patients have been instructed to do so by their clinics);
    - taking public transportation, including buses and aircraft; and
    - not confining themselves to their home.

- There is wide variance in the information provided patients with regard to wastes. Some patients are told to store and dispose wastes; others are told to simply "flush three times." In at least one state, law enforcement officials were called in to deal with an individual who was disposing of contaminated materials in municipal trash.

This information should require NRC to consider a re-evaluation of the "occupancy factor" used in NUREG-1492. Moreover, the NUREG does not speak to the exposures of hotel workers or passengers on aircraft because it assumes patients will not engage in those activities that would impact these people.

To date, in response to questions about the sufficiency of our current approach, NRC staff has stated that public health and safety has not been compromised because the doses to non-caregivers are unlikely to exceed 5 mSv (500 mrem). While this may be true, there is no data to support such a claim and NRC has not assessed the doses that might be incurred by hotel

[2] Personal communication with Commissioner Magwood, September 28, 2013

workers or others[3]. We also have not spoken to the matter of whether it is appropriate that non-caregivers be routinely exposed without their knowledge.
Given the operational experience and anecdotal information that is already available to us, it is appropriate to verify whether the assumptions in NUREG-1492 are valid considering a significant number of patients are not receiving appropriate information, not following the instructions given, or are unable to follow the instruction due to their living circumstances.

The Commission should direct the staff to do the following:

1) **Develop a standardized model of guidelines for instructions clinicians can provide patients.** This step would not constitute new requirements, but provide licensees with a clear model they could adopt as a best practice. This action would help reduce the variability of instructions provided to patients and eliminate some of the uncertainty regarding NRC's expectations. 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 definitive guidance for patients. As part of this guidance, NRC could include a model "patient acknowledgment form" that could be read and signed by the patient and countersigned by an appropriate representative of the licensee. The suggested form would be, ideally, a very simple, 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 of 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:

        - Transportation from the clinic to home
        - Arrangements for protecting others once arriving at home
        - Minimizing the exposure of people both inside and outside the home

[3] In the SRM for SECY-12-0011, “Data Collection Regarding Patient Release”, the Commission instructed staff to proceed with a project to explore the exposure issues associated with patient release. Staff has formulated a project that expects to explore this issue analytically using time/motion studies to consider the exposures that might be encountered by members of the public beyond those in contact with a patient as a result of family or caregiver relationships. The Office of Nuclear Regulatory Research has indicated that it plans to develop a NUREG for this task by March 31, 2015. It remains to be seen how budgetary limitations might impact this plan, but this work could provide valuable information to inform a Commission decision regarding the potential need for additional protective measures.

- Managing biological wastes and trash
- Emergency care

3) **Develop a joint website or a link with relevant medical organizations and patient advocacy groups to provide clear, consistent patient information regarding:**

   - What is Radioactive Iodine (RAI)
   - Basic radiation safety
   - RAI treatment
   - Preparing for RAI treatment
   - What to expect before and after receiving the treatment
   - Side effects of RAI treatment
   - Precautions to take after receiving treatment
   - Risks to others, with an appropriate statement as to the risks presented to young children and pregnant women.

   Currently, according to patients, it is simply unclear to many people what instructions they are expected to follow and what the risks may be to others. The level of uncertainty is high for many patients, and it would be appropriate for NRC to take a positive action to alleviate some of these concerns.

4) **Ultimately, in addition to revising Regulatory Guide 8.39 and subsequently NUREG-1556, staff should 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:

   - 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.

   - 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.

   - 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.

   - Development of requirements for releasing patients who are likely to expose young children and pregnant women to levels above the public dose limit.

cc: CFO
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